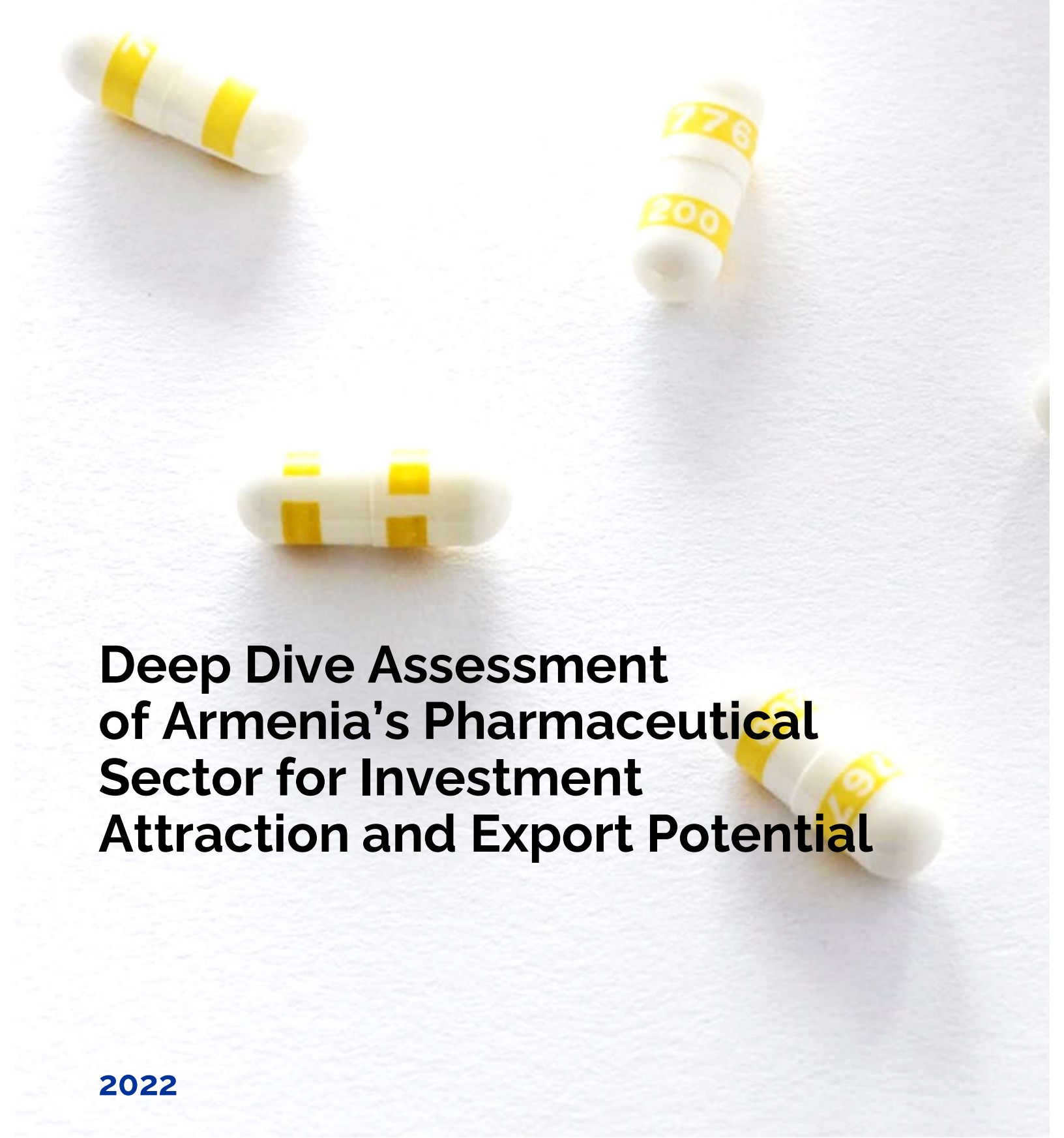


Deep Dive Assessment of Armenia's Pharmaceutical Sector for Investment Attraction and Export Potential

2022

European Bank for Reconstruction and Development

EU4Business

ENTERPRISE ARMENIA

pwc

Table of Contents

Glossary
List of Commodity Codes

30	**Pharmaceutical products**
3001	**Glands and other organs (extracts, secretions thereof) for organo-therapeutic uses, dried, powdered or not, heparin and its salts, other human or animal substances for therapeutic or prophylactic uses N.E.C.**
300120	Glands and other organs: extracts of glands or other organs or of their secretions, for organo-therapeutic uses
300190	Glands and other organs: heparin and its salts, other human or animal substances prepared for therapeutic or prophylactic uses, N.E.C. in heading 3001
3002	**Blood (human or animal) for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, modified immunological products, (from biotechnological processes or not); vaccines, toxins, microorganism cultures (not yeasts), similar products**
300210	Blood, human or animal, antisera and other blood fractions and modified immunological products, whether obtained by means of biotechnological processes
300220	Vaccines for human medicine
300230	Vaccines for veterinary medicine
300290	Toxins, cultures of microorganisms (excluding yeasts) and similar products
3003	**Medicaments (not goods of heading no. 3002, 3005 or 3006) of two or more constituents mixed for therapeutic or prophylactic use not in measured doses or in forms or packings for retail sale**
300310	Medicaments containing penicillin, streptomycin or their derivatives, for therapeutic or prophylactic uses, (not in measured doses, not packaged for retail sale)
300320	Medicaments containing antibiotics other than penicillin, streptomycin and their derivatives, for therapeutic or prophylactic uses, (not in measured doses, not packaged for retail sale)
300339	Medicaments containing hormones/other products of 29.37 but not containing antibiotics (excl. meds. containing insulin) not put up in measured doses/forms/packagings for RS
300390	Medicaments (not containing antibiotics, hormones, alkaloids or their derivatives), for therapeutic or prophylactic uses (not packaged for retail sale)
3004	**Medicaments (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale**
300410	Medicaments containing penicillin, streptomycin or their derivatives, for therapeutic or prophylactic uses, packaged for retail sale

300420	Medicaments containing antibiotics (other than penicillin, streptomycin or their derivatives), for therapeutic or prophylactic uses and packaged for retail sale
300431	Medicaments containing insulin (but not containing antibiotics), for therapeutic or prophylactic uses and packaged for retail sale
300432	Medicaments containing corticosteroid hormones, their derivatives or structural analogues (but not containing antibiotics), for therapeutic or prophylactic uses and packaged for retail sale
300439	Medicaments containing hormones (but not insulin), adrenal cortex hormones or antibiotics, for therapeutic or prophylactic uses and packaged for retail sale
300440	Medicaments containing alkaloids or their derivatives (but not hormones or antibiotics), for therapeutic or prophylactic uses and packaged for retail sale
300450	Medicaments containing vitamins or their derivatives, for therapeutic or prophylactic use and packaged for retail sale
300490	Medicaments consisting of mixed or unmixed products n.e.c. in heading no. 3004, for therapeutic or prophylactic uses and packaged for retail sale
3005	**Wadding, gauze and bandages (dressings, adhesive plasters, poultices) impregnated or coated with pharmaceutical substances or in forms or packings for retail sale or for medical, surgical or veterinary use**
300510	Dressings, adhesives and other articles having an adhesive layer and packed for retail sale for medical, surgical, dental or veterinary purposes
300590	Wadding, gauze, bandages and similar articles (excluding adhesive dressings) impregnated or coated with pharmaceutical substances and packaged for retail sale
3006	**Pharmaceutical goods**
300610	Pharmaceutical goods: sterile surgical catgut, suture materials, tissue adhesives, laminaria, laminaria tents, absorbable surgical or dental hemostatic, and surgical or dental adhesion barriers
300620	Pharmaceutical goods: blood-grouping reagents
300630	Pharmaceutical goods: opacifying preparations for x-ray examinations, diagnostic reagents designed to be administered to the patient
300640	Pharmaceutical goods: dental cements and other dental fillings, bone reconstruction cements
300650	Pharmaceutical goods: first aid boxes and kits
300660	Pharmaceutical goods: chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides
300670	Pharmaceutical goods: gel medications designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments
300691	Pharmaceutical goods: appliances identifiable for ostomy use

List of Abbreviations

API	Active Pharmaceutical Ingredient
CAGR	Compound Annual Growth Rate
CCG	Commodity Code Groups
CDMO	Contract Development and Manufacturing Organisation
CEE	Central and Eastern Europe
CIS	Commonwealth of Independent States
CMO	Contract Manufacturing Organisation
COGS	Cost of Goods Sold
Covid-19	Coronavirus disease
CPI	Corruption Perception Index
CRO	Contract Research Organisation
EAEU	Eurasian Economic Union
EU	European Union
FDI	Foreign Direct Investment
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GII	Global Innovation Index
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GNI	Gross Net Income
GVP	Good Pharmacovigilance Practice
HDI	Human Development Index
ISO	International Organisation for Standardisation
IT	Information Technology
MENA	Middle East and North Africa
OECD	Organisation for Economic Co-operation and Development
OTC	Over the Counter
R&D	Research and Development
RA	Republic of Armenia
ROI	Return on Investment
RX	Prescription Drugs
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UAE	United Arab Emirates
UN	United Nations
UNDP	United Nations Development Programme
US	United States
USD	US Dollar
VAT	Value Added Tax
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WMA	World Medical Association
WTO	World Trade Organisation

Executive Summary (1/2)

The pharmaceutical and life science industry is in transition, as **large and small players look to global markets for growth**. Following significant activity in 2020, the **volume of acquisitions and divestitures will continue to rise, driven by companies looking to shed non-core business units and focus on building speciality platforms** - such as cell and gene therapies or mRNA - to drive value through innovation. In addition, **increasing pricing pressure is forcing companies to re-examine business models** to protect their bottom line. **Some may rethink global operating models**, while others may **adjust go-to-market approaches** to optimise profitability. Other companies may build on prior successes, growing revenue from their existing product portfolios by **capturing opportunities in previously untapped markets**.

With over 67% of the late-stage development pipeline comprised of life science companies that have never commercialised a product before, we expect a wave of new market entrants. **Companies must have a strong understanding of the local requirements of the countries they are looking to enter in order to capitalise on the market opportunities and to minimise risks.** Often, companies understand what it takes to operate in larger, more established markets. However, as they expand into new geographies or look to change models in smaller markets, **access to key information is critical.** Local market requirements can be dynamic and exist across a wide range of **functions, including regulatory, supply chain, legal, quality and commercial.** And these requirements will nearly always **require the coordination of cross-functional teams**. The significant variation of requirements and timelines for conducting local business can add further complexity.

In some countries, **companies must have a pharmaceutical licence** and conduct manufacturing in the country to commercialise products in the market. However, **in other countries, local manufacturing is not a requirement to enter the market** but can lead to beneficial pricing and preferential tender considerations. And it is not just manufacturing requirements that can pose a barrier to entry. **Some markets** require companies to **own import testing laboratories locally**, **hold their regulatory licenses in a local entity** or employ quality representatives in the market. Some markets allow companies to outsource some of these activities, but this varies from country to country.

The **timelines** to obtain regulatory approvals, business licenses, quality approvals and distribution permits **vary significantly and are often sequential.** This **timing needs to be factored into planning** early on, so **realistic market entry targets can be set**.

> **"Access and affordability of medicines must become the focus for pharmaceutical organisations as they look to pursue greater social purpose."**

The pharmaceutical and life sciences industry escaped the worst of Covid-19's financial impact and were among sectors that continued to grow during the pandemic, supported by the continued need for medicines, and the sharp rise in demand for vaccine and diagnostic test development and production. The pace of Covid-19 vaccine development has paved the way for further harnessing of scientific innovation and global collaboration. Other factors influencing the case for change in pharmaceuticals and life sciences include the demands of an ageing population and technical innovation opening up new classes of drugs and biologics.

As a result, the industry should see an opportunity to maintain a course of continued growth while ensuring focus on sustainability and social responsibility goals.

> **"The pace of Covid-19 vaccine development has paved the way for further harnessing of scientific innovation and global collaboration."**

Executive Summary (2/2)

Our Report provides an overview of the pharmaceutical industry and studies the prospects of investments in the **Armenian pharmaceutical market**. Considered as one of the most **dynamically growing sectors** of the Armenian economy, the Pharmaceutical sector was **valued at USD 246m in 2021, accounting for 1.9% of country's GDP and 16.5% of total healthcare expenditures**. Despite facing long-term geographical and geopolitical challenges Armenia has been **implementing a program of reforms aimed at attracting trade and foreign investment** by improving the business environment and streamlining tax and customs administration. Although the **Government of Armenia has taken major steps to help grow production, ease access to the consumer market, help implement GMP standards, provide tax incentives**, further interventions and support in educational reforms, digitally enabled operating models, regulatory mechanisms, reimbursement policies and international partnerships will define the development of the pharmaceutical industry in Armenia in the coming decade.

There are **24 pharmaceutical companies** that are specialised in the production of medicines, out of which **10 are GMP certified.** The **production of pharmaceutical products** reached its peak in 2020, with a **revenue of USD 24.5m.** More **than 70% (USD 18.3m)** of produced pharmaceutical products were **exported in 2020. Russia was the main destination**, followed by Georgia and Uzbekistan

As a member of the Russian-led Eurasian Economic Union (EAEU) **Armenian products have direct access** to the Russian, Belarusian, Kazakh, Kyrgyz and other markets with a **combined population of about 190 million** and **a combined gross domestic product of nearly $2 trillion**. Russia remains the largest pharmaceutical trade partner for Armenia in the region with imports from Armenia reaching to USD 66.3m over the last ten years.

As the global **Clinical Trials** market valued at USD 48.4 billion in 2020 is expected to reach USD 84.43b by 2030, with a growing prevalence of chronic disorders, increasing demand for advanced treatments and innovative drug development, developing countries are in a race to take their share of the market. Low cost of **Generics** as an alternative to branded drugs and large number of patent-expired branded drugs, initiatives by governments and other regulatory bodies across the globe are the main growth factors for generics market that is projected to reach approximately USD 575b by 2030 from 391b in 2020. **R&D spending in the pharmaceutical sector** totalled nearly USD 200b globally. Over the last ten years, it has increased almost two times. The advancements in science and technology are augmenting the growth of R&D operations by pharmaceutical companies globally. Although the costs have increased by 130% in the last five years, the profits on R&D projects have stalled. The **API market** driven by an increase in the prevalence of cancer, cardiovascular disorders, and diabetes, as well as by ageing populations has a global market valued at 180b USD and expected to reach USD 356b by 2030. **The CRO/CMO** market has been driven by the growing need for state-of-the-art processes and production technologies. The global CRO/CMO market is valued at USD 160b in 2020, and expected to reach USD 237b by 2026 at a CAGR of 6.5%

Our report suggests that **Clinical trials, R&D and API sub-sectors** have the highest socio-economic impact while stimulating the GDP per capita, development of the pharmaceutical industry, partnerships with foreign companies, development of the health care industry, creation of new jobs, attracting qualified specialists and leading to a higher HDI, life expectancy and improved quality of life. **Generics sub-sector** will increase the accessibility of medicines for the population in the short-term. The most **significant factor boosting the growth** of certain sub-sectors in the pharmaceutical sector is the **growing need for robust processes and production technologies**..

.

Methodology

Overview

The Pharmaceutical sector is an important part of Armenia's economy and could potentially become one of the fastest growing sectors, in the context of the ongoing Covid-19 pandemic and current geo-political turbulence. The objective of this assignment is to develop a comprehensive assessment of Armenia's pharmaceutical sector and present a Report that will highlight the investment attraction and export potential from Armenia. This Report will also form the basis of a separate assignment to develop an Investment Attraction Strategy that will enable Enterprise Armenia to reach out to targeted multinational companies and present Armenia's pharmaceutical sector value proposition to prospective investors.

Project approach and deliverables

The following section presents the methodology and tasks that were carried out as a part of the approach to the assignment. Our methodology was designed on the basis of the tasks described in the Terms of Reference. We used a range of tools & methods developed over years of successful delivery of high-quality services to ensure the collection of quality data, systematic analysis, creative thinking, evidence-based recommendations, and most importantly stakeholder engagement. The project was divided into 3 stages: **data gathering, market analysis, and sectoral analysis.**

The project started with the mobilisation of the project team and key stakeholders, providing a common understanding of national policy and institutional context of the project, project objectives, implementation approach, timeline, quality assurance, critical success factors, and monitoring mechanism discussed and agreed upon.

Disclaimer

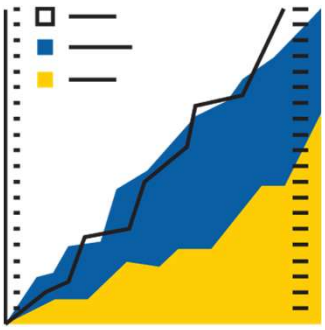
This survey is based on the data gathered for the period between 2010 to 2020. The most complete and up-to-date information was limited to 2020. The analyses and report preparation started in February 2022 before the commencement of the conflict between Russia and Ukraine and the following global geo-political turbulences. Further developments in the political situation may result in actual circumstances being different from our projections described in this Report. There may be a differences between predicted and actual results and conclusions, and such differences may prove to be significant. We are prepared to update the report as part of an additional scope if there is new information available.

Stage 1

Data gathering and validation

Consisted of **Data gathering and validation** to assess the current state of Armenia's pharmaceutical sector, global trends and local statistics, identifying at least 5 sub-sectors with the potential to offer attractive opportunities to investors according to "desirability" and "feasibility" criteria, using desk-based review, review of in-house databases, analysis of government databases such as the general Statistics office of Armenia, key existing government vision and strategy documents, and reports from Armenia MoH and other sources publicly available.

We standardized the definitions to allow comparisons and benchmarking with International Best Practices. Extensive secondary research including international data, broker & analyst reports, business information libraries and databases - current global pharmaceutical market and FDI (Foreign Direct Investment) trends (especially considering the Covid-19 pandemic) was performed during this stage. Field work (site visits) and stakeholder interviews - investors, private sector or industry associations, international chambers of commerce, relevant line ministries, industrial park management authorities, researchers and universities, financial and technical partners, embassies from key investor countries were also performed during this stage.
Existing data was validated and assumptions regarding the most viable sub-sectors and segments in the list of potential pharmaceutical sub-sectors completed by conducting stakeholder interviews.



Stage 2

Market analysis

Market analysis was conducted with an objective to evaluate the market and each of the sub-sectors for their potential to attract FDI over the next 5 years along two key dimensions: "desirability" and "feasibility". Modelling & forecasting tools were used to allow quantitative and qualitative data sets to be combined with related macroeconomic and demographic drivers to create models and forecasts, including simulation models.

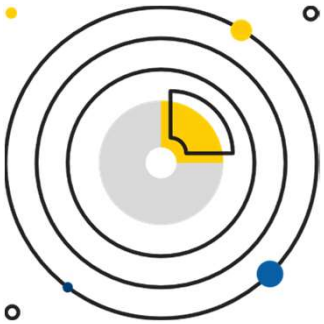
Our interviews were designed to obtain qualitative data on the pharmaceutical sector in Armenia. The goal was not only to collect an objective point of view and perception of the current state of the sector, but also the expectations of different parties, participants and policymakers. In addition, our research was aimed at informing Armenia's strategic priorities and reforms to ensure the advancement of investments in the pharmaceutical sector and to support the export potential of companies. As part of our research, in-depth interviews were carried out with two broad groups of respondents:

- sector representatives, including producers, pharmaceutical chain representatives and representative offices
- experts and policymakers, including sector-related associations and institutes and government representatives

List of respondents is presented in Annex 1.

Stage 3

Target sectoral analysis



Sectoral analysis was performed to identify the market for each sub-sector to be targeted for investment opportunities and specify companies and investment funds for each sub-sector. Modelling and forecasting tools allowed quantitative and qualitative data sets to be combined with related macroeconomic and demographic drivers to create models and forecasts, including simulation models, socio-economic impact analysis.

Target markets for each of the identified sub-sectors, with the highest potential of generating investments, in the current Covid-19 context and beyond were identified based on the global FDI database and criteria. International Standard for Good Manufacturing, Distribution and Storage Practices (GMP / GDP / GSP) and steps taken by the state to implement the standard in Armenia were described. Antimicrobial Resistance (AMR) risk management as part of GMP and its application for Armenia's pharmaceutical sector were also studied.

Continuous quality control was performed to ensure a focused approach to processes and profiling.

Disclaimer

Some analyses were conducted based on the available information and data as of 1 March 2022 and others based on the United Nations (UN) Comtrade database reflect data as of 31 December 2020.

16

During our research, we held **16** in-depth interviews with experts and representatives of the field from public and private entities.

Interviews

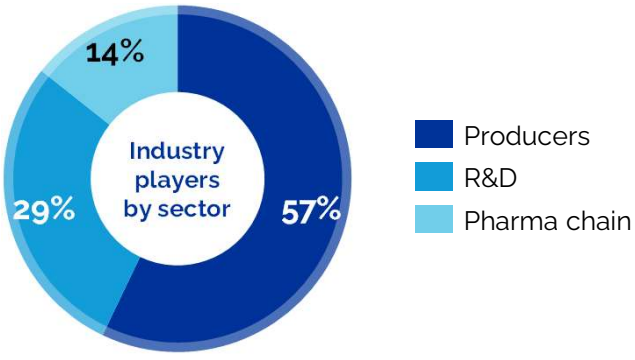
The interviews were conducted with a questionnaire consisting of open questions divided into four parts:

- Questions related to the pharmaceutical sector and the details of operations in Armenia.
- Questions covering research and development (R&D) processes in the pharmaceutical sector (company) and in the country.
- Questions related to the regulatory framework of the pharmaceutical sector (sector) and barriers faced by pharmaceutical companies in Armenia, as well as possible solutions currently available for eliminating barriers.
- Questions on international trade and exports.

The Report covers the past 10 years and provides an overview of overall trends in the sector over the transitional period and in the context of Covid-19. Commodity code groups (CCG) were analyzed in order to evaluate market expenditures for different product types. CCGs also enable a benchmarking analysis of demand and supply in countries from the region.

The interviewed companies operate in the following sub-sectors:

Figure 1: Industry players by sector



1 Armenia: Country profile

Section summary

Armenia is classified as an upper middle-income country by the World Bank, achieving notable success in reducing poverty rates and controlling inflation through most of 2020. Despite facing long-term geographical and geopolitical challenges Armenia has been **implementing a program of reforms aimed at attracting trade and foreign investment** by improving the business environment and streamlining tax and customs administration. With the most liberal investment regime among EAEU countries, Armenia can. **proudly announce itself as an attractive location with international and regional operations focused on EAEU markets**

The country has benefited from Generalized System of Preferences and a free trade agreement with neighboring Georgia. **The government has aggressively pursued strategies to improve tax administration, reduce the size of the shadow economy, and put the government's stock of debt on a downward trajectory**. Tax reforms have aimed at lowering rates, broadening the base, and improving administration. At the same time, the government has **committed** to **greater social spending** and capital expenditures that can provide a basis for **continued economic growth.**

Armenia: Country profile

Armenia is a landlocked country in the southern Caucasus. Situated between the Black and Caspian seas, it is bordered by Georgia and Azerbaijan to the north and east and by the Islamic Republic of Iran and Turkey to the south and west.

A general understanding on the country's profile, including demographics, Gross Domestic Product (GDP) growth trends, taxation and the healthcare sector in Armenia is useful in projecting consumer demand in the pharmaceutical sector, future population trends, productivity growth and government spending.

Since independence, Armenia's overall economy and quality of life has improved as a result of considerable reforms. Economic growth, however, has been volatile, as the country is still sensitive to external shocks. During 2020, serious challenges were posed to the global economy, as well as Armenia, because of the spread of coronavirus disease in 2019 (Covid-19).

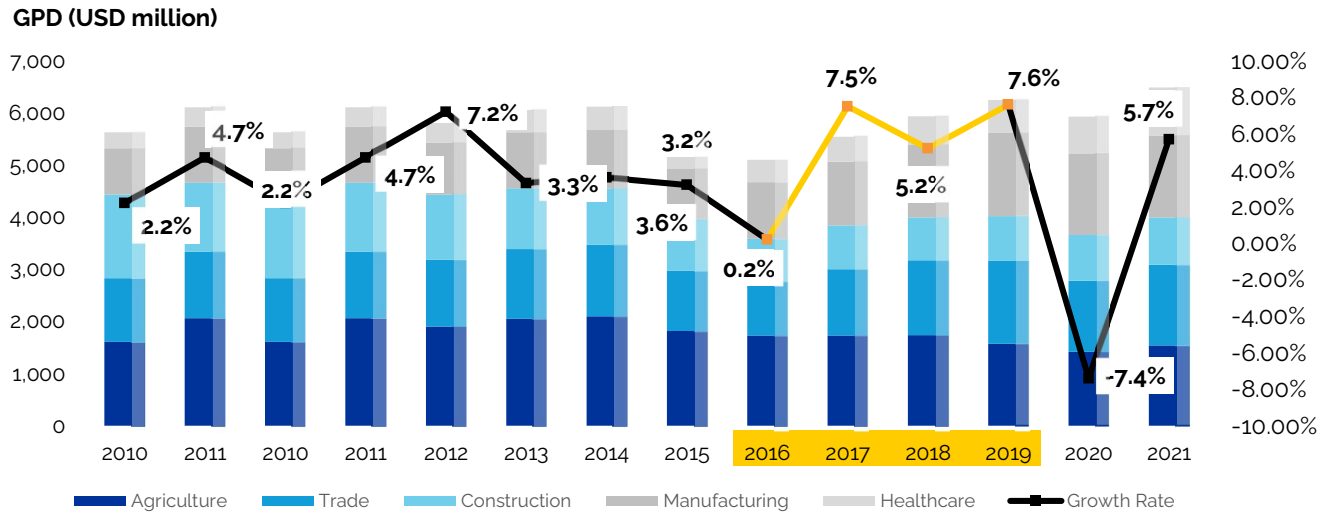
Covid-19 and the hostilities over Nagorno-Karabakh severed the challenges for Armenia compounding certain issues, including the need to upgrade the infrastructure, diversify exports and investments, upskill the labor force and strengthen the legal framework.

1.1 Economic snapshot

Armenia is an upper-middle-income country with a GDP per capita of USD 4,680 in 2021.[1] Following a slight decrease between 2013 and 2016, the Armenian economy demonstrated steady growth from 2016 to 2019. During the last decade, GDP grew at an average of 4.5%, reaching a peak of 7.6% in 2019 (a 32.9% increase over 2018)[2]. However, due to the external shocks during 2020 (Covid-19 pandemic and Nagorno-Karabakh war), the Armenian Government implemented a crisis management program, causing GDP to plummet by 7.6% (Figure 2). Like Armenia, in 2020, neighbouring Georgia and Azerbaijan also registered negative GDP growth rates of -6.2% and -4.3%, respectively.[3]

This downturn was followed by signs of recovery of the economy in 2021, with an economic growth rate of 5.7% in Armenia.[4]

Figure 2: GDP by sector, USD million, real growth rate (YoY change, %)

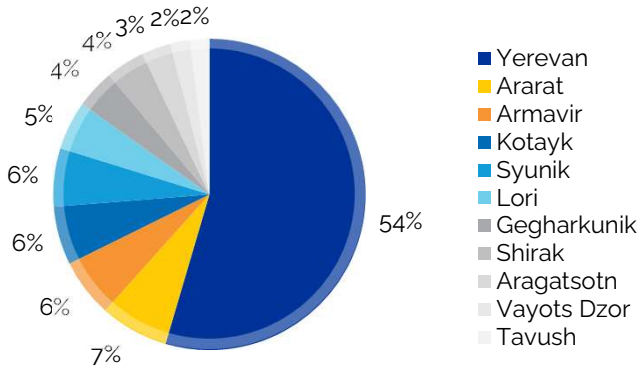


Sources: Statistical Committee of Armenia; World Bank

Yerevan is the largest administrative, economical, scientific and cultural center in the Republic of Armenia and the most important regional transport and transit junction, with a GDP share of more than 50% for the last decade.

More than half of the country's gross output was provided by Yerevan, followed by Ararat marz (region) (Figure 3).[5] Tavush, Shirak and Gegharkunik are the least developed marzes (regions) and have the smallest GDP per capita. These differences highlight the enormous variation in economic development across Armenia.

Figure 3: GDP structure by region, %



Sources: Statistical Committee of Armenia; World Bank

[1] Statistical Committee of Armenia
[2] Ibid
[3] World Bank (2021), World Development Indicators (database)
[4] Statistical Committee of Armenia
[5] Ibid

The country's most important trade partner in 2021 was Russia, which accounted for 28% of Armenia's exports and 37.2% of imports (Figure 4 and Figure 6). Armenia's trade relationships with other members of the Eurasian Economic Union (EAEU), however, are much less consequential. The European Union (EU), on the other hand, is a very important trade partner, especially for exports. About 21.7% of Armenia's exports went to the EU in 2021, with the most important export markets being Bulgaria (6.6%) and the Netherlands (6.3%) (Figure 6). On the other hand, 19.2% of Armenia's imports came from the EU. Germany (4.2%), Italy (3.6%) and Netherlands (1.6%) were the main sources of imports.
Beyond the two trading blocs, China (13% of imports and 10.3% of exports), Switzerland (0.6% of imports and 11.9% of exports) and Iraq (5.9% of imports and 0.1% of exports) were Armenia's other major partners.[6]

Armenia's mining industry was responsible for most of its exports in 2021. Mineral products (32.5%) and processed foods (20.6%) accounted for over half of the country's exports. Other major export industries were precious metals (11%) and metals (12.1%) (Figure 7). Armenia's imports were less concentrated in specific industries. Mineral products (17.5%) and machinery, equipment and mechanisms (16.8%) formed the largest categories for import in 2021 (Figure 5).[7]

Figure 4: Import destinations (2020)

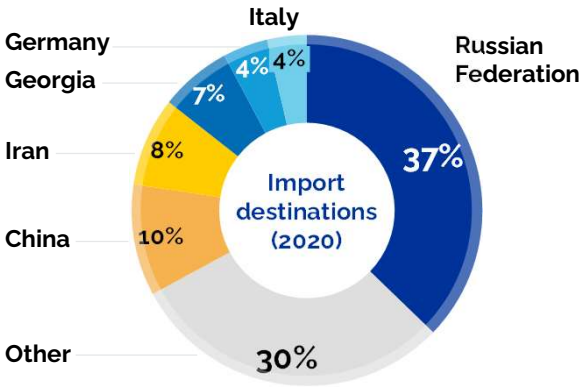


Figure 6: Export destinations (2020)

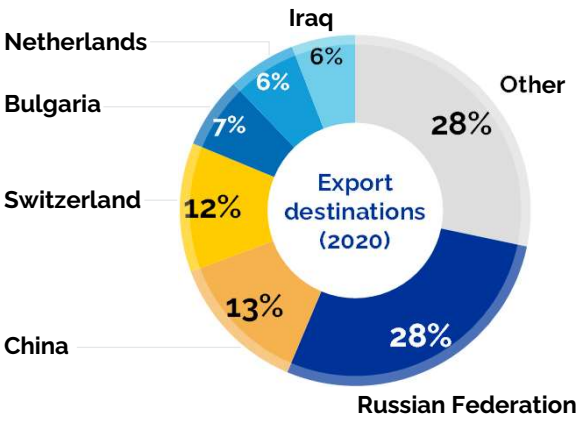


Figure 5: Import by category (2020)

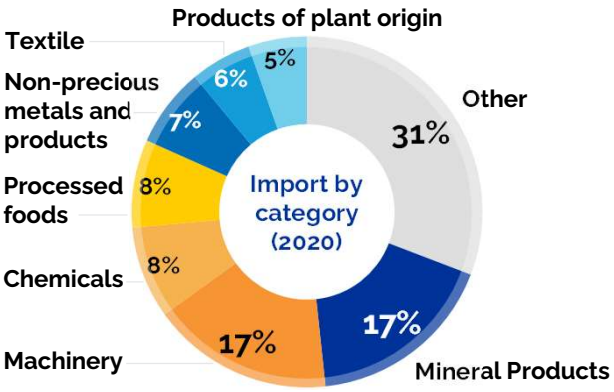
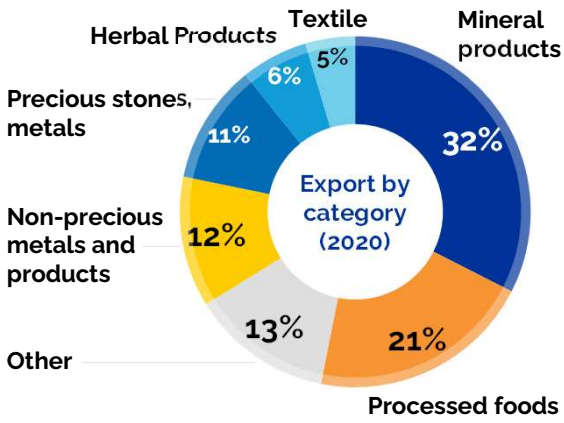


Figure 7: Export by category (2020)

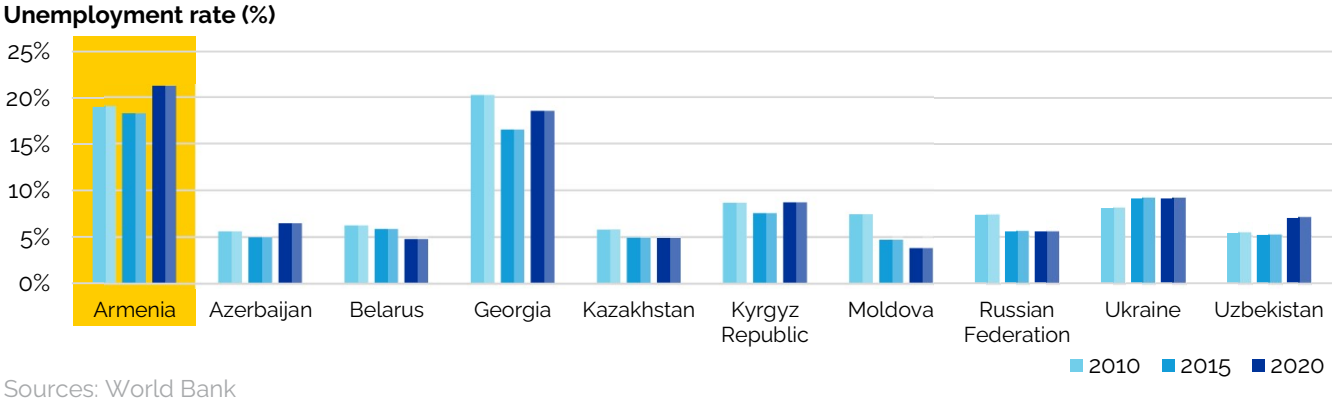


Source: State Revenue Committee of Armenia

[6] State Revenue Committee of Armenia
[7] Statistical Committee of Armenia

Armenia has had a high unemployment rate over the past years. In 2010 the rate was 19.0%, while in 2020[8] it reached 21.2%, which is considerably higher than in comparable countries (Figure 8).[9] In total, there are 1.3m employed in Armenia, while the number of unemployed in 2020 is 61,320 people (39,653 men and 21,667 women).[10] The largest proportion of unemployed are people with general secondary education (more than 50%).

Figure 8: Unemployment, total (% of total labor force)



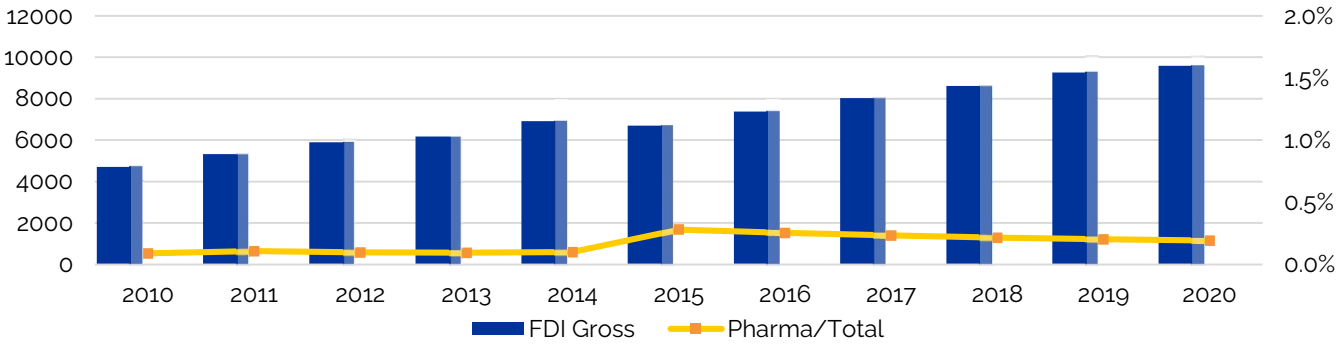
Sources: World Bank

1.2 FDI trends

During the last decade, the Armenian government has carried out numerous regulatory reforms that have contributed to improving the investment climate. Foreign investment in Armenia is regulated mainly by the Law "On Foreign Investments". Foreign investors are subject to general legislation that provides equal treatment to foreign and local investors. The law lays out the types and forms of foreign investment, sets the rights and guarantees the protection of foreign investments, establishes additional privileges for foreign-owned entities and outlines the process for settling commercial disputes. However, many investors still have concerns about weak competition policies, high levels of operational business risk, cronyism and vested interests.[11]

Armenia saw a consistent increase of gross Foreign Direct Investment (FDI) inflow during the last decade, reaching USD 9.6b in 2020[12] (Figure 9). It is important to highlight that the share of FDI in the pharmaceutical sector has never exceeded 0.3% of total gross FDI inflow. In 2020, investments in the pharmaceutical sector totaled USD 18.4m.[13]

Figure 9: Gross FDI inflow, USD million, share of the pharmaceutical sector in total gross FDI inflows, %



Source: Statistical Committee of Armenia

[8] Data for 2021 was not available
[9] World Bank (2021), World Development Indicators (database)
[10] Statistical Committee of Armenia
[11] World Bank (2017), Future Armenia: Systematic Country Diagnostic
[12] Data for 2021 was not available
[13] Statistical Committee of Armenia

Russia remains not only Armenia's most important trading partner, but also largest foreign investor, accounting for 50.6% of gross FDI inflow in 2020. Russian FDI was mostly focused on real estate and mining. France (10.2%) and Germany (5.1%) were the EU member states that invested the most, following Russia. France has focused on the beverage industry and water supply and sanitation services, while Germany has concentrated on mining and electricity, gas, steam and air conditioning supply.

Generally, the largest investments have been in the electricity, gas, steam and air conditioning supply sector (43.4% of the total) during 2020, followed by telecommunications (16.2%).

Figure 10: FDI Inflow, Top 10 Countries (2020)

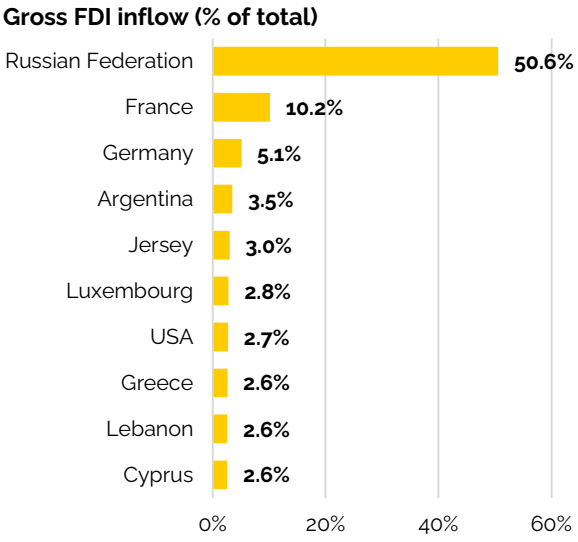
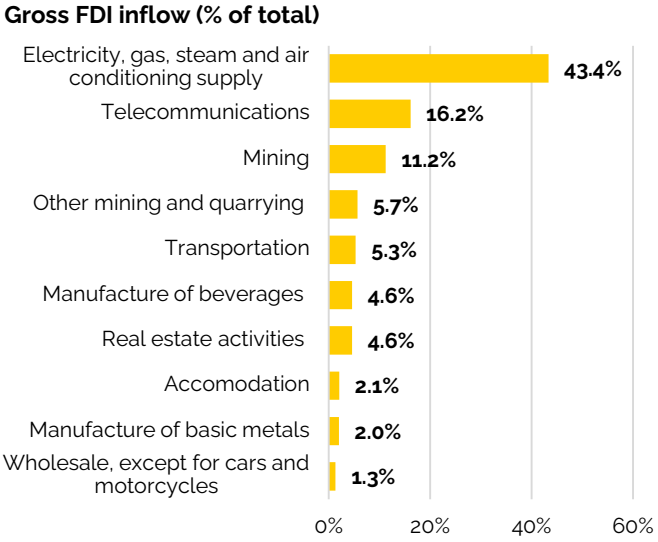


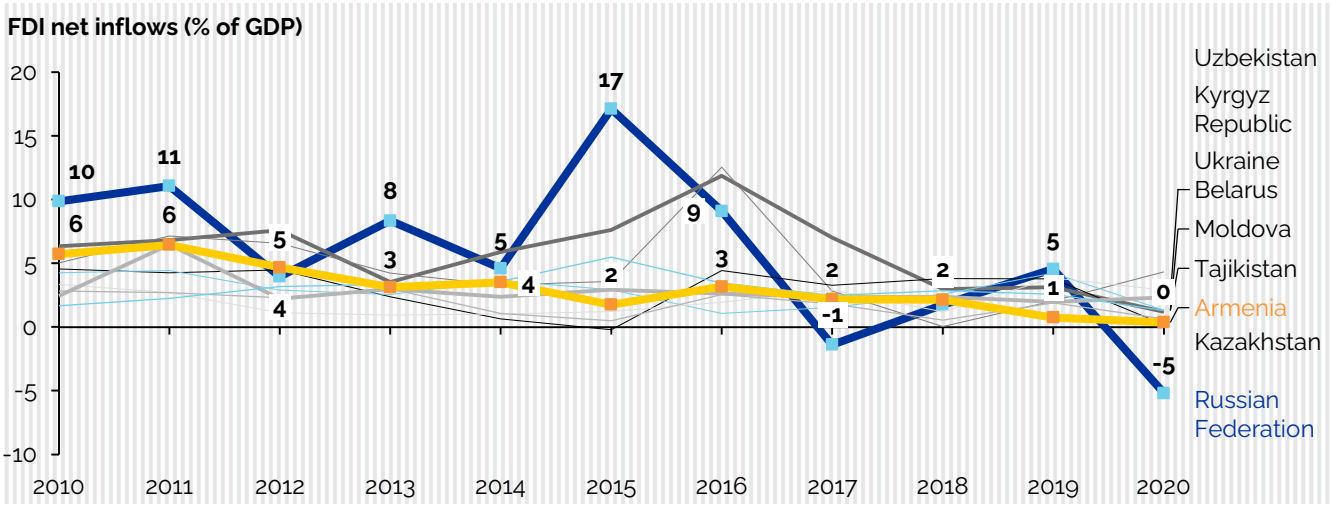
Figure 11: FDI Inflow, Top 10 Sectors (2020)



Sources: Statistical Committee of Armenia

As in other Commonwealth of Independent States (CIS) countries, net FDI inflows as a percentage of GDP have been in a downturn since 2011 in Armenia.[14] The index dropped to 0.4% in 2020, while the average for the CIS region was 0.9%, with the highest indicators in Kazakhstan (4.3%), Uzbekistan (2.9%), Belarus (2.3%) and Moldova (1.3%) (Figure 12). The highest fluctuations were reported for Azerbaijan and Kyrgyzstan, while the ratio of net FDI inflows to GDP for the rest of the countries generally have remained constant over time.

Figure 12: FDI, net inflows (% of GDP)



Source: World Bank

[14] World Bank (2021), World Development Indicators (database)

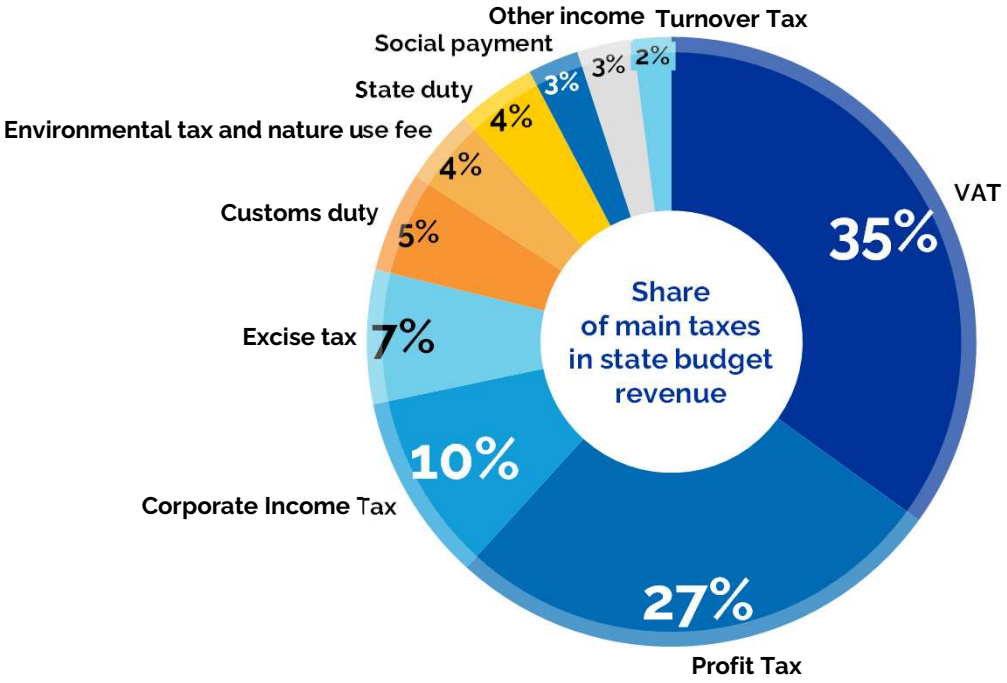
1.3 Taxes and investment incentives

The tax system in Armenia is generally favorable to business. In accordance with the Armenian Tax Code, medium and large businesses pay taxes under the general tax regime, while smaller businesses can take advantage of special tax regimes that reduce the size of the tax burden and the amount of paperwork.

- General tax regime: In general tax regime the taxpayers are subject to 18% corporate income tax (CIT) and 20% value-added tax (VAT).
- Turnover tax: Turnover tax is a form of sales tax that replaces CIT and VAT, the rates normally range from 1.5% to 5%. Only taxpayers with annual sales of less than approximately USD 240,000 can qualify for this tax regime.
- Micro-businesses: Micro-businesses, defined as businesses with annual sales of less than approximately USD 50,000. Taxpayers in this tax regime are exempt from business tax.

Tax revenue of the Republic of Armenia's (RA) State Budget in 2021 totaled USD 3.2b, an increase of 14.6% from 2020. Most taxes are paid exclusively to the federal budget. Local budgets receive revenue only from the tax on property in municipalities and several duties and local payments, in addition to federal budget subsidies. VAT is the largest revenue item, contributing almost a third of budget revenue. Tax revenue from VAT amounted to USD 1.1b (35% of total tax revenue) in 2021. Profit tax amounted to 27% of tax revenue, making it the second largest contributor to total tax revenue.

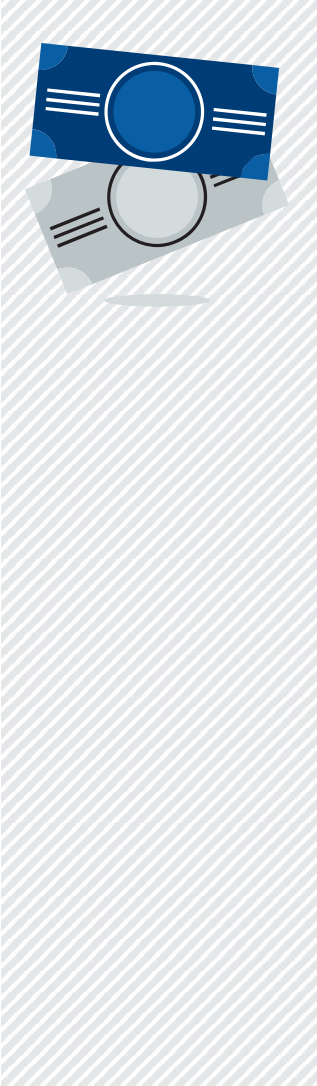
Figure 13: Share of main taxes in state budget revenue, USD million, 2021



Source: State Revenue Committee

Armenia has double taxation treaties with 46 countries. The benefits of these treaties are easily accessible by providing supporting residency documentation from foreign tax authorities. The treaties generally apply automatically when a local company holds an appropriate residency certificate issued by foreign tax authorities.

Armenia currently offers different investment incentive provisions of both, fiscal and non-fiscal nature. According to the Law "On Foreign Investment" (1994), different ad hoc incentives can be provided to investors on a case-by-case basis in targeted sectors and industries that are strategic priorities for the Armenian economy. Below is a quick overview of the relevant incentives currently offered in Armenia based on a desktop review of current legislation.[15]



1. Profit tax benefits have been adopted to support job creation projects selected by Armenian Government decrees.
2. A profit tax exemption has been provided for agricultural production through 1 January 2025.
3. Exporters may enjoy 0% VAT and 0% excise tax rates.
4. A profit tax exemption and reduced personal income tax rate (10%) are provided to certified Information technology (IT) start-up companies having up to 30 employees.
5. VAT and profit tax exemptions have been adopted for the border territories of Armenia and for investment projects above USD 3.9m in Dilijan and the adjacent territories of the Tavush marz (region) (except those in the mining and chemical production sectors).
6. A customs duty exemption is in place for materials and equipment/technology imported from non-EAEU countries that cannot be replaced by materials and equipment produced by EAEU countries for investment projects in priority sectors of the economy.
7. Medical equipment, sales of medical products, medical services are exempted from VAT payments.
8. Privileges are in place for companies that are resident in free economic zones.

Armenia's efforts to attract investments over the past decade were primarily geared towards manufacturing industries in order to generate employment, without any obvious focus on targeting specific global value chains. According to the Investment Policy Review[16] of Armenia, many incentives have been adopted or revised without adequate impact assessments.

Several of them run counter good practice by offering tax privileges that are not time-bound or by providing tax holidays rather than encouraging capital investment and reinvestment. In the context of shifting overall policy priorities towards attracting higher value-added segments of specific value chains, it will be important for the Armenian government to align its incentives policy accordingly

[15] Law on Foreign Investment, 1994; Tax Code, 2016; UNCTAD, 2019
[16] Investment Policy Review, UNDP (2021)

1.4 Healthcare

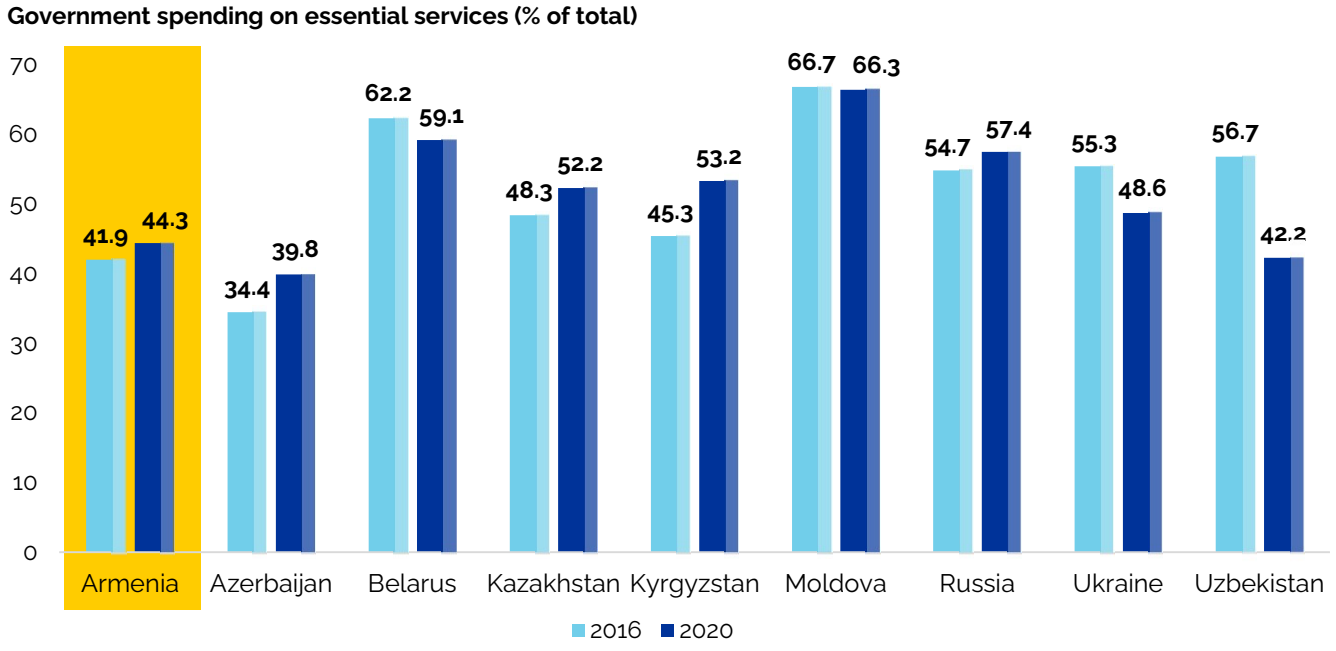
Current situation

Like other CIS countries, Armenia inherited an oversized healthcare system with widely distributed health facilities and abundant hospital beds. In subsequent years, **the Armenian government has identified major reforms for the healthcare system with the objective of improving cost efficiency.** The government has reformed and decentralized the healthcare system into three administrative divisions: municipal and community, which provide localized primary care; regional, which provides secondary care; and national, which provides tertiary care. While these levels of treatment are managed by separate levels of government, the Ministry of Health oversees overall healthcare policy. The government has taken steps to address the issues that the healthcare sector is facing. Furthermore, the government has implemented new healthcare policies to combat the increased prevalence of cardiovascular disease and cancer.

The government's focus on healthcare improvements, emphasized by a plan to build a mandatory health insurance system, will considerably increase the country's healthcare sector's development potential. The system, on the other hand, is distinguished by a lack of public funding, resulting in a disproportionate financial burden for the population. This has resulted in limited access to healthcare services, a lack of disease awareness, and subpar health results.

Spending on essential services, which include education, health and social protection, in Armenia is slightly lower than in comparable countries. In 2020[17], the proportion of total government spending on essential services was 44.3%, while in most other countries it was approximately 50% or higher (Figure 14).[18]

Figure 14: Proportion of total government spending on essential services (education, health and social protection) in 2020, %



Source: Interstate Statistical Committee of the CIS

[17] Data for 2021 was not available
[18] Interstate Statistical Committee of the CIS

In recent years, 5-7% of the state budget has been allocated to the health sector. The budget primarily funds the purchase of medical services, while funds for construction costs is limited. During 2021, USD 226m was allocated to the healthcare industry from the state budget expenditures, which was slightly higher than the budget allocated during 2020.[19]

Table 1: State budget expenditures and health budget

Year	State budget expenditures (USD million)	Health budget (USD million)	Health budget as a percentage of the state budget
2015	2,732	176	**6.45%**
2016	2,867	184	**6.42%**
2017	2,818	178	**6.31%**
2018	3,033	174	**5.74%**
2019	3,432	187	**5.44%**
2020	3,778	223	**5.89%**
2021	3,674	227	**6.19%**

Source: Law "On the state budget of Armenia for 2020"

Population and life expectancy

The population of Armenia has steadily fallen since the early 1990s, primarily as a result of emigration driven by socioeconomic and political factors. However, the population increased by 0.19% in 2020 and is expected to increase by 0.03% in 2025.

Table 2: Indicators of population growth

Indicator	1990	2000	2005	2010	2015	2020	2025f
Population, % YoY	x	-0.63	-0.65	-0.37	0.45	0.19	0.03
Population, total, **male,** '000	1,714.80	1,440.90	1,401.90	1,346.40	1,375.30	1,393.80	1,399.80
Population, total, **female,** '000	1,823.40	1,628.70	1,579.40	1,531.00	1,550.20	1,569.50	1,577.40
Population, total, '000	3,538.20	3,069.60	2,981.30	2,877.30	2,925.60	2,963.20	2,977.30
Population ratio, **male/female**	0.94	0.88	0.89	0.88	0.89	0.89	0.89

Source: World Bank

[19] Law "On the state budget of Armenia for 2020"

Armenia has made considerable strides in improving public health. In 2020[20], the average life expectancy at birth was 73.5, up from 70.7 in 2000. This places Armenia above the average for upper-middle-income countries. The average life expectancy was 68.4 at birth among men and 78.6 among women.

The main causes of death in 2020 were cardiovascular diseases (47.3%), cancer (14.8%) and external factors (10.6%). More than 84% of disability-adjusted life years are caused by noncommunicable illnesses.[21] For the prevention and control of many diseases, access to high-quality healthcare is critical. However, expanding access to high-quality care in Armenia is hampered by financial constraints.

External factors

The Covid-19 pandemic and the Nagorno-Karabakh hostilities have put pressure on the healthcare system in both urban and rural areas of Armenia. The first Covid-19 infection in Armenia was registered on 28 February 2020. In order to prevent the spread of the disease, a state of emergency was declared in the country. By the middle of September 2020, Armenia managed to reduce the number of Covid-19 cases. However, the number of Covid-19 cases began to rise sharply as a result of the large-scale war unleashed against the Nagorno-Karabakh on 27 September 2020.

During 2020, Armenia registered the highest number of confirmed Covid-19 cases per million people among CIS countries. As of the beginning of 2022, the death rate per million people for Armenia (2,687) was the second highest in the region after Georgia (3,483). For the same period, deaths per million people from the virus were 2,556 in Moldova, 2,354 in Ukraine, 2080 in Russia, 959 in Kazakhstan, 818 in Azerbaijan and 592 in Belarus.[22]

The pandemic's impact on medicine consumption has been highly variable, encompassing both peaks in chronic medicine usage, known as hoarding, and then returning to a more typical trend, with the average for developed markets reaching baseline numbers by the end of 2020.

1.5 Country rankings

The attractiveness of Armenia for foreign investors is largely a product of different macroeconomic and microeconomic factors. To measure the country's investment attractiveness, four effective measures were considered; credit rating, the Corruption Perception Index (CPI), Index of Economic Freedom, OECD (Organisation for Economic Co-operation and Development) FDI Regulatory Index and Global Innovation Index (GII). Social indices such as Gini coefficients and the Human Development Index (HDI) were also analyzed.

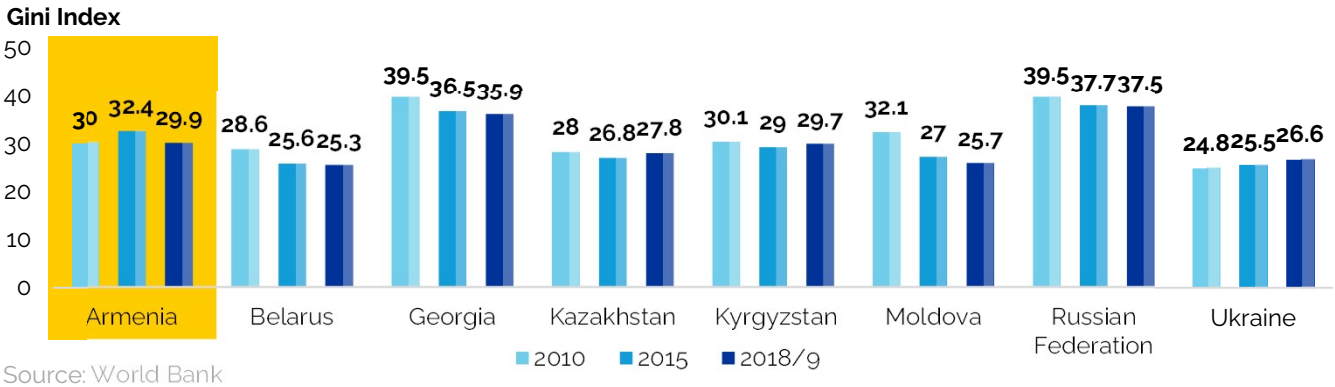
[20] Data for 2021 was not available
[21] Statistical Committee of Armenia
[22] OurWorldInData.Org (2020), Coronavirus Pandemic (Covid-19)

Gini Index

The Gini index measures the extent to which the distribution of income or consumption expenditure among individuals or households within an economy deviates from a perfectly equal distribution. A Gini index has a scale of 0-100.[23]

The Gini index in Armenia was reported at 29.9 in 2019,[24] according to the World Bank collection of development indicators.[25] The index has remained stable since 2010. The index was approximately similar for other comparable countries as well, except Russia and Georgia, which have slightly higher numbers and thus less equality (Figure 15).

Figure 15: Gini index, 2010-2019

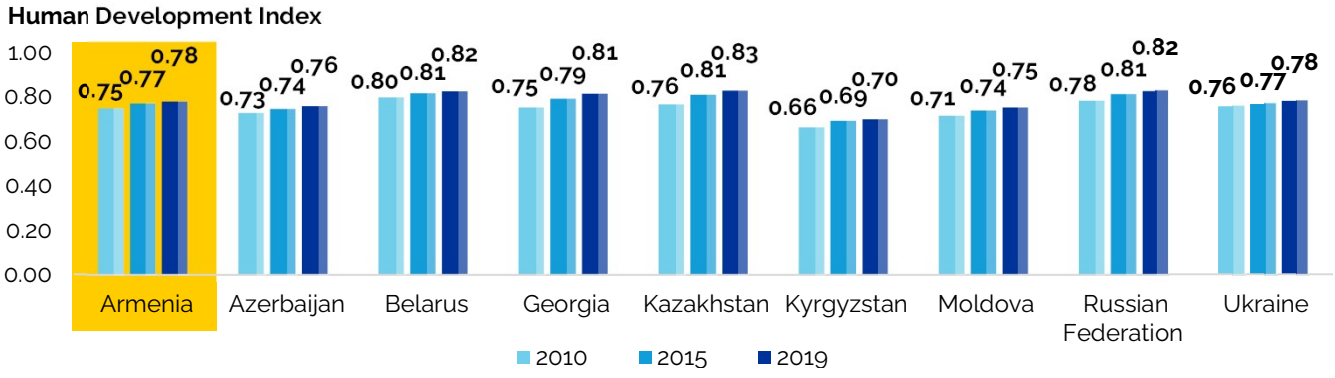


Source: World Bank

Human Development Index

The Human Development Index (HDI) is a summary measure of average achievement for each country. The Index is calculated by considering three key dimensions of human development: life expectancy, access to education and living standards.
Each country is given a HDI between 0 and 1.[26]
In 2019[27] Armenia was classified as a country with high human development index of 0.78, which increased in comparison to an index of 0.75 in 2010. Belarus, Georgia, Kazakhstan and Russia have demonstrated higher HDI but maintaining a similar growth rates since 2010 (Figure 16).[28]

Figure 16: Human Development Index in Armenia, 2010-2019



Source: UNDP (The United Nations Development Program)

[23] 0 indicates perfect equality and a coefficient of 100 shows maximum inequality
[24] Data for 2020/2021 was not available
[25] World Bank (2021), World Development Indicators (database)
[26] Very high human development (0.8-1.0), high human development (0.7-0.79), medium human development (0.55-. 70), and low human development (below 0.55)
[27] Data for 2020/2021 was not available
[28] Human Development Reports, UNDP

Credit ratings

A credit rating is an independent assessment by credit rating agencies showing the creditworthiness of a country. A credit rating generally provides investors insights into the level of risk associated with investing in the debt of a particular country, including any political risk and can also give information about the country's risk of default.

As of March 2022, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Russia and Uzbekistan have the following credit ratings (S&P, Moody's and Fitch).

Table 3: Credit ratings

	S&P	Moody's	Fitch
Armenia	B+	Ba3	B+
Azerbaijan	BB+	Ba2	BB+
Belarus	CCC	Ca	CCC
Georgia	BB	Ba2	BB
Kazakhstan	BBB-	Baa2	BBB
Russia	CC	Ca	C
Uzbekistan	BB-	B1	BB-

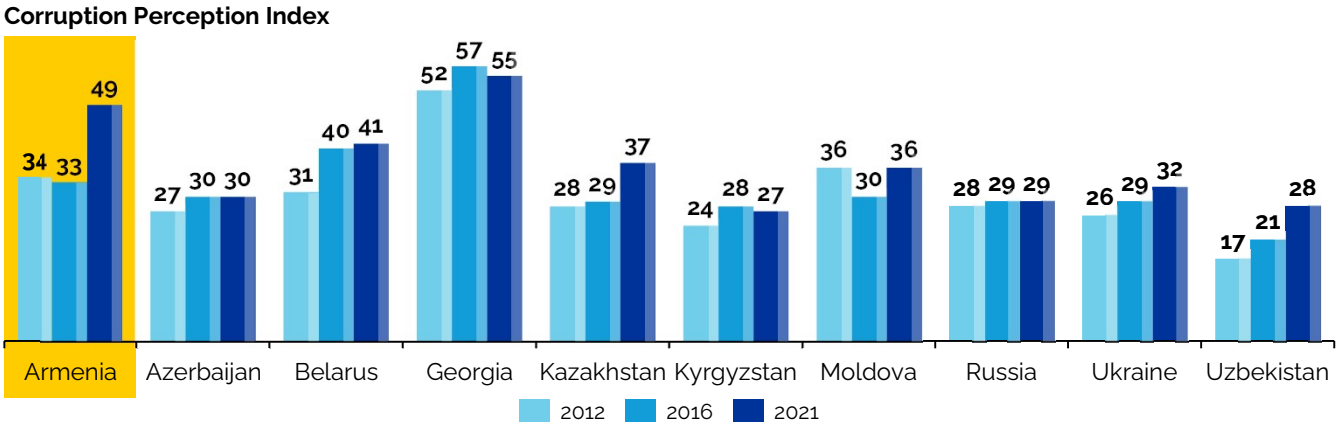
Armenia's credit rating in 2022 was affirmed at B+ by Fitch with stable outlook and at Ba3 by Moody's with negative outlook. **S&P last reviewed the Armenian credit system in 2021, giving a rating of B+ with a positive outlook.**

Corruption Perception Index

The Corruption Perceptions Index ranks 180 countries and territories by their perceived levels of public sector corruption, giving each economy a score between 0 and 100.[29]

Armenia considerably improved its position in the Corruption Perceptions Index last year. According to Transparency International, following the revolution in 2018 and the formation of a new parliament, Armenia has started to demonstrate significant progress in advancing anti-corruption policy reforms. In 2021, the Corruption Perceptions Index score in Armenia was 49 out of 100, while the average score in emerging economies was 38.[30] Only Georgia in compared countries had better results with a score of 55 in 2021 (Figure 17).

Figure 17: Corruption Perception Index, 2012-2021



Source: Transparency International

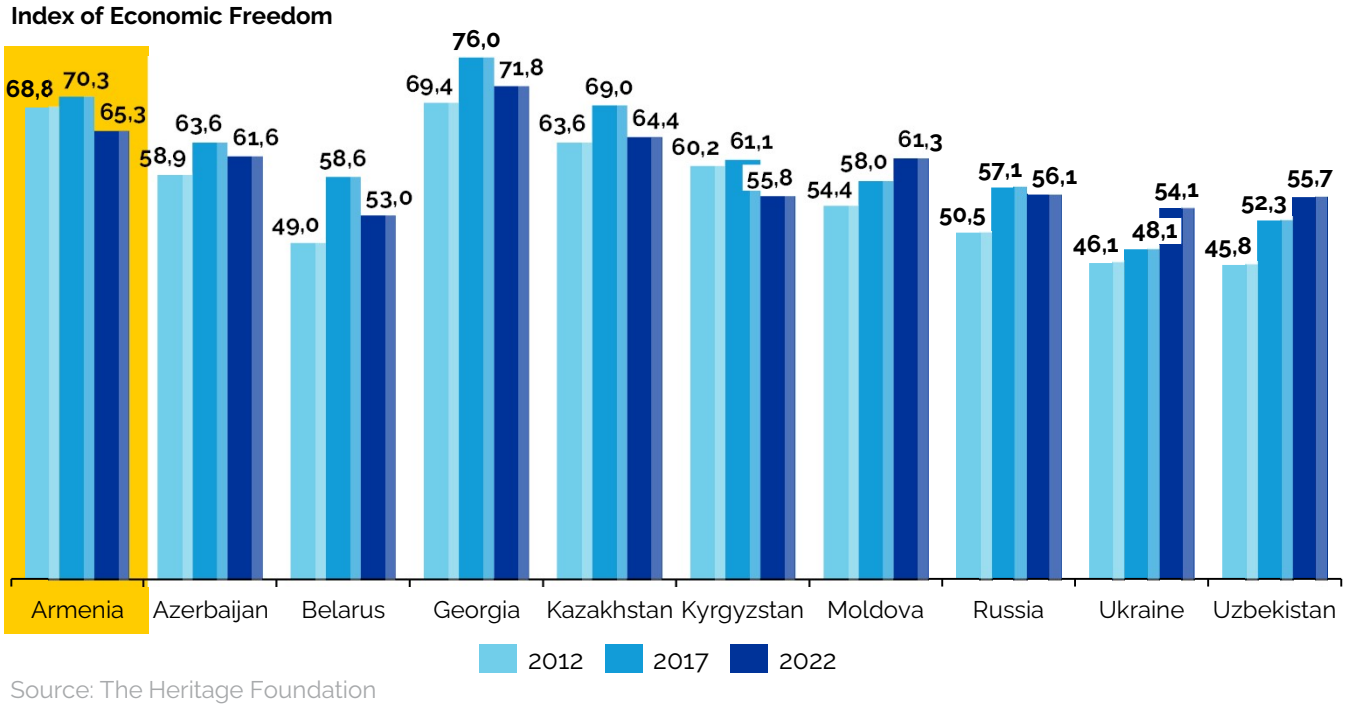
[29] The higher the corruption perception index (0-100), the less corrupt the economy is perceived
[30] Transparency International

Index of Economic Freedom

The Index of Economic Freedom published by the Heritage foundation measures economic freedom of 184 economies based on 12 quantitative and qualitative factors. These indicators are divided into four groups: rule of law (property rights, government integrity, judicial effectiveness), government size (government spending, tax burden, fiscal health), regulatory efficiency (business freedom, labor freedom, monetary freedom) and open markets (trade freedom, investment freedom, financial freedom). Considering all these freedom scores, each country receives a score between 0 and 100[31], indicating its level of economic freedom.

In the 2022 report, which takes into consideration economic policies and conditions covering the period from July 1, 2020, through June 30, 2021, Armenia had a score of 65.3, ranking 58th among 184 economies. In comparison, the scores for 2012 and 2017 were 68.8 and 70.3 correspondingly. In the 2022 report, from comparable countries, only Georgia (71.8) had a better score than Armenia (Figure 18).[32]

Figure 18: Index of Economic Freedom, 2012-2022



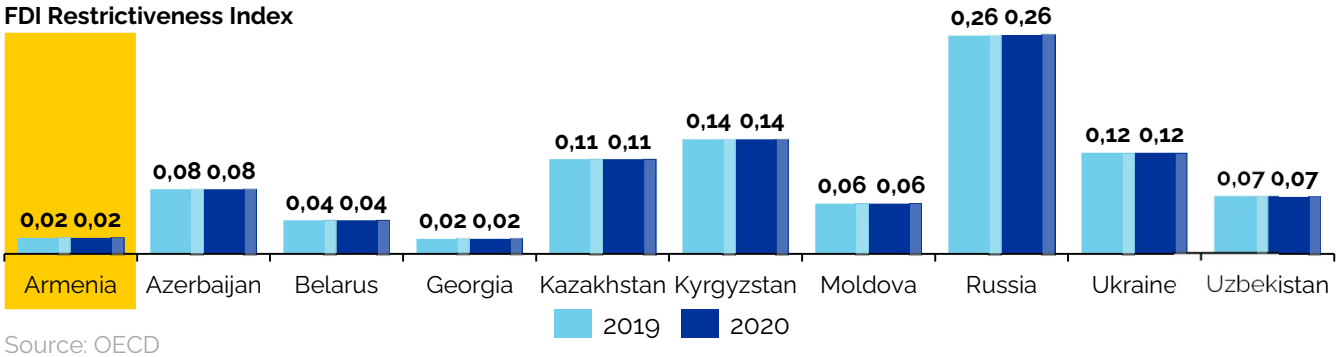
Source: The Heritage Foundation

[31] The higher the score, the better is economic freedom situation in the country
[32] The Heritage Foundation

OECD FDI Restrictiveness Index

OECD's FDI Regulatory Restrictiveness Index measures statutory restrictions that can affect foreign direct investment by considering four main types of restrictions: foreign equity limitations, screening or approval mechanisms, restrictions on the employment of foreigners as key personnel and operational restrictions. The final score is being calculated by assessing nine component sectors[33] based on the mentioned criteria for all economies and taking a weighted average. The total score ranges from 0 to 1.[34]
In 2020[35] Armenia had a total score of 0.019, which was the second-best score among comparable countries after Georgia (0.018). Russia and Kyrgyzstan had the closest scores to 1 among compared countries with total scores of 0.262 and 0.137 in 2020 respectively (Figure 19).[36]

Figure 19: OECD FDI restrictiveness, 2019-2020

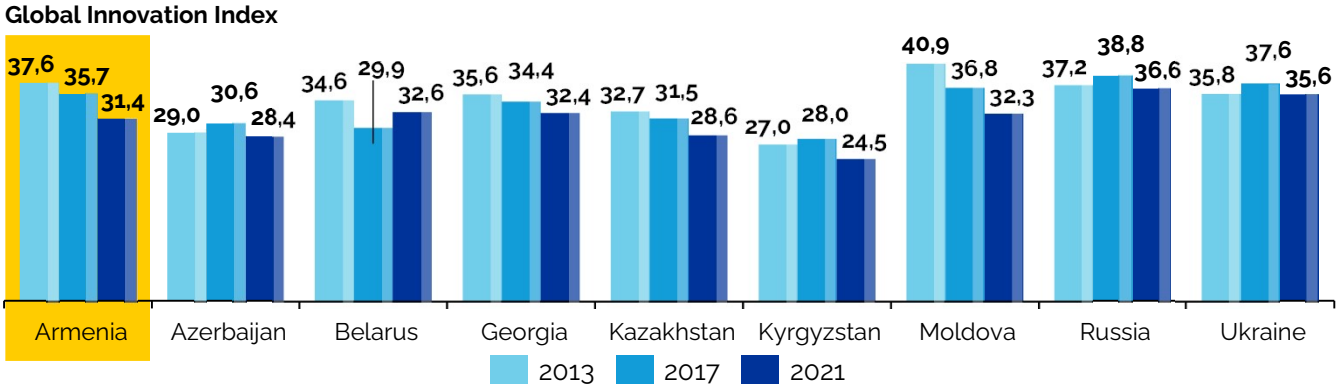


Source: OECD

Global Innovation Index

The Global Innovation Index (GII) was developed by the World Intellectual Property Organization (WIPO). Considering the most recent global innovation trends, the GII ranks the innovation ecosystem performance of economies around the globe each year while highlighting innovation strengths and weaknesses and particular gaps in innovation metrics in a score range of 0 and 100.[37]
In 2021, Armenia had a score of 31.4, ranking 69th among the 132 economies featured in the Index. In all the comparable countries, GII scores fell between 2013 and 2021 (Figure 20).[38]

Figure 20: Scores in Global Innovation Index, 2013-2021



Source: Global Innovation Index

[33] Business services, financial services, telecommunications, media, transport, distribution, electricity, manufacturing and primary sector.
[34] 0 is open and 1 is closed
[35] Data for 2021 was not available
[36] OECD
[37] 0 means no innovation and 100 means extremely innovative
[38] Global Innovation Index

2 Overview of the pharmaceutical sector

Section summary

Considered as one of the most **dynamically growing sector of the Armenian economy**, the Pharmaceutical sector **accounted for 1.9%** of the country's GDP. Negative trade balance in the pharmaceutical sector of more than USD 140m in 2020 with USD 18,5 m (CAGR of 13% since 2010) of exports and USD 161 m (CAGR of 7% since 2010) of imports create a huge potential for the local market. Although, 5,6% of all employees in the country work in the human health and social work sector, for a continuous development of the sector and to reduce the existing gaps in the labour market, create better opportunities, professionals with required level of education, knowledge, and skill sets is crucial.

Although the **Government of Armenia** has taken major steps to **help grow production**, **ease access to the consumer market, help implement GMP standards, provide tax incentives**, further interventions and **support in educational reforms**, adoption of an **agile and digitally-enabled operating models, regulatory mechanisms, reimbursement policies and international partnerships** are some of the few steps that will define the development of the pharmaceutical industry in Armenia in the coming decade.

Pharmaceutical sector overview

2.1 Armenian pharmaceutical sector

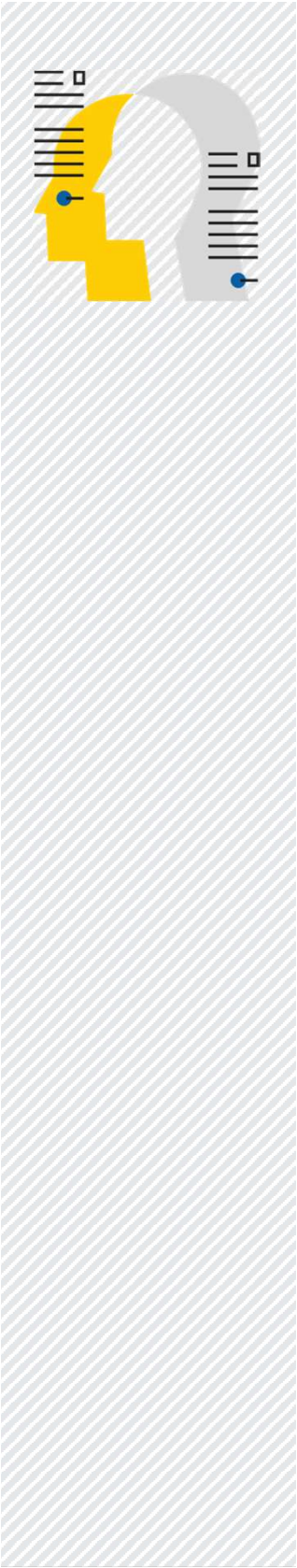
According to Government Action Plan for 2021-2026, approved by Annex 1 of the Government Decision No. 1902 of 18 November 2021, the Government has set five priority development areas: jewellery and diamonds, light and heavy industry, hardware and pharmaceuticals.

The Armenian **pharmaceutical sector** has been one of the country's **most dynamic sectors over the last decade** and has become increasingly **important to the Armenian economy**. One of the **key drivers** has been Armenia's **adoption of the EU Good Manufacturing Practice (GMP) standards in 2010** under Government of Armenia Decree No. 1603-N "On the Approval of Rules of Good Manufacturing Practice". The introduction of the GMP has laid the foundation to produce medicines in compliance with the international standards. The list of GMP certified Armenian pharmaceutical companies is presented on the website of the Ministry of Health.

Armenia's pharmaceutical market had a **volume of USD 246m in 2021**. This number accounted for **1.9% of the country's GDP** and 16.5% of total health expenditures. On a per capita basis, pharmaceutical sales in Armenia reached USD 83 in 2021.

Total healthcare spending in Armenia in 2021 reached USD 1.5b (11.3% of GDP), amounting to USD 504 per capita.[39]

[39] Fitch Pharmaceutical sector report Armenia 2022



Workforce

Armenia's public and private higher educational institutions train specialists for the pharmaceutical sector. Twelve private and public institutions offer education in pharmacy, including master's and PhD. The most well-known institutions are the Yerevan State Medical University (YSMU), Yerevan State University (YSU) and Russian-Armenian University (RAU).

These universities usually graduates general pharmacists who in most cases continue their professional careers in retail pharmacies. There are **no relevant specializations like production technologists or quality & standard specialists**, including Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP), to work in the production of pharmaceutical products.

Armenia is also home to scientific research institutes that operate in various areas. The **two key research institutes are the Institute of Fine Organic Chemistry and the Institute of Molecular Biology.** Both operate under the National Academy of Sciences of the Republic of Armenia and play an important role in the development of Armenia's pharmaceutical sector. Apart from these two institutes, the Institute of Biochemistry, ArmBiotechnology Scientific and Production Centre, Institute of Organic Chemistry, Molecular Structure Research Centre, Armenian Institute of Applied Chemistry also contribute to the development of education and research.

2

key research institutes contribute to the development of Armenia's Pharmaceutical sector

5,6%

of all employees in the country work in the human health and social work sector

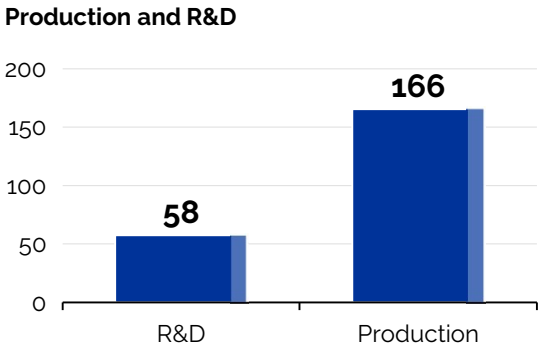
In the pharmacology sector, a total of 59,100 people (12,500 men and 46,600 women, or about **5.6% of all employees in the country**) work in the **human health and social work sector**, according to data for 2020.[40]

[40] Statistical Committee of Armenia

In the 2020/2021 academic year, the total number of new students in Armenian higher educational institutions was 17,027, including 935 students in the healthcare field.[41] **Despite a 41% increase in the number of graduates, the number of new entrants increased by only 3.9%** between 2015/2016 and 2020/2021 academic years (Figure 23). The total number of university students in healthcare fields in 2020 was 6,898. There are 12 medical institutions in Armenia (10 in Yerevan, 1 in Shirak and 1 in Tavush).

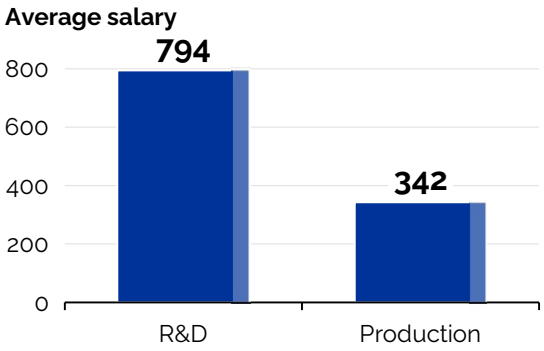
According to interview results, local producers and R&D firms on average have 160 and 57 employees respectively, 90% of them have higher education. In both sub-sectors subject matter employees exceed 85% of all employees, mainly consisting of technologists, chemists, analysts, R&D and quality assurance specialists. The average salary per sub-sector is presented below:

Figure 21: Average number of employees



Source: Statistical Committee of Armenia

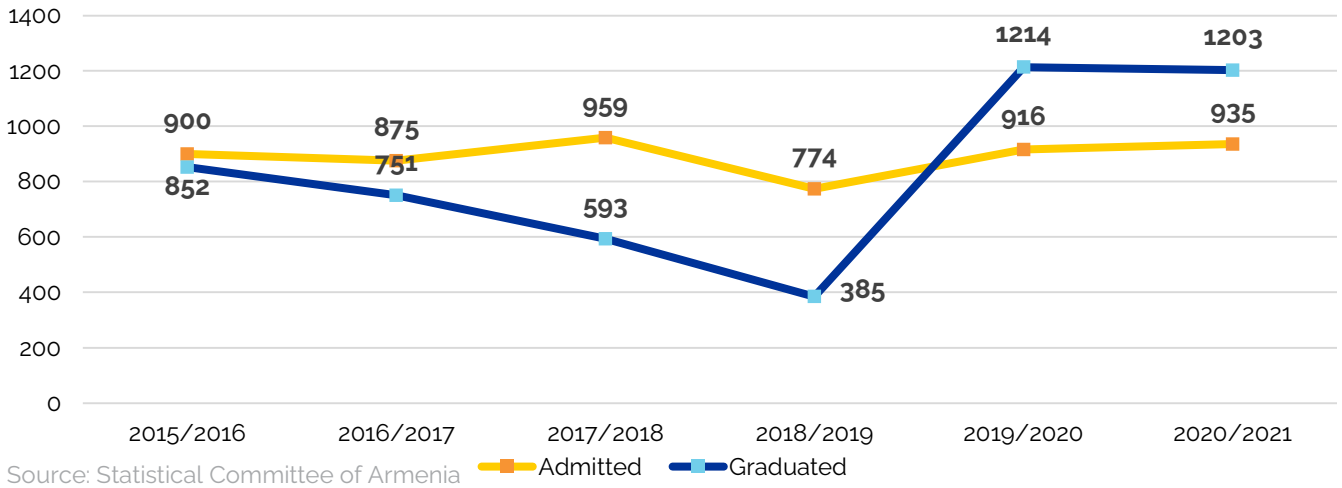
Figure 22: Average salary, USD



Source: Interview results

According to the Statistical Committee of Armenia, the average annual salary in the health sector in Armenia in 2020[42] was USD 5,395, which is like that in other EAEU countries and neighboring countries, apart from Russia, where salaries are higher, and Kyrgyzstan, where they are lower.

Figure 23: Number of entrants and number of graduates from higher educational institutions in healthcare



Source: Statistical Committee of Armenia

However, the interview result shows that the salary differs for professional and non-professional workers in the field. The differences between the two groups are significant: non-professional workers earn annually from USD 3,000 to USD 4,000, while professional workers earn from USD 7,500 to USD 12,500 on average.

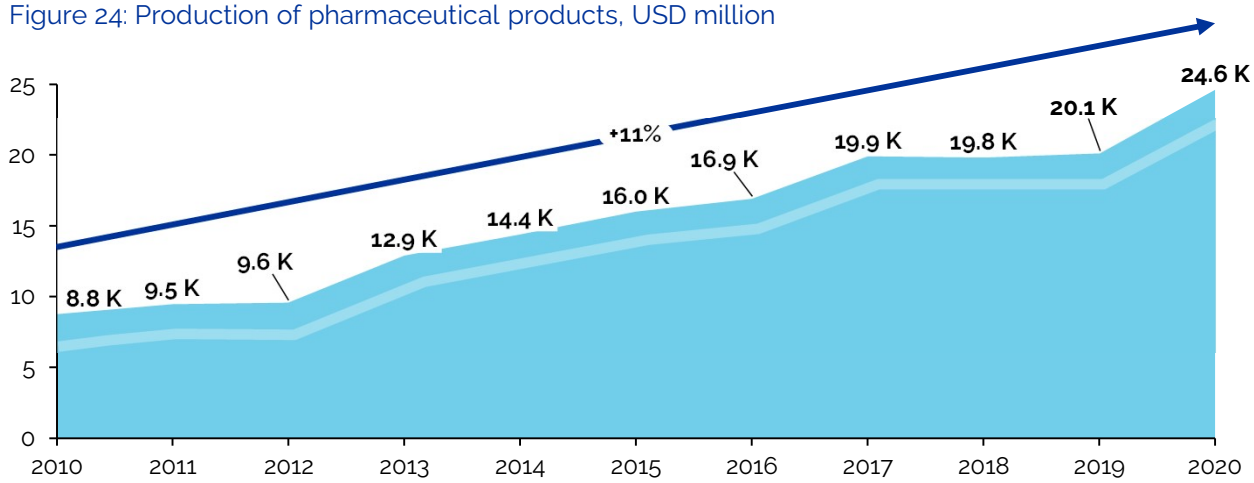
[41] Statistical Committee of Armenia.
[42] Data for 2021 was not available

One of the biggest obstacles for the local producers, as well as the representative offices and institutes, has been finding qualified staff that meet their minimum requirements. The current workforce does not have the required level of knowledge, creating an ask for investing resources in training and upskilling their employees. In addition to that the staff should also participate in different training programs for professionals, organized in Armenia and abroad. Although, the Armenian research organizations and institutes have not voiced concerns on finding qualified employees, their main concern is lack of continuing education and training outside of Armenia to provide international exposure.

Production

The **24 pharmaceutical companies** operating in Armenia **manufacture 360 registered medicines** and **91 registered veterinary drugs**. These companies produce infusion solutions, eye drops, tablets, capsules, ointments, etc. The **production of pharmaceutical products** reached a **peak of USD 24.6m in 2020**.[43]

Figure 24: Production of pharmaceutical products, USD million



Source: Statistical Committee of Armenia

Only 14.3% of interviewed producers have representative offices and production facilities outside of Armenia.

Market Entry Analysis

The **market entry to pharmaceutical sector** was analysed using Porter's 5 Forces based on the **stakeholder interviews and PwC analysis**. According to the results, the **sector has medium competitive rivalry**. The **supplier power is relatively low**, provided, most of the materials are imported and can be easily replaced. The **buyer power is evaluated as medium**. The overall **threat of new entrants is evaluated as medium**, as there might be obstacles in some of the sub-sectors. Lastly the **threat of substitute products is evaluated high,** as local products might be easily replaced with imported products.

Competitive Rivalry (Medium)
There are several medium-sized producers and organisations that mostly produce generics, biologically active supplements and medical supplies. Sector growth is slow, since more firms compete in gaining market share both from local companies, and companies that import products to the market. The barriers for entry are also high. Overall, competition is moderate in the pharmaceutical sector.

[43] Statistical Committee of Armenia, Data for 2021 was not available

Supplier Power (Low)
Pharmaceutical products require various types of raw materials. As there are no local producers, importers or distributors specializing in pharmaceutical raw materials in Armenia, pharmaceutical companies import raw materials on their own. In the global market, on the other hand, the choice for suppliers is numerous, making it easier for Armenian pharmaceutical companies to choose the best possible option for importing raw materials while mitigating risks of being dependent on one supplier, making supplier power in the sector low.

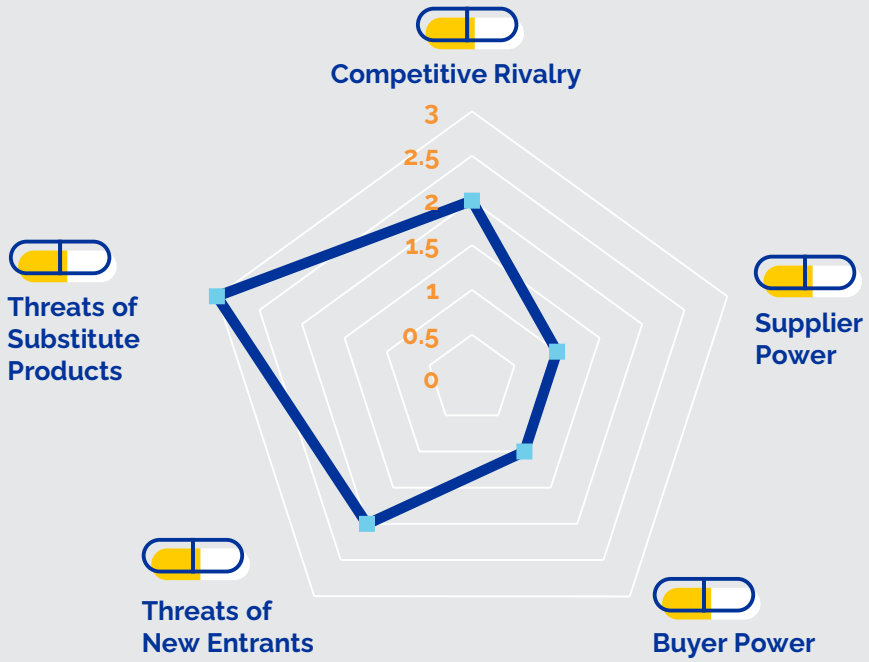
Buyer Power (Medium)
Larger customers such as hospitals and healthcare organisations can exert pressure to keep prices in check. However, individual (& smaller) customers have very little bargaining power in this sector. This is largely because of the prices increase for generic drugs over time. Overall, the bargaining power in the sector depends on the volumes and can be considered as medium.

Threat of New Entrants (Medium)
Entering the production sector requires long-term processes such as R&D, registration, and lengthy approval processes from regulatory authorities. It can be expensive and risky. Additionally, there are no specific privileges for local producers in the pharmaceutical sector or readily available experienced workforce. On the contrary, some of the sub-sectors of the pharmaceutical sector are easy to enter, like R&D and CRO. Therefore, the overall threat of new entrants is evaluated as medium.

Threat of Substitute Products (High)
Generally, there is enough availability of substitute products in the pharmaceutical sector, and as the demand continues to increase, the sector strives. Local producers tend to concentrate on generics and biologically active supplements. Demand for imported products in the market is strong as for the customers, it is easy to switch to substitute products. In addition, many imported products from Russia, China and India, comprising 20% of Armenian pharmaceutical imports, are priced lower than the European and considered to have similar or equally similar quality, making it is easier for consumers to shift to another product.

***Valuation of assumptions and grading was done based on industry expertise.**

Figure 25: Market entry analysis for the pharmaceutical sector in Armenia based on Porter's 5 forces

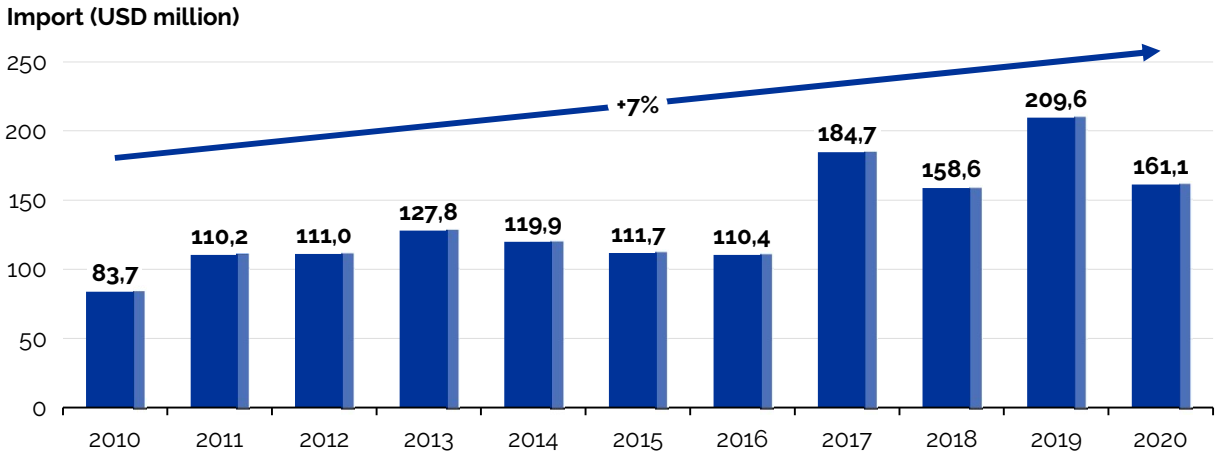


Source: PwC analysis

Imports[44]

Armenia imported **USD 161.1m** worth of pharmaceutical products in **2020 (a CAGR of 7% in the last decade)** . The highest growth of 67% was registered between 2016 and 2017, when the total volume of imports reached USD 184.7m in comparison to USD 110.4m in the previous year, but the largest volume of imports of pharmaceutical products (USD 209.6m) was registered in 2019. After a 32% increase in imports of pharmaceutical products in 2019, imports fell by 23.1% in 2020.

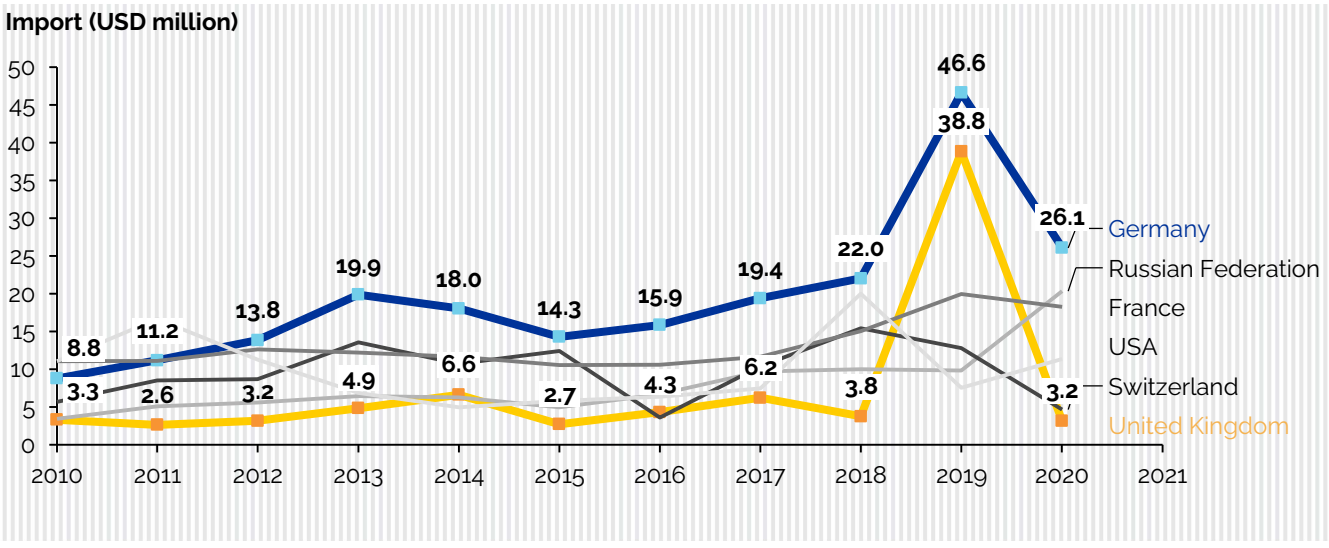
Figure 26: Imports of pharmaceutical products, 2010-2020



Source: UN Comtrade

Over the last three years, **Germany has been the largest provider** of pharmaceutical products to Armenia, followed by **France and the United Kingdom**. In 2020, pharmaceutical products worth USD 26.1m were imported from Germany, accounting for 16.2% of all imported pharmaceutical products. The value of pharmaceutical imports from Germany between 2019 and 2020, however, fell by 44% from USD 46.6m. The second largest source of pharmaceutical imports for Armenia in 2020 was Russia. The value of pharmaceutical products imported from Russia amounted to USD 20.3m in 2020. **In contrast with Germany, the value of imports from Russia increased by 108%** (from USD 9.8m to USD 20.3m) **in 2020.**

Figure 27: Imports of pharmaceutical products by country, 2010-2021



Source: UN Comtrade

[44] UN Comtrade

Over the last 10 years, the **largest share** of pharmaceutical products imported to Armenia were for the **3004 CCG** (medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses). This group **accounted for 85.2%** of pharmaceutical product imports during this period. The import of 3004[45] CCG products has **remained stable over the last 10 years** and reached USD 132.1m (82% of total 30[46] CCG) in 2020. Imports of 3004 CCG products amounted to USD 132.7m in 2018 (19% decrease) and USD 181.1m in 2019 (36.4% increase).

The **second largest group** of products, which accounted for 11% of imports, is **represented by 3002[47] CCG**, which presents blood, antisera, other blood fractions, immunological products, vaccines, toxins, cultures of microorganisms, etc. Imports of 3002 CCG products have also **remained relatively stable over the last 10 years**, reaching USD 21.7m (13.5% of total 30 CCG) in 2020. Imports of 3002 CCG products amounted to USD 20.5m in 2018 (24% increase) and USD 22.2m in 2019 (7.9% increase).

Figure 28: **Imports** of pharmaceutical products by four-digit CCG, 2010-2020 average

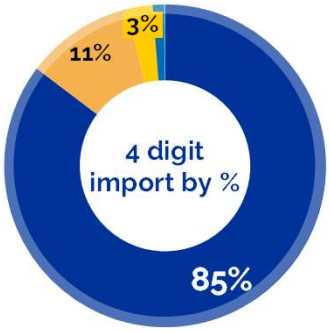
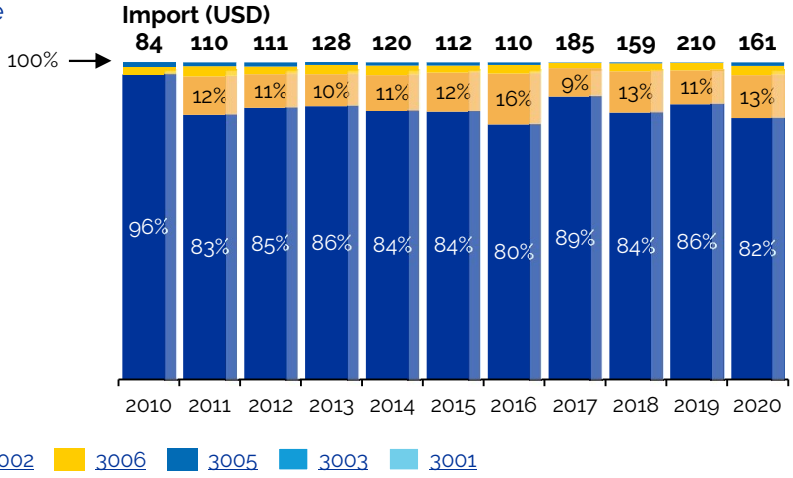


Figure 29: **Imports** of pharmaceutical products by four-digit CCG, 2010-2020



Source: UN Comtrade

The largest group of products imported to Armenia over the last 10 years have been medicaments consisting of mixed/unmixed products for therapeutic/prophylactic uses (300490[48] CCG). Imports amounted to USD 1.1b or 73% of total pharmaceutical products (Group 30[49]) and 85.6% of Group 3004 imports from 2010 to 2020.

[45] Medicaments (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale
[46] Pharmaceutical products
[47] Blood (human or animal) for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, modified immunological products, (from biotechnological processes or not); vaccines, toxins, microorganism cultures (not yeasts), similar products
[48] Medicaments consisting of mixed or unmixed products
[49] Pharmaceutical products

Over the last ten years, the largest three groups of products under the 3002[50] CCG are 300230[51] (USD 49.9m or 30.6%), 300220[52] (USD 36.8m or 22.5%) and 300210[53] (USD 28.3m or 17.3%). In 2020, the second largest group after vaccines for human medicine (27.6%) were blood, human or animal, antisera, other blood fractions and immunological products (25.9%).

3002[50] CCG

300230[51]	300220[52]	300210[53]
USD 49.9m or 30.6%	**USD 36.8m or 22.5%**	**USD 28.3m or 17.3%**

Figure 30: Top five imports of pharmaceutical products by six-digit CCG, 2010-2020 average

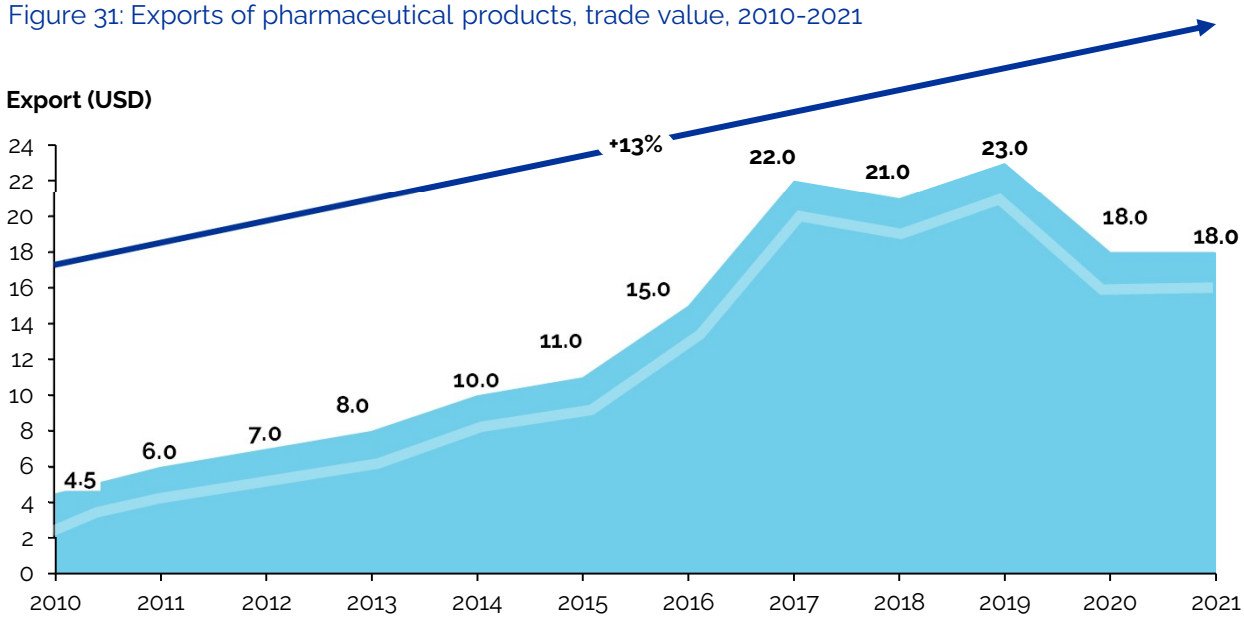
Source: UN Comtrade

[50] Blood (human or animal) for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, modified immunological products, (from biotechnological processes or not); vaccines, toxins, microorganism cultures (not yeasts), similar products
[51] Vaccines for veterinary medicine
[52] Vaccines for human medicin
[53] Blood, human or animal, antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes

Exports

Armenia exported pharmaceutical products worth a total of USD 18.3m in 2020. More than 70% of the pharmaceutical products manufactured in Armenia in 2020 were exported. A record USD 23.1m of pharmaceutical products were exported in 2019.

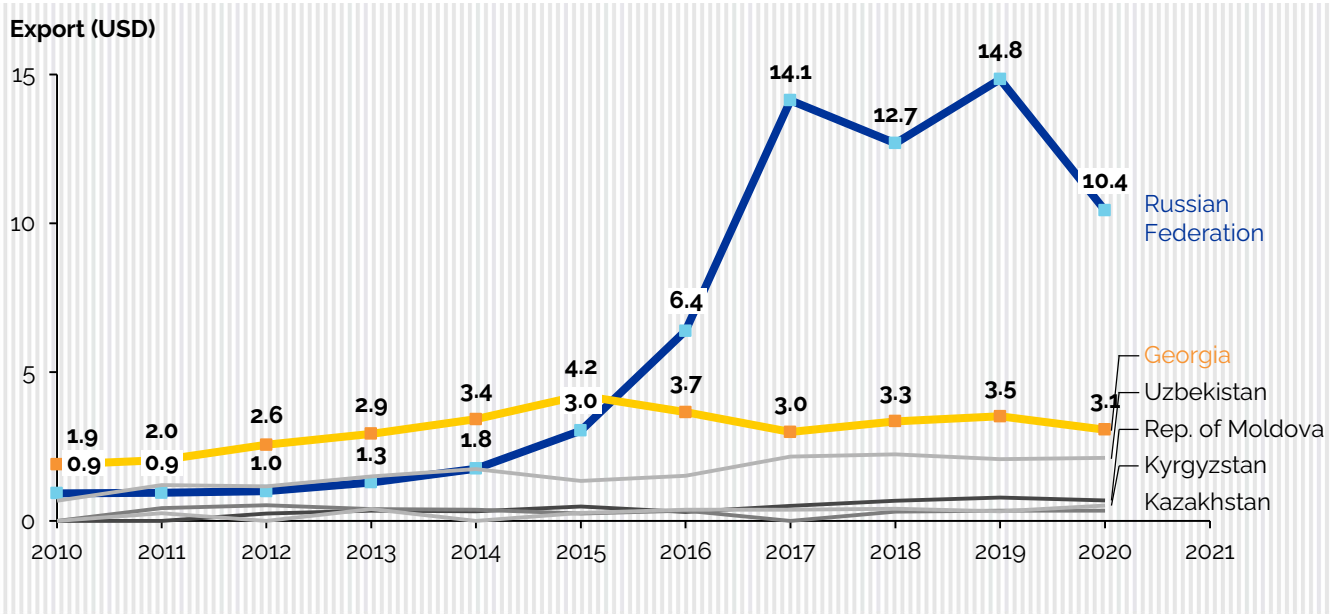
Figure 31: Exports of pharmaceutical products, trade value, 2010-2021



Source: UN Comtrade

Russia is the largest consumer of Armenian pharmaceutical products, followed by Georgia and Uzbekistan. In 2020, a total of USD 10.4m worth of Armenian pharmaceutical products, representing 56.9% of all pharmaceutical exports, were exported to Russia. In 2020, total pharmaceutical exports fell by 20% over the previous year (USD 23.1m in 2019). In 2020, the second largest recipient of pharmaceutical exports was Georgia. Armenia exported USD 3.1m worth of pharmaceutical products to Georgia in 2020.

Figure 32: Exports of pharmaceutical products by country, 2010-2021

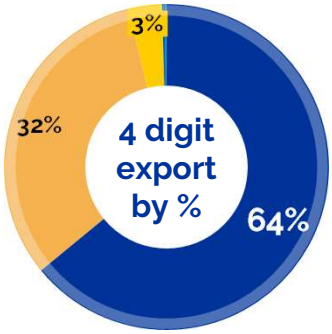


Source: UN Comtrade

Over the last 10 years, most of the pharmaceutical products exported from Armenia were for the 3004[54] CCG, i.e. medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses. This group accounted for 64.1% of total pharmaceutical product exports during this period. Exports of 3004 CCG products have remained stable over the last 10 years and reached USD 10.7m (58.4% of total 30[55] CCG) in 2020. The exports peak of 3004 CCG products was USD 13.5m in 2017. Since that exports decreased by 12.5%, 3.4% and 6.1% for the next three years respectively and reached USD 10.7m in 2020.

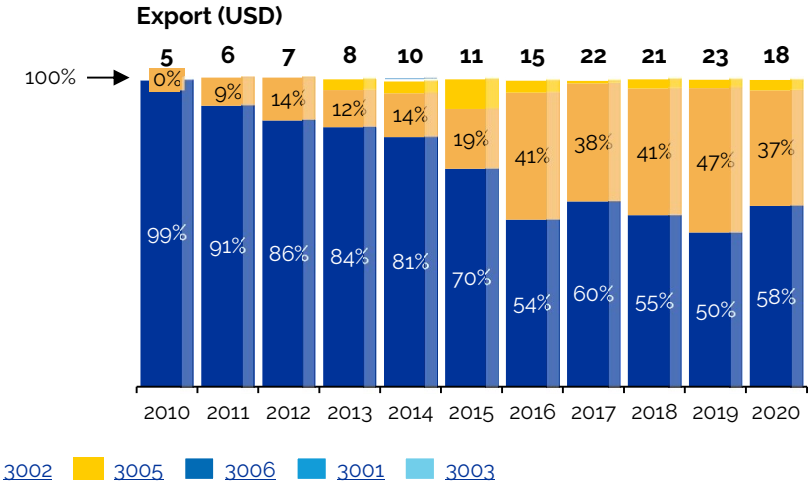
The second largest group of products–32.1% of exports–was from the 3002[56] CCG. Exports of 3002 CCG products have remained relatively stable over the last 10 years and amounted to USD 6.8m (37.4% of total 30 CCG) in 2020.

Figure 33: **Exports** of pharmaceutical products by four-digit CCG, 2010-2020 average



Source: UN Comtrade

Figure 34: **Exports** of pharmaceutical products by four-digit CCG, 2010-2020



Source: UN Comtrade

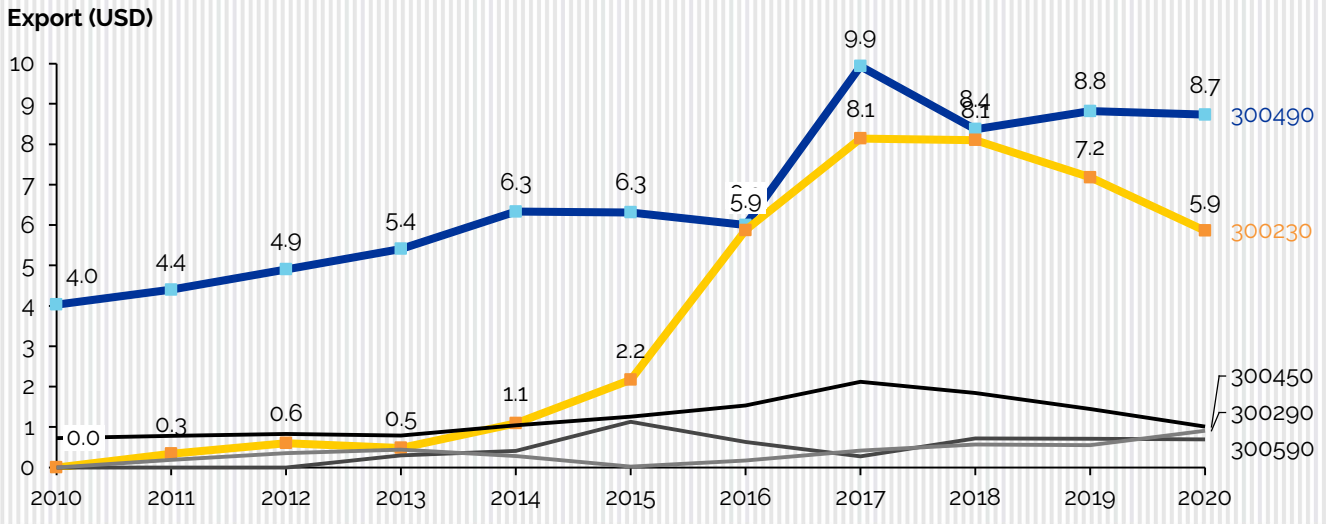
The largest share of pharmaceutical products exported from Armenia over the last 10 years was accounted for by medicaments consisting of mixed/unmixed products for therapeutic/prophylactic uses (300490 CCG)[57]. This group accounted for USD 73m or 49.9% of total pharmaceutical products (group 30[58]) and 78% in group 3004[59] imports from 2010 to 2020.

[54] Blood, human or animal, antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes
[55] Medicaments (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale
[56] Pharmaceutical products
[57] Blood (human or animal) for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, modified immunological products, (from biotechnological processes or not); vaccines, toxins, microorganism cultures (not yeasts), similar products
[58] Pharmaceutical products
[59] Medicaments (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale

Over the last ten years, the largest two groups of products under the 3002[60] CCG consisted of veterinary vaccines and human blood, animal blood prepared for therapeutic/prophylactic/ diagnostic uses, toxins, cultures of microorganisms and similar products and accounted for approximately 92.8% of exported products under the 3002 CCG.

The largest group of products exported from Armenia to Russia over the last 10 years have been 300230[61] CCG.

Figure 35: Exports of pharmaceutical products by six-digit CCG, 2010-2020 average



Source: UN Comtrade

The vast majority of interviewed local producers were exporting their products, the percentage of which differed across the companies. The main destinations for the exports were Russia, Georgia, Uzbekistan, Ukraine, Kazakhstan, Belarus. The perception of general rules for registration and examination of medicines for medical use in the EAEU differed among local producers. Some of them were viewing this as an opportunity to enter the 180-million-person market of EAEU, while others were thinking this could lead to higher competition by Russian companies, as they receive subsidies from their government. Many companies thought it would be strategic for the future to consider North Africa and Middle East countries as a possible direction for promoting export.

Import and Export effect on Pharmaceutical market development in Armenia

Negative trade balance in the pharmaceutical sector of more than USD 140m in 2020 with USD 18,5 export and USD 161 import, shows huge potential for the local market. More than 95% of Armenian import in pharmaceutical sector consisted of 3004 and 3002 CCG products, out of which the highest numbers accounted for 300490 CCG code and was evaluated at USD 106m in 2020 constituting more than 65% of total pharmaceutical import. Currently local producers cover only 4% of Generics market and less than 3% of total retail market in Armenia, leaving a big opportunity to cover the domestic market by local producers.

[60] Blood (human or animal) for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, modified immunological products, (from biotechnological processes or not); vaccines, toxins, microorganism cultures (not yeasts), similar products
[61] Vaccines for veterinary medicine

Export of Armenian pharmaceutical products increased significantly in recent years from USD 5m in 2010 to USD 18m in 2020. The biggest export volumes accounted for 3002 and 3004 CCG with almost the same share as import (~96%). CCG 3002 had one of the highest share mostly due to huge share of export of veterinary vaccines (300230). Although 300490 code also contributed to an equally high share of export and doubled in the last 10 years. The main producers of this category of products are Liquor, Aprimed and Pharmatech.

Russia is the main trade partner of Armenia with more than 55% share of export and more than 10% of import. Most of the exports from Armenia were directed to post-soviet countries.

The sections in the following chapters will describe the rationale, assessment and investment attractiveness of certain sub-sectors for Armenia considering the geographical, economical and social implications of these sub-sectors. The review and assessment will also be based on the integrity of such sub-sectors in the cycle of pharmaceutical product invention and production, global trends, desktop research, and PwC analyses. Clinical Trials, Generics, API, Research & Development, Contract Research Organizations (CRO) and Contract Manufacturing Organizations (CMO), Standards Development,

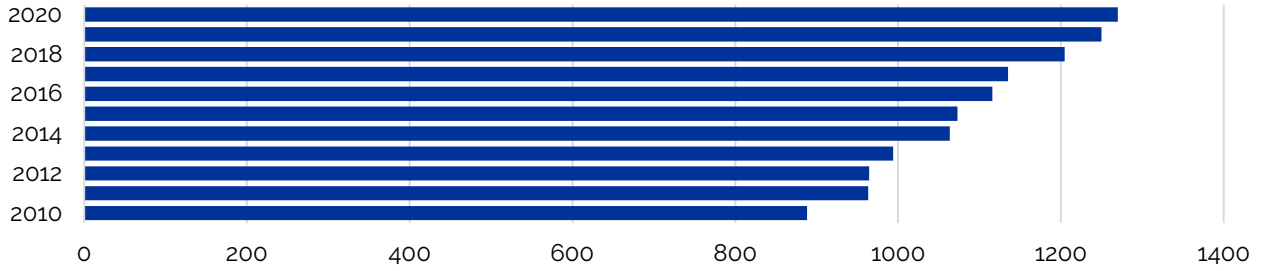
2.2 Global Pharmaceutical Sector

Market overview

The pharmaceutical sector represents the development, manufacturing, and sale of branded and generic drugs. Starting from 2017, the market has grown at an average annual rate of 5.8%. Over this time, global pharmaceutical consumption has increased, largely driven by the growing need for pharmaceuticals to treat age-related and chronic disorders, as well as changes in clinical practice.[62]

In 2020[63], the value of the market was in the order of USD 1.24 t compared to USD 888.2 b in 2010. This represents about 1.5% of global GDP and more than 13% of global health expenditures. The value of the market is expected to rise and reach almost USD 1.6 t by 2025.[64]

Figure 36: Global pharmaceutical revenue (USD b)



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Revenue	888.2	963.2	964.4	993.8	1063.6	1073.1	1115.7	1135.1	1204.8	1250	1270

Source: Fitch Global Pharmaceuticals & Healthcare Report

[62] González Peña, O., López Zavala, M., & Cabral Ruelas, H. (2021). Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater
[63] Data for 2021 was not available
[64] Fitch Global Pharmaceuticals & Healthcare Report | Q1 2022

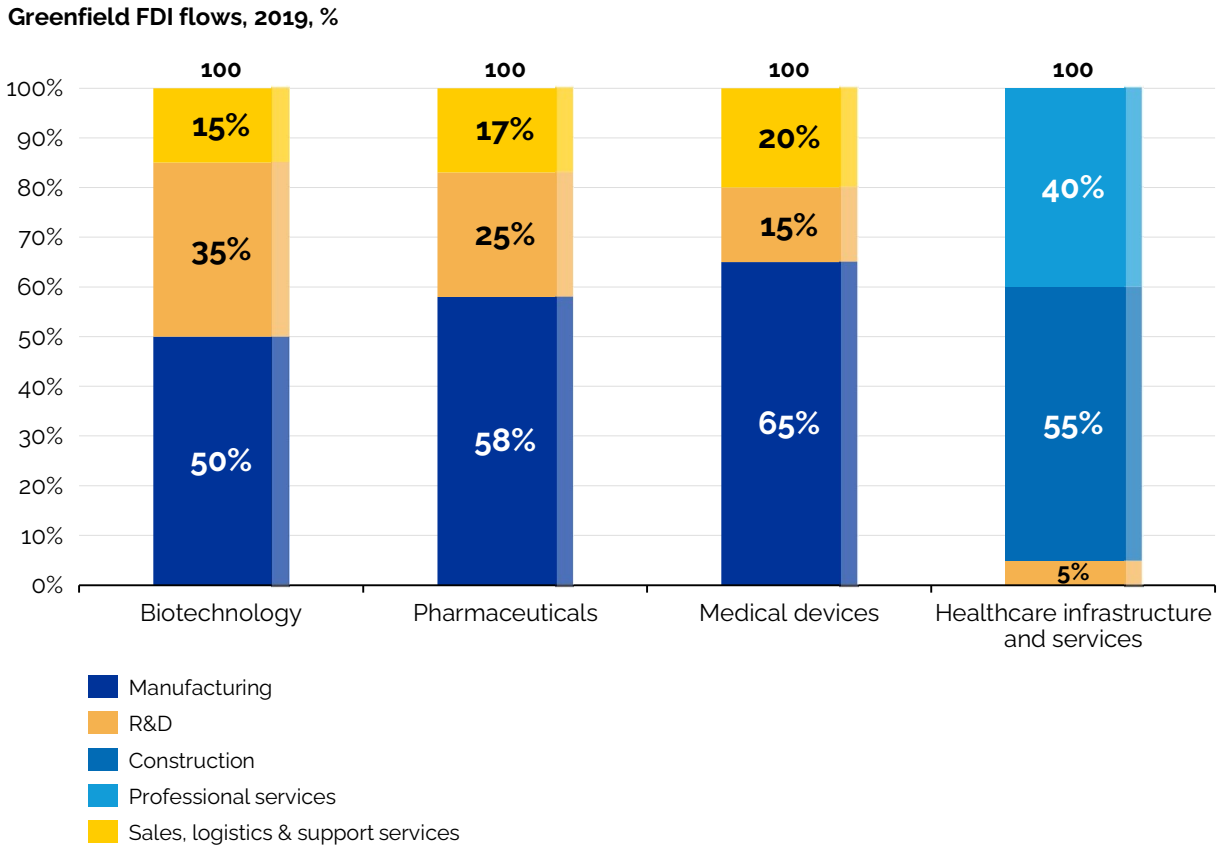
The global driver of the pharmaceutical market is North America (48.9%), with the United States (US) as the leading pharmaceutical market. However, recently emerging markets like Brazil, India, Russia, Colombia and Egypt are becoming important players in the sector. The pharmaceutical market is expanding in Latin America as well, although its contribution to the global market is still not as significant. The Chinese pharmaceutical sector has been among the fastest growing markets in recent years.[65]

Greenfield FDI in the health sector by activity

Healthcare goods and technologies – including pharmaceuticals, biotechnologies, and medical devices – together were responsible for more than 90% of global greenfield FDI projects in the health sector in 2019.

Investments in manufacturing were dominated by R&D and distribution of healthcare goods and technologies. FDI in healthcare infrastructure and services typically entail construction and professional services (e.g., operation and management of healthcare facilities, hospital and other medical services). This contrast in economic and investment activities suggest that the insecurities and opportunities connected with private foreign engagement, as well as the policy implications, are unique to each healthcare segment.[66]

Figure 37: Greenfield FDI in the health sector by activity



Source: OECD - Can FDI improve the resilience of health systems?

[65] González Peña, O., López Zavala, M., & Cabral Ruelas, H. (2021). Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater
[66] OECD (2020), Can FDI improve the resilience of health systems?

Companies and products

The largest players in the pharmaceutical sector are multinational companies from the US, Japan and Western Europe. Most of these companies are engaged in the commercialization of medicine and some are specialized in the production of medical devices. The five largest pharmaceutical companies in the world in terms of market capitalisation are listed below.[67]

Table 4: Biggest pharmaceutical companies in the world in terms of market capitalisation

Company name	Country	Market capitalisation	Revenue 2021
Johnson & Johnson	US	USD 467b	**USD 93.8b**
Roche	Switzerland	USD 342b	**USD 62.8b**
Pfizer	US	USD 296b	**USD 81.3b**
AbbVie	US	USD 289b	**USD 56.2b**
Eli Lilly	US	USD 273b	**USD 28.3b**

Branded and patented medicines account for the largest share of the pharmaceutical sector. In 2018, oncologic, antidiabetic, respiratory, autoimmune disease, antibiotic and vaccine drugs were the top revenue generating pharmaceutical products, with revenues of roughly USD 100b, USD 79b, USD 61b, USD 54b and USD 41b, respectively (Figure 38).

As for specific drugs, the products that generated the most sales in 2018 were Humira (AbbVie, anti-inflammatory), with revenue of nearly USD 20b, Eliquis (BS/Pfizer, anticoagulant), with revenue of nearly USD 9.9b, and Revlimid (Celgene, immunomodulator agent), with revenue of nearly USD 9.7b. Other top revenue generating products are shown in Figure 39.

Figure 38: Global revenue by pharmaceutical group (USD b)

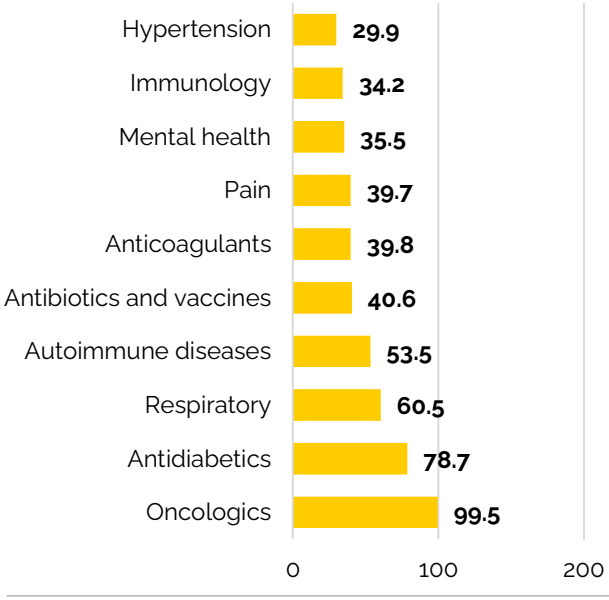
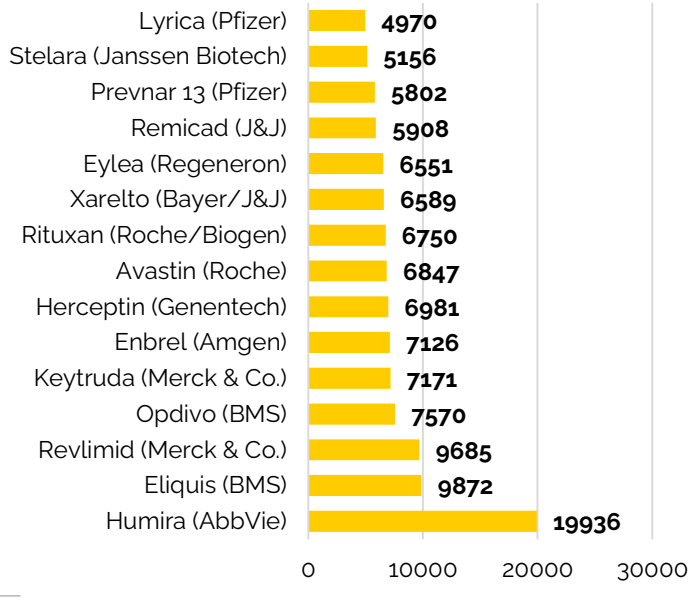


Figure 39: Top pharmaceutical products by sales worldwide (USD million)



[67] Yahoo Finance

Pharmaceutical sector perspectives

In 2020, the Covid-19 pandemic had an enormous impact on the pharmaceutical market. In the coming years, Covid-19 will continue to affect revenues and investments in new chemical and biological entities due to the efforts to generate more (and more effective) vaccines. Despite the pandemic, however, the global pharmaceutical sector has shown resilience by quickly adapting to demand spikes. The pharmaceutical sector is vital for human and economic development because it provides a diverse variety of commodities and services.

The worldwide medication market is predicted to expand at a compound annual growth rate (CAGR) of 3-6%, reaching approximately USD 1.6 t in 2025, including spending on Covid-19 vaccines.[68] Through 2025, new brand investment in developed countries is expected to increase by USD 196b, not considering the impact of Covid-19 vaccines and novel therapies, driven by a historically high number of new pharmaceuticals.

With increased spending, the sector is also a primary source of innovation. The adoption of innovative treatments is offset by patent lifecycles and competition from generics and biosimilars. Historically, significant improvements in healthcare access were the primary drivers of change in medicine use in emerging countries, but the trend is slowing and will result in volume losses across many markets.[69]

Impact of Covid-19 on the pharmaceutical sector

Covid-19 had a huge impact on the global economy, including in the pharmaceutical sector. At the same time, the pandemic provided an opportunity for market players for vaccines, prescription medicines and medical devices. Other major impacts of the pandemic on the pharmaceutical sector include supply chain disruptions, changes in the R&D processes and self-sufficiency incentives.

Demand for prescription medicines and medical devices increased and shortages arose as Covid-related hospitalizations increased, requiring more medicine and more medical devices like ventilators.

Another consequence of Covid-19 was the disruption of supply chains. Many countries introduced restrictions on the export of several types of medicines and medical devices in order to meet local demand. For example, a supply shortage arose in the Active Pharmaceutical Ingredients (API) sector. In China and India, which are key global suppliers of APIs and finished pharmaceutical products, the pandemic caused manufacturing processes to slow down , leading to price increases and shortages of essential medicines, including antibiotics.

Another sector affected by the pandemic was R&D. Many global manufacturers amid the pandemic concentrated their R&D efforts on developing vaccines and treatments against the virus. As of 2022, 119 Covid-19 vaccines were in clinical trials and 12 were approved for full use.[70]

To realise responsible growth, pharmaceutical and life science companies must continue to adapt. **Current market dynamics** present an opportunity to do so, but also raise challenges.

[68] Fitch Global Pharmaceuticals & Healthcare Report, Q1 2022
[69] IQVIA, The Global use of Medicines
[70] The New York Times

Market dynamics to consider

Changing profile of innovative medicines
Today, 65% of the global drug pipeline consists of specialty medicines. Many are for rare and ultra-rare diseases with high unmet needs. As a result, most new drugs being launched have significantly higher per patient treatment costs. And while nine in ten companies have identified personalised medicine as an opportunity, the ability to better target need and the costs associated with doing so presents an obvious tension.

Overall healthcare affordability
Meeting the needs of an ageing population coupled with advances in science and technology present the pharmaceutical industry and the buyers of medicines with an affordability challenge. That challenge is exacerbated by the economic pressure Covid-19 has placed on healthcare systems across the world. Public healthcare systems are likely to feel the greatest pressure to reduce expenditure overall, which will present a significant challenge to ensuring patients maintain access to high-cost innovative treatments. The price of drugs – often viewed in isolation – will increasingly need to be seen in the context of total cost of healthcare while meeting health equity goals.

Geographic diversity
Historically, a large proportion of innovative medicine revenues has come from the United States with its sizable domestic market and prices often 30% to 40% higher than some other developed markets. As a result – and driven by an opportunity to demonstrate social responsibility – a larger portion of growth must come from an increasingly diverse set of countries, including emerging markets. **Emerging market drug expenditure totalled $346 billion in 2019 compared to $609 billion in developed markets,** and the gap is expected to continue closing over the coming years.

Markets differ in terms of reimbursement policies, pricing models, importation costs and regulatory requirements. To prosper on a broader geographic canvas will require more than transplanting existing operating models to new markets. With these dynamics in mind, **pharmaceutical companies will need to find the right balance between access and continued profit generation to achieve responsible growth.**

We believe there are a clear set of actions that the industry should consider. Some of these are already on the agenda, while others may provide a fresh perspective on how to achieve responsible growth.

- **Adopt an agile and digitally-enabled operating model**
- **Review pricing and reimbursement policies**
- **Minimise access concerns through partnerships**
- **Industry specific Education & Professional Development Reforms**

[68] Fitch Global Pharmaceuticals & Healthcare Report, Q1 2022
[69] IQVIA, The Global use of Medicines
[70] The New York Times

3 Overview of the legal and regulatory framework in the pharmaceutical sector

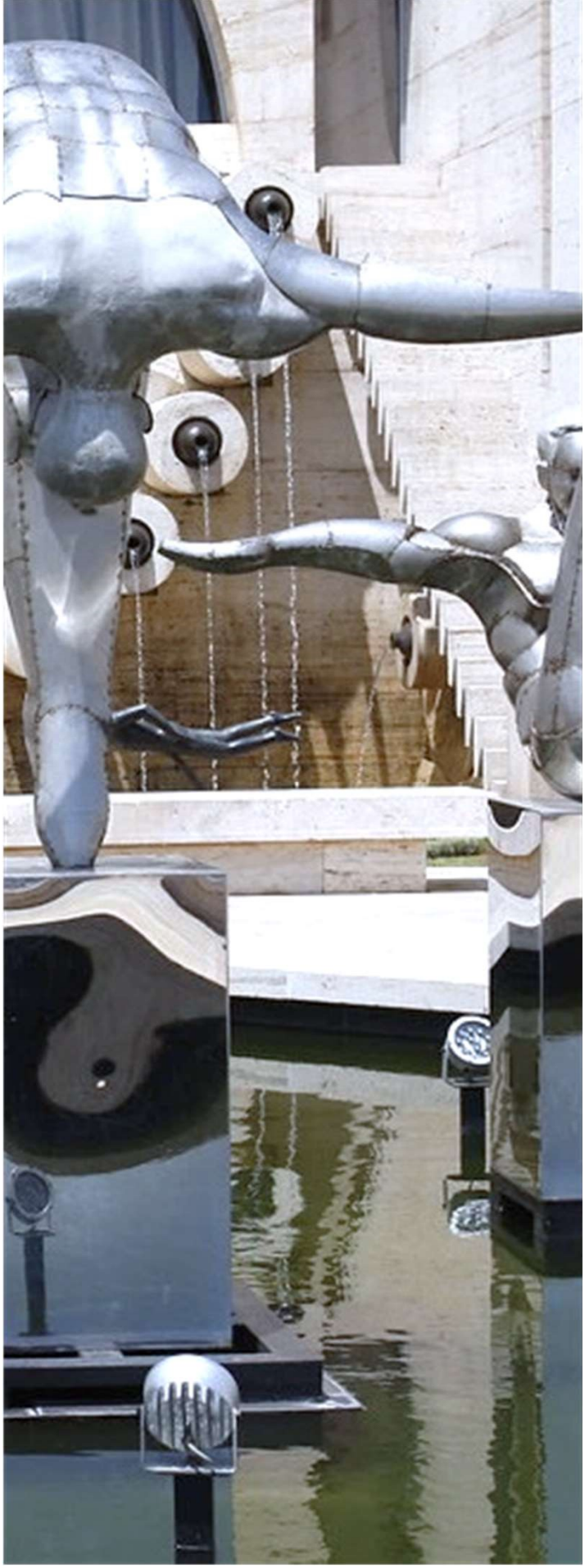
Section summary

Although the **pharmaceutical sector** in Armenia has undergone **fundamental changes** that have **enhanced the quality of pharmaceutical production** and related services, there is still a lack of clarity in many areas such as import licensing, customs procedures, and intellectual property rights enforcement, particularly since Armenia's accession to the Eurasian Economic Union (EAEU) and the adoption of the EAEU Customs Code. Membership in the EAEU is forcing Armenia to **comply stricter standardization, sanitary, and phytosanitary requirements in line with EAEU**.

.

Tariffs have also increased, granting protection to several domestic industries. All Armenian goods circulating in the territory of the EAEU must meet EAEU requirements following the end of relevant transition periods. The sometimes unpredictable and inconsistent application of customs requirements and procedures represents a barrier to trade.

Overview of the legal and regulatory framework in the pharmaceutical sector



3.1 Pharmaceutical policy and legislation

In recent years, the pharmaceutical sector in Armenia has undergone fundamental changes that have enhanced the quality of pharmaceutical production and related services. The cornerstone of changes was the introduction of GMP standards.

Import and export of medicines

The legislative framework for the import and export of medicines in Armenia is presented in Annex 2. **The Regulation on the Import of Medicines into the Customs Territory of the Eurasian Economic Union**[71] defines the procedure for the **import of medicines** included in Section 2.14 of the **Unified List of Goods** into the customs territory of the EAEU.

The import of registered medicines is carried out if there is information about the inclusion of medicines in the Unified Register of Medicines of the EAEU or in the corresponding state Register of Medicines of the member state.

[71] Annex No. 10 to EEC Board Decision No. 30 of 21 April 2015 On Non-Tariff Regulation Measures"[2]
[72] Provided by the Protocol on Non-Tariff Regulation Measures against Third Countries, Annex No. 7 to the EAEU Treaty of 29 May 2014

The Unified Register[73] is an information resource formed within the framework of an integrated system and contains information about medicines registered in accordance with the established Rules for Registration and Examination of Medicines of the EAEU.

The Unified Register is formed and maintained based on information submitted electronically by authorized bodies.

The Registry contains a certain set of information that makes it possible to identify a particular drug, including:

- serial number of the registration certificate of the medical product
- name of the reference state, states of recognition (if any)
- date of registration of the medical product
- expiration date of the registration certificate of the medical product, etc.

The information contained in the Unified Register, with some exceptions, is publicly available.

The introduction of **good distribution practices** is a **guarantee of the quality and safety of pharmaceutical products at the stages of import, transportation and storage**. For the import of medicines in EAEU member states, currently, a wholesale license and shipping documents are sufficient.

Licensing issues for all players in the pharmaceutical market are handled at the level of national regulation.

Intellectual Property

Intellectual property systems are essential for enterprises to be able to finance research and development of medical technology, medicines and vaccines, as well as to attract FDI to these research-intensive sectors. In order to implement the "Intellectual Property" Section of the Treaty [74] on the Eurasian Economic Union ("Treaty"), several regulatory documents were approved, including:

- Protocol on the Security and Protection of Intellectual Property Rights (Annex 26 to the Treaty) ("Protocol");
- Agreement on the Coordination of Actions for the Protection of Intellectual Property Rights

Chapter 52 of the Customs Code of the EAEU outlines the measures on protection of intellectual property.

In accordance with the Treaty on the Eurasian Economic Union[75], generally parties in one Member State in the territory of another Member State are granted national treatment with regard to intellectual property rights. The activities of the Member States related to the protection of intellectual property rights should be carried out in accordance with the norms of fundamental international treaties. Member States that are not parties to these regulations locally regulate the protection of intellectual property rights, including the definition of the legal regime in relation to certain types of intellectual property carried out in accordance with the Protocol.

[73] The Rules for the Formation and Maintenance of the Unified Register were approved by the Eurasian Economic Commission Board Order No. 177 of 22 December 2015.
[74] "Intellectual Property" Treaty, Section XXIII, Article 90
[75] Ibid

Section IX of the Protocol (Patent Rights) defines that the rights to an invention, utility model and industrial design are protected in accordance with the procedure established by the legislation of the Member States. At the same time, the Protocol contains rules on the signing of international treaties, including agreement on the coordination of actions for the protection of intellectual property rights.

This agreement is aimed at creating legal grounds for information exchange and assistance in suppressing violations of intellectual property rights in the EAEU, and provides for:

- coordination of actions to prevent, detect, suppress and investigate violations of intellectual property rights, as well as to improve the activities of the authorised bodies of the EAEU states in this area;
- exchange of information on the protection of intellectual property rights;
- analysis and generalisation of experience in the suppression of violations of intellectual property rights, as well as forecasting trends in the prevention, detection, suppression and investigation of offences in this area;
- planning and implementation of coordinated actions to protect intellectual property rights
- development of regulations for information exchange of the authorised bodies of the EAEU states with the Eurasian Economic Commission

In accordance with Chapter 52 of the EAEU Customs Code (Article 384), customs authorities may take measures to protect intellectual property rights included in the unified customs register of the Member States or the national customs register of intellectual property. In addition, the customs authorities may suspend the release period of intellectual property that is not included in the unified customs register of intellectual property of the Member States or the national customs register of intellectual property objects without a statement from the copyright holder.

At the same time, ensuring the protection of intellectual property in the pharmaceutical sector in the EAEU is reflected in the Rules for Registration and Examination of Medicines for Medical Use. According to the Rules, when submitting applications associated with the registration of a medical product, it is necessary to indicate information about the intellectual property rights to this drug operating on the territory of the EAEU member state. In addition, it is necessary to specify information about the patent number, validity in the territory of this state, the date of issue, the validity period and the owner of the patent.

The applicant also submits a certified copy of the patent or licence agreement that provides the right to manufacture and sell a registered medical product. In addition, they submit a letter stating that the intellectual property rights of third parties protected by a patent or transferred under a licence are not violated in connection with the registration of the medical product. Although there is no clear provision in the Rules for Registration and Examination of Medicines, if information about intellectual property rights is not specified, the applicant's incomplete package of documents to register the product will likely be rejected.

[76] "Intellectual Property" Treaty, Section XXIII, Article 90
[77] Ibid

In fact, the Customs Code and the Rules for Registration and Examination of Medicines of the EAEU create a so-called "patent linking" mechanism whereby the decision to allow a certain medicine into the markets of the EAEU member states, (registration, marketing, pricing) is dependent on patent protection.

As a result, EAEU member states will have to harmonise their legislation with the norms of EAEU legislation and introduce strict rules on the protection of intellectual property. At the same time, four of the five EAEU member states (except Belarus) are members of the World Trade Organisation (WTO) and, accordingly, parties to the Agreement on TRIPS, according to which WTO member countries are not obliged to provide broader protection of intellectual property in their laws than provided for by the Agreement (Article 1, paragraph 1 of the TRIPS Agreement).

3.2 State registration of medical products

Registration of medicines is carried out by the Ministry of Health of Armenia and entrusted to the Gabrielyan Scientific Centre for the Examination of Medicines and Medical Technologies, which is the authority charged with examining registration materials. The legal acts governing the process of state registration of medicines are presented in Annex 3.

There are established deadlines for medical product registration::

- The maximum period of state registration is 150 calendar days, which includes an examination period of no more than 140 calendar days.
- The maximum period of registration of medicines registered in a country that is a member of an international professional organisation determined by a decree of the Armenian Government is 31 calendar days, including an examination period of no more than 21 calendar days.
- State re-registration is carried out within a period of no more than 31 calendar days, including an examination period of no more than 21 calendar days.

Upon registration, a certificate is issued in the name of the owner. The registration certificate is valid for five years. Together with the registration certificate, the packaging layout, instructions for use and a brief description of the drug are also approved.

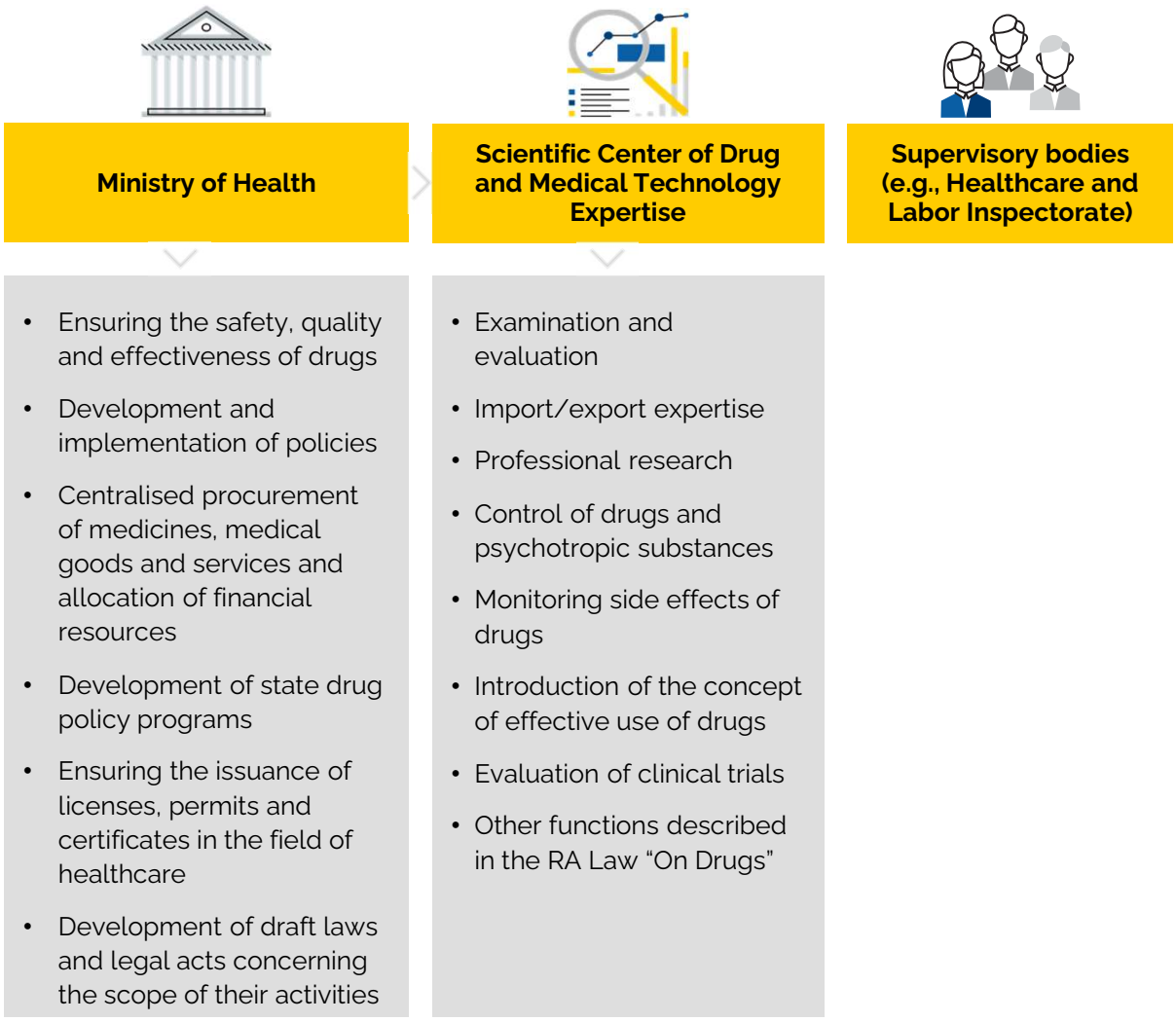
Armenian producers consider that local regulations do not protect their rights. Drug registration process is costly and time-consuming in Armenia in comparison with other countries, like Georgia. Producers believe that the Government can support them by giving preferential treatment in public tenders, which will help them to expand local sales and will trigger diversification of their production.

.

Authorised bodies and state regulation

The Ministry of Health of Armenia is the authorised body that oversees the state regulation of drug circulation.

Figure 40: State regulation of the pharmaceutical sector



Sources: Law of Armenia "On Drugs" and RA Prime Minister's decree on the approval of the Ministry of Health's charter

In Armenia, it is permitted to produce, import, distribute, release, sell and use drugs that are registered in Armenia except for cases where Armenian legislation does not require registration.[78] Armenian legislation stipulates the regulation of and control over prices for reimbursable drugs (specifically, base prices for reimbursable drugs and maximum mark-ups for wholesale and retail sales).

Many European countries also regulate maximum and minimum prices for drugs. For example, when registering drugs in certain countries, the relevant authority (for instance, the Ministry of Finance or the Ministry of Healthcare) also sets the maximum and minimum price for the drug. In setting the maximum price for socially important drugs, the state regulates the market in order to prevent unjustified and unreasonable price increases and to ensure that sales margins are not too large. The minimum price is set to prevent dumping.

[78]Article 15 and 24, Law of Armenia "On Drugs".

3.3 International standard for GxP practice

Good Manufacturing Practice (GMP)

The legislative framework on GMP in Armenia is presented in Annex 4. The GMP Rules of the EAEU are a supranational document of direct effect (that is, they take precedence over national legislation in their legal force and Member States do not need to adopt any national laws concerning their entry into force) (Annex 5).
The new version of the 15 GMP Application is much wider in scope. New sections have been added related to:

- transport verification
- package validation
- qualification of engineering systems
- validation of analytical methods

Additionally, the requirements on process validation have been expanded. The qualification of engineering systems is now officially part of qualification activities. The new requirements exclude the possibility of retrospective validation.
In comparison with the previous version, additions were made in relation to the fact that:

- any planned changes that may affect the quality of products should be documented and their impact on the validation status or on the approved control strategy should be assessed
- computerised systems are subject to validation in accordance with the requirements set out in GMP
- the instructions included in Part 3 of GMP should be taken into account

Good Distribution Practice (GDP)

Armenian legal norms for supporting the production and distribution of medicines in accordance with international standards are presented in Annex 7.
In the EAEU Rules[79], the distribution process should be organised in accordance with the requirements of the quality system and the necessary elements to maintain it thorough documentation, analysis and risk assessment that are aimed at identifying and eliminating the causes and processes that may have a negative impact on product quality. Additionally, the EAEU Rules prescribe not only the existence of a system for tracking critical processes, but also the supporting documents for them.
The legislative framework for sales, transportation and storage (Annex 6) include the following requirements:

- Supply chain control is provided
- Key stages require justification and validation
- A quality manual should be developed
- A change management system should be implemented
- A periodic review of the quality system should be carried out
- More attention must be paid to human factors
- Premises, equipment and processes must be validated
- All deviations must be recorded
- More detailed documentation requirements are needed

[79]Approved by Eurasian Economic Commission Council Decision No. 80 of 3 November 2016, the rules of Good Distribution Practice (GDP) of the EAEU fully comply with the EU Rules

- A customer assessment should be carried out;
- A system of work with claims, refunds, work with counterfeit drugs and product recalls is provided;
- An assessment of the quality system through self-inspection is required.

Good Clinical Practice (GCP)

Approved by Eurasian Economic Commission Council Decision No. 79 of 3 November 2016, Good Clinical Practice (GCP) is an international ethical and scientific standard for planning and conducting research involving individual subjects, as well as for documenting and presenting the results of such research. Compliance with this standard serves as a guarantee that the rights, safety and well-being of research subjects are protected, consistent with the principles laid down by the Helsinki Declaration of the World Medical Association (WMA), and that clinical trial data are reliable.

The purpose of this EAEU standard is to establish uniform rules with the countries of the European Union, the US and Japan in order to facilitate the mutual recognition of clinical trials by the authorised bodies of these countries. The Standard is identical to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH) guideline for Good Clinical Practice International Conference, which was developed taking into account the requirements on good clinical practice in the EU, the US and Japan, as well as Australia, Canada and the World Health Organisation (WHO).

However, Paragraph 7 of Article 14 of the Law of the Republic of Armenia "On Medicines" establishes certain restrictions concerning individuals who may not be involved in clinical trials conducted in Armenia, including the following:

1. Individuals who have been arrested, detained or imprisoned
2. Military personnel
3. Minors, except in cases when the investigational medical product is intended for minors and if the results of clinical studies of the same medical product in adults were positive. The consent of the minor's parent or legal guardian must be provided in writing before the minor may participate in a clinical trial
4. Pregnant women and nursing mothers

Legislative framework for conducting clinical trials in Armenia is presented in Annex 8.

Rule of practice of pharmacovigilance of the Eurasian Economic Union

The legislative framework for conducting pharmacovigilance in Armenia is presented in Annex 9. The Rules of Good Pharmacovigilance practices (GVP) of the Eurasian Economic Union (EAEU) were prepared on the basis of the GVP Rules of the European Medicines Agency in force since 2012 in the European Union and have been applied in Russia and other EAEU Member States since 2016.

There are minor differences in the structure and content of sections of the EU GVP Rules and the EAEU GVP Rules, particularly in the definitions of terms (in the EU GVP Rules, definitions are

presented in a more detailed form, supplemented with examples, subsections and links to other documents), and in the supplements and appendices to the EU GVP Rules (the presence of drawings, templates, examples, algorithms and tables that are absent in the EAEU GVP Rules). Our analysis of these differences in relation to the assessment of the effectiveness of pharmacovigilance systems and the practical activities of registration certificate holders, drug developers and regulatory authorities has shown that both documents are harmonised but also contain slight differences that are of crucial importance.

3.4 Effect of legislative framework on the pharmaceutical sector

Legislation in Armenia is supportive for development of key pharmaceutical sub-sectors. Presence of unified legislation base with EAEU countries and supportive legislation of Russia, as a key market in the region allows Armenian products to be subject to the same rules in public tender procedures as for local producers, based on 44 Federal Law of Russia. Thus, the "third product is out" rule is valid in following conditions – for the corresponding purchase, at least two applications must be submitted with a proposal for the supply of goods produced in the member countries of the EAEU by two different manufacturers. Also, confirmation of the origin of goods has been updated in 2021 - presence of entries in the registers or Russian industrial products (Armenian products may be introduced their) will be recognized as confirmation of the production of a particular product on the territory of Russia or the EAEU countries. That means that generally during the public procurements in Russia Armenian products shall be evaluated equally, and same preferential rules shall be applied as for Russian products.

For Armenia, this creates greater opportunities for development of sub-sectors with high degree of foreign participation in the current Russian market, especially in Generics and API production, Clinical Trials, Standards development and R&D. (These sub-sectors have greatly suffered due to current sanctions). There are also upcoming opportunities for foreign, non-EAEU companies to develop CRO and CMO projects in Armenia that will push local production of products and services for the EAEU market. Presence of GMP, Good Distribution Practice (GDP), GCP certifications and international scientific cooperation will support these opportunities and allow the Armenian pharmaceutical market to develop globally.

[79]Approved by Eurasian Economic Commission Council Decision No. 80 of 3 November 2016, the rules of Good Distribution Practice (GDP) of the EAEU fully comply with the EU Rules

4 Trade statistics of Eurasia and selected countries

Section summary

Armenia became a member of the Russian-led Eurasian Economic Union (EAEU) in 2015. This membership **provides Armenian products direct access** to the Russian, Belarusian, Kazakh, Kyrgyz and other **markets** with a combined **population of about 190 million and a combined gross domestic product of nearly $2 trillion**. In the Pharmaceutical industry, **Russia** remains the **largest trade partner** for Armenia in the region with imports from Armenia reaching to USD 66.3m over the last ten years. However, despite massive growth of roughly 1300% from 2010 to 2020, the trade value is still rather insignificant.

2020 was a year of **crisis for all Eurasian Economic Union (EAEU) member states**. As a result, mutual trade suffered as well. For Armenia, the drop in foreign trade with EAEU member states was due to Russia Georgia and Kazakhstan. However, trade with Belarus, Moldova, Uzbekistan remained fairly stable, while Ukraine, and Kyrgyz Republic showed a slight increase in the pharmaceutical trade.

Trade statistics Eurasia and selected countries

4.1 Russia

Background[80]

The Russian pharmaceutical sector is one of the largest in the world and the largest in CEE, with a revenue of USD 24.2b in 2021. The sector was responsible for 1.4% of GDP and 22.7% of the total healthcare sector. Pharmaceutical expenditures in Russia in 2021 amounted to USD 166 per capita.

Market highlights[81]

- Russia's healthcare expenditure in 2021 was worth USD 106.7b, equating to USD 732 per capita and representing 6.0% of the country's GDP
- Local production is encouraged in the country. As a result, it is expected that large-volume exporters will work with local partners to set up manufacturing operations and obtain government subsidies
- Pharmaceutical companies in Russia will continue to integrate vertically, with a primary focus on production, distribution and retail
- In volume terms, the market for commercial medicines has expanded by 11%, owing to a rise in the domestic manufacturing of generic and lower-cost drugs
- Through mergers and acquisitions, regional pharmacy retail chains and local independent pharmacies have consolidated, resulting in consistent quality of service and product costs for consumers
- Germany, France and the US were until 2020 Russia's primary suppliers. A diverse range of pharmaceutical products, well-established logistics and innovative, premium solutions are the primary competitive advantages of these supplying markets

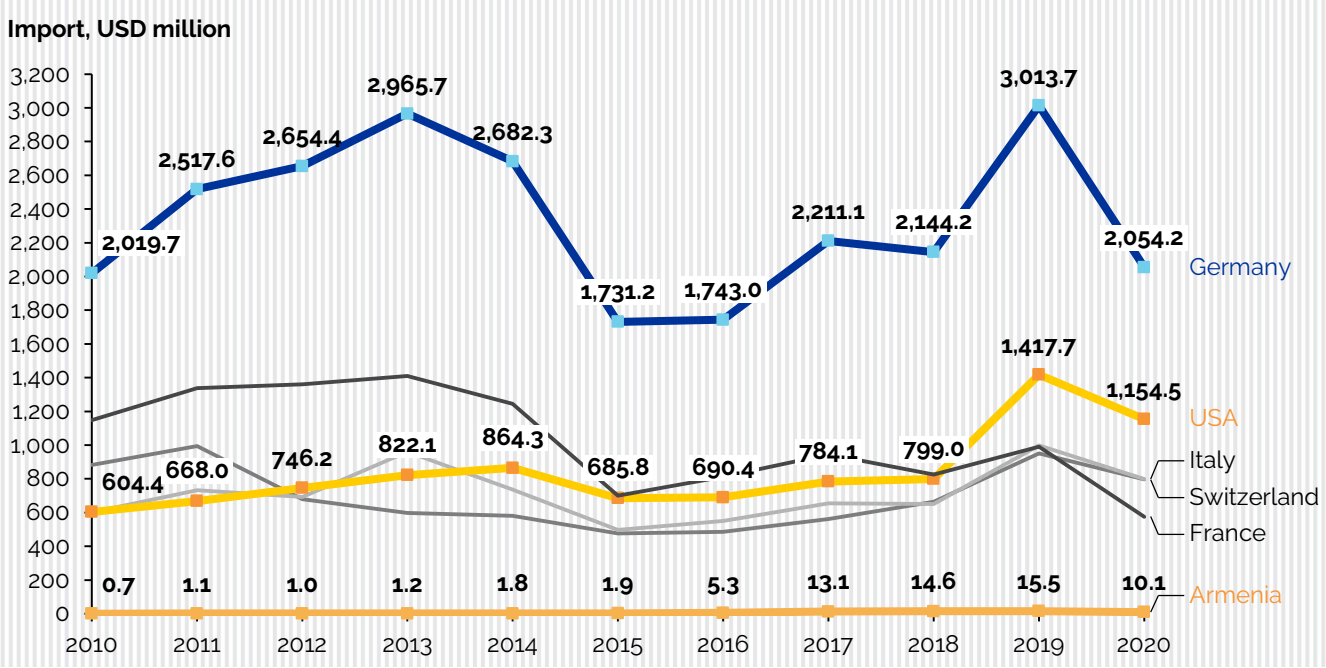
[80] Fitch Pharmaceutical sector report Russia 2022
[81] Fitch Pharmaceutical sector report Russia 2022

- The active advertising of medications in the Russian market by major suppliers such as Bayer, Sanofi and Novartis has boosted their penetration across all main channels
- Medicines that have been registered under particular rules can be disseminated and sold throughout the EAEU, including in Russia, Kazakhstan, Belarus, Armenia, and Kyrgyzstan, without having to go through registration procedures in each of these countries

Import Structure

Between 2010 and 2020[82] pharmaceutical products worth USD 128b were imported into Russia. Pharmaceutical products are largely imported from Germany, with a minimum import value of USD 1.7b in 2015 and a maximum of USD 3b in 2019. Imports from Armenia totalled USD 66.3m over the last ten years. However, despite massive growth of roughly 1300% from 2010 to 2020, the trade value is still rather insignificant in comparison with other countries. Armenia ranks 54th among sources of pharmaceutical product imports to Russia between 2010 and 2020.

Figure 41: Imports of pharmaceutical products by country



Sources: UN Comtrade

300490[83], 300210[84] and 300420[85] were the top three products by six digit CCG among imports over the last ten years (USD 73.4b, USD 8.6b, and USD 6.2b, respectively). From 2010 to 2020, imports of 300490 and 300210 were primarily from Germany, while imports of 300420 were primarily from Italy.

[82] Data for 2021 was not available
[83] Medicaments consisting of mixed or unmixed products
[84] Blood: human or animal, antisera and other blood fractions, and modified immunological products
[85] Medicaments containing antibiotics

From 2010 to 2020, the most commonly imported six digit CCGs from Armenia were 300490 and 300450[86], as well as 300320[87] starting from 2016 (USD 19.3m, USD 10.7m and USD 28.2m, respectively).

300490

USD
19.3m

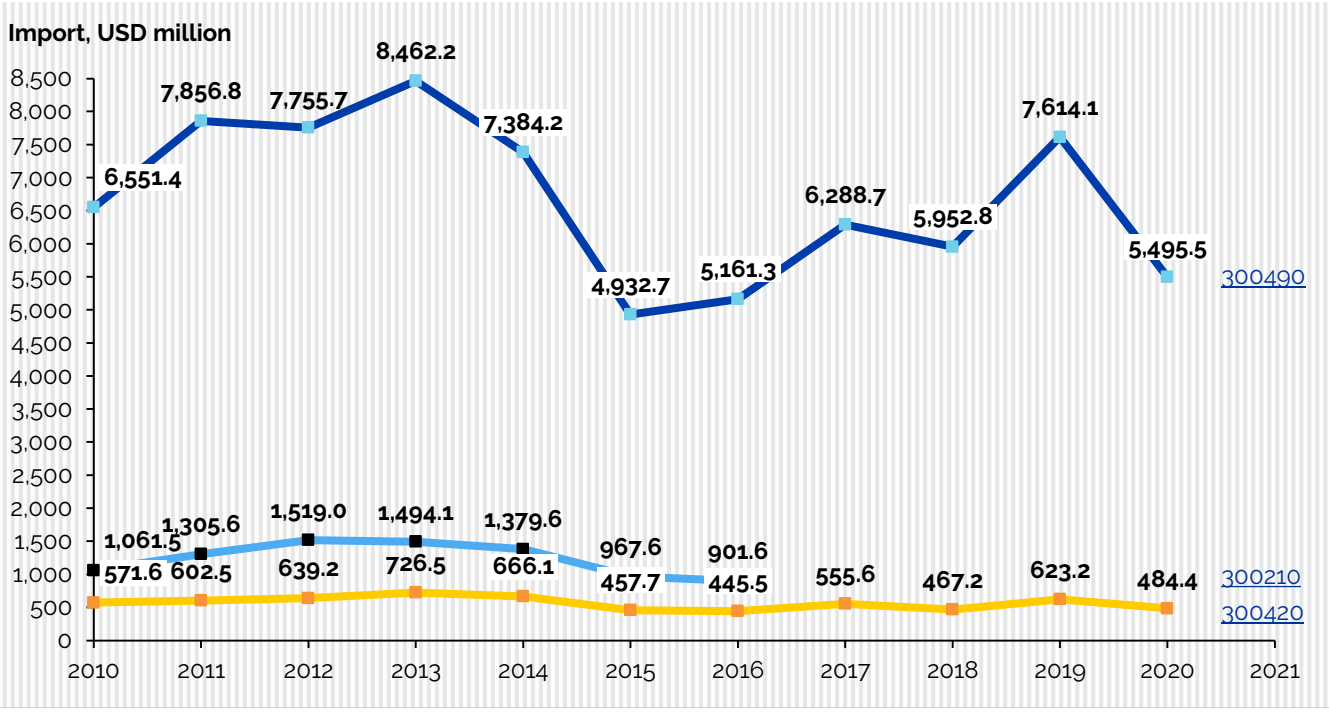
300450

USD
10.7m

300320

USD
28.2m

Figure 42: Imports of pharmaceutical products, six digit CCGs



Sources: UN Comtrade

[86] Medicaments containing vitamins or their derivatives
[87] Medicaments containing antibiotics other than penicillins, streptomycins and their derivatives

Figure 43: SWOT analysis for Russia's pharmaceutical market

Strenght

- Market Size
- High diseases burden per capita (non-communicable diseases)
- High demand for chronic disease treatment drugs
- Market entry and access
- Intellectual property regulations

S

Weaknesses

- Insufficient fundings
- Drug pricing policies not transparent
- Complex reimbursement and purchasing policies
- Policy changes are independent of stakeholder interests
- Intellectual property enforcement (despite WTO accession)
- Ambivalent stance from state on import substitution

W

Opportunities

- Strong market growth potential, given the country's forecasted population growth,
- Favorable epidemiological and demographic profile
- Strong market growth for generic drugs (low solvency and desire to reduce public expenditure on pharmaceutical goods)
- Rapidly growing HIV -positive population highlights an unmet need for anti-HIV drugs

O

Threats

- Significant macroeconomic risks
- Increased government interference in business and corruption
- Currency volatility
- Enforcement of patent laws & other regulations remain weak
- Indigenous production plans pose risks for firms exporting to Russia
- Geopolitical tensions, sanctions or trade restrictions on imported goods.

T

4.2 Georgia

Background[88]

Georgia's pharmaceutical market had a total revenue of USD 646m in 2021. The sector had 3.5% share in the country's total GDP and accounted for 51.2% of all healthcare spending. On a per capita basis, Georgia's pharmaceutical market was worth USD 162 in 2021.

Market highlights[89]

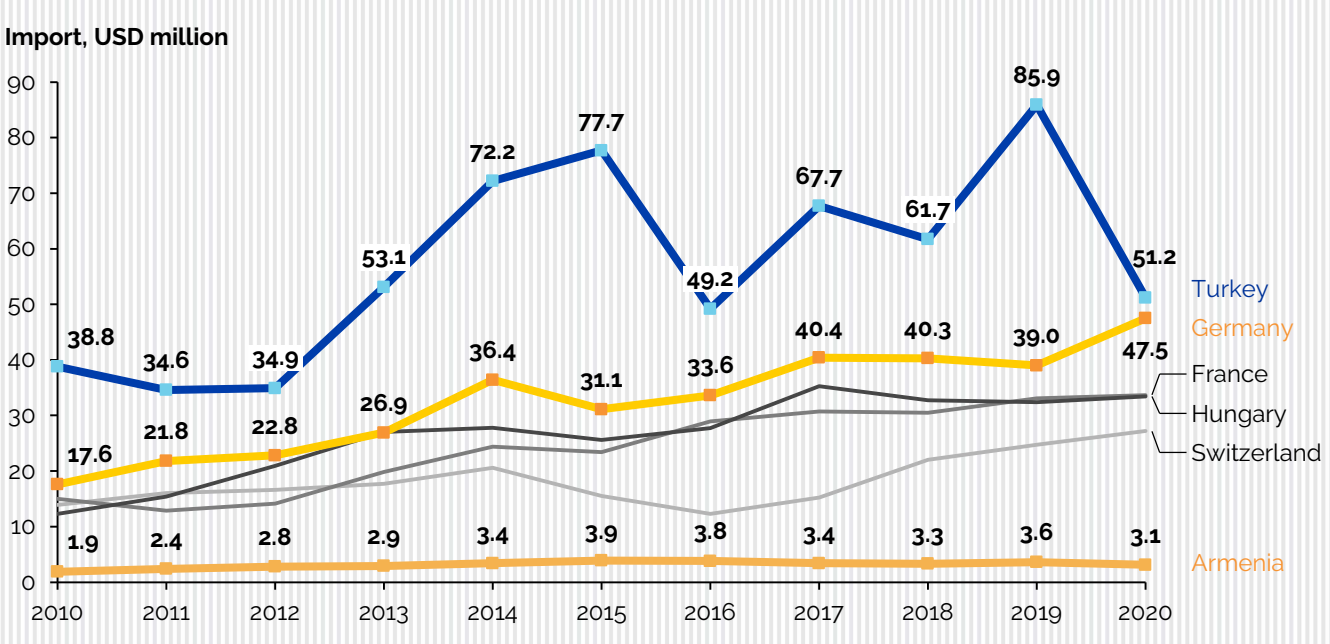
- Georgia's overall healthcare spending was USD 1.3b in 2021, accounting for 6.8% of the country's GDP and translating to USD 317 per capita;
- Although no major global pharmaceutical companies have manufacturing operations in Georgia, many do have local representative offices;
- In the country, there are about 50-60 active pharmaceutical producers;
- Aversi-Rational (founded in 1994 and employing roughly 8,000 people) and GM Pharmaceuticals dominate the local manufacturing landscape. Around 90% of local medicine is produced in this way. Aversi-core Rational's business is packaging. In addition, the company operates 230 pharmacies in more than 20 hospitals and clinics across Georgia.

Import structure

Georgian pharmaceutical imports reached USD 3,7b between 2010 and 2020, with imports slowly increasing. Over this ten-year period, imports of pharmaceutical products to Georgia climbed from USD 221m in 2010 to USD 395n in 2020. Georgia imports pharmaceutical products primarily from Turkey, with a minimum of USD 34.6m in 2011 and a maximum of USD 85.8m in 2019.

Imports from Armenia amounted to USD 34.5m over the last decade. Armenia is the 25th largest source of imports of pharmaceutical products for Georgia.

Figure 44: Imports of pharmaceutical products by country



Sources: UN Comtrade

[88] Fitch Pharmaceutical sector report Georgia 2022
[89] Fitch Pharmaceutical sector report Georgia 2022

The top three products imported over the last decade by six digit CCG were 300490[90], 300420[91] and 300290[92] (USD 2.7b, USD 182m, and USD 116m, respectively). The overall increase was largely driven by 300490, which achieved a peak value of USD 307.6m in 2019.

From 2010 to 2020, the most commonly imported six digit CCGs from Armenia were 300490, 300590[93] and 300230[94] (USD 26.6m, USD 4.9m and USD 2m, respectively).

300490

USD
2.7b

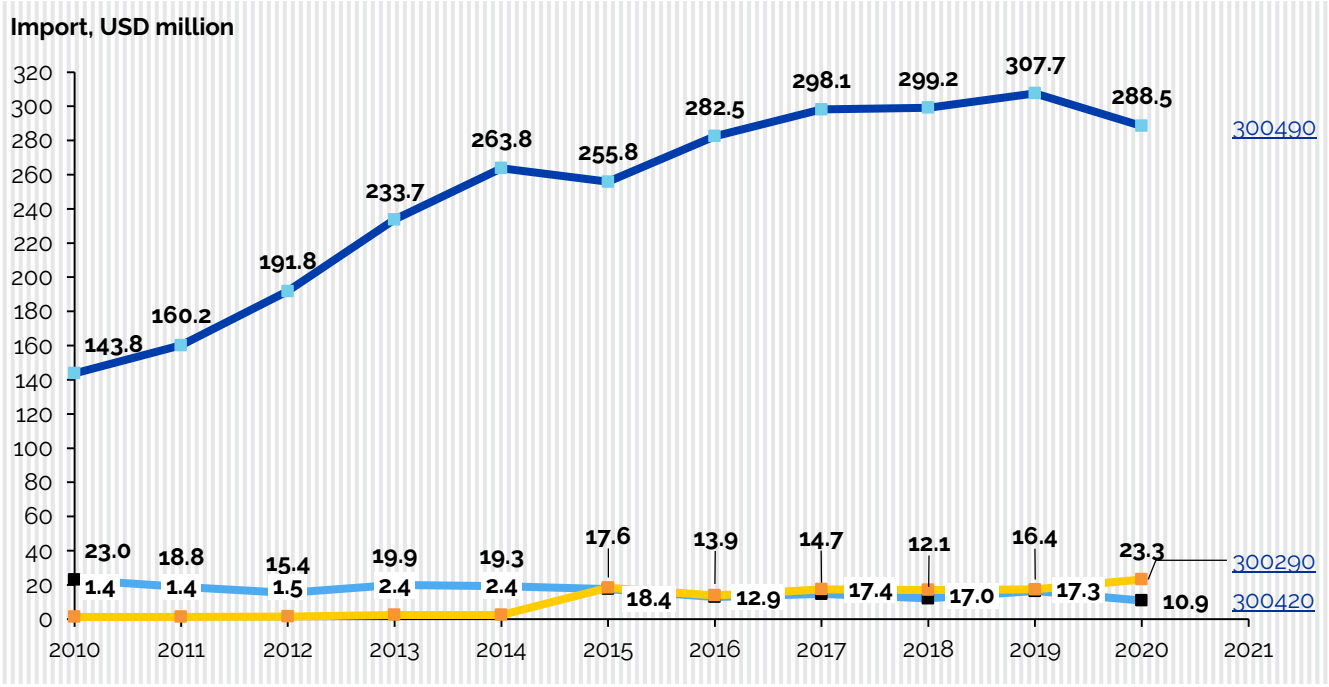
300420

USD
182m

300290

USD
116m

Figure 45: Imports of pharmaceutical products, six digit CCGs



Sources: UN Comtrade

[90] Medicaments consisting of mixed or unmixed products
[91] Medicaments containing antibiotics
[92] Toxins, cultures of microorganisms
[93] Wadding, gauze, bandages and similar articles (excluding adhesive dressings)
[94] Vaccines for veterinary medicine

Figure 46: SWOT analysis for Georgia's pharmaceutical market

Strenght

- Universal healthcare coverage programme
- Attractive business environment relative to neighbours
- Relatively low degree of corruption and prerequisites for a stable business environment

S

Weaknesses

- Limited Market size
- Relatively small population
- Pharmaceutical pricing unregulated
- Considerable market pressure to reduce drug prices

W

Opportunities

- Regulatory environment adopting international best practices
- Significant demand and voiced government support for generics
- Tax incentives provide favourable conditions for local manufacturing
- International funding for healthcare system transformation

O

Threats

- Domestic drug production will increase competition
- Economic reliance on Russia and political alignment with the West poses political and economic risks
- Healthcare funding policies will lead to greater scrutiny on drug prices

T

4.3 Moldova

Background[95]

Pharmaceutical sales in Moldova reached USD 402m in 2021 . This number equated to 3.3% of the country's GDP and 35.1% of total healthcare expenditures. On a per capita basis, the pharmaceutical sector in Moldova in 2021 amounted to USD 100.

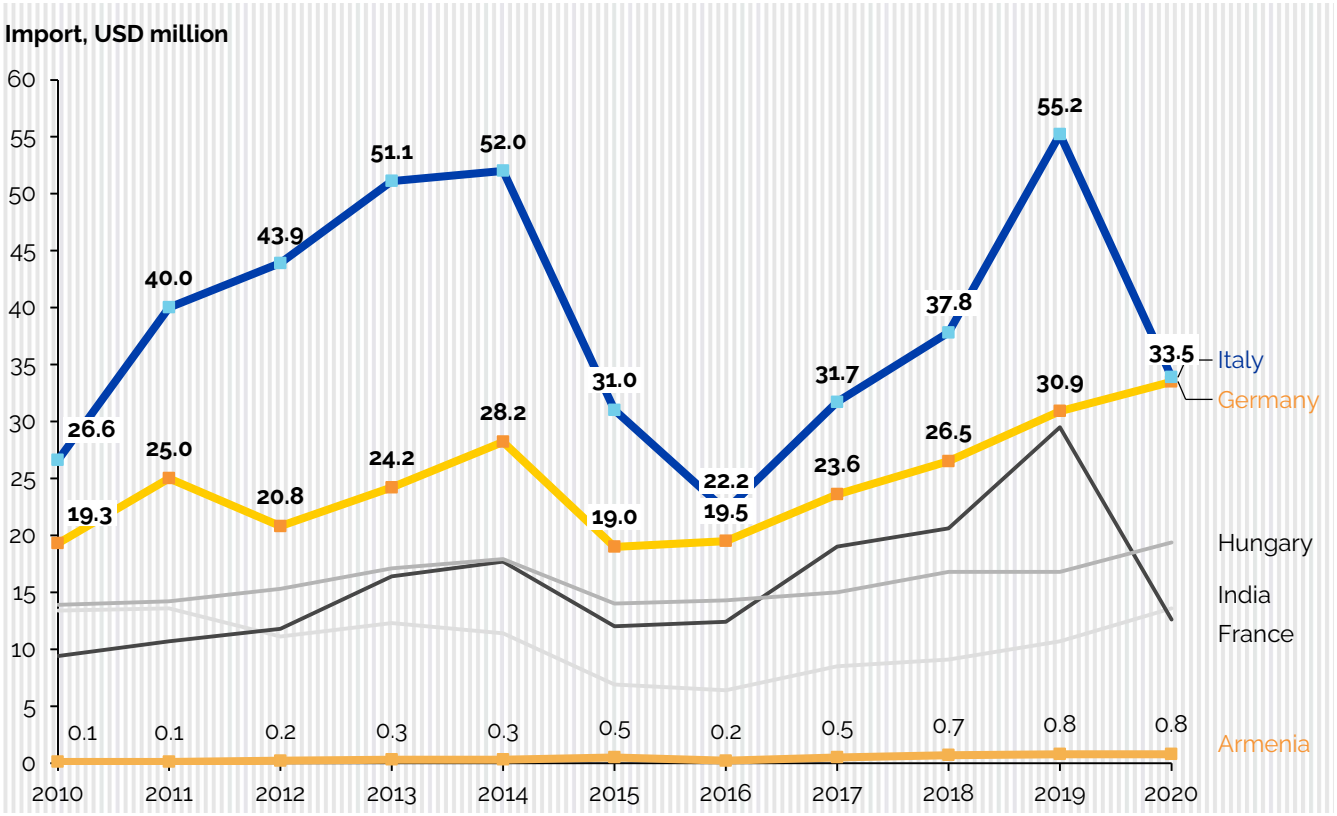
Market highlights[96]

- Moldova's healthcare spending is was calculated to have reached USD 1.1b in 2021, equivalent to USD 284 per capita and 9.3% of GDP;
- In 2021, the government spent USD 800m on healthcare, with the private sector accounting for 33.6% of the total;
- Local manufacturers must be licensed by law. However, legislative measures do not require manufacturers (domestic or international) to follow the GMP, despite a draft laws in the works;
- Farmaco, Depofarm, New Tone and Farmaprim are all well-known local pharmaceutical companies. They are constrained in terms of production capability and portfolio.
- Only 20% of pharmaceutical expenditures are made using public funding, while nearly 80% of purchases are made by the private sector.

Import structure

Moldova's imports of pharmaceutical products increased by 43% between 2010 and 2020 (from USD 178.8m to USD 255.9m), reaching a peak of USD 275.4m in 2019. Between the mentioned period compound annual growth rate (CAGR) equals 3.6%.

Figure 47: Imports of pharmaceutical products by country



Sources: UN Comtrade

[95] Fitch Pharmaceutical sector report Moldova 2022

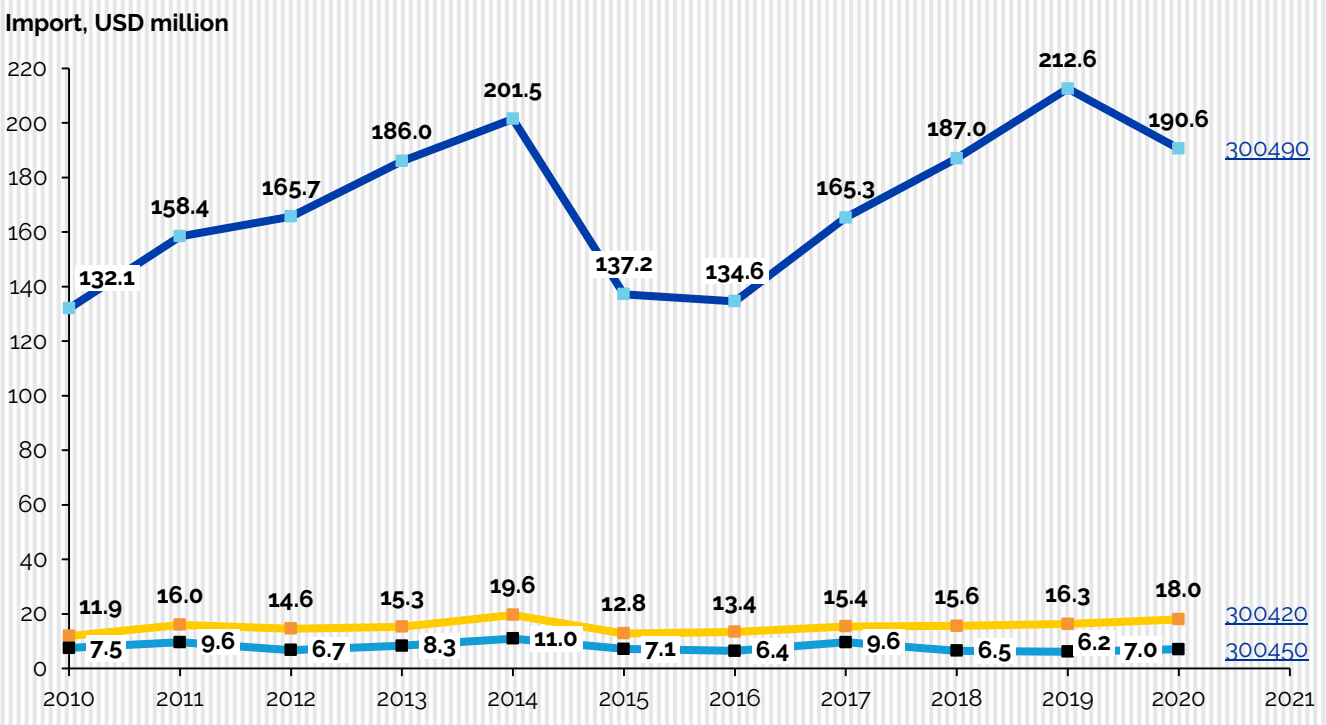
[96] Fitch Pharmaceutical sector report Moldova 2022

The top three products imported over the last decade by 6 digit CCG are 300490[97], 300420[98] and 300450[99] (USD 1.9b, USD 169m and USD 88m respectively). The overall increase is largely due to 300490, which achieved a peak value of USD 212.6m in 2019.

Imports from Armenia totalled USD 4.6m from 2010 to 2020, making Armenia the 43th largest source of imports of pharmaceutical products for Moldova

Between 2010 and 2020, the most commonly imported six digit CCGs from Armenia were 300490 and 300420, reaching USD 3.9m and USD 0.6m respectively.

Figure 48: Imports of pharmaceutical products, six digit CCG



Sources: UN Comtrade

[97]Medicaments consisting of mixed or unmixed products
[98]Medicaments containing antibiotics
[99]Medicaments containing vitamins or their derivatives

Figure 49: SWOT analysis for Moldova's pharmaceutical market

Strenght

- Government's commitment to increasing access to healthcare
- Well-established immunisation program provides opportunities for vaccine manufacturers
- Support from neighboring countries, IFIs and the Council of Europe will assist Moldova's ambitions for healthcare system transformation

S

Weaknesses

- Small overall market size & low per capita spending on healthcare
- Lack of adequate access to healthcare
- Corruption, informal payments limit access and inflate prices
- Overuse of free emergency services due to underdeveloped primary care and inability to pay out-of-pocket
- Limited scale and capabilities of local producers
- Dependency on low margin generic products

W

Opportunities

- Large treatment-naive population is an attraction for clinical trials organisations
- Liberalisation of retail pharmacy continues to drive pharmaceutical demand
- Planned introduction of universal healthcare and elimination of co-payments for essential medicines will support system wide pharmaceutical consumption
- Willingness to embrace technology across the healthcare segment

O

Threats

- Pharmaceutical market vulnerable to economic turbulences
- Dubious pricing policies
- Demographic inequality, shrinking population, emigration and low birth-rate
- Geopolitical tension between Russia and neighbouring countries threatens trade flows
- Corruption & cumbersome bureaucracy continues to deter foreign investment

T

4.4 Kazakhstan

Background[100]

Pharmaceutical market in Kazakhstan, which is the largest pharmaceutical market in Central Asia, reached a value of USD 1.7b in 2021. The market's share in the country's total GDP for the same year was 0.9% and for the total healthcare sector it was 29.4%. Despite being the largest in Central Asia, the market has one of the lowest per capita spending in the CEE region, amounting to USD 90.

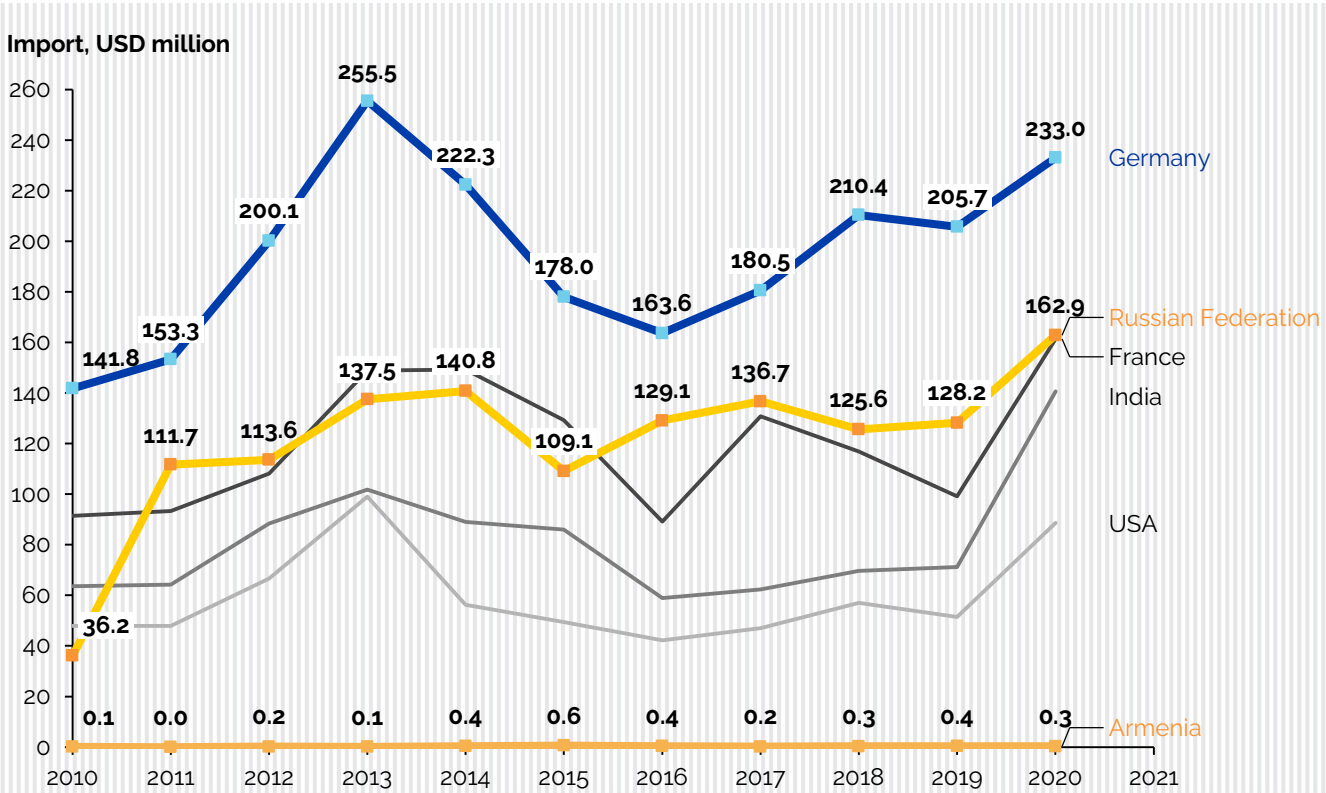
Market highlights[101]

- Kazakhstan's overall healthcare expenditures in 2021 reached USD 5.8b, or 3.2% of GDP, equating USD 299 per capita;
- Kazakhstan has 524 medical organisations providing primary healthcare services, with the private sector accounting for around 30% of the total;
- The government established a new 2020-2025 State Programme for the Development of Healthcare in July 2019, which includes initiatives to raise medical worker pay and modernise infrastructure.

Import statistics

Between 2010 and 2020, Kazakhstan purchased pharmaceuticals worth a total of USD 13.4b. Kazakhstan's pharmaceutical imports peaked in 2013 at USD 1.6b. Kazakhstan imports pharmaceutical items primarily from Germany. Between 2010 and 2020, the minimum value of imports from Germany was USD 141.6m in 2010 and the maximum was USD 255.6m in 2013.

Figure 50: Imports of pharmaceutical products by country



Sources: UN Comtrade

[100] Fitch Pharmaceutical sector report Kazakhstan 2022
[101] Fitch Pharmaceutical sector report Kazakhstan 2022

The top three products imported over the last decade by six digit CCG are 300490[102], 300220[103] and 300420[104] (USD 7.5b, USD 790m and USD 788m respectively). Kazakhstan mainly imports items listed under 300490.

Imports from Armenia totalled USD 2.8m over the last decade. Armenia is the 60th largest source of imports of pharmaceutical products for Kazakhstan.

The most commonly imported six digit CCGs from Armenia between 2010 and 2020 were 300490 and 300420. For 300420, however, imports halted in 2018.

Figure 51: Imports of pharmaceutical products, six digit CCG

Sources: UN Comtrade

[102] Medicaments consisting of mixed or unmixed products
[103] Medicaments containing antibiotics
[104] Medicaments containing vitamins or their derivatives

Figure 52: SWOT analysis for Kazakhstan's pharmaceutical market

Strenght

- Effective import substitution policies and localisation of production
- No VAT on pharmaceuticals or active pharmaceutical ingredients
- Key export destinations (Central Asia and other CIS countries)
- A substantial degree of market transparency
- A reform-minded government and substantial political stability

S

Weaknesses

- Out-of-pocket expenditure restricts access to expensive drugs
- Government procurers hold a unilateral power to revise terms & conditions
- Preferential treatment of local producers in government tenders
- The retail distribution system remains opaque and fragmented
- Slow drug registration process

W

Opportunities

- WTO accession will push the regulatory harmonisation process
- Increased healthcare funding and primary care provision are set to improve access and demand for modern, high-quality generic medicines
- Increased capacity in local drugs manufacturing
- A small but fast-growing clinical trial sector
- The Comprehensive Plan for the Development of the Pharmaceutical sector plans to both bolster pharmaceutical investment and boostself-sufficiency

O

Threats

- Russian companies enjoy lower costs and better local knowledge and enhanced market position under the customs union
- Continued poor enforcement of intellectual property legislation

T

4.5 Belarus

Background[105]

In 2021 Belarus had a pharmaceutical market worth of USD 1.3b, which equated to 2.3% of the country's GDP and 38.2% of total healthcare expenditures. On a per capita basis, the pharmaceutical market in Belarus in 2021 reached USD 140.

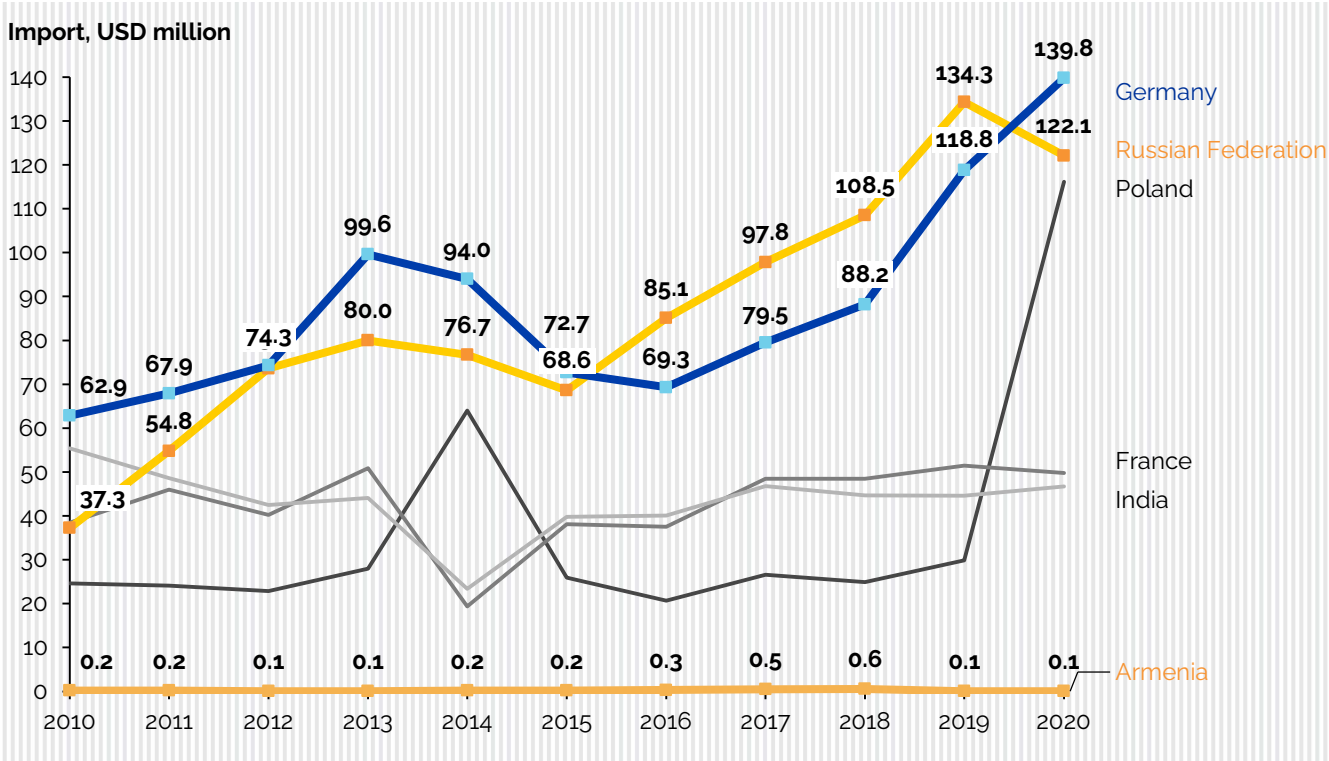
Market highlights[106]

- Healthcare spending in 2021 was calculated to be USD 3.5b (6.0% of GDP), or USD 367 per capita;
- By value, prescription medicine sales accounted for 62.9% of overall drug sales, with generic products accounting for 83.8% of that (or 52.7% of the total);
- Currently, 26 pharmaceutical companies are operating in Belarus, including five that are state-owned;
- Belarus has 609 hospitals, 810 clinics, 436 outpatient departments, 2,358 medical and obstetrics aid stations, and 140 emergency departments, according to the country's Ministry of Healthcare.

Import statistics

Belarus imported USD 7.9b worth of pharmaceutical products between 2010 and 2020. The highest figure was in 2020, when Belarus imported USD 1b worth of goods. Imports of pharmaceutical products were growing stable between 2010 and 2020 with a CAGR of 6.1%.

Figure 53: Imports of pharmaceutical products by county



Sources: UN Comtrade

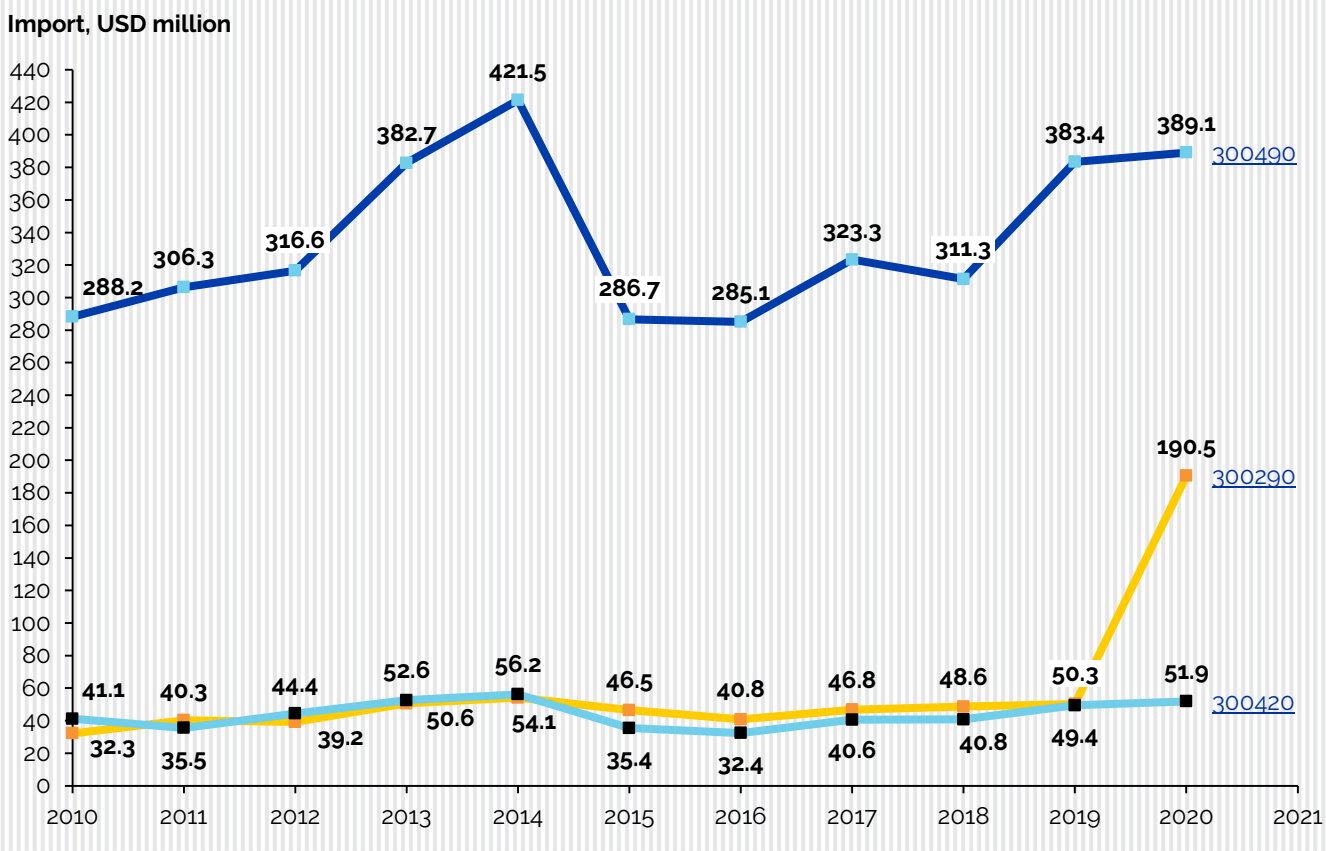
[105] Fitch Pharmaceutical sector report Belarus 2022
[106] Fitch Pharmaceutical sector report Belarus 2022

The top three products imported over the last decade by six digit CCG are 300490[107], 300290[108] and 300420[109] (USD 3.7b, USD 640m and USD 480m respectively). Belarus imports a wide variety of products registered under 300490.

Imports from Armenia over the last 10 years have amounted to USD 2.7m. Armenia was the 53rd largest source of imports of pharmaceutical products for the mentioned period.

From 2010 to 2020, the most frequently imported six digit CCGs from Armenia were 300490 and 300230.[110]

Figure 54: Imports of pharmaceutical products, digit CCG



Sources: UN Comtrade

[107] Medicaments consisting of mixed or unmixed products
[108] Toxins, cultures of microorganisms and similar products
[109] Medicaments containing antibiotics
[110] Vaccines for veterinary medicine

Figure 55: SWOT analysis for Belarus's pharmaceutical market

Strenght

- Continued double-digit local currency growth
- Extensive universal healthcare system
- Government committed to provide incentives to attract contract manufacturing

S

Weaknesses

- Reimbursement restricted to products bought in state pharmacies and hospitals
- Low per capita spending on pharmaceuticals
- Corruption in public sector procurement
- Inflationary pressures artificially increase top-line local currency figures
- Limited access to innovative medicines

W

Opportunities

- Future potential for economic liberalisation and opening of the economy as EU ties increase
- Government support for local manufacturing could provide investment opportunities
- Increased demand for high-end pharmaceutical products

O

Threats

- Preferential treatment for Russia based companies due to dependence on Russian financial aid
- Unified EAEU drugs market creates a risk for reduction in drug prices and increases competition
- Currency volatility threatens investment and imports

T

4.6 Kyrgyzstan

Background[111]

Kyrgyzstan's pharmaceutical market is one of the smallest and least developed ones in the CEE region, with a market size of just USD 214m in 2021. The sector's share in Kyrgyzstan's GDP in 2021 was 3% and for total healthcare spending it amounted to 38.4%. The country's pharmaceutical spending were amongst the smallest ones on a per capita basis as well, amounting to just USD 36 in 2021.

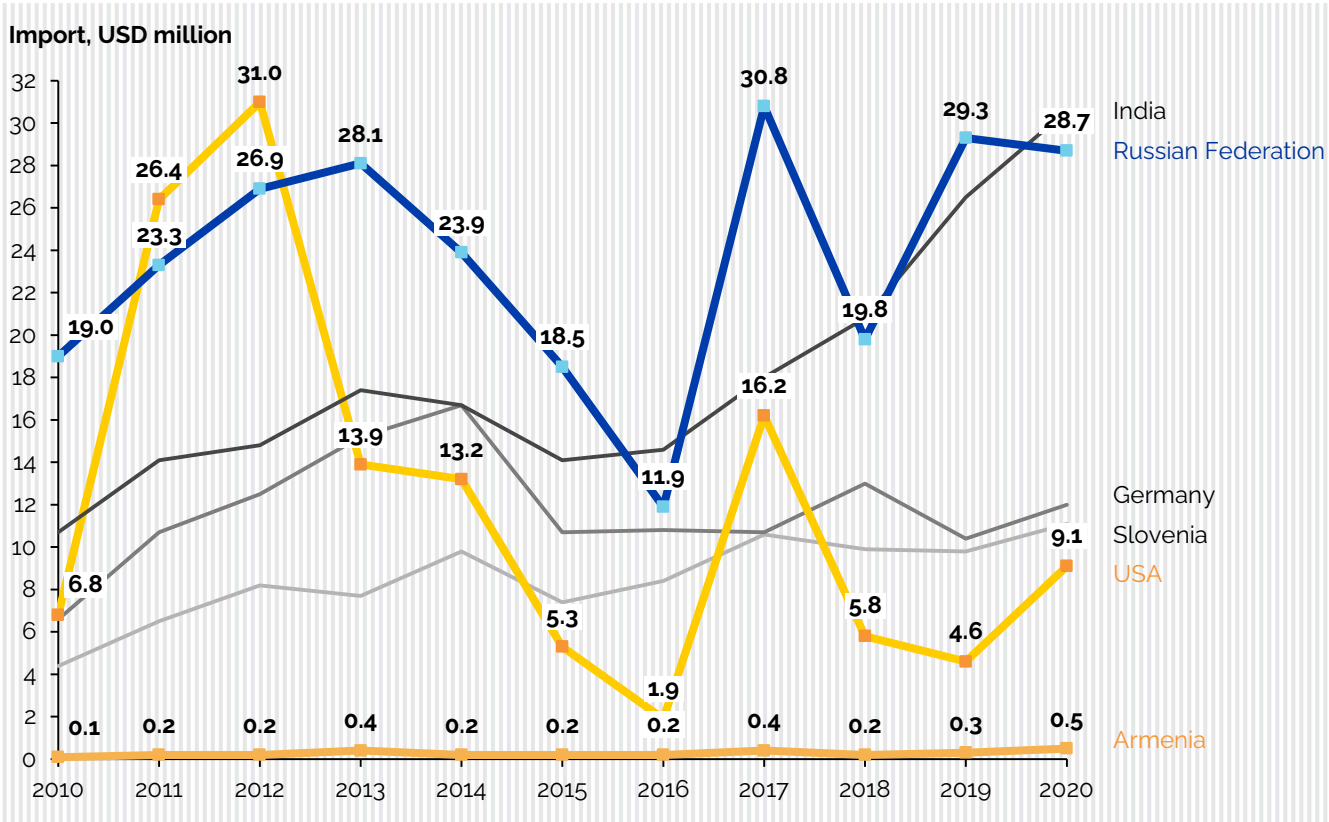
Market highlights[112]

- In 2021, Kyrgyzstan's overall healthcare spending reached USD 628m (7.7% of GDP), amounting to USD 95 per capita;
- Public healthcare funding accounted for little over 56% of total spending, emphasising the enormous out-of-pocket costs associated with treatment, which are a significant barrier to access.

Import statistics

From 2010 to 2020, USD 1.8b worth of pharmaceutical products was imported to Kyrgyzstan. Kyrgyzstan attained its highest amounts of imports in 2014 at USD 199m. Kyrgyzstan's imports of pharmaceutical products increased from USD 108m in 2010 to USD 195m in 2020, an increase of 80% with a CAGR of 6.1%.

Figure 56: Imports of pharmaceutical products by country



Sources: UN Comtrade

[111] Fitch Pharmaceutical sector report Kyrgyzstan 2022

[112] Fitch Pharmaceutical sector report Kyrgyzstan 2022

The top three products imported over the last decade by six digit CCG were 300490[113], 300420[114] and 300220[115], which totalled USD 1.4b, USD 99m and USD 47m, respectively. Generally, Kyrgyzstan imports products registered under 300490.

Imports from Armenia over the last 10 years amounted to USD 2.9m. Armenia was the 43rd largest source of imports of pharmaceutical products for Kyrgyzstan for the period.

The most commonly imported six digit CCGs from Armenia were 300490 and 300450[116] from 2010 to 2020. The 300490 code was responsible for 98% of imports from Armenia over the same period.

Figure 57: Imports of pharmaceutical products, digit CCGs

Sources: UN Comtrade

[113] Medicaments consisting of mixed or unmixed products
[114] Medicaments containing antibiotics
[115] Vaccines for human medicine
[116] Medicaments containing vitamins or their derivatives, for therapeutic or prophylactic use and packaged for retail sale

Figure 58: SWOT analysis for Kyrgyzstan's pharmaceutical market

Strenght

- Regulatory flexibility on drug pricing
- High demand for drug supplies
- Niche market for antiretrovirals due to prevalence of HIV

S

Weaknesses

- Low per capita spending on healthcare.
- Low demand for branded and innovative medicines,
- High incidence of counterfeit drugs
- Access to healthcare services and pharmaceutical products
- Poor transport network
- High sales and distribution costs

W

Opportunities

- Regulatory alignment with EAEU peers will streamline operating environment
- Continued health reforms to improve accessibility and affordability of medical services and boost demand for drugs
- Appetite to support clinical trials (TurkoVac Phase 3 CT agreement)
- Drug registration simplification will boost competitiveness of local drug manufacturers

O

Threats

- Subdued economic growth and solvency
- Exchange rate fluctuations
- New regulations to limit wholesale and retail markups
- High reliance on imported medicines

T

4.7 Ukraine

Background[117]

The Ukrainian pharmaceutical market, being one of the 10th largest pharmaceutical markets in CEE, had a volume of USD 4.7b in 2021. The market accounted for 2.7% of Ukraine's GDP and for 31.2% of total health spending during the same year. On a per capita basis, however, the country's expenditures were amongst the lowest ones in the CEE region, amounting USD 108.

Market highlights[118]

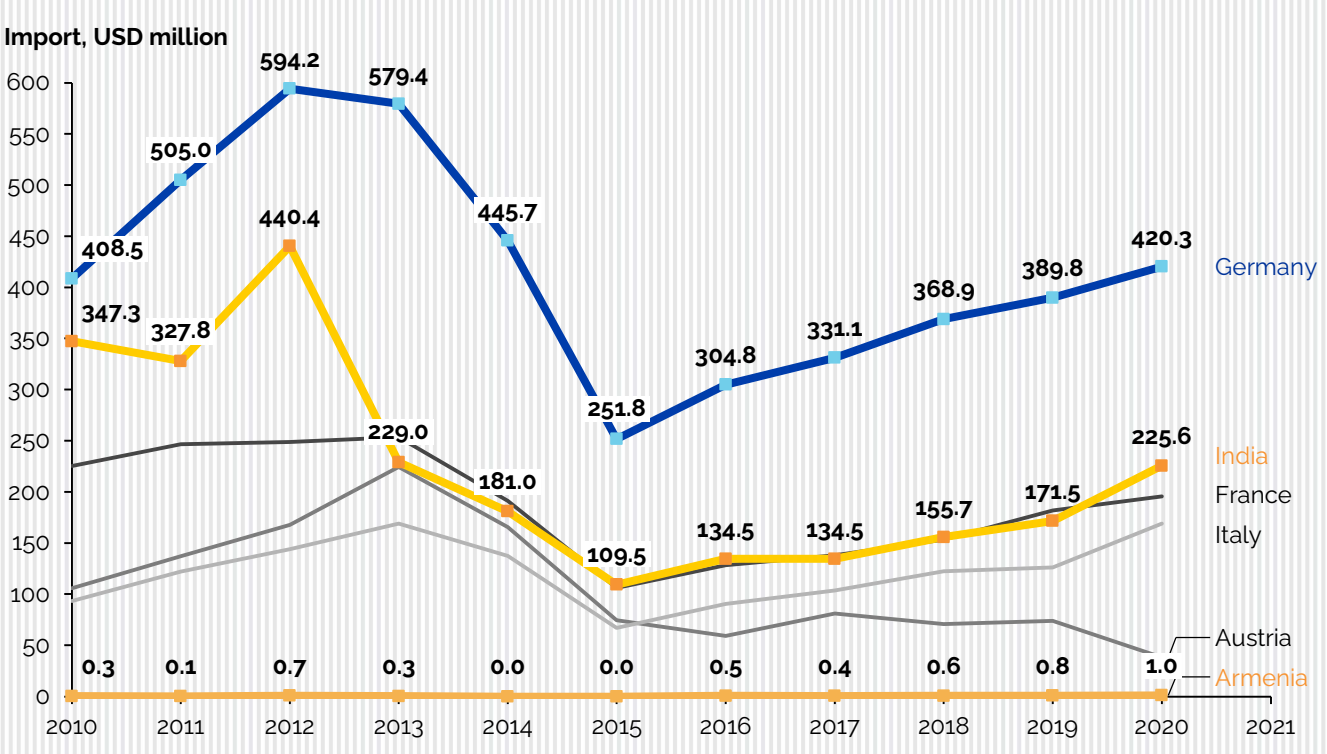
- In 2021, Ukraine's total health expenditures were USD 15b, accounting for 8.7% of GDP and equating USD 345 per capita
- Prescription medicine sales dominate the market, with generics accounting for 65.5% of total sales;
- Patented pharmaceuticals accounted for 27.7% of overall pharmaceutical sales.

Import statistics

USD 25.4b worth of pharmaceutical products were imported to Ukraine between 2010 and 2020. In 2020, Ukraine recorded an import volume of USD 2.3b. Over a ten-year period, Ukraine's pharmaceutical product imports remained stable, a decrease of 4% was recorded.

From 2010 to 2020, Germany was the main source of imports of pharmaceutical products (USD 4.6b) to Ukraine. India and France were the next two largest import sources, with USD 2.5b and USD 2b, respectively.

Figure 59: Imports of pharmaceutical products by country



Sources: UN Comtrade

[117] Fitch Pharmaceutical sector report Ukraine 2022
[118] Fitch Pharmaceutical sector report Ukraine 2022

The top three imported products by six digit CCG over last 10 years were 300490[119], 300420[120] and 300450[121]. Imports of these products amounted to USD 14b, USD 1.8b and USD 1.6b respectively. Ukraine generally imports products registered under 300490.

Imports from Armenia between 2010 and 2020 reached USD 4.7m, ranking Armenia as the 62th source of imports of pharmaceutical goods for Ukraine.

From 2010 to 2020, the most commonly imported six digit CCGs from Armenia were 300490, 300290[122] and 300420.

Figure 60: Imports of pharmaceutical products, six digit CCG

Sources: UN Comtrade

[119] Medicaments consisting of mixed or unmixed products
[120] Medicaments containing antibiotics
[121] Medicaments containing vitamins or their derivatives
[122] Toxins, cultures of microorganisms and similar products

Figure 61: SWOT analysis for Ukraine's pharmaceutical market

Strenght

- Population and demographics (ageing population)
- Fragmented market
- Market reliance on imported medicines

S

Weaknesses

- Per capita spending on healthcare and drugs is very low compared with other CEE states
- Cumbersome regulatory system (pharmaceutical sector)
- Domestic Patent laws do not follow best international practices and standards
- High out-of-pocket spending on drugs
- Market opportunity currently limited largely to generics and OTC medicines

W

Opportunities

- Widespread health reforms provide significant upside to healthcare accessibility
- Treatment naive population
- Demand for low-cost generic drugs and affordable treatments
- WTO accession and new reforms agenda
- Lessened regulatory load on multinationals

O

Threats

- Overburdened and corrupt judiciary system
- Lack of effective enforcement of Patent laws.
- Lack of competitiveness within the sector
- Protectionist approach prevents foreign direct investment
- Geopolitical tensions with Russia threatens civil stability and resource allocation

T

4.8 Uzbekistan

Background[123]

The pharmaceutical market of Uzbekistan is one of the smallest in the CEE region with a revenue of USD 638m in 2020.[124] The sector's share in the country's GDP was 1% and in total healthcare expenditures it was 18%. Per capita pharmaceutical consumption was calculated at USD 19 in 2020.

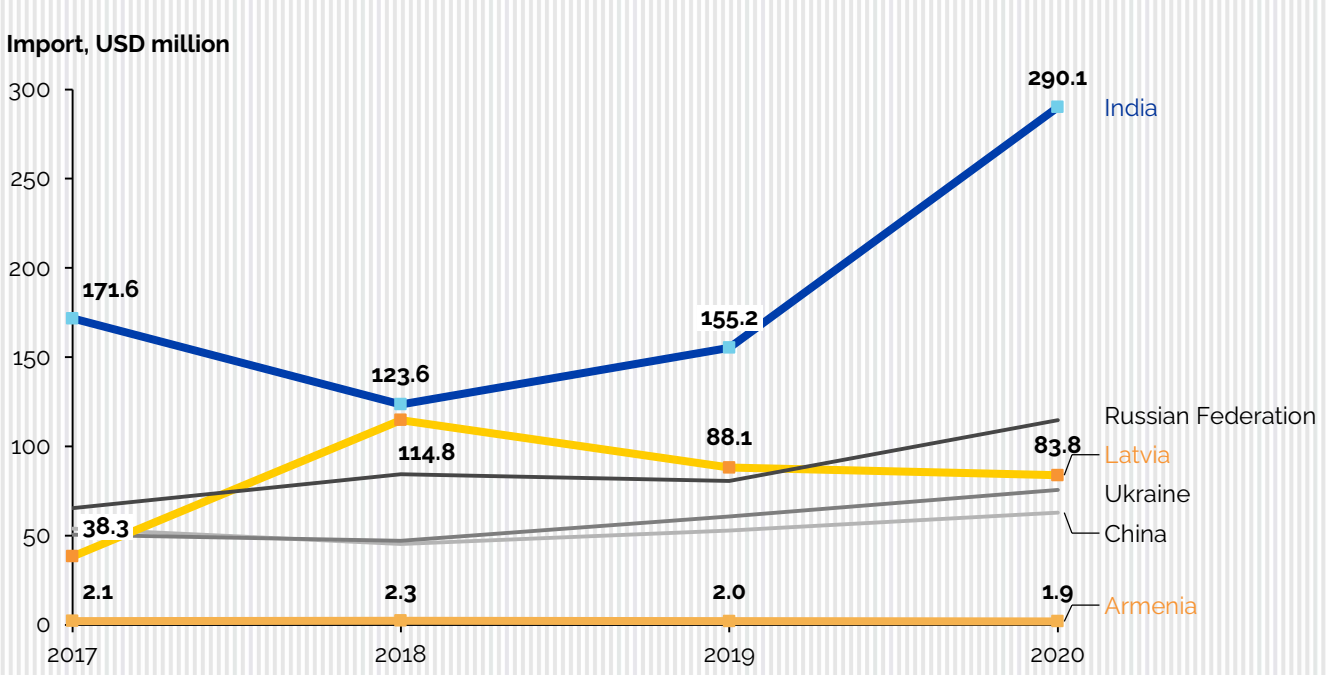
Market highlights[125]

- In 2020, Uzbekistan's healthcare spending were USD 3.6b (6% of the country's GDP) and USD 106 per capita
- Public health spending accounted for 42.5% of total expenditures in 2020.
- Despite rising spending on patented medications, the generic sector will remain dominant in the long run, owing to volume.
- Uzbekistan is now receiving money from a number of international charities and institutions to help it implement its most recent healthcare reform plan, the Universal Healthcare Coverage (UHC) Partnership, which runs from 2019 to 2025.

Import statistics

From 2017 to 2020[126], Uzbekistan imported USD 3.7b worth of pharmaceutical products, including USD 1.1b in 2020 alone. Over this period, Uzbekistan's pharmaceutical imports increased by about 42%.

Figure 62: Imports of pharmaceutical products by country



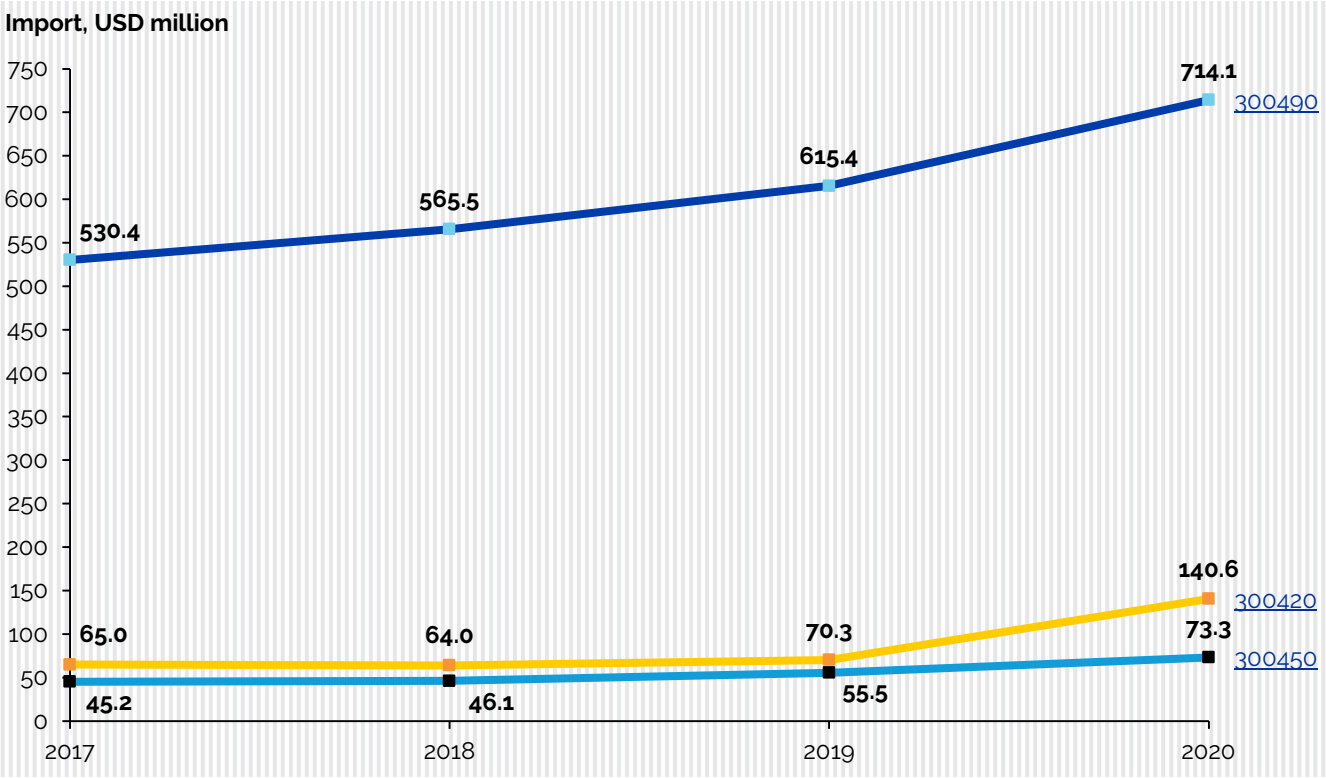
Sources: UN Comtrade

[123] Fitch Pharmaceutical sector report Uzbekistan 2022
[124] Data for 2021 was not available
[125] Fitch Pharmaceutical sector report Uzbekistan 2022
[126] Data before 2017 was not available

Over the past four years, the top three products in terms of six digit CCG code were 300490[127], 300420[128] and 300450[129] with USD 2.4b, USD 340m, and USD 221m respectively. In general, Uzbekistan buys products with the 300490 code.

Imports from Armenia over the last 4 years amounted to USD 8.3m. Armenia is the 31th largest importer of pharmaceutical products. The most commonly imported six digit CCGs from Armenia are 300490, 300230[130] and 300432[131]. Imports of 300230 fell dramatically in 2020.

Figure 63: Imports of pharmaceutical products, six digit CCGs



Sources: UN Comtrade

[127] Medicaments consisting of mixed or unmixed products
[128] Medicaments containing antibiotics
[129] Medicaments containing vitamins or their derivatives
[130] Vaccines for veterinary medicine
[131] Medicaments containing corticosteroid hormones, their derivatives or structural analogues (but not containing antibiotics), for therapeutic or prophylactic uses and packaged for retail sale

Figure 64: SWOT analysis for Uzbekistan's pharmaceutical market

Strenght

- Government committed to improve access to healthcare
- Emerging state-financed primary care sector and screening facilities
- Well-developed universal immunisation programme
- Strong and sustained market growth

S

Weaknesses

- High out-of-pocket expenditure on health services
- Poor primary care standards and levels of training
- Shortages of modern technology & equipment
- Poorly developed pharmaceutical facilities
- Poorly enforced intellectual property
- rights and deficient regulations
- Sizeable market for counterfeit pharmaceuticals

W

Opportunities

- Continued and developing relationships with major world economies
- Health reform drive will significantly improve access to healthcare
- Upcoming WTO accession to benefit the business environment
- Ongoing economic reform to benefit overall health sector development
- A large treatment-naïve population
- Established research institutions attractive to clinical trials organisations
- Growing demand for high-end products (e.g. patented products)

O

Threats

- Health reform implementation slower than originally envisaged
- Lack of human resources and capacity
- Domestic manufacturers' dependency on imported materials

T

Key sub-sectors trends, dynamics, growth opportunities

Section summary

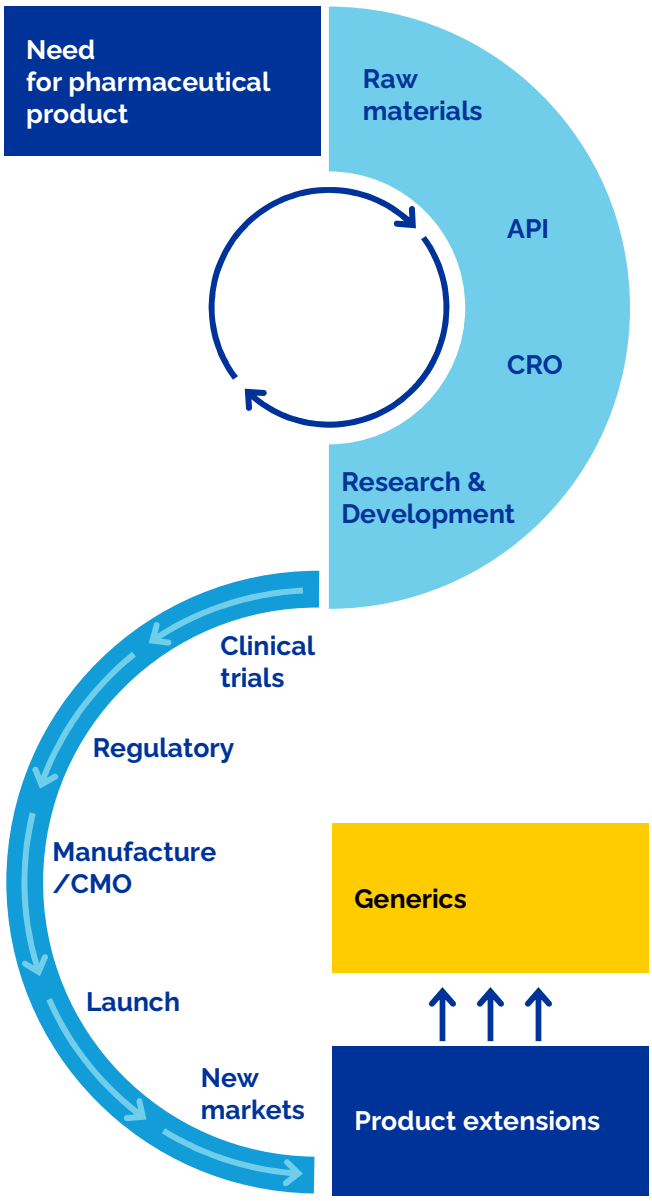
The global **clinical trials** market size was valued at USD 48.4b in 2020 and is predicted to hit USD 84.43 b by 2030 with a registered CAGR of 5.7% during the forecast period 2021 to 2030. The market is expected to be dominated by Phase III, with Phase I expected to witness the fastest growth. The global **API market** size is expected to reach USD 356b by 2030 from at USD 179.6b in 2020, expanding growth at a CAGR of 7.1% over the forecast period 2021 to 2030. Global **generic drugs market** was worth USD 390.6b in 2020 and is projected to reach approximately USD 574.6b by 2030 attaining a CAGR of 5.6% between 2021 and 2030 .

As the global generic drugs market is huge, it is very likely to continue growing The **global biopharmaceutical CMO and CRO** market size is expected to reach USD 54b by 2030, registering a CAGR of 6.6% over the forecast period. The sub-sector is consolidating as a means of enhancing profitability. Through consolidation, the large CMOs could expand their geographical presence and penetrate multiple markets.
The most significant factor boosting the growth of sub-sector in the pharmaceutical sector is the growing need for robust processes and production technologies.

Key sub-sectors trends, dynamics, growth opportunities

The scope of this section is to study the various stages in the life cycle of a pharmaceutical product (Figure 65) while analysing key sub-sectors of pharmaceutical product lifecycle trends, dynamics and defining the ones that potentially present the highest growth opportunities for Armenia

Figure 65: Life cycle of a pharmaceutical product.



Rationale for identifying these sub-sectors

The study identifies the following sub-sectors:

1. Clinical trials
2. Generic
3. Research & Development
4. API and raw materials
5. Contract Research Organisations (CRO) and Contract Manufacturing Organisations (CMO)
6. Standards development (additional opportunities)
7. Certification (additional opportunities)

5.1 Clinical trial

According to the World Health Organisation, a clinical trial is defined as 'any research study that prospectively assigns human participants…to one or more health-related interventions to evaluate the effects on health outcomes' – these 'interventions' include drugs, as well as biological products, medical devices and surgical procedures among others. Clinical Trials are a type of clinical research that are performed in people and are intended at assessing a behavioral, surgical, or medical intervention. Clinical Trials act as the prime way employed by the scientists to investigate if a new therapy, a medical device or a novel drug is secure and efficient in individuals.

Before a drug candidate can begin the clinical trial process, it is tested by its manufacturer through preclinical studies for toxicity, otherwise known as its ability to cause serious harm, as well as pharmacokinetic information. . Clinical trials can be divided into five phases, with every phase playing a distinct purpose within the clinical trial:

0. **Phase 0** is also commonly known as human micro-dose studies because it involves a very small group of participants, usually between ten and 15, who have been given a low, sub-therapeutic dose of the drug.
1. **Phase I** trials are the first full human study the drug will be subject to and therefore they primarily focus on its safety and tolerability. This stage involves a slightly larger number of participants than phase 0 studies, often between 20 and 100 subjects. This stage of the clinical trial is often organized as a dose escalation study – where the first small group of participants receive a very low dose of the drug.
2. If a drug is well tolerated in phase I, it progresses to **Phase II**. In this stage the number of patients is increased once more, with as many as several hundred participants being used to gauge the efficacy of the drug. During this test period researchers can also pinpoint related side effects and continue safety assessments from previous studies.
3. **Phase III** trials concentrate on discovering the efficacy of the drug and differ from phase I and phase II studies because they occur over a longer time period, involve more patient participants and happen under conditions that reflect daily clinical life.
4. Following approval from national regulatory authorities, some drugs continue in the clinical trial process and enter **Phase IV**, which is also known as a post-marketing surveillance trial. Phase IV studies allow drug companies to uncover more information about the side effects and safety of the drug, as well as provide an opportunity for researchers to learn the longer term risks and benefits. They are sometimes required by regulatory authorities or by investors into the drug.

According to Precedence Research, the global clinical trials market size was valued at USD 48.4b in 2020 and is predicted to hit USD 84.43 b by 2030 with a registered CAGR of 5.7% during the forecast period 2021 to 2030.[132]

The market is expected to be dominated by Phase III, with Phase I expected to witness the fastest growth. Phase III is one of the most critical phases assessing the effectiveness of the new intervention, as well as its value in clinical practice. North America has been dominating the overall market, owing to the presence of big outsourcing firms and increasing R&D in the region. This is mainly due to factors such as the increasing R&D investments and increasing demand for drug development

Factors driving the growth of the clinical trials market:

- growing prevalence of chronic disorders
- increasing number of clinical trials in developing regions
- growing number of biologics
- increasing demand for advanced treatments such as personalised medicines
- outbreak of viral diseases
- increasing cases of cancer globally
- growing geriatric population
- growing research and development expenditure

To sum up, clinical trials are a rapidly developing sub-sector in the pharmaceutical sector. Global trends contribute to funding and expanding new trials. Growth of the sub-sector is related to the development of the Research & Development sub-sector.

5.2 API and Raw materials

API stands for active pharmaceutical ingredients. A substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings. Pharmaceutical raw materials include both active pharmaceutical ingredients and inactive ingredients or excipients.

[132] Clinical Trials Market (By Phase: Phase 1, Phase 2, Phase 3, and Phase 4; By Study Design: Observational, Interventional, and Expanded Access; By Indication: Oncology, Autoimmune/Inflammation, Diabetes, Central Nervous System, Cardiovascular, Pain Management, and Others) - Global Market Size, Share, Trends Analysis, Segment Forecasts, Regional Outlook 2021 – 2030

The global API market size is expected to reach USD 356b by 2030 from at USD 179.6b in 2020, expanding growth at a CAGR of 7.1% over the forecast period 2021 to 2030.[133]

Presently, the pulmonology segment has been experiencing a high peak in growth due to the pandemic, as the pharmaceutical sector is at the lead of the combat against Covid-19 and has responded to this global challenge by guaranteeing the availability of medicines in spite of supply chain interruptions. The oncology segment is also expected to grow significantly during the forecast period owing to the high prevalence of cancer in the last few decades, and the disease is expected to claim a more prevalent population during the forecast period. Market players are continuously developing new APIs to cater to the need in the oncology segment globally. North America currently dominates the market for active pharmaceutical ingredients and is expected to continue its stronghold for a few more years.

Main drivers of API market:

- continuously growing prevalence of chronic illness,
- escalating significance of generics,
- the cumulative uptake of biopharmaceuticals,
- surge in sedentary lifestyle,
- increase in geriatric population

:In conclusion, the growth of the API market depends on the developing pharmaceutical sector in general.

5.3 Generics

Pharmaceutical products usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. These medications are inexpensive and similar to branded drugs in power, and route of delivery, consistency, efficiency, and usage. These are subject to administration regulations in different nations, rather than associated with a particular company. These drugs are proven to be as safe and effective as their brand name formulation, which has already been marketed.

According to Precedence Research, the global generic drugs market was worth USD 390.6b in 2020 and is projected to reach approximately USD 574.6b by 2030, attaining a CAGR of 5.6% between 2021 and 2030 [134].

As the global generic drugs market is huge, it is very likely to continue growing. The Asia Pacific region has shown the fastest growing trend in the global generic market owing to increased awareness among the people related to any disorder, the rise in population can also be attributed to the increase in demand for generic drugs.

[133] Active Pharmaceutical Ingredient Market Size, Share & Growth Analysis, By Synthesis (Biotech, Synthetic), By Type (Generic API, Innovative API), By Type of Manufacturer (Captive, Merchant), By Application (Cardiology, CNS & Neurology, Nephrology, Ophthalmology, Pulmonology, Gastroenterology, Oncology, Endocrinology, Others) - Global Industry Analysis, Trends, Regional Outlook and Forecast 2021 – 2030

[134] Generic Drugs Market (Drug Type: Simple Generics and Super Generics; By Brand: Pure generic drugs and Branded generic drugs; By Route of Drug Administration: Oral, Topical, Parental, and Others; By Therapeutic Application: Central nervous system (CNS), Cardiovascular, Dermatology, Oncology, Respiratory, and Others; By Distribution Channel: Hospitals Pharmacies, Retail Pharmacies, and Others) - Global Industry Analysis, Market Size, Share, Growth, Trends, Region Outlook, And Segment Forecasts, 2021 – 2027

Crucial factors contributing to the market growth:

- The low cost of generics as an alternative to branded drugs
- Large number of patents expired branded drugs
- Initiatives by governments and other regulatory bodies across the globe
- High availability

5.4 Research & Development

R&D refers to the pharmaceutical research and development of new medicines. The process begins with understanding the disease and selecting a target (usually a receptor site on a cell) that can potentially be affected by a drug molecule.

In 2020, research and development spending in the pharmaceutical sector totalled nearly USD 200b globally.

Investment in R&D in the pharmaceutical sector not only benefits population health, but also, in the medium term, other features are discovered, such as cost savings in healthcare and lower operational costs in the pharmaceutical sector.
In 2019, the pharmaceutical sector spent USD 83b on research and development. These costs were incurred for a number of operations, including the discovery and testing of novel medications, the development of incremental advancements such as product expansions, and clinical testing for safety monitoring or marketing. The amount of money that pharmaceutical companies dedicate to R&D is governed by the amount of revenue they expect to receive from the creation of a new drug, the expected cost of developing that drug, and policies that influence drug supply and demand.
Pharmaceutical companies spent more than 25% of their revenues on R&D on average in 2018 and 2019, making them one of the highest spenders in this sector. Some big pharmaceutical companies have increased their R&D efforts to create vaccines [135]:

Table 5: Pharmaceutical companies' R&D investment % in revenue

Company name	R&D investment, USD		% in revenue
Merck	USD	**13.6b**	**28.3%**
Johnson & Johnson	USD	**12.2b**	**14.8%**
Pfizer	USD	**9.4b**	**22.4%**
Novartis	USD	**9b**	**18.5%**
Roche	USD	**6.5b**	**24.1%**

[135] R&D percentage in revenue of pharmaceutical companies

Private expenditure on pharmaceutical R&D has surged significantly in recent years, resuming a decades-long trend that was stopped in 2008 when generic versions of certain top-selling drugs became accessible, as well as the 2007–2009 recession. Spending on medication R&D, in example, surged by approximately 50% between 2015 and 2019. Many of the medications licensed in recent years are expensive specialty drugs for a small number of potential patients. The top-selling medications in the 1990s, on the other hand, were lower-cost drugs with vast patient populations.[136]

5.5 CRO/CMO

CROs are popular because they offer a more cost-effective solution for firms seeking to produce new medicines for large and niche markets alike. By outsourcing research to CROs, the costs of conducting a trial are reduced massively as the firm will not need the infrastructure, space or manpower to run trials or conduct research themselves. Before CROs became an established method of pursuing approval for a drug, many companies would only take action when there was a sense of guaranteed approval for large markets. This has made research into new medicines a much more feasible and affordable prospect for the average firm, reducing their general overhead costs.

A contract manufacturing organization also serves other firms within the pharmaceutical sector on a contractual basis, but instead of providing research services, CMOs offer comprehensive drug development and manufacturing services. Again, this assists the hiring company with scalability and allows them to focus on more important areas of their business, such as research or marketing. Alternatively, pharmaceutical firms may outsource drug manufacturing work to a CMO if they lack the expertise or facilities required to produce the quantity and/or form of a drug that is needed to perform pre-clinical and clinical trials. The demand for the services that CMOs offer has resulted in fast growth for the CMO sector over the last decade, and this will continue as the need for CMOs increases.

The global biopharmaceutical CMO and CRO market size is expected to reach **USD 54b by 2030**, registering a **CAGR of 6.6%** over the forecast period.[137]
There are some significant insights:

CMOs and CROs are consolidating as a means of enhancing profitability in the competitive market.

Through consolidation, the large CMOs could expand their geographical presence and penetrate multiple markets.

The most significant factor boosting the growth of sub-sector in the pharmaceutical sector is the growing need for robust processes and production technologies, which have proven highly effective in meeting regulatory requirements.

There is also a tendency among pharmaceutical companies to outsource idea generation, and early discovery work, such as basic research, target identification, validation, and hit discovery, to third party organisations.

[136] R&D spending trends
[137] Ricky Martin (2018), The CRO / CMO Industry: What You Need to Know

5.6 Standards development

The standards are widely used in International Organization for Standardization (ISO) laboratories, pharmaceutical manufacturing, food processing and mining laboratories. Standards are one of the main characteristics that ensure the accuracy of measurement results issued by laboratories. The main international recommendations to produce reference standards are ISO Guide 34, ISO/International Electrotechnical Commission (IEC) 17025:2005. Market research has shown that there are no manufacturers of standards with patents on the EAEU market - from mining to pharmaceuticals, either non-international standards are used, or they are mainly obtained from the countries of the European Union or the US.

5.7 Certification

GxP (Good…Practice,) is a globally recognized quality system for medicines. The GxP system covers all stages of the life cycle of medicines, from pharmaceutical development, testing, production, storage to use by the end consumer.

- GLP (Good Laboratory Practice) is a quality system that covers the organizational process and conditions under which non-clinical studies of medicines related to health and environmental safety are performed.
- GCP (Good Clinical Practice) is an international ethical and scientific standard for planning and conducting research involving a human as a subject, as well as documenting and presenting the results of such research. GCP rules are designed to ensure the validity of the results of clinical trials, as well as the safety and protection of the human rights and health of people participating in these trials as subjects.
- GMP (Good manufacturing practice) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

6

Value proposition and overview of key sub-sectors in Armenia and the target countries

Value proposition and overview of key sub-sectors in Armenia and the target countries

6.1 Rationale and brief information on the selection of target countries

For the sub-sector analysis, target countries were selected from **EAEU**, **Commonwealth of Independent States**, **Middle East and North Africa (MENA)** region and **Europe**. The final list of target countries included Azerbaijan, Belarus, Czech Republic, Georgia, Jordan, Kazakhstan, Kyrgyzstan, Lebanon, Moldova, Russia, Serbia, Tunisia, Ukraine and Uzbekistan.

The selection rationale:

- For EAEU countries: **Joint EAEU market** and **legislation**, **comparable level of healthcare** with Armenia, **similar pharmaceutical sector** and **GDP per capita**
- For CIS countries (non-EAEU members): **Geographical proximity**, comparable **potential trade partners** with Armenia, **comparable levels of healthcare** with Armenia, **similar pharmaceutical sector**, **resource availability**, **educational system** and **macroeconomic factors**
- For MENA region and EU countries: **Geographical proximity** and similarity (landlocked), **comparable level of population**, **macroeconomic factors** and **available resources**

For the API and CRO/CMO sub-sectors, the sample list of countries was modified due to limited data availability from open and closed sources and lack of these sub-sectors in the chosen target countries. **Criteria** for choosing the countries for these sub-sectors was limited to **presence of sub-sector** in the country, **adequacy of available data**, **socio-economic similarities** (GDP per capita, income group, economic growth rates), **geographical characteristics** and pharmaceutical **sector maturity**.

Sub-sector summary: Clinical trials

As the global clinical trials market valued at USD 48.4b in 2020 is expected to reach USD 84.43b by 2030, with a growing prevalence of chronic disorders, increasing demand for advanced treatments and innovative drug development, developing countries are in a race to take their share of the market. While Russia has the largest share of the clinical trials market in the EAEU, emerging economies like Belarus, Moldova and Georgia, the Czech Republic and Serbia are clearly focusing on this sub-sector.

Offering convinced advantages as a site for clinical trials, Armenia could also increase its presence in the global market thanks to its low human capital costs, prevalence of more than 90 rare diseases and a developed legislative base. Despite lack of an immediate local demand for clinical trials and increasing demand for generic drugs, accounting for 70% of the total retail pharmaceutical market, potentially, Armenia could absorb a part of the growing EAEU clinical trials market, which is forecasted to grow significantly due to supranational registration in the EAEU by 2025 and grow its share in the clinical trials market substantially by prioritizing profitable areas such as respiratory, anti-infective, ophthalmology and pain/anaesthesia, as well as participating and partnering with global players, especially in the financially attractive Phase III trials.

70% of the costs of clinical trials are workforce-related and Armenia with its cost-effective, qualified workforce could offer relevant advantage over its regional competitors. Overcoming the biggest restraining factor of GLP certified laboratories is the key task before the sector and should be immediately addressed.

6.2. Overview of clinical trials sub-sector

Clinical trials are **research studies involving people and aimed at evaluating a medical, surgical, or behavioral intervention.** They are the primary way that researchers find out if a new treatment, a new drug or diet or medical device is safe and effective. There are **3 main phases of clinical trials.** The FDA typically requires Phase I, II, and III trials to be conducted to determine if the drug can be approved for use.

Phase I trials are the earliest phase trials and **Phase III are later** phase trials. Some trials have an earlier stage called Phase 0, and there are some **Phase IV trials** done after a drug has been licensed. During this phase, a device's or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become clear until more people have taken it over a longer period.

The **factors driving** the clinical trials market **growth** are:

- growing prevalence of chronic disorders
- increasing number of clinical trials in developing countries
- growing number of biologics
- increasing demand for advanced treatments for personalized medicine
- outbreak of viral diseases
- increasing cases of cancer
- growing geriatric population
- growing research and development expenditure

Clinical trials is a rapidly developing sub-sector in the pharmaceutical industry. Global clinical trials market size was valued at **USD 48.4b in 2020** and is predicted to reach USD **84.43 b by 2030**. The market is expected to be dominated by Phase III, with Phase I expected to witness the fastest growth. Phase III is one of the most critical phases assessing the effectiveness of the new intervention, as well as its value in clinical practice.

6.2.1 Overview of target countries: Clinical trials

EAEU

The **mutual recognition of clinical trials conducted in EAEU** member countries is **governed** by agreements on **how clinical trials are to be conducted**. The procedure is regulated by Council of the Eurasian Economic Commission Decision No. 85 of 3 November 2013 "On the Approval of Rules for Good Clinical Practice in the Eurasian Economic Union", Board of the Eurasian Economic Commission Recommendations No. 11 of 17 July 2018 "On the Guidelines for General Issues related to Clinical Trials", and Eurasian Economic Commission Recommendations No. 19 of 3 November 2020 "On the Guidelines for the Use of Biostatistical Preparations in Clinical Trials of Medicinal Products". The focus of the regulations is on generating reliable results of preclinical trials, ensuring the safety of participants in clinical trials and in making timely adjustments to clinical trials that are planned or being carried out.

Russia [138]

Russia is a **highly attractive** location for outsourced clinical trials. Although there are **many issues** with Russia's centralized healthcare system in terms of **restricted access to services** in more rural

[138] Fitch Pharmaceutical sector report – Russia

areas, the presence of many large regional and city hospitals allows for **short enrolment periods**, as many patients can be enrolled in the same trial at the same hospital.

Given the lack of access to high-quality medicines, there is an **increasing demand for clinical trials** from both physicians and patients alike. **Patient dropout rates are low: an average of 14%** leave clinical trials before they are completed, **in contrast to reported figures of 24% in other countries**. **Legislation** is **less challenging** for multinational firms, exemplified by the removal of the necessity to perform pre-clinical studies before a trial can begin. According to Smooth Drug Development, the first ISO 9001:2008 (a quality management system) certified CRO in Russia, the **regulatory approval process takes just 35 working days**, which is comparable to European clinical trial timelines. Unlike in other countries, where regulations continue to inhibit the clinical research sector–the prime example being India–the Russian Government began to introduce reforms to its legislation in 2012 with the aim of streamlining the approval process and making **Russia a more attractive place** to perform clinical trials. These changes, which came into effect in 2015, have been **"quite positive",** according to the Association of Clinical Trials Organizations (ACTO). Russia has also **reduced the duty levied on medicines imported** for use in clinical trials, from 7.7% to 3% for chemically synthesized drugs, and maintains a 3% levy on biologics. New regulatory changes are already underway as a result of the imposed sanctions against Russia.

Kazakhstan[139]

The **market for clinical trials** in Kazakhstan remains largely **underdeveloped**, with only a handful of trials over the last decade. **In 2020, only 4 (four) new clinical trials were registered** in the country (three in New Phase III and one in New Phase II). While this was up from no trials registered in 2019, it was below the six new trials in 2018. Nevertheless, the ever-growing **search for new patient populations** and **low-cost bases to perform clinical trials** will **result in significant expansion in the market**. Kazakhstan retains several research institutes that would make potentially attractive partners for medical research. In December 2018, Kazakhstan adopted a new Ministry of Health bill that proposes to conduct clinical studies on various vulnerable groups of the population. **Kazakhstan's strengths as a location for clinical trials include ethnic diversity**, a **treatment-naive patient population**, **low number of studies per patient**, **moderate investigator fees and a motivated patient population in search of higher quality of care** in major cities, where medical facilities are usually well-equipped. In addition, there is no need for local clinical trial insurance as long as global insurance includes Kazakhstan.

Belarus[140]

The clinical trials sector in Belarus is in its **infancy**. While **low costs are an advantage, red tape** and **poorly equipped facilities** remain a **problem**. The number of clinical trials conducted in Belarus has fallen dramatically: the number of **Phase 3 trials has dropped three times** in the last four years and there were virtually no other trials conducted in other Phases in 2021, compared with more than **15 trials** in 2017. Improvements in the country's regulatory regime, as well as in the wider political environment, are a prerequisite to more investment in the clinical trials sector.

Kyrgyzstan[141]

Most of **Kyrgyzstan's population** can be classified as **treatment-naive**. However, given the basic nature of healthcare and laboratory facilities, there is **relatively little clinical research** being undertaken in Kyrgyzstan. Several sites in the state sector, including the Kyrgyz National Research

[139] Fitch Pharmaceutical sector report – Kazakhstan
[140] Fitch Pharmaceutical sector report – Belarus
[141] Fitch Pharmaceutical sector report – Kyrgyzstan

Centre for Tuberculosis, the National Centre under the Ministry of Health of Kyrgyzstan, a couple of city clinical hospitals, and the Republican Dermatology Clinic, are equipped to conduct clinical trials. **As of 2019, there was only 1 (one) clinical trial in IV stage active in Kyrgyzstan**. This underscores the country's ambition to become more involved in pharmaceutical development and bodes well for the future of the market.

The EU and MENA region

Czech Republic[142]

Low costs are a major attraction of **emerging clinical trial markets in Europe**. However, the region also offers other benefits. The high proportion of **treatment-naïve patients**, who have not had **access to the latest treatments** and are **therefore not resistant to a wide array of medicines**, is also a key factor in this region in contrast to more developed markets. **Patient enrolment** is, therefore, **higher and dropout rates are lower**, as generally there is better access to services under clinical research projects when compared with standard healthcare provisions. As in Western Europe, the key markets in CEE, including the Czech Republic, Hungary and Poland, have **large patient populations concentrated** in bigger cities, which is **essential for fast patient recruitment.** As with most developed and publicly-funded healthcare systems, CEE markets offer centralized medical services. There is a broad network of large specialist clinics and hospitals to support fast recruitment even with rare diseases.

Serbia[143]

Serbia has considerable educational and human capital assets, as well as **good hospitals** in major cities and towns. **Key medical staff is well-educated** and usually **competent in English**, and a number of **researchers possess experience in clinical trials both at home and abroad**. **High patient recruitment rates**, especially in the area of oncology and rare diseases, are another factor promoting the country's research and development environment. **Serbia has emerged as a desirable destination for clinical trials**, building on its pre-war reputation as a **multicenter research base that complies with Good Clinical Practice (GCP), as well as on its strong pharmaceutical sector.**

Lebanon[144]

Lebanon has one of the most active clinical trial industries in the Middle East. ClinicalTrials.gov recorded **272 studies** that were **either active or that had been completed** as of February 2016. In 2014 alone, 23 new clinical trials were registered–the majority of which were Phase III. By 2018, the number of new trials registered in Lebanon reached 39. From 2014 to 2018, Phase III trials accounted for 35% of new trials registered. **Despite** of this, as a result of the **recent economic, financial and humanitarian crises, there has been a gradual decline in the number of clinical trials registered.**

Jordan[145]

As of 2020, seven New Clinical Trials were registered in Jordan, including two in New Early Phase I, two in New Phase II, two in New Phase II/ New Phase III and one in New Phase I/Phase II.

[142] Fitch Pharmaceutical sector report – Czech Republic
[143] Fitch Pharmaceutical sector report – Serbia
[144] Fitch Pharmaceutical sector report – Lebanon
[145] Fitch Pharmaceutical sector report – Jordan

Tunisia[146]

Tunisia has a **relatively well-established clinical trials system** compared with many of its African peers. The country has **adopted laws and decrees** to **improve regulatory practices**. The environment is **well equipped to support clinical trials** in terms of regulation, **expertise and resources**. Clinical trial procedures are overseen by the Ministry of Higher Education & ScientificResearch, the Ministry of Public Health, and the General Directorate of Scientific Research and Technological Information, which work to ensure that the regulations are clear, easy to follow and well documented. Clinical trial organizations in Tunisia can conduct clinical trials professionally, and the country's experience on research projects with multinational drug makers highlights Tunisia's reputable clinical research environment.

Non-EAEU countries

Ukraine[147]

Ukraine permits importing unregistered drugs, bulk substances and samples of biological materials for scientific research. The right to sell such substances is not provided, but they can be imported for further development, registration and exhibition at trade shows. Ukraine also has substantial and still untapped potential as a site for clinical trials and research, given the ageing but still substantial infrastructure of Soviet-era research institutes. Nevertheless, the poor state of the Ukrainian healthcare system and the country's economic turmoil presently make it a poor hosting country for clinical trials.

Moldova[148]

Clinical trials continue to be limited in size and scope. Pharmaceutical firms that have conducted clinical trials in the country include. GLP certified laboratories are not already present.

Azerbaijan[149]

Clinical trials are not commonplace in Azerbaijan on account of the country's nascent pharmaceutical market and the lack of funding sources for pharmaceutical research. Nevertheless, clinical trial legislation is in place, with all such initiatives needing to be placed on a national register.

Uzbekistan[150]

Over the long term, some experts have forecasted that CIS countries, with the possible inclusion of Uzbekistan, will be the main areas of growth for clinical trials in Europe. The country's existing research institutes have the potential to lead the research process. Further growth in this region will be heavily dependent on successful reforms and funding for healthcare development. Moreover, the development of clinical trials will require investment in local hospitals and scientific institutes, as well as efforts to ensure such issues as informed consent are addressed in a highly undemocratic context. By any measure, Uzbekistan represents an opportunity further in the future, pending improvements in the overall risk environment and continued investment in

[146] Fitch Pharmaceutical sector report – Tunisia
[147] Fitch Pharmaceutical sector report – Ukraine
[148] Fitch Pharmaceutical sector report – Moldova
[149] Fitch Pharmaceutical sector report – Azerbaijan
[150] Fitch Pharmaceutical sector report – Uzbekistan

the reasonably well developed, but ageing, scientific research infrastructure. **Major hurdles–including a lack of transparency in regulation**–still remain, and they must be resolved before the country's clinical testing potential can be fully realized.

6.2.2 Overview of clinical trials sub-sector in Armenia

Clinical trials in Armenia are **regulated by EAEU** rules and **require approval by the regulatory authorities**. Local rules on clinical trials are laid out in the Law of the Republic of Armenia of 17 May 2016 "On Medicines". **Ethical approval is required**, and **all trials must be registered in national or international registers**. All clinical trials must **comply with Good Laboratory Practice** requirements. The Armenian population is **largely treatment-naive**. However, the **small population size** and the country's **underdeveloped facilities** mean that there are **limited opportunities for pharmaceutical testing and trials**. Currently, there is only one clinical trial in progress, which is led by Emory University and Fogarty International Centre of the National Institute of Health[151].

Armenia offers convinced **advantages** as a site for clinical trials, including[152]:

- high levels of professionalism among doctors;
- extensive medical practices in a variety of fields;
- doctors who are professionally and financially motivated to participate in clinical studies;
- developed legislative base;
- relatively few restrictions (military, prisoners, and, in some cases, pregnant women).

Presence of around 90 types of rare diseases among the Armenian population that requires additional study using clinical trials.

One of the key **aspects** for the development of the clinical trials market **is GLP certification**. **Laboratories** in Armenia have applied for this certification but **have not been able to achieve it**. In addition, Armenia's **low population growth and lack of ethnic diversity** is also drawing back the development of this sub-sector. There is a **low local demand for innovative drugs** in Armenia and the EAEU due to localization and a **strong market share held by generics.**

[151] Governmental clinical trials statistics
[152] Fitch Pharmaceutical sector report – Armenia

Table 6: Comparison of industry drivers in target countries

	GLP laboratories	Clinical trials market	Pre-clinical trials on animals	Innovative drugs	Low-cost workforce
Armenia		●	●		●
Russia	●		●		
Belarus		●	●		
Kyrgyzstan			●		●
Kazakhstan		●	●		●
Czech Republic	●			●	
Serbia	●		●	●	
Lebanon		●	●	●	●
Jordan	●	●	●	●	
Tunisia	●			●	
Ukraine	●		●		●
Moldova		●	●		●
Azerbaijan	●	●	●		●
Uzbekistan		●	●		●
Georgia	●	●	●		●

The most important driver for development of clinical trials is GLP certified laboratories, that are not widely represented in EAEU region. (Table 6). MENA region and European countries have a higher local demand for innovative, original drugs, rather than EAEU and CIS countries where share of generics is higher than 80% on an average. Another important factor is the cost of labor, where Armenia benefits over two leading countries in clinical trials - Russia and Belarus. In the MENA region and the EU, the cost of labor is higher than in the CIS region.

According to the information obtained during expert interviews, the clinical trials sub-sector is among the areas with significant growth potential. According to the experts, Armenia has the potential to develop opportunities in this direction, and once the existing gaps in the **regulatory landscape are addressed and** resolved, Armenia can achieve great success.

6.2.3 Armenian clinical trials market compared with the target countries and an overview of potential markets

In Armenia, there is **little local demand** for clinical trials due to the prioritization and increasing demand for generic drugs, which accounts for 70% of the total retail pharmaceutical market. **Potentially, Armenia could absorb a part of the growing EAEU clinical trials market, which is forecasted to grow significantly due to supranational registration in the EAEU by 2025 and considering the sanctions pressure on Russia and Belarus. As a result, Armenia's share of the EAEU clinical trials market could grow substantially.** . In 2020, Russia and Belarus jointly covered 94% of the USD 250m clinical trials market in the EAEU. Kyrgyzstan and Kazakhstan, as well as non-EAEU countries from the CIS region - Azerbaijan and Uzbekistan, who do not have well developed systems to support clinical trials have conducted only 57 clinical trials, in comparison to 946 in the EAEU.

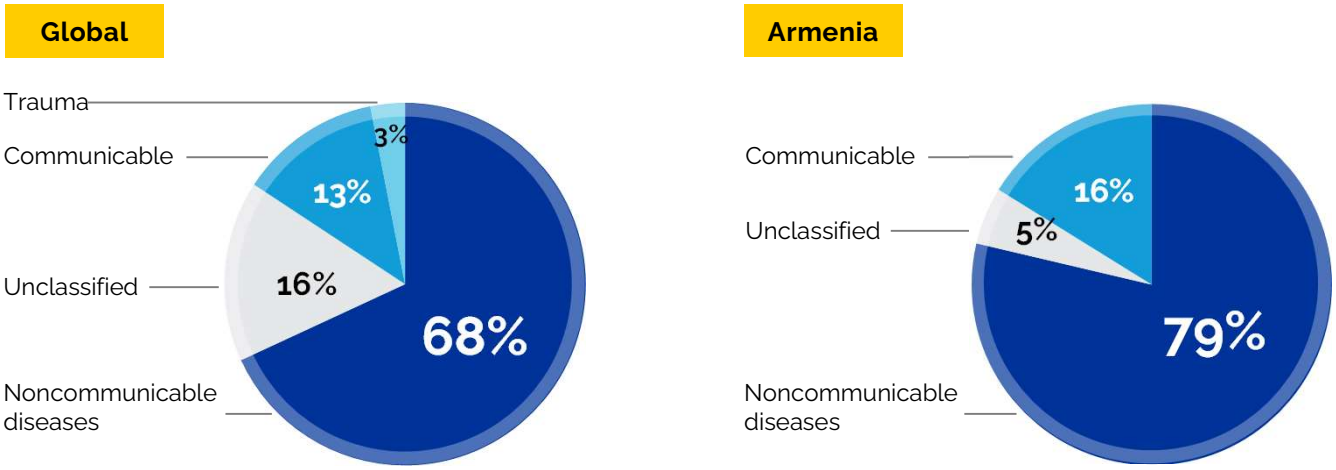
Global Clinical Trials Market:
USD 48b in 2020

Forecast:
2x by 2030

Armenia could also increase its presence in the global market thanks to its **low human capital costs**, as well as due to the prevalence of more than **90 rare diseases** and a **developed legislative base. Most of the clinical trials currently** done in Armenia are **ordered by globally based companies.** Georgia and Moldova, who increased their number of clinical trials between 2010 to 2020 by 186% and 192%, respectively, could serve as good examples. Georgia increased the number of clinical trials from 46 to 132 and Moldova from 26 to 76 by working with global clinical research organizations based out of these countries. Georgia prioritized non-communicable diseases, with gastroenterology accounting for 43% of all clinical trials while Moldova prioritized non-communicable diseases with musculoskeletal and digestive diseases accounting for more than 30%.

Armenia could expand its participation in global clinical trials and prioritize profitable areas such as respiratory, anti-infective, ophthalmology and pain/anesthesia, as well as Phase III trials.

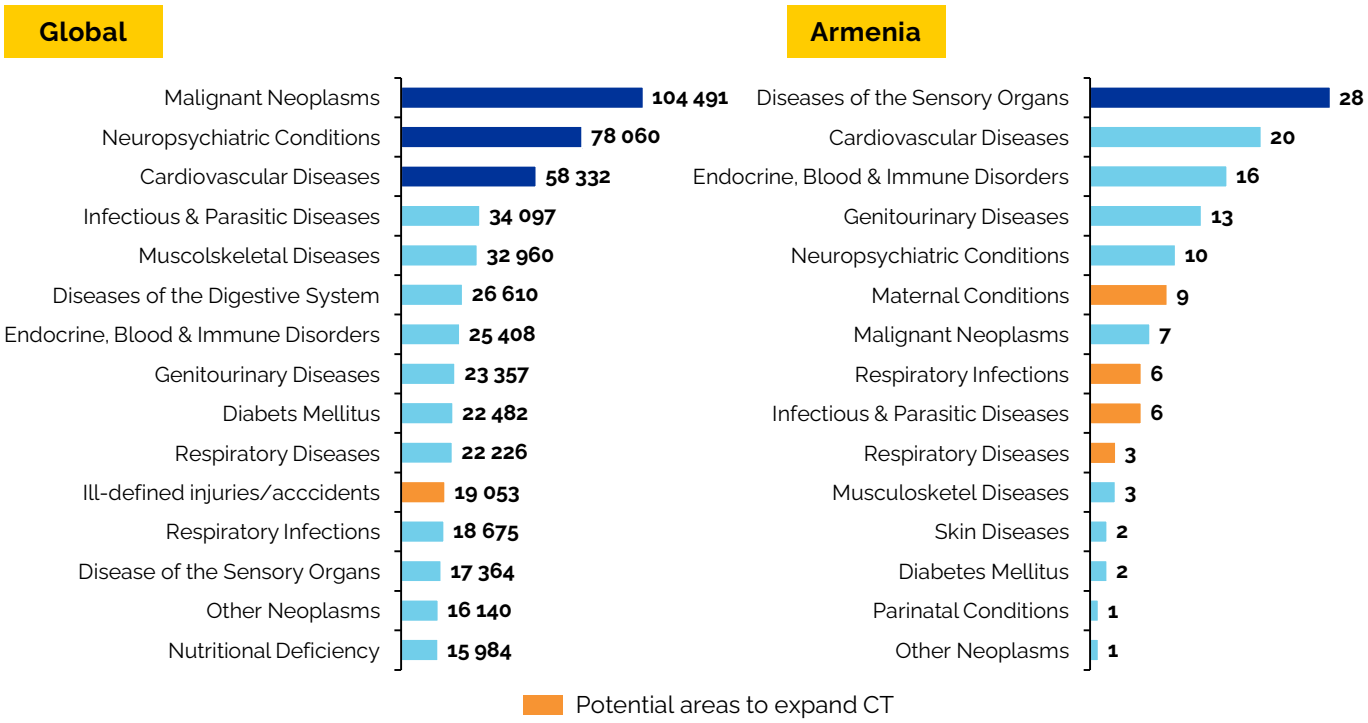
Figure 66: Clinical trials by category[153]



The **Noncommunicable diseases** category (79%) **has the biggest share** of clinical trials in Armenia (Figure 66). It is slightly higher than the average Global share of this category (68%). It is worth a note that there are **no clinical trials in the field of trauma in Armenia**, while globally it accounts for 3%.

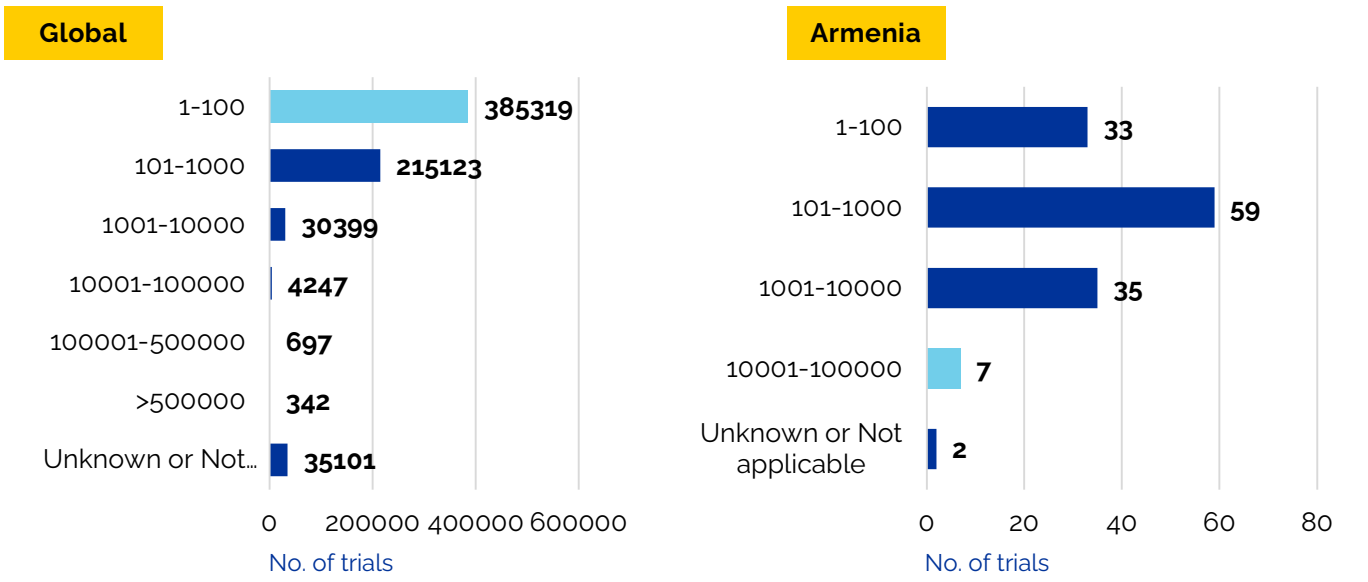
[153] WHO – Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants 2022

Figure 67: Trials by sub-category



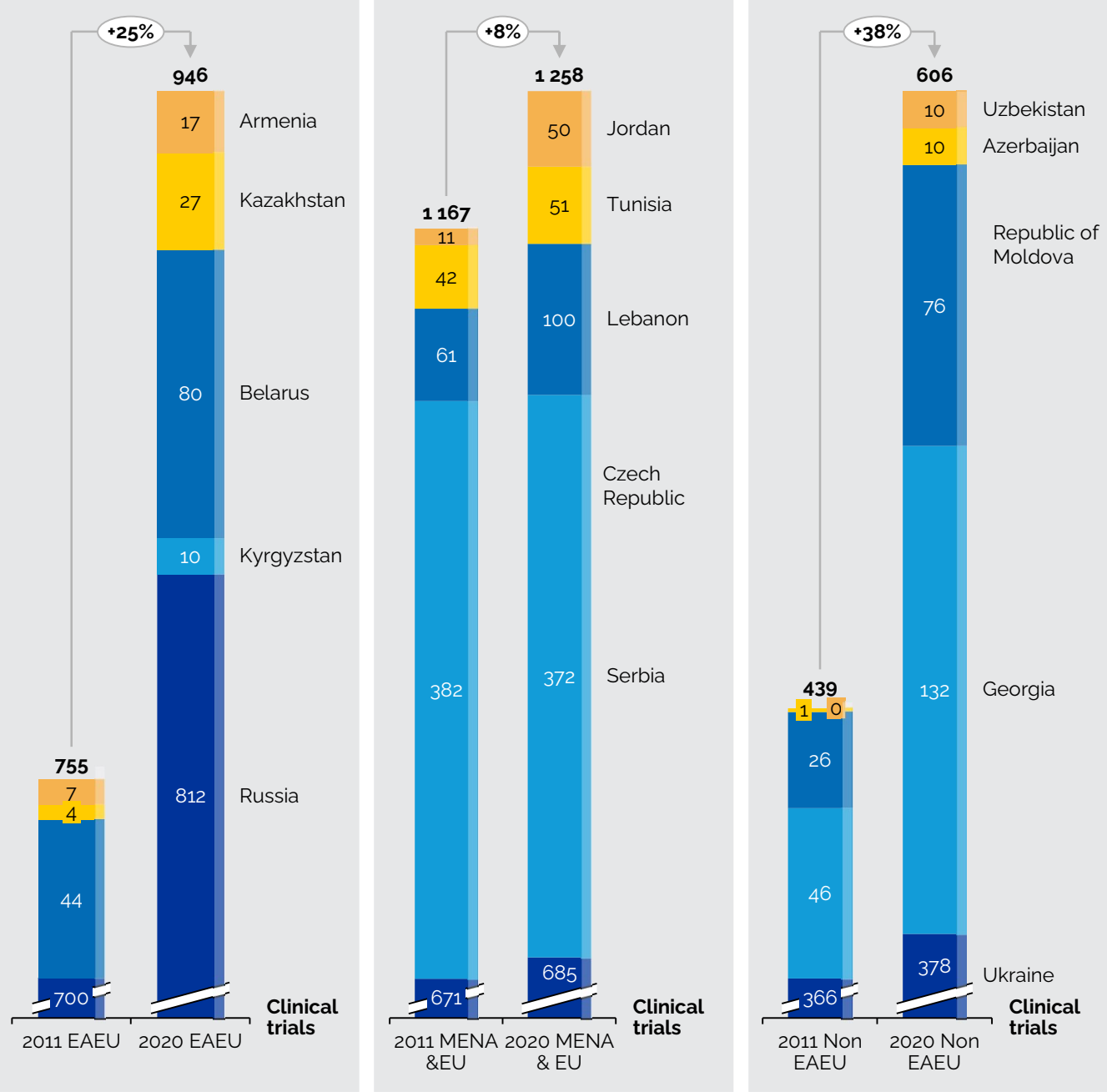
The most popular sub-category of clinical trials in Armenia are the Diseases of the Sensory Organs (28). (Figure 67) Globally the top 3 subcategories are Malignant Neoplasms, Neuropsychiatric Conditions and Cardiovascular Diseases.

Figure 68: Trials by sub-category



Most global trials are done in small and medium-sized groups of participants, so the size of the population in Armenia does not prove to be an obstacle for clinical trials, but remains an overall barrier for the number of clinical trials that could be potentially conducted in Armenia

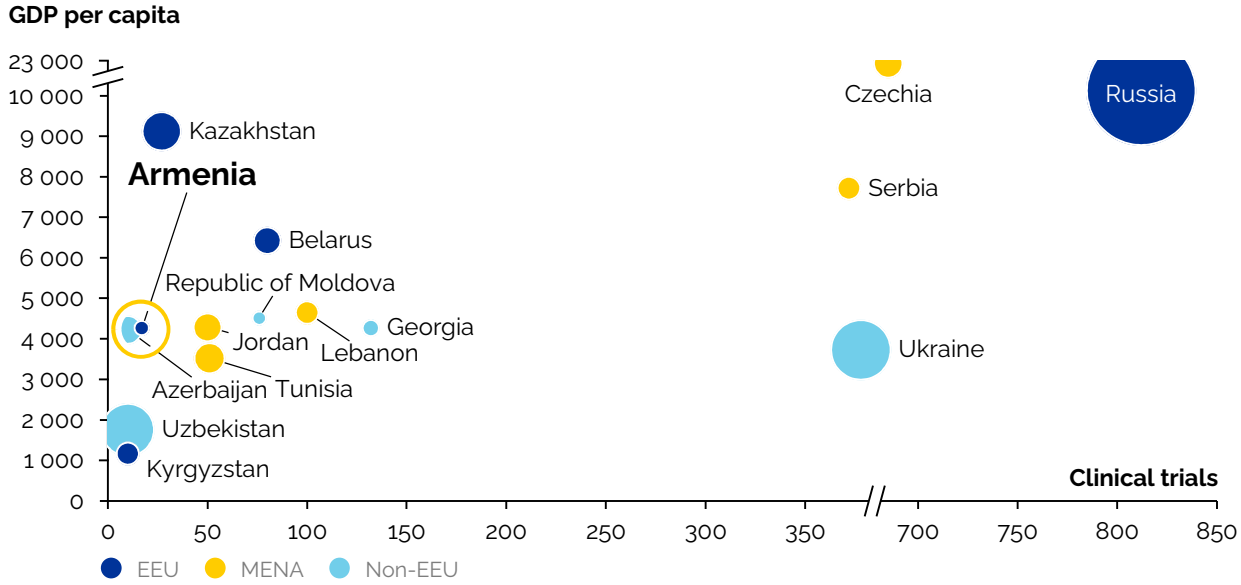
Figure 69: Clinical trials in the target countries, 2011-2020



Between **2011 -2021** the number **of clinical trials in Armenia have increased by 142%,** growing from 7 (seven) in 2011 to 17 (seventeen) in 2021 (Figure 69) this is higher than the **global average of 103% over the same period** (World Health Organization)). In the **last ten years**, Armenia conducted a **total of 117 clinical trials** representing **86% of all clinical trials done in modern Armenian history**

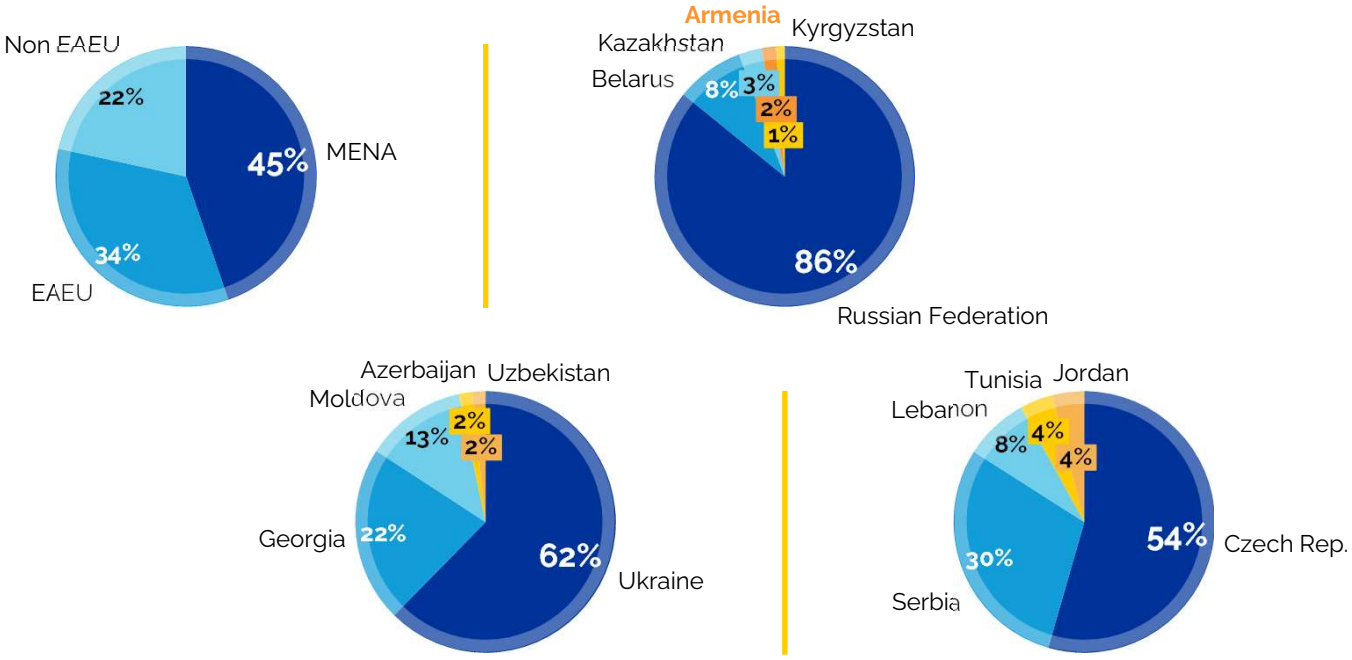
Armenia has followed the same trends as the rest of the world in terms of the **predominance of trials related to communicable and non-communicable diseases.** Although a **significant number** of trials have been conducted in the area of **malignant neoplasms** (15% of the total) and **neuropsychiatric diseases** (11%) at the global level, such studies still account for a small share, suggesting there is potential for growth.

Figure 70: GDP per capita, population and number of clinical trials in target countries[155]



We can see a higher correlation between GDP per capita with the number of clinical trials rather than with population (Figure 70). Russia has the biggest number of clinical trials among target countries. (Figure 70) Armenia's value of GDP per capita and number of trials is comparable with Azerbaijan. Despite its higher GDP per capita, Kazakhstan conducts a small number of clinical trials. European countries in 2021 performed only 19,94 clinical trials per million citizens compared to 6,8 in EAEU countries and 5,6 in Armenia156.

Figure 71: Share of total clinical trials in the target countries in 2020, %



Within the target group of countries, there is a significant increase is clinical trials number in the non-EAEU countries (Figure 71), mostly because of Georgia. In the EAEU region, where Russia has a dominant share of clinical trials market, most countries grew faster than Russia, but the number of clinical trials in those countries are still minor. MENA region and EU countries have a flatter dynamics, Jordan and Lebanon share has significantly grown.

[155] Statista

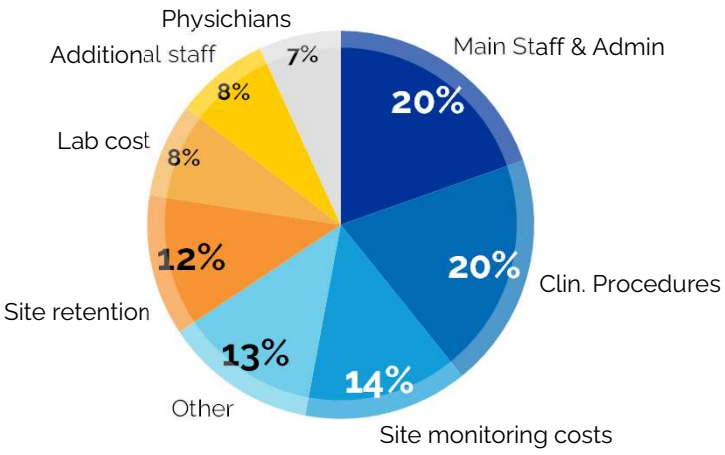
6.2.4 Clinical trials cost structure

Successful clinical development of a drug, from preclinical testing to marketing approval, requires a vast number of resources and funding. Drug development costs are on the rise, and pharmaceutical/biotechnology companies are seeking solutions for faster and cheaper development. The table below describes a typical distribution of costs based on its type and elements.

Table 7: Clinical trials cost structure

Type of cost	Elements
Per patient	• Patient recruitment costs • Patient retention costs • Registered nurse and clinical research associate costs • Physician costs • Clinical procedure costs • Central laboratory costs
Per site	• Per patient costs listed above multiplied by the number of planned patients • Site recruitment costs • Site retention costs • Administrative staff costs • Site monitoring costs
Per study	• Per site costs listed above multiplied by number of sites • Data collection, management and analysis costs • Cost of institutional review board • Cost of source data verification

Figure 72: Clinical trials costs[157]



Up to 70% of the costs of clinical trials are **workforce-related** costs (Figure 72).

[156] Number of clinical trials by year, country, WHO region and income group 2022
[157] Cost of Clinical Trials: A Breakdown by Ryan Lindeborg, Software Engineer at CRIO, 2018

Figure 73: Average cost of clinical trials by indication

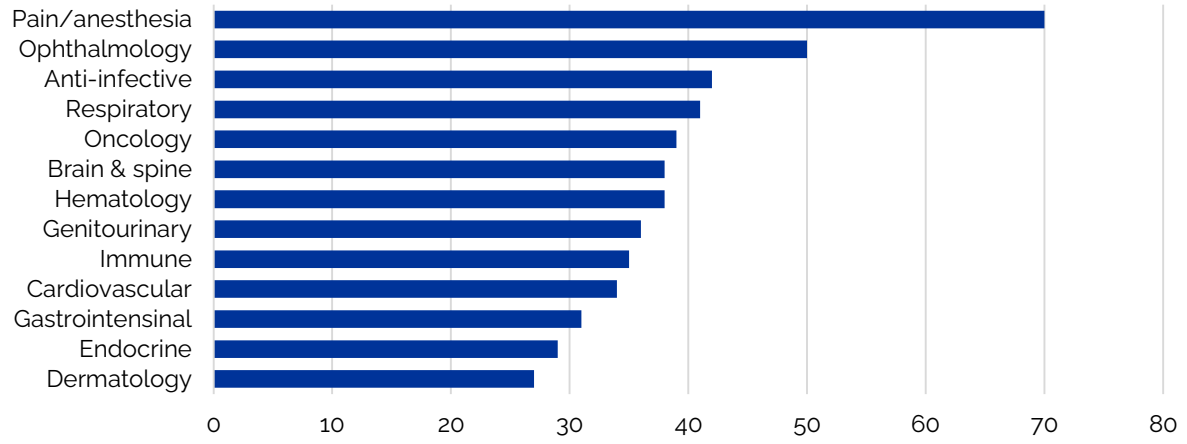
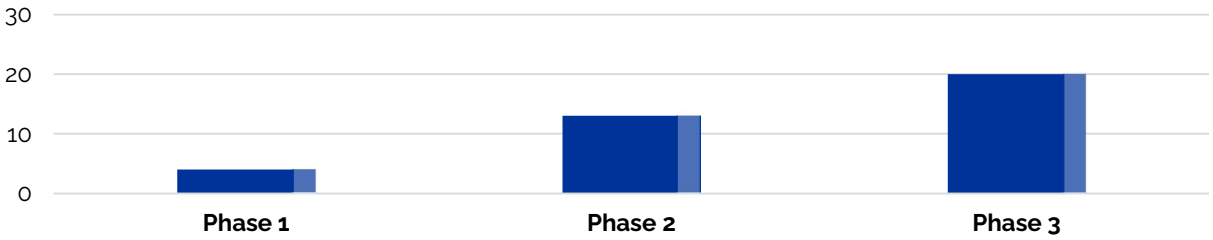


Figure 74: Average cost of clinical trials by phase



Some clinical trials **cost more than USD 40m** on an average, including specialties like **respiratory, anti-infective, ophthalmology and pain/anesthesia** (Figure 73). If we compare across phases, the least expensive phase is the first, with an average cost of USD 4m. The **most expensive is the third phase**, at more than USD 20m[158].

6.2.5 Market evaluation and potential

Global clinical trials market was **valued at USD 48b in 2020** and is **predicted to reach USD 84b by 2030**,

In 2020, the total EAEU clinical trials market was valued at USD 250m, Russia accounting for 86% (USD 210m) while Armenia's share in the clinical trials market was 2% (USD 5m). The **clinical trials market in Russia**, as the anchor country in the EAEU, is **forecasted to grow** significantly **through 2025**, due to the **Russian Government's decision to switch all medicines to supranational registration in the EAEU**. As part of this process, pharmaceutical companies will need to **re-register their drugs**, which will further **stimulate the development of clinical trials**.[160]

As a fact that the costs of clinical trials are workforce-related costs and make up to 70%, Armenia offers an important advantage, including a qualified workforce that is almost 12 times more cost effective than the global average. Armenian clinical trials market could be a good fit for the EAEU, as well as Global markets, considering the expected growth, but the biggest restraining factor is that till date none of the Armenian laboratories are GLP certified, although the three specialized universities and the available human capital could easily create a professional platform for developing the clinical trials market.

[158] How Much Does a Clinical Trials Costs, by Patricia Ledesmo, Head of Clinical Operations at Sofpromed, 2020
[159] Precedence Research - Clinical Trials Market 2021
[160] Drugs registration and patenting in Russia - 2020
[161] Glassdoor - worldwide average salary in clinical trials

6.2.6 SWOT analysis for the Armenian clinical trials sub-sector

Figure 75: SWOT analysis for Armenia clinical trials

Strenght

- Relatively cheap workforce
- Positive trends in the Armenian clinical trials market
- Accepted pre-clinical trials on animals
- Local and EAEU legislative base
- Availability of necessary qualification and universities
- 90 rare diseases in Armenia requiring additional studies

S

Weaknesses

- Non of current laboratories have passed GLP certification
- Poor awareness about pros of clinical trials
- Exodus of high-quality labor
- Unmet demand for innovative medicines
- Population Limitations

W

Opportunities

- Increasing trends in the global Clinical Trials activities
- Laboratories to get GLP certified
- Supranational registration process in EAEU market
- Better ROI
- Potential socio-economic impact

O

Threats

- Regular adjustments in the EAEU regulations
- Not achieving GLP certification
- Population decline and demographics
- Geo-political issues

T

Sub-sector summary: Generics

Low cost of generics as an alternative to branded drugs and large number of patent-expired branded drugs, initiatives by governments and other regulatory bodies across the globe are the main growth factors for generics market that is projected to reach approximately USD 575b by 2030 from USD 391b in 2020.

In the region, countries, like Ukraine and Kazakhstan have the highest share of generics with both R_X and OTC categories making up to 90% of total pharmaceutical products sales. Russian growing generics market forecasted to reach USD 15b by 2030 has an even higher potential market for export of Armenian generics. (currently 28%). Pharmaceutical market in Armenia is valued at USD 230m, of which generics account for 70% of the total. Retail market shares 75% of the total pharmaceutical market and is valued at USD 170m.

Most drugs produced domestically are those on the country's vital and essential drugs list. This highlights the relatively nascent state of the sector. While the market is and will remain heavily reliant on imported pharmaceuticals, generic medicines produced domestically cost a reported 10-30% less than imports. As a result, domestic industry growth continues to be promoted, as do exports to regional markets. Armenia has storage facilities under Good Distribution Practice (GDP) certification that are owned by local producers and distributors.

Further support from the government and cost benefits for domestic manufacturing will help develop the generics market and access other neighboring markets in the Commonwealth of Independent States (CIS) and Central Asia region providing significant export opportunities, particularly as many of these emerging markets are set to expand considerably in the coming years. An increase in the "local" production and diversification of the portfolio of generics products could not only result in increasing exports to Russia and EAEU countries but also increase the domestic consumption of such products.

6.3 Overview of generics sub-sector

Generics are pharmaceutical products that are usually intended to be interchangeable with the originator brand product, manufactured **without a license** from the original manufacturer and **marketed after the expiry of the patent** or other exclusivity rights. These medications are **inexpensive** and similar to branded drugs in strength, route of delivery, consistency, efficiency and usage. Generics are subject to administrative regulations in different nations, rather than associated with a particular company. These drugs have proven to be as safe and effective as the brand name formulation, which has already been marketed.

Global generic drugs market was worth **USD 391b in 2020** and is projected to reach approximately **USD 575b by 2030.**[166] and likely to continue growing. The global generic drug market has grown the fastest mostly in the Asia-Pacific region owing to the increased public awareness and engagement in their personal healthcare. The rise in population can also be attributed to the increase in demand for generic drugs.

Factors driving the generics market **growth** are:

- The low cost of generics as an alternative to branded drugs
- Large number of patent-expired branded drugs or about to expire
- Initiatives by governments and other regulatory bodies across the globe
- Frequent use of robotic process automation (RPA)
- Chronic illnesses
- Immunotherapies, gene and cell therapies, and antibody-drug conjugates

These factors will also contribute significantly to the expected growth of APIs over the next five years. Furthermore, when a blockbuster drug's patent expires, generic versions of the molecule emerges almost immediately, hence creating opportunities for the high demand for APIs in drug development.

[166] Generic Drugs Market (Drug Type: Simple Generics and Super Generics; By Brand: Pure generic drugs and Branded generic drugs; By Route of Drug Administration: Oral, Topical, Parental, and Others; By Therapeutic Application: Central nervous system (CNS), Cardiovascular, Dermatology, Oncology, Respiratory, and Others; By Distribution Channel: Hospitals Pharmacies, Retail Pharmacies, and Others) - Global Industry Analysis, Market Size, Share, Growth, Trends, Region Outlook, And Segment Forecasts, 2021 - 2027

6.3.1 Overview of target countries: Generics

EAEU

In most EAEU countries, low-cost drugs and self-treatment are the **only accessible affordable drugs for a large segment of the population**. Government policies that aim to initiate reimbursement over the medium term involve purchasing cheaper generics in large volume procurements. Generic medicine sales will continue to drive overall market growth. Currently, generics account for more than **80% of the EAEU pharmaceuticals market** and this figure is forecasted to grow in the coming years.

Russia[167]

Russia's generic medicine market was **worth USD 10b in 2020**, accounting **for 70.5% of the prescription drug market. In 2021**, the generics market is expected to grow **by 12.0%** in local currency terms (+10.1% in USD terms) to reach USD 11b. The generics market is expected to grow at a CAGR of 9.1% by 2025 and reach USD 15b. By 2030, it is forecasted that generic sales will expand to USD 19b.

Low-cost drugs and self-treatment are the only affordable forms of healthcare for a large segment of the population, and government policies that aim to initiate reimbursement over the medium term involve purchasing cheaper generics in large volume procurements. This will compound the challenges faced by innovative drug makers on top of concerns regarding intellectual property enforcement and regulatory approval delays. Generic medicine sales will continue to drive overall market growth.

However, **Russia's patented drug market will remain dwarfed by the size of its generic and OTC medicine markets**, as the cost of these drugs is prohibitive to consumers and as the state provides limited funding for purchases. While demand for prescription medicines will increase as access to healthcare services grows, the patented medicine segment is expected to remain in the shadow of the generic drug market.

Kazakhstan[168]

Generic drugs comprise the **vast majority of Kazakhstan's pharmaceutical demand** in volume terms. The generics market is forecast to grow by **2026** at a CAGR of **12%** in local currency terms and 13.5% in USD terms to **reach USD 1.4b**. By 2026, the sub-sector's the prescription market is expected to increase, **rising to 61.5%,** respectively. The generic drug sector is forecast to reach **USD 2.3b by 2031**, growing at CAGRs of 11.4% and 12.1% in local currency and USD terms, respectively.

Belarus[169]

Generics **dominates the market** because of the government's **continued efforts to increase domestic production** of pharmaceuticals through a biased medicine tendering process, import substitution efforts and pricing controls. Total pharmaceutical market of Belarus evaluates **USD 520 m in 2020** and was increased by 21% in value and decreased by 5% in volume. Generic drugs account for **80%** of the market.

[167] Fitch Pharmaceutical report report – Russia
[168] Fitch Pharmaceutical sector report – Kazakhstan
[169] Fitch Pharmaceutical report report – Belarus

Kyrgyzstan[170]

Growth in Kyrgyzstan's pharmaceutical market is volatile, **given much dependency on private spending to procure medicines**. In 2022, market forecasted to **grow by 18.9% in USD terms to USD 286m, from USD 241m in 2021**. The lack of affordable basic medical care in Kyrgyzstan will continue to limit drug maker opportunities. Only producers of non-branded generic and over-the-counter medicines will find a place in the market. Generic **drugs account for 82%** of the market.

The EU and MENA region

Czech Republic[171]

The Czech generic medicines market is forecast to expand at a CAGR of 6.7% in local currency terms, increasing from **USD 1.1b in 2021 to USD1.6b in 2026**. By 2031, the market will reach **USD 2.1b, growing at a CAGR of 5.5% in local currency and 7.7% in USD terms.** Given the urgent need for increased generic medicine uptake to ensure market sustainability, it is anticipated that generic drugs will take on a greater share of the total market through the forecast period and beyond. Generic medicine sales accounted **for 23.1% of total pharmaceutical sales in 2021.** This figure is expected to fall to 22.6% by 2031. Since the global economic crisis of 2008, the country has focused on cost-containment. This has affected both drug pricing and reimbursement. However, the market **share of generic medicines** in the Czech Republic is somewhat **below the EU average**, given a **lack of adherence to the country's generic substitution policy** that was introduced in 2007. While this has **resulted in larger sales of innovative medicines** in recent years, **opportunities for generic drug makers have been limited**. The growing pressure on healthcare financing which has been exacerbated by the coronavirus pandemic, will lead to an increase in market share for generic medicines.

Serbia[172]

Serbia's generic medicine market reached **USD 956.7m in 2021**, accounting for 61% of the total drug market and 66.8% of prescription drug sales in value terms. Non-patented medicine sales are expected to reach USD 1.1b in 2022, with growth at 10.5% in local currency (15.7% in USD terms) as the economy recovers. The SPC waivers, which will be in place from mid-2022, are also expected to support the sector's growth.

The generic drug market is expected to expand **to USD 1.4b in 2026**, accounting for 63.1% of the total drug market, 69.4% of the prescription market. Growth is projected to proceed at a five-year CAGR of 7.4% in local currency terms and 8.4% in USD terms. **By the end of 2031, generic sales are forecast to reach USD 1.9b.** By this point, generics will account for a similar 63.2% share of the total drug market (70.3% of prescription sales) at a CAGR of 6.6% in local currency and 7% in USD terms. Two themes will remain key to the development of the generic pharmaceutical market in Serbia: the depreciation of the dinar and the country's regulatory environment. Innovative drug makers in Serbia are continually frustrated by the regulatory process for inclusion on the reimbursement list, highlighting the market's limited potential for patented drugs. Moreover, the continued depreciation of the dinar will limit purchasing power for medicines. This will affect the patented sector more harshly. **The government's continued focus on increasing healthcare accessibility**, with cheaper generic medicines favored by the indebted healthcare system. However, the loss in spending power due to currency weakness will also temper growth within the generic segment, although to a lesser extent.

[170] Fitch Pharmaceutical sector report – Kyrgyzstan
[171] Fitch Pharmaceutical report – Czech Republic
[172] Fitch Pharmaceutical sector report – Serbia

Lebanon[173]

In 2021, sales of generic drugs in Lebanon **reached USD 356m**. In 2022, the sector is **expected to grow by 114.2%** in local currency terms **but decline by 5.3%** in USD terms, translating to a value of USD 337m. Generic drug sales are **forecast to increase to USD 402m by 2026** at a CAGR of 16.7% in local currency terms and 2.5% in USD terms). By 2031, the generics market is expected to reach USD 570m at a CAGR of 12.1% in local currency terms and 4.8% in USD terms. The generic drug segment is expected to continue to gain market share over the period, increasing to 37% of the market by 2026 and 41% by 2031.

Jordan[174]

Generic medicines will **remain an important segment** in Jordan's pharmaceutical market. Over the next 10 years, the market share of genetics **will increase at the expense of patented medicines**. Sales of generic drugs are expected to grow at a comparatively fast rate through 2031, with the **government's encouragement of generic substitution** acting as a significant **growth driver**. The Jordanian government may attempt to make more use of **local manufacturing** in order to control drug expenditures, even though competition among companies is fairly limited as prices are controlled by the government. In 2021, **generic drug sales in Jordan represented 50.8%** of overall pharmaceutical expenditures, compared with 35.6% for patented medicines. Generic drug expenditures are forecast to increase from USD 495m in 2021 to USD 419m in 2022, and further to USD 645m by 2026 at a five-year CAGR of 5.5% in both local currency and USD terms. **By 2031, expenditures on generics will increase to USD 781m**, with growth marginally increasing at a 10-year CAGR of 4.7% in local currency and USD terms. By this time, generic drug sales will account for a 60.5% share of total pharmaceutical expenditures in Jordan, with patented medicines representing a smaller yet notable 37% share.

Tunisia[175]

As is the case in other North African pharmaceutical markets, including Algeria and Morocco, Tunisia is actively encouraging the local production of generic medicines in order to reduce healthcare costs and improve the population's access to medicines. Local players such as Teriak Laboratories, the Society of Pharmaceutical Industries of Tunisia (SIPHAT) and Opalia Pharma are dominant generic drug makers in the Tunisian pharmaceutical landscape. **Generic drugs account for 66% of local medicine production**, with the remainder being licensed medications.

Non-EAEU

Ukraine[176]

Ukraine's generic medicine market reached USD 2b in 2021, accounting for 43.3% of the total drug market and for 65.5% of the total prescription drug market. **By the end of 2022, the market will reach USD 2.2b**, having grown by 9.9% in local currency terms on account of steady demand. In 2026, the generic drug market is expected to expand to USD 2.7b, accounting for 44% of the total drug market and reflecting a five-year CAGR of 7.6% in USD terms.

[173] Fitch Pharmaceutical report – Lebanon
[174] Fitch Pharmaceutical sector report – Jordan
[175] Fitch Pharmaceutical report – Tunisia
[176] Fitch Pharmaceutical report – Ukraine

Moldova[177]

Moldova's generic medicine market reached USD 221m in 2020, accounting for 59.3% of the total drug market. In 2021, the figures reached USD 234m or USD 55 per capita. **By 2025, the generic drug market will be worth USD 274m**, accounting for 60.7% of the total drug market. Between 2020 and 2025, the market is expected to grow at a CAGR) of 5.6% in local currency terms and 4.4% in USD terms. By 2030, generic sales are forecast to increase to USD 317m, accounting for 62.1% of the total drug market and expanding at a CAGR of 3.6% in USD terms.

Azerbaijan[178]

Total retail Pharmaceutical market is **valued at more than USD 510m in 2021**, growing 8,3% in value and decreasing 7,7% in volume compared to 2020. **Share of generics in the total retail market evaluates 85%.** Despite recent government incentives to boost the pharmaceutical sector in an effort to diversify away from petrochemicals, Azerbaijan's medicine production capacity is still minimal. Although government initiatives have led to an uptick in foreign investment in the generic medicine sector in recent years, a noticeable increase in domestic production is not likely in the short-to-medium term. The market will, therefore, remain almost exclusively reliant on imported pharmaceuticals. While government support for expanding local capacity is growing, any increase in production will likely be consumed locally and therefore ensure that the trade balance remains firmly in negative territory. Demand for medicines is met predominantly by Europe-based firms and will remain almost exclusively generic drug-based given the low purchasing power of the population and weak regulatory environment.

Georgia[179]

For many years, branded medicines dominated the pharmaceutical market in Georgia. However, in the last few years, there has been a trend toward increased generic medicine uptake, partially due to the free market policy of pharmaceutical regulation in the country. **Total pharmaceutical market in Georgia evaluated more than 350 m USD.** Although none of them have manufacturing facilities in the country itself, all of the big players in generic medicine production have manufacturing bases in the CIS/Central and Eastern Europe as an export hub for the region. The domestic pharmaceutical manufacturing industry comprises eight large and 13 medium-sized producers, according to the most recent Georgian National Investment Agency (GNIA) Investment Opportunities in the Pharmaceuticals Sector report. According to the report, 92**% of total domestic medicine production (USD 78m) originates from a handful of large firms**. Two main firms (Aversi-Rational and GM Pharmaceuticals) account for around 90% of local medicine production. However, neither is able to manufacture active ingredients.

Uzbekistan[180]

Sales of generic drugs reached USD 314m in 2020. Generic medicines accounted for just under half of the market (49.3%) in value terms and an overwhelming share in volume terms in 2020. Generic drugs, which account for virtually all of domestic production, dominate the pharmaceutical market due to cost and accessibility considerations. Generic drugs also dominate prescription drug sales, representing 64% of total sales in 2020. Generic drugs are forecast to grow at a CAGR of 11% in local currency terms (5.9% in USD terms) between 2020 and 2025 to USD 419m.

[177] Fitch Pharmaceutical sector report – Moldova
[178] Fitch Pharmaceutical report report – Azerbaijan
[179] Fitch Pharmaceutical report report – Georgia
[180] Fitch Pharmaceutical report report – Uzbekistan

By 2030, the generic drug sector will grow at a CAGR of 8.8% in local currency terms and 4.7% in USD terms **to USD 498m in 2030**. The generic sector is expected to remain dominant in the long term, accounting for just under 49% of the total market, despite increased spending on patented drugs.

6.3.2 Overview of generics sub-sector in Armenia

Armenia[181]

Pharmaceutical market in Armenia is valued at USD 230m, of which **generics account for 70%** of the total. **Retail market shares 75% of the total pharmaceutical market** and is valued for 170m USD, showing a 7,6% increase in value and 1,5% increase in volume. **More than 300 pharmaceutical companies** sell their products in the Armenian market, but the leading 200 companies, mostly from the EU, Russia and the US, cover more than 60% of the market. Key local producers include Arpimed, Liqvor and Pharmatech, which specialize in the production of generics and currently cover less than 4% of total Armenian retail market.

In recent years, the local market has grown at a stable CAGR of 5%, although with some variability: Liqvor grew by 15% and Pharmatech by 6%, while Arpimed retracted by 9% 2021 vs 2020.

More than 40% of local sales come from preparations of standard solutions and fluoroquinolones.

Other types of products have smaller shares and are highly diversified.

Pharmaceutical production is **almost exclusively centered on generic medicines.** The vast majority of drugs produced domestically are those on the country's vital and essential drugs list. This highlights the relatively nascent state of the sector. While the market is and will remain heavily reliant on imported pharmaceuticals**, generic medicines produced domestically cost a reported 10-30% less than imports**. As a result, domestic industry growth continues to be promoted, as do exports to regional markets**. Armenia has storage facilities under Good Distribution Practice (GDP) certification** that are owned by local producers and distributors.

According to interview results, local producers are mainly specialized in producing generics, biologically active supplements and medical supplies. Majority of the interviewed private companies producing generics were small and medium sized companies, with 50 to 150 employees on an average. The structure of all companies was composed of both professional and non-professional workers. The salary for the two groups largely differs: the salary for non-professional workers ranged between USD 238 to USD 298, while for professional workers it was around USD 595 to USD 992.

professional workers vs **non-professional workers**

USD **595 – 992**

USD **238 – 298**

[181] Fitch Pharmaceutical sector report – Armenia

Key importers into Armenia include Russia, India, Belarus and Ukraine[182]. More sophisticated products are imported from the EU and the US. The domestic market is small with limited growth potential and drug makers seek to export products to neighboring markets. The easy **access to neighboring markets** in the Commonwealth of Independent States (CIS) and Central Asia region provides **significant export opportunities**, particularly as many of these emerging markets are set to expand considerably in the coming years. Major emerging markets in the Middle East also represent opportunities for growth (Table 8).

The CIS region (primarily Moldova, Belarus, Russia, Tajikistan, Uzbekistan, Kazakhstan and Georgia**) is the largest beneficiary of pharmaceutical exports from Armenia**. In 2015, the region accounted for 57% of all pharmaceutical exports in 2015, led by Georgia (36% of exported drugs). The formation of the Eurasian Economic Union (EAEU) single medicine market in May 2017 has supported export growth within the CIS region through the reduction of trade tariffs and harmonization of medicine registration legislation.

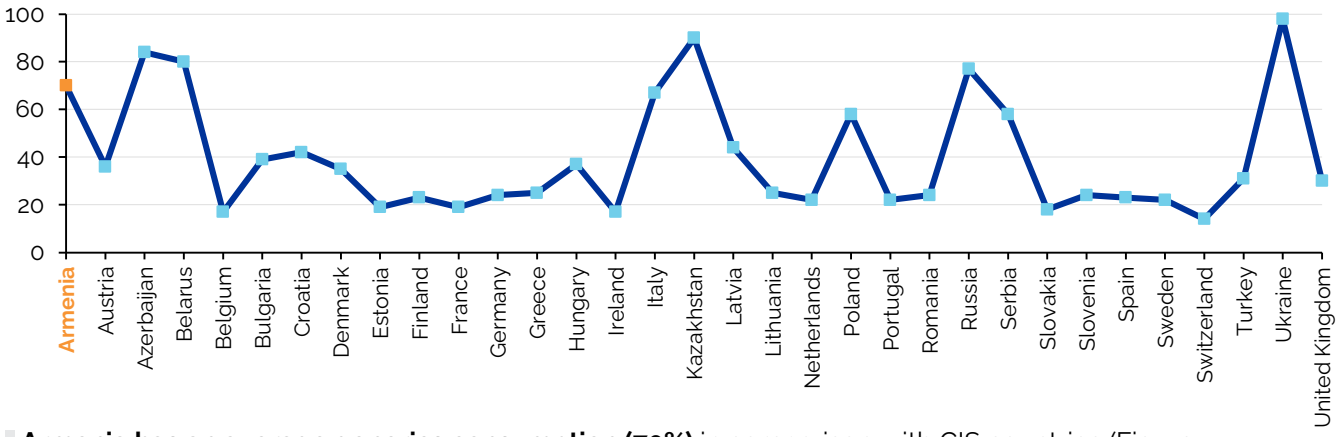
Table 8: Comparison of industry drivers between targeting countries

	Share of Generics	CMOs	Export/Local use of domestic products	Supportive legislation for domestic manufactures	GDP per capita (low)
Armenia	●		●		●
Russia	●	●		●	
Belarus	●	●		●	●
Kyrgyzstan	●		●		●
Kazakhstan	●		●	●	●
Czech Republic		●	●		
Serbia		●			
Lebanon	●	●	●	●	●
Jordan		●	●	●	●
Tunisia	●	●		●	●
Ukraine	●	●		●	●
Moldova	●	●	●		●
Azerbaijan	●			●	●
Uzbekistan	●	●			●
Georgia	●	●	●		●

In most of the target countries, including Armenia, **generics account for most of the pharmaceutical market**. Another important factor is **the presence of CMOs**, which make it possible to develop cheaper manufacturing facilities. **Export-oriented local production**, especially with a small local market, has the potential to support growth in the generics category. Supportive local legislation is extremely crucial and may help generics to increase their share of the local market**. Low GDP per capita** decreases the purchasing power of local markets and drives the consumption of cheaper medicines.

[182] UN Comtrade

Figure 76: OTC Generics share by country[183]



Armenia has an average generics consumption (70%) in comparison with CIS countries (Figure 76), where the number is frequently higher than 90%. In developed countries, this figure is typically lower at around 30% of the total pharmaceutical market.

Figure 77: Share of RX and OTC drugs[184]

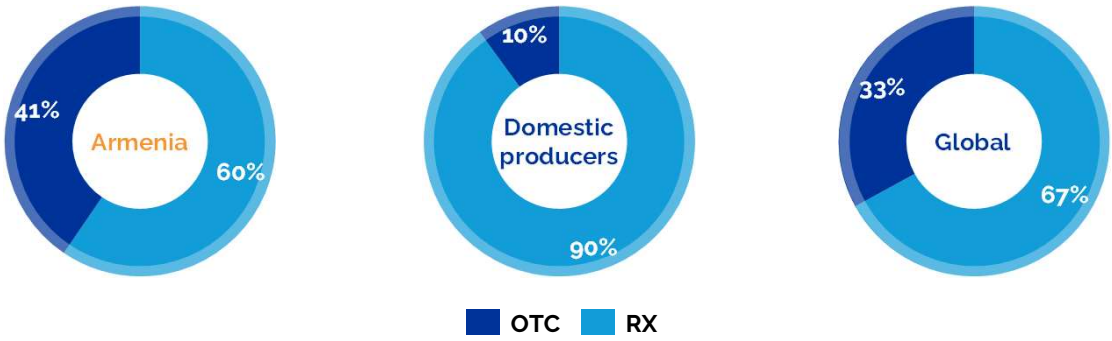
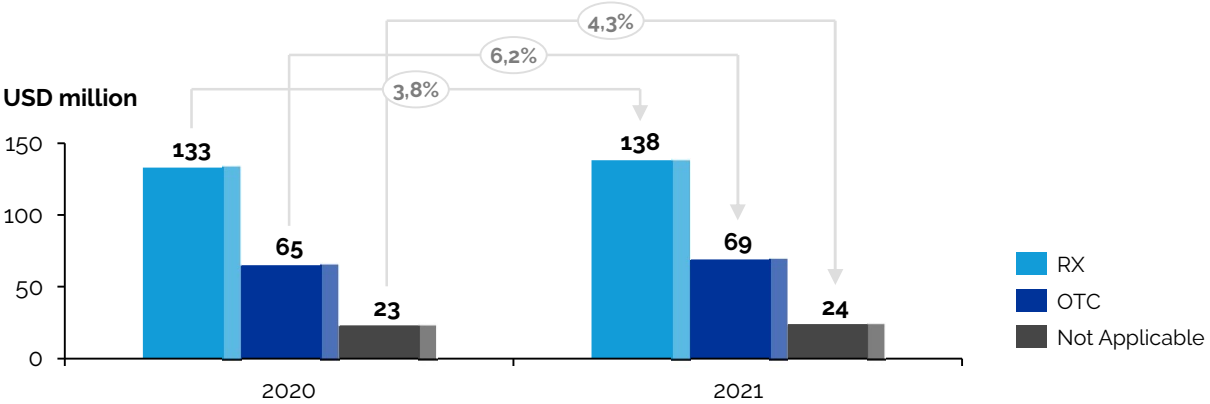


Figure 78: RX and OTC drug dynamics in Armenia, 2020/2021, USD million



Domestic consumption of OTC drugs is higher than that of prescription (RX) drugs in Armenia (Figure 77). In contrast to global trends, the main driver of growth in the Armenian pharmaceutical market is OTC drugs, which has grown faster than other categories **(7% increase in 2021)** (Figure 78). In domestic manufacturing, there is also a significant imbalance between the RX and OTC sectors**. Around 90% of all drugs produced domestically are RX.** The potential to develop the OTC sector via local manufacturing requires a deeper analysis of the OTC market.

[183] Statista - Generics share by country
[184] IQVIA - Armenia market report 2020-2021

Figure 79: Armenian OTC market analysis, 2021[185]

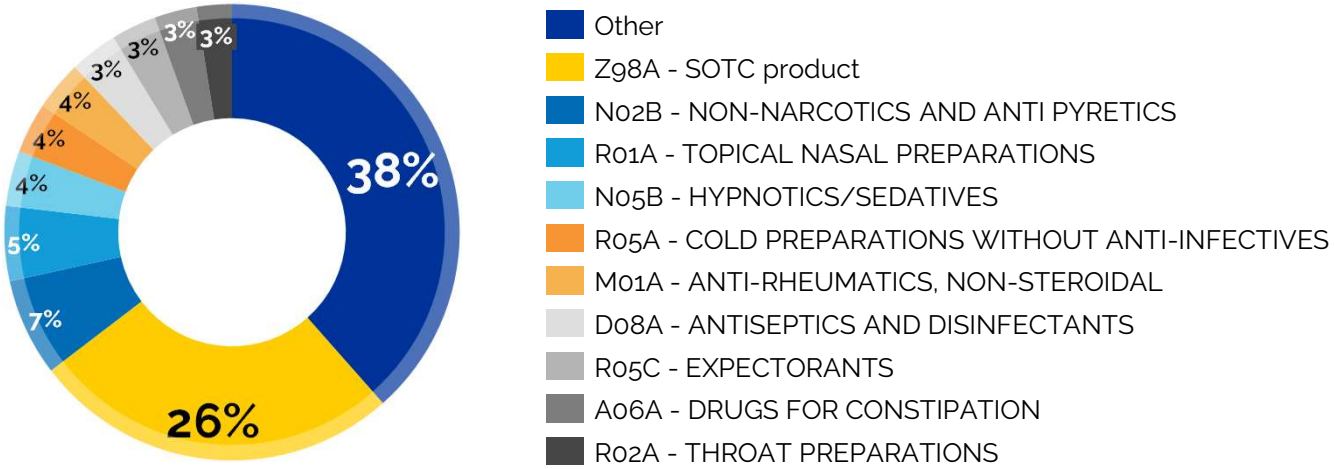
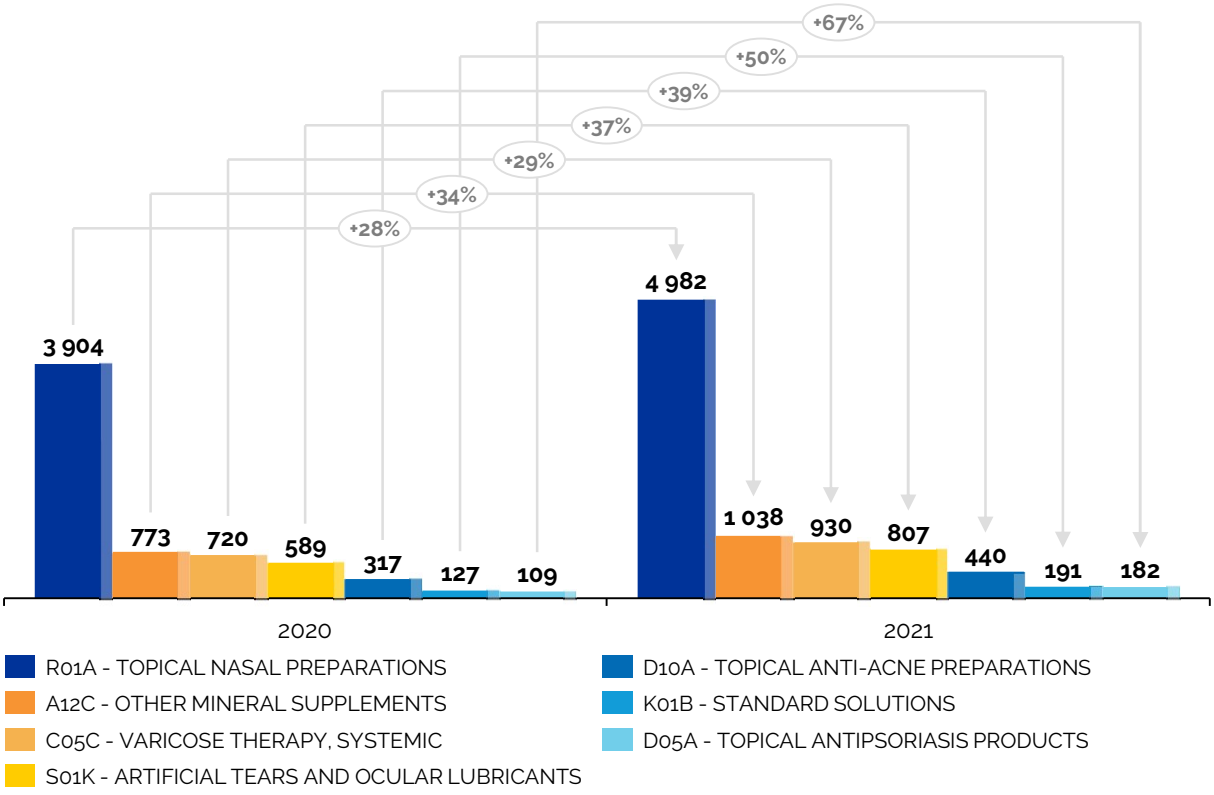


Figure 80: Key increasing product categories, OTC 2021/2020, USD thousand



A deeper analysis of the OTC market (Figure 79) demonstrates the lack of diversification among local OTC product groups. The **top 10 groups account for more than 60% of the domestic OTC market**. **The fastest growing** categories in the Armenian pharmaceutical market include **anti-psoriasis products, standard solutions and anti-acne medications** (Figure 80). Although these categories may be low value, they suggest that there is growth potential. **Topical nasal sprays, other mineral supplements and varicose therapy could be potential focus areas for local producers**, given the trends in the market and the market share held by these groups (**more than 7% of the total pharmaceutical market**).

[185] IQVIA - Armenia market report 2020-2021

6.3.3 Generics cost structure[186]

Figure 81: Generics cost structure

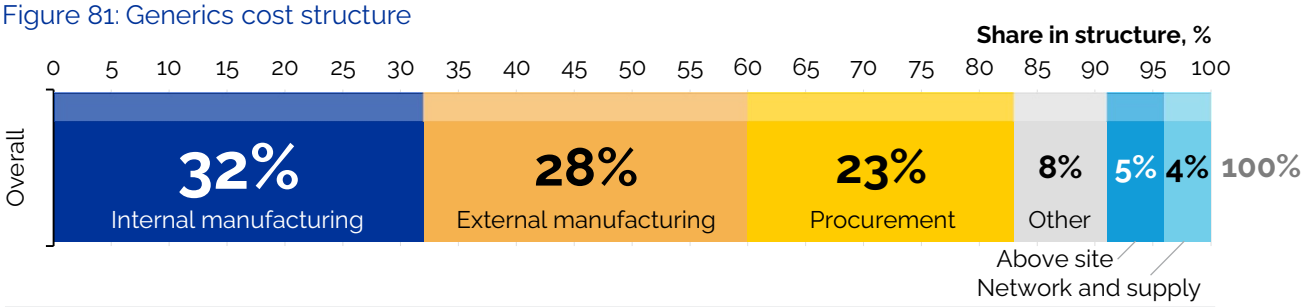
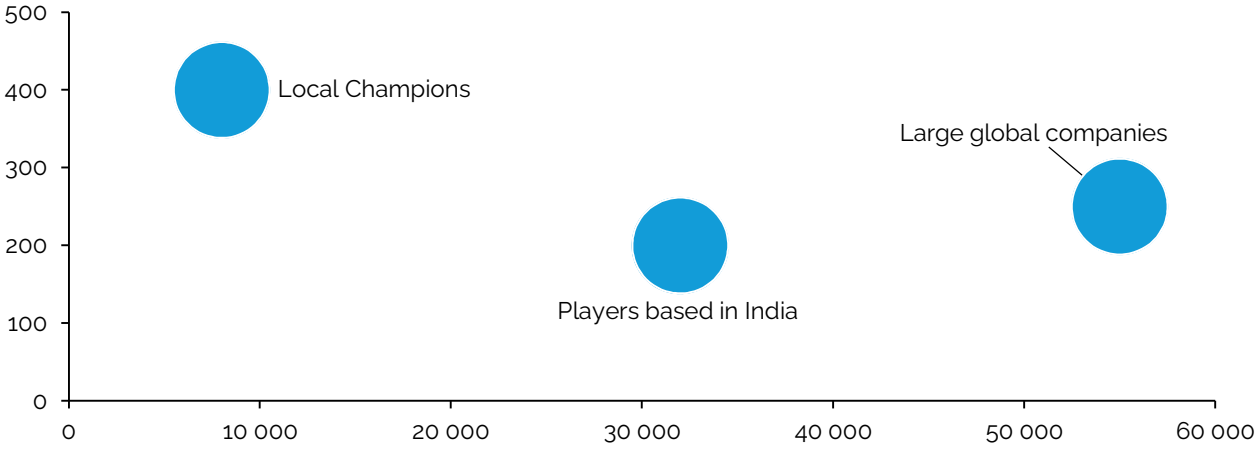


Figure 82: Location as a factor for manufacturing unit costs



Generics cost structure consists of **manufacturing costs, procurement, above site and network and supply**. (Figure 81) The manufacturing cost has the biggest share (**32% - internal and 28% - external)**. There are three types of generic production companies:

Local Champions: These companies could ramp up their manufacturing process in Armenia, with an average Cost **of Goods Sold (COGS) from 50% to 55%,** These companies should focus on increasing volume per SKU, per site and overall. This could be achieved by closely integrating commercial and technical operations. However, because of the specific needs of the different markets that these companies serve, reducing complexity will likely be more difficult.

Players based in India: These companies were selected as they are among the most cost-effective generics producers. The average **COGS of these companies is low, at only 35% to 40%.** By expanding to additional markets, they will naturally increase the diversity of their portfolios. However, low labor costs will not be sufficient to maintain their cost advantage. These firms will have to boost their operational efficiency as well

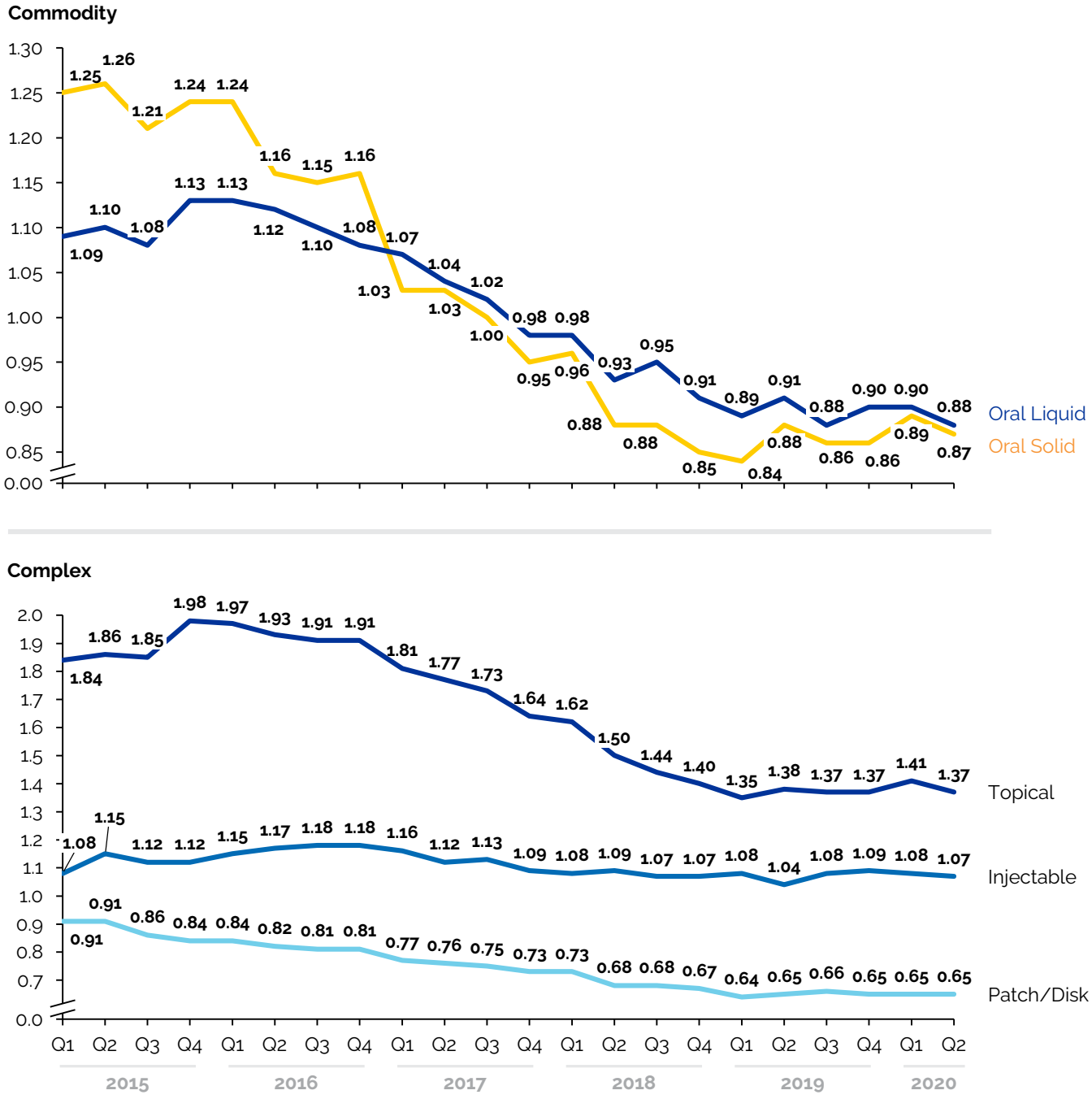
Large Global Companies: Given that the median **COGS of these firms is 45% to 50%,** they should continue to optimize their portfolios and networks in lockstep.

Most products in the OTC Armenian market are produced by Large Global Companies that do not enjoy large COGS benefits compared with local manufactures.

Large global companies have competitive advantages due to the scale effect. (Figure 82). In other words, they can produce more units with lower cost. It is **more profitable by approximately 25% than Local Champions**. (Figure 82)

[186] BCG - Getting a Grip on COGS in Generic Drugs

Figure 83: National average drug acquisition cost dynamics of generic drugs



The cost pressures that generic and biosimilar drug companies feel today are unlikely to diminish any time soon. **Production costs** for generics **have fallen by nearly 50%** (Figure 83) in the last five years, while competition has increased significantly. The key factor in the production of generics is now **volume**. Doubling the total production volume of generics **can lead to a 15% to 20% reduction in the cost per unit**. If production volumes exceed the threshold of 30b to 40b units, then unit costs start to increase.

According to respondents, approximately 60% of the cost structure of operations incurred by local generic producers were raw materials. However, getting quality raw materials is one of the biggest challenges for producers, as there are no products that they can purchase from the local market. Most of the raw materials, including bottles and other packaging materials, are being imported from other countries, such as Russia, China, EU countries.

Key recommendations to achieve success in the generics market:

1 **Toll Manufacturing**:

is less than asking CMOs to manage the entire manufacturing process. By providing raw materials or semi-finished goods to a CMO to finish production, companies can **reduce COGS by 5% to 10%.**

2 **Contract Development and Manufacturing Organization** (CDMO) Partnerships:

by using molecules that could be developed in-house, internal R&D allows companies **to reduce development costs by 10% to 20%.** For all other molecules, partnerships with contract development manufacturing organizations are a good option if the company does not possess the needed capabilities internally.

3 **Digitization of manufacturing facilities:**

industry 4.0 technologies will help **accelerate improvements** in drug manufacturing COGS as greater use of automation, robotics and predictive analytics increases asset utilization and end-to-end supply chain transparency. Although the digital capabilities of generics companies potentially lag those of innovative biopharma, selected agile innovations supported by solid economics and investments will help to reduce those gaps. Over the next decade, **generics companies will likely follow** the path of innovative biopharma brands that have embraced **flexible manufacturing and that produce new drug products in small-volume facilities** that can be easily **adapted for different products.**

6.3.4 Market evaluation and potential

In recent years, the Armenian **retail market** has grown at a **stable rate of 5%**[187]. The total Armenian pharmaceutical market in 2021 was valued at more than **USD 231m** out of which the generics **account for about 70%** of the market **(USD 162 m)**. Local producers that are specialized in producing generics, generated sales of **almost USD 9m for the local market**. Armenia could increase its **domestic consumption** of local generics, which **currently accounts for 4%** of the market (compared with 50% in Russia and 20% in Ukraine).
In the generics market, the **most attractive niche is OTC generic products,** that are almost not covered by local producers in Armenia. Currently local manufactures **export 64% of generics** that has resulted in a significant increase in recent years **(360% over the last ten years**) and **reached USD 18.3m in 2020.**
Exports could drive a second wave of development in the generics market. **The most promising market** for exporting generics **is Russia**, due to its **growth trends in generics consumption**, and now **more than 50% of total pharmaceutical exports** from Armenia are delivered **to Russia**. An increase in the "local" production and diversification of the portfolio of generics products could not only result in increasing exports to Russia and EAEU countries but also increase the domestic consumption of such products.

[187] IQVIA - Armenia market report 2020-2021

6.3.5 SWOT analysis for the Armenian generics sub-sector

Figure 84: SWOT analysis for the Armenian generics sub-sector

Strenght

- Positive trend in local pharmaceutical market
- Presence of local pharmaceutical manufacturing companies
- Local manufactures have higher volumes of export over import
- Joint EAEU market
- Domestic and Regional consumption of generics

S

Weaknesses

- Highly competitive
- Decreasing costs trend for Generics production
- Lack of government support & cost benefits for domestic manufacturers
- Low level of socio-economic impact of generics market development
- Low domestic consumption of local generics

W

Opportunities

- Increase cost benefits of local manufacturing
- Increase the governmental support for domestic generics manufacturing
- Increase level of local generics consumption in Armenia and EAEU
- Development of OTC generics category

O

Threats

- Cost competitiveness in domestic and international markets
- Sanctions burden for operations outside EAEU
- No development of innovative drugs in Armenia
- No government support for local producers

T

Sub-sector summary: R&D

R&D spending in the pharmaceutical sector totaled nearly USD 200b globally. Over the last ten years, it has increased almost two times. The advancements in science and technology are augmenting the growth of R&D operations by pharmaceutical companies globally. Although the costs have increased by 130% in the last five years, the profits on R&D projects have stalled. Effective cost management and need-based R&D will provide the basis for investments in R&D in the future. With the rise in R&D spending, the pharmaceutical sector is entering a new era of advanced medical development. Mostly driven by foreign companies, within the analyzed group of countries, Jordan has the highest level of development of R&D in pharmaceutical industry, where pharmaceutical sector is striving to become a research-based industry for this country.

Armenia's R&D capabilities in pharmaceutical industry is in its nascency. Armenia invested 0,18% (USD 22m) of its GDP in 2019 in R&D, out of which 11% (USD 2,5m) was invested in the Armenian pharmaceutical sector. Government investments in global pharmaceutical sector R&D is valued at 22% of total pharmaceutical investments, so total investments in pharmaceutical sector R&D in Armenia could be evaluated as almost USD 11m.. Armenian R&D studies could well be used for the Russian market with it`s significant budget (2,5 b USD) for R&D until 2030 and sanctions burden. With the available scientific and human capital resources, Armenia could largely enter in the R&D market by taking part in the full cycle of pharmaceutical R&D process, specializing in therapeutic categories, like oncology or anti-infectives or in the development of generics such as Jordan, Lebanon and Serbia.

6.4 Overview of R&D sub-sector

Large companies spend on a variety of R&D activities, including clinical testing, new drug development, Food and Drug Administration (FDA) approval, safety monitoring, etc. In contrast, small companies allocate most of their resources to testing new drugs that are then sold to larger firms. Market growth is expected to continue, thanks to the increasing prevalence of R&D in all industries. Certain investors are prioritizing firms that follow aggressive R&D strategies. In some cases, small businesses are bought out by larger firms in the industry for their R&D.

R&D is the first step in a new product development and is considered as a crucial engine of economic growth, encouraging innovation, inventiveness and progress. It is the backbone of industries like biotech and pharmaceuticals, as well as information and computer technology. Although a capital-intensive investment, R&D can lead to discoveries that boost earnings and improve consumer well-being.

Investing in R&D is about more than just demonstrating that your company is **forward-thinking and innovative**. In order to stay ahead of the competition and continue to meet customer expectations in today's highly competitive economy, companies must update and remodel their products. Although this requires a large capital investments, there is a direct link between R&D expenditures and profitability. Innovation, then, can help a company develop and succeed in the long run.

One of the most important advantages of R&D in business is the **tax benefits that may be achieved from participating in R&D initiatives**. Companies that invest in R&D are rewarded by the governments with a tax credit lowering their tax bills. Some companies look towards creating their R&D centers in foreign countries and use beneficial tax regimes.

Total R&D pharmaceutical market is valued at almost **17 b USD in 2021** and is expected to reach **25 b USD between 2021 and 2025.**

6.4.1 Overview of target countries: R&D

EAEU

Russia [191]

The government has been a key source of funding for research and development **ventures as part of its Pharma 2020 strategy** (recently updated to 2030), funding early-stage ventures and committing itself to financially assisting domestic pharmaceutical companies to produce biologics and innovative drugs. The government has established state enterprises such as Rusnano to fund biotech drug development abroad and within Russia. State-owned Natsimbio (part of the Rostech Group) has expanded rapidly into the production of blood-plasma medicines, vaccines and human immunodeficiency virus (HIV) and hepatitis drugs, quickly becoming a solid supplier of medicines for the state. The **budget** for the Pharma 2020 vision was reported to be **USD 3.3b**, of which **80% was allocated towards pharmaceutical R&D**. However, Russia still spends a small share of its GDP on R&D in comparison with its Organisation for Economic Co-operation and Development (OECD) peers (1.1% of GDP compared to the OECD average of 2.6%). Where the Pharma 2020 policy focused on infrastructure development for pharmaceutical production, the Pharma 2030 program is expected to outline ambitious plans to expand the Russian pharmaceutical sector's footprint on a global scale. The creation of a "high-performance export-oriented pharmaceutical sector" is amongst the priorities of the strategy in Russia.

[191] Fitch Pharmaceutical sector report – Russia

Kazakhstan [192]

The local market does not have research and development capacity to support the production of original drugs. The level of support from the government is also insufficient. Almost all investments are made from public organisations, whereas **governmental spending is only 0.3% of GDP.**

Belarus [193]

The National Academy of Sciences of Belarus (NASB) is the main government agency involved in R&D. The **authorities** have recently emphasized the need for the NASB to **encourage innovation and involve local skilled professionals in various research activities**. Biotechnology has been put forward as the next area of focus. The government is also targeting the development of domestic pharmaceutical sector capabilities to increase domestic supply and export potential.

Kyrgyzstan [194]

Due to the **nascent nature of the country's pharmaceutical capabilities**, **there is no local R&D sector.** Opportunities for technology transfer are also limited due to the lack of domestic expertise and human capital. However, as the country **begins to digitize its healthcare service,** opportunities in this area are likely to grow.

The EU and MENA region

Czech Republic[199]

The country has around 60 biotech firms, the majority located near Brno. The government is keen on investing in biotechnology to diversify the economy. It is believed that the Czech Republic's poor patent protection regime may prevent the country from emerging as a biotech hub. In October 2011, a new interdisciplinary institute, the Central European Institute of Technology (CEITEC), was launched in Brno. The institute, funded by the EU's Research and Development for Innovation program, is engaged in life sciences and materials research. CEITEC has core facilities for proteomics, genomics, tomography, structural analysis, molecular and functional imaging. The Biocev centre in Vestec, funded by the EU to the tune of USD 121.3m, is a joint venture by the Academy of Sciences and Charles University in Prague. It runs projects for the development of new drugs, advanced diagnostics, new tissues for harmed organs and the development of natural antibiotics.

In January 2014, the Czech Health Ministry prepared a holistic strategy for medical research development in the country, along with a program of financial funds for research. The Ministry stated that USD 350m will be required from the state budget between 2015 and 2022 to support applied medical research, with total spending on research amounting to USD 390m. The strategy is aimed at bringing Czech medical research in line with international standards and to improve the health of the Czech population.

[192] Fitch Pharmaceutical sector report - Kazakhstan
[193] Fitch Pharmaceutical sector report – Belarus
[194] Fitch Pharmaceutical sector report – Kyrgyzstan
[195] Fitch Pharmaceutical sector report – Lebanon
[196] Fitch Pharmaceutical sector report - Jordan

Serbia [198]

R&D in the Serbian pharmaceutical sector is mostly **concentrated between three biggest domestic players**: Galenika, Hemofarm (a subsidiary of Stada) and Zdravlje (a subsidiary of FrontierPharma). Galenika's research is undertaken within the Galenika a.d. R&D Institute, which has a total of 135 employees. The institute conducts research on **the synthesis and biosynthesis of new pharmaceutical active substances and generics**. Hemofarm owns an R&D center that employs 100 researchers. Zdravlje **mostly focuses on generic**s, and its R&D is thus mostly focused on **formulations, dosage and purity**. Other notable players in the R&D field are the Institute of Molecular Genetics and Genetic Engineering of Serbia (IMGGI) and the Torlak Institute.

The country is also aiming to become a regional nanotechnology hub and was in discussions with an Israel-based institute in late 2021 on collaboration opportunities.

Lebanon

R&D activity in the country is limited. While all drug manufacturers in Lebanon are generic medicine producers, **a few do conduct some element of research within their own labs** in an aim to enhance the efficiency and quality of generic products. However, advanced medicines produced by some local manufacturers tend to be under license from multinational drug makers. Local drug makers Arwan and Benta Pharma are the only manufacturers in Lebanon to produce biosimilar products or biological drugs that require advanced biotechnology systems.

Jordan

The **country is a good location for pharmaceutical research and development** as it has a high level **of education, particularly in the medical and engineering sectors**. The competitive wage rates in the country, educated workforce and easy access to other MENA region countries provide significant opportunities for pharmaceutical companies to set up operations in Jordan. The government is encouraging investment in R&D to transform Jordan's pharmaceutical sector into a research-based industry, enabling it to produce higher-value patented products. **Jordanian drug companies** are currently investing the majority of their money in manufacturing, with profits accounting for **around 10% of the industry's revenues**. Only about **4% of turnover is allocated to R&D**, while the multinational average is estimated at around 12-20% of annual sales. As a result, Jordan's drug market is expected to remain heavily reliant on generic drugs for the near future.

Tunisia [197]

Tunisia has yet to establish a fundamental pharmaceutical research policy and R&D spending remains limited. Although the Tunisian pharmaceutical sector has seen investments from multinational drug makers, the **bulk of this is spent on upgrading manufacturing capability and little is spent on actual research**.

Non-EAEU

Ukraine [200]

The **country has many skilled scientists**, but the pharmaceutical sector **lacks the funding required to develop the R&D industry**. The National Academy of Sciences of Ukraine does extensive research on theoretical and experimental oncology, radiation medicine, cryobiology

[197] Fitch Pharmaceutical sector report – Tunisia
[198] Fitch Pharmaceutical sector report – Serbia
[199] Fitch Pharmaceutical sector report – Czech Republic
[200] Fitch Pharmaceutical sector report - Ukraine

and cryo-medicine, molecular and cell biology, genetic engineering, microbiology and virology. Ukraine has a well-developed scientific community, a skilled labor force and an established distribution system for medical products. Research facilities, known as NII or NPP, have had some R&D success, notably in diabetes research, in recent years**. However, little has flowed to the local commercial industry and these facilities have suffered from years of underinvestment**, while researchers have been lured into the private sector in Ukraine or abroad.

Azerbaijan[201]

Azerbaijan's pharmaceutical **research and development capabilities are relatively limited**, which is illustrative of the nascent nature of the country's market and the lack of public sector funding for such initiatives. **Local companies** have expertise **in generic drug manufacturing**, but the market remains reliant on imported patented medicines.

Georgia[202]

Pharmaceutical R&D is very limited in Georgia. Medicine manufacturers predominantly focus on secondary manufacturing (mixing active pharmaceutical ingredients with other ingredients to produce a consumable medicine) as well as packaging. While there has been growth in investment in the country's pharmaceutical sector in recent years due to government initiatives, it has been entirely **focused on the generic medicine sector**. Therefore, a minimal amount of pharmaceutical R&D is conducted. Georgia has an R&D niche in bacteriophages. The Eliava Institute, which has been running since the 1920s, continues to develop these medicines **through collaborations with a number of local and international research institutions and universities.** These medicines have never gained approval in the West as a viable therapy for bacterial infections, such as typhus, salmonella, dysentery and gastroenteritis as an alternative to antibiotics.

Uzbekistan[203]

The government has stated its commitment to **pharmaceutical R&D** as part of its strategy to **boost domestic pharmaceutical manufacturing**. Key areas of interest are **cancer, HIV and diabetes**, as well as flu and cardiovascular medicines. **Research is conducted by one of 15 centers**, including some that operate under the state-backed pharmaceutical conglomerate Uzpharmsanoat. Research institutes include Tashkent Research Institute of Vaccines and Sera, Uzbek Chemical and Pharmaceutical Research Institute, Institute of Chemistry of Vegetable Substance, Institute of Bioorganic Chemistry, Institute of Chemistry and Physics of Polymers, Botanika R&D Center, Oriental Medicine Research Institute and Vaktsina NPOers. Together, they employ **around 800 staff.** The Bio-organic Chemistry Institute, the Plant Chemistry Institute of the Academy of Sciences, and the Tashkent Scientific Research Institute of Vaccines and Sera are tasked with developing full-cycle production of medicines. Tashkent Institute for Physician

Training opened a new center for molecular medicine and nanotechnology to conduct research and develop new pharmaceutical treatments and medical devices at local hospitals and primary care clinics. Omnivest, a Hungarian company that is building a vaccines plant in a joint venture with Uzpharmsanoat, has also announced plans to set up a centre for stem cell therapy and gene therapy research in Tashkent.

[201] Fitch Pharmaceutical sector report – Azerbaijan
[202] Fitch Pharmaceutical sector report – Georgia
[203] Fitch Pharmaceutical sector report - Uzbekistan

6.4.2 Overview of R&D sub-sector in Armenia

Given the nascent nature of its pharmaceutical manufacturing industry, **Armenia's R&D capabilities in this area are limited today**. The country **invests very little in R&D across all industries**.

External R&D funding in Armenia is rather modest, given the rating of countries in **the GII 2019 (82nd out of 129 countries)**. Only Azerbaijan is rated lower (100th place) in the subregion. **Gross government spending on R&D** has steadily declined since 2015 (when it stood at 0.3%), indicating a low priority science and technology policy. The **officially registered figure was approximately 0.2% of GDP in 2019**, which is similar to the level in Azerbaijan (0.2%), but well below the subregional average of 0.3%. The official figure is a lower bound as it only includes costs to the public sector.

Over the past few years, the **number of researches** in Armenia **has fallen 12%** mainly due to demographic trends and insufficient funding. According to an EU background report on the Horizon 2020 program, **natural sciences** accounted **for 54.2%** of research across all fields in 2018, followed by the humanities (including Armenology, which is growing in importance) at 14.3%. There is limited official data on investment in R&D in the commercial sector. According to a pilot survey on innovation, 34.9% of innovative enterprises were engaged in their own research and development in 2017, 33.2% purchased machines, hardware and software, and 19.6% were engaged in innovation in the market. Armenian researchers have a significant number of joint international publications, driven in part by the country's diaspora networks.

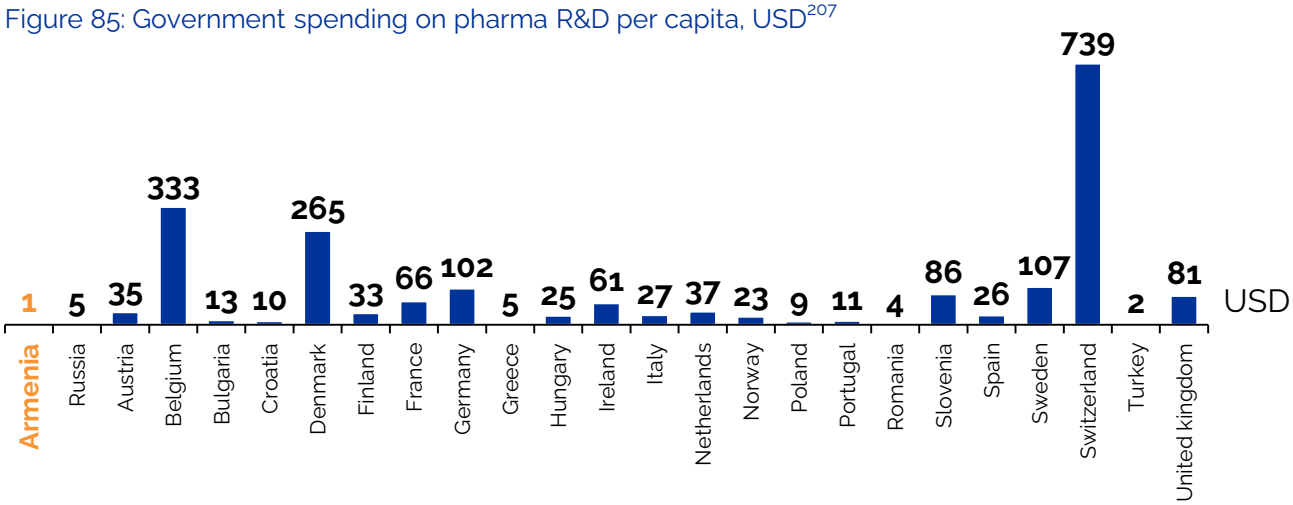
But **Armenia has some vast R&D resources and human capital in the areas of biochemistry, molecular genetics and microbiology.** The **lack of government investment is covered by the private sector**. In 2020, an R&D center was established for the continuous development of Liqvor as a scientific therapeutic manufacturer with high therapeutic efficiency, self-development and approaches. The R&D center carries laboratory studies and scientific research to improve production, introduce the latest technologies in pharmaceutical production and offer effective solutions. Azad's R&D lab currently employs 30 highly skilled engineers. Azad has consistently invested in the further development and expansion of its API portfolios. Process research on new APIs is performed under the supervision of Azad's chemists based in Switzerland and at their R&D labs in Armenia on the development of innovative chemistry and polymorphic forms of APIs that are then patent protected. In addition, using the above facility and expertise, Azad offers contract R&D to third parties interested in synthetic route development of specific APIs.

Table 9: Comparison of industry drivers between targeting countries

	Government R&D support	Qualified workforce	Data Analytics in R&D	Local demand for innovative drugs
Armenia		●		
Russia	●	●	●	
Belarus	●	●		
Kyrgyzstan				
Kazakhstan	●	●	●	
Czech Republic	●	●	●	●
Serbia	●	●		●
Lebanon		●		●
Jordan	●	●	●	●
Tunisia		●		●
Ukraine		●		
Moldova				
Azerbaijan		●		
Uzbekistan	●			
Georgia		●		

Government support in most target countries is low (Table 9), but has started to increase in recent years, mostly via the support of educational institutions in Uzbekistan, Kazakhstan, Belarus and Czech Republic. **The necessary workforce of high skilled workers are usually based at universities**. Most target countries have a **low demand for innovative drugs and consumption of generics.** Data analytics is not common in most target countries, although some countries have launched **big pharma data analytics process** and started to issue online prescriptions.

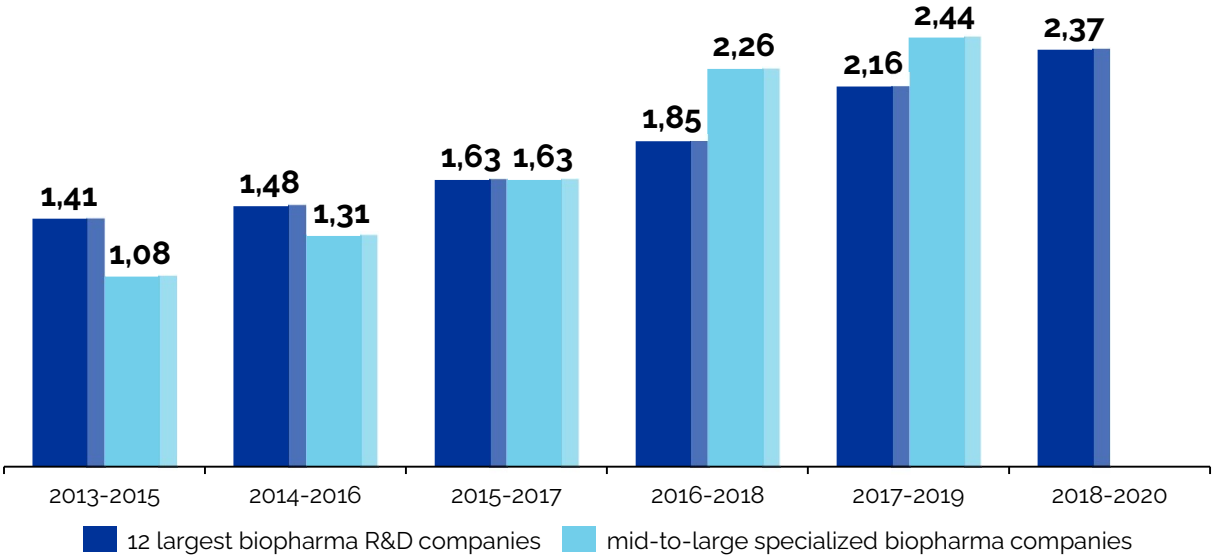
Figure 85: Government spending on pharma R&D per capita, USD[207]



Government support **of R&D in Armenia is less than USD 1 per capita**. (Figure 85) Although Turkey's per capita expenditure on R&D is comparable, its larger population results in significant investments.

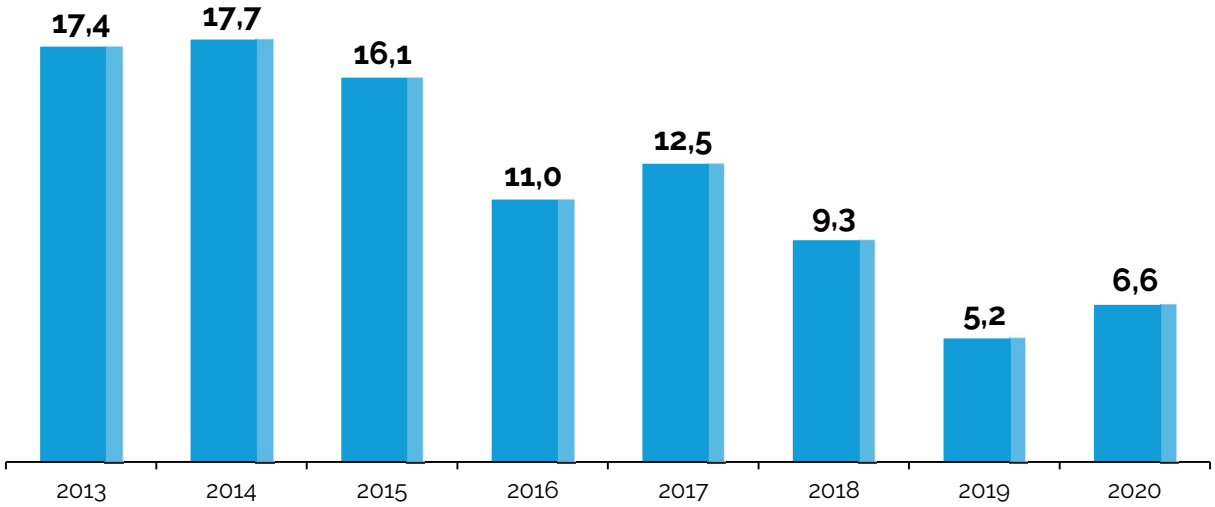
[204] Statista - R&D pharma expenditures, Armenia calculated value

Figure 86: Three-year average R&D costs to develop a pharmaceutical compound from discovery to launch, 2010 to 2020, by study cohort (USD b) [205]



R&D costs to develop a pharmaceutical compound from discovery to launch, **significantly grew from 2010 to 2020**. (Figure 86) with a **CAGR of 7,7% and a stunning 168% in last 7 years.**

Figure 87: Percentage return on investments in R&D among mid cap biopharma companies, 2013 to 2020



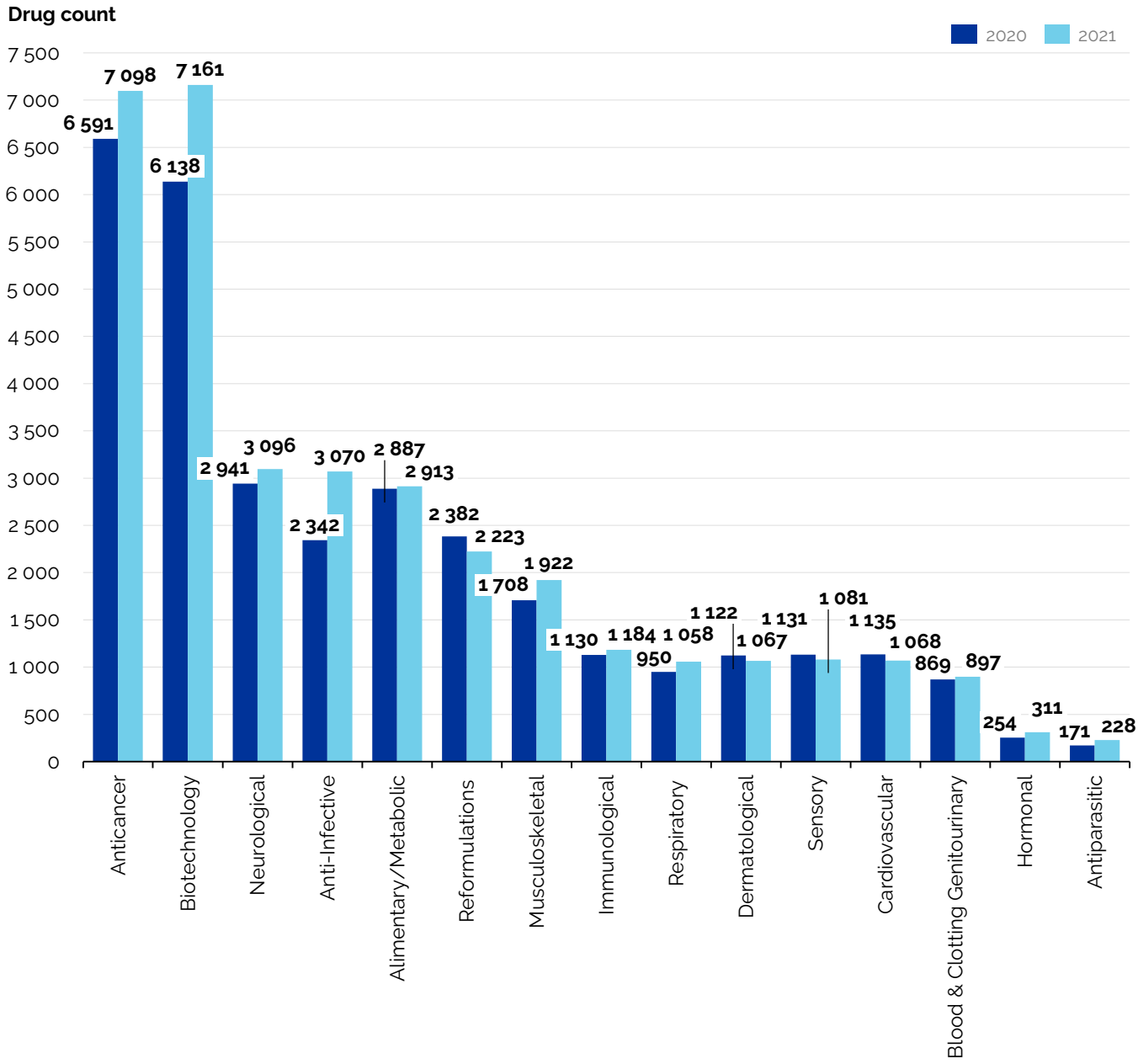
ROI in R&D decreased by 38% (from 17.4% in 2013 to 6.6% in 2020) (Figure 87). This is related to the increased competition among mid cap biopharma companies and increasing costs of R&D, that makes this market more competitive.

The biggest issue that has affected the pharmaceutical R&D market is the increasing cost, especially on extension cohorts, which have increased by 130% in the past five years.

Increasing R&D costs in pharmaceutical sector requires additional governmental support, due to the significant decrease of return on investments in research and development. Return on Investment (ROI) fell by almost three times in the last seven years, making this industry less attractive for investors.

[205] Statista - cost to develop R&D compound

Figure 88: Leading therapeutic categories worldwide by number of R&D products in 2020/2021 [206]



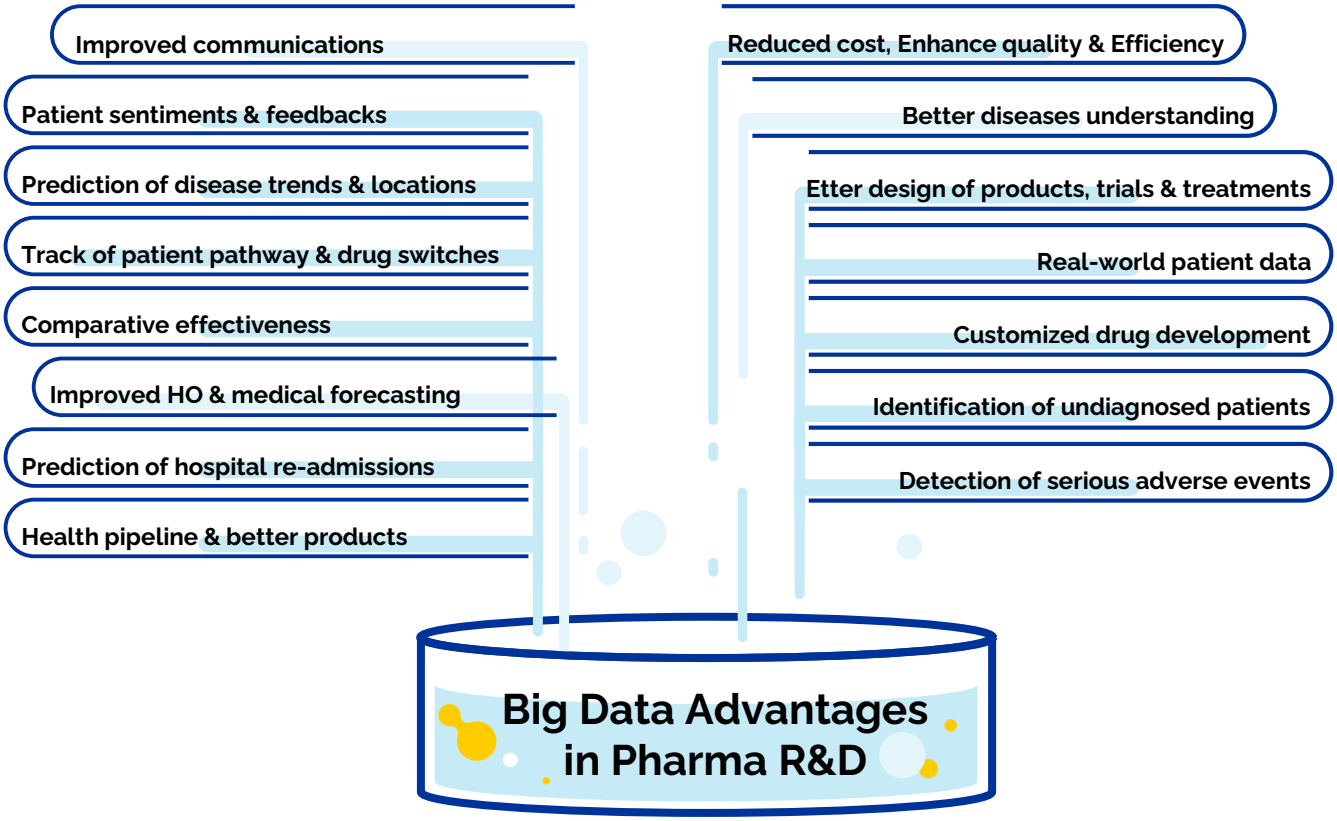
Anti-infectives account for the largest percentage increase of any group by far, up an astronomical 22.4% due to the Covid-19 pandemic (Figure 88), although biotechnology are still the leading categories. Elsewhere, though, the other therapeutic area counts were almost entirely flat. Neurologicals increased by just six drugs to 3,063, while alimentary/metabolics posted exactly the same number of candidates as last year, 2,599. These classes grew by 10.2% and 8.0%, respectively, last year. It is worth noting that drugs can be counted more than once in this graph, as many cross a number of therapeutic areas (for example, antiarthritic drugs could be considered both musculoskeletal and immunological). This is particularly true of anti-cancers, where almost half of the drugs (48.8%) also fit into the biotechnology group.

The advancements in science and technology are augmenting the growth of R&D operations by pharmaceutical companies globally. With the rise in R&D spending, the pharmaceutical sector is entering a new era of advanced medical development.

[206] Iqvia - Global trends in R&D

Big data in pharmaceutical R&D

Figure 89: Advantages of Big Data implementation in R&D [207]



Big data infrastructure enables faster data processing, which, in-turn, allows organizations to support scientific analytics and derive more focused business outcomes for next-gen research (Figure 89). Big data architecture includes a radical integrated repository, along with scalable collaborative interfaces and advanced analytics with flexible deployment options.

The big data healthcare market was valued at USD 23.7b in 2020 and is expected to reach USD 58.4b by 2026, registering a CAGR of 16.24% during the forecast period. Owing to this growth, the pharmaceutical sector is becoming more patient-centric and realizing the value of patient outcomes, improved safety and efficacy, connected research and care through better data insights.

Big data has enabled consolidation and collaboration among different internal and external healthcare stakeholders and will benefit pharmaceutical sector companies by breaking the silos that separate internal functions and enhance integrated, consistent research and care management. This will, in turn, **help the sponsors improve the quality and efficiency of research and healthcare delivery and, ultimately, of business outcomes.**

The **development of online prescriptions** is also a good opportunity for big data in pharma. Using online prescriptions and disease dynamics makes it possible to **gather data beyond the results of clinical trials, which have a limited number of patients**, and provide an opportunity to get a complete picture of how the drug will behave in real conditions.

Online prescriptions are already present in some CIS countries, such as Russia and Kazakhstan, and partially in Ukraine and Belarus, but have not been fully implemented in healthcare systems, except in Russia, where online prescriptions have the same power as paper ones.

[207] Wipro - Big data breathes life into next gen pharma r&d report

6.4. R&D cost structure

Sample cost structure for R&D firms includes distinct services, applications and solutions are divided into three operating segments: Commercial Solutions, R&D Solutions, and Integrated Engagement Services. This structure is made on the basis of companies that are engaged in R&D: IQVIA, Incyte, Biogen.

Figure 90: Sample cost structure for R&D firm in 2021, USD million [209]

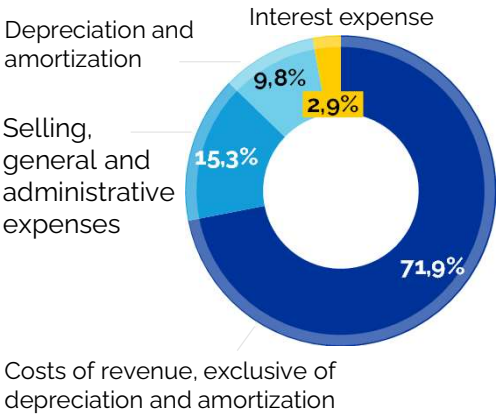
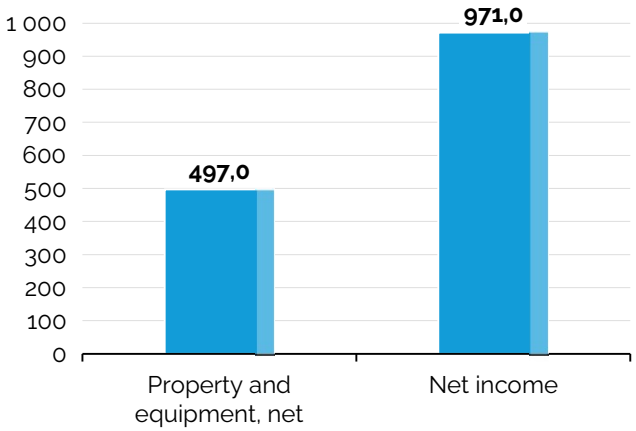


Figure 91: PPE and net income of a sample R&D company[210]



The main item in the cost structure is the cost of revenue (71.9%), which is approximately USD 9.2b (the figure includes remuneration for employees engaged in scientific research) (Figure 90).

The balance sheet of a sample R&D company includes property and equipment as fixed assets. (Figure 91) In 2021, Plant Property Equipment (PPE) was equal to USD 497m, while after tax profit was USD 971m. Thus, the cost of the selected fixed assets will be fully paid off in half a year from ongoing work. Significant differences between cost of PPE and net income are explained by the fact that R&D companies engaged in scientific research, not in manufacturing. From this point of view, human capital and technology are the main drivers at R&D companies.

6.4.4 Market evaluation and potential

Armenia invested 0,18% (USD 22m) of its GDP in 2019 in R&D, out of which 11% (USD 2,5m) was invested in the Armenian pharmaceutical sector.

Government investments in global pharmaceutical sector R&D is valued at 22% of total pharmaceutical investments, so total investments in pharmaceutical sector R&D in Armenia could be evaluated as almost USD 11m.

In 2020, R&D spending in the pharmaceutical sector totaled nearly USD 200b globally. Over the last ten years, it has increased almost two times. Although the costs have increased by 130% in the last five years, the profits on R&D projects have stalled. Effective cost management and need-based R&D will provide the basis for investments in R&D in the future.

[209] https://s24.q4cdn.com/326377938/files/doc_financials/2021/ar/IQV-2021.12.31-10K-Final-w-Exhibits.pdf
[210] Ibid

6.4.5 SWOT analysis for the Armenian R&D sub-sector

Figure 92: SWOT analysis for the Armenian R&D sub-sector

Sub-sector summary: API

The API market driven by an increase in the prevalence of cancer, cardiovascular disorders, and diabetes, as well as by ageing populations has a global market valued at 180b USD and expected to reach USD 266b by 2030. Peptide APIs are also driving the growth as they are more stable and hence allow manufacturers to produce them in larger quantities. Saud Arabia has actively invested in the development of API's over analyzed countries, where API industry is dynamically growing, domestic players having created partnerships and joint ventures with global pharmaceutical manufacturers.

Armenia currently has no API production facilities and imports 100% of APIs. We estimate that the local demand for key APIs could be covered by internal production. Local companies have invested in API development, but at foreign production plants. Within the region, only Russia and Ukraine have API production amongst post-Soviet countries. The current demand for APIs in Russia is more than USD 1.7b. Armenia occupies a special niche in the development of APIs. During the Soviet era, six R&D institutes and all R&D facilities within state universities were actively involved in the development of APIs that were used in the production of medicines.
These institutes continue to operate today, developing and patenting new APIs and driving pioneering research in various areas of cardiovascular, oncological, neuropsychiatric, infectious, and neurodegenerative diseases.

6.5 Overview of API sub-sector

API refers to active pharmaceutical ingredients that are used in finished pharmaceutical products to furnish pharmacological activity or otherwise have a direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have a direct effect in restoring, correcting or modifying physiological functions in human beings. Pharmaceutical raw materials include both APIs and inactive ingredients or excipients.

The global API market is expected to reach USD 356b by 2030 (from almost USD 180b in 2020), with a CAGR of 7.1%. [213] Market players are continuously developing new APIs to cater to the global needs of the oncology segment. North America currently dominates the market for APIs and is expected to continue to do so for a few more years.

Of all the segments, in the past few years, the pulmonology segment has grown at a record pace due to the pandemic. The oncology segment is also expected to grow significantly during the forecast period owing to the high prevalence of cancer in the last few decades and into the forecast period.

The API market has been driven by the increase in the prevalence of cancer, cardiovascular disorders, and diabetes, as well as by ageing populations. Moreover, programs, demographic change, increased R&D investments and advancements in technology and pharmaceutical manufacturing processes have all supported market growth.

Key drivers of growth in the API market:

- Continuously growing prevalence of chronic illness
- Escalating significance of generics
- Cumulative uptake of biopharmaceuticals
- Urge in sedentary lifestyles
- Ageing populations.

6.5.1 Overview of target countries: API

Russia [214]

The API market in Russia was valued at USD 3.34b in 2020 and is expected to reach USD 4.72b by 2026 at a CAGR of 5.92%. Although Russia is heavily dependent on imported APIs, the expansion of investment in healthcare infrastructure from government and non-government institutes are ensuring the supply of drugs and APIs manufactured in the domestic market. **Due to the Covid-19 pandemic, imports from India and China fell. This benefited local producers in Russia.**

The Russian government has prioritized the domestic production of drugs. The country has implemented the Current Good Manufacturing Practices (CGMP) program to align with EU and US regulations on drug manufacturing. Russia has attracted significant investments thanks to government initiatives and growth in the domestic market. Sun Pharma acquired a stake in AO Biosintez, a Russian API manufacturer. Saneca Pharma is expanding its small-batch API production in Russia. Companies such as Sanofi-Aventis and Novo Nordisk have invested in insulin facilities in Russia.

[213] Active Pharmaceutical Ingredient Market Size, Share & Growth Analysis, By Synthesis (Biotech, Synthetic), By Type (Generic API, Innovative API), By Type of Manufacturer (Captive, Merchant), By Application (Cardiology, CNS & Neurology, Nephrology, Ophthalmology, Pulmonology, Gastroenterology, Oncology, Endocrinology, Others) - Global Industry Analysis, Trends, Regional Outlook and Forecast 2021 – 2030
[214] Fitch Pharmaceutical sector report - Russia

The Government is encouraging foreign investment by creating special economic zones (SEZs) that offer additional tax benefits. The Russian Government has adopted legislation on domestic production and R&D hubs. Companies will find complementary partners within the region, as it offers local market access and geographic expansion with support from Russian Government initiatives.

One of the primary objectives set by the Government in the Pharma 2030 program is to provide the pharmaceutical sector with a sufficient range and quantity of raw and locally produced materials. The list of strategically important drugs published on 1 August this year, which included 215 drugs, among them for the treatment of Covid-19, clearly identified the need for specific local raw materials. **Russian domestic products cover 15% of total consumption in the API market.**

Ukraine[215]

Ukraine has almost no production of active pharmaceutical ingredients, **local API producers cover less than 5% of total domestic market consumption**. **About 80% of APIs are imported from China and India.** The quality of APIs is largely the responsibility of distributors. Distributors that import APIs and products "in bulk" independently take samples for laboratory analysis and quality control for compliance with regulations and are responsible for the quality of these drugs in accordance with the law. Laboratory analysis of APIs and products "in bulk" is carried out in laboratories for quality control and the safety of medicines certified by the Ministry of Health.

Brazil[216]

The API market in Brazil was valued at USD 2.8b in 2020 and is expected to reach USD 4b by 2026 at a CAGR of 6.29%. Brazil has a universal and free public healthcare system. The taxes paid by Brazilians cover all kinds of services and treatments offered by the national health system ("Sistema Unico De Saude") with no additional fees. Although disposable income has increased significantly over the past few years, the Brazilian population's purchasing power is still relatively low. Cholesterol medication and high blood pressure medicines are some of the prominent drugs that do not require a prescription.

The local API industry is dynamic and growing. Several initiatives are aimed at developing biotech API drugs. The government has attracted new investments in the pharmaceutical sector with initiatives to support the development of the healthcare industry. **The emphasis of the government is to substitute imports with local products and form partnerships between foreign and domestic companies.** Recently, several organizations have strengthened their presence in Brazil through mergers and acquisitions, expansion of operations and new product launches. Several state and municipal governments in **Brazil are promoting incentive program to support investment in the pharmaceutical sector and promote domestic manufacturing infrastructure.**

Mexico[217]

The API market in Mexico was valued at USD 1.3b in 2020 and is expected to reach USD 1.8b by 2026 at a CAGR of 5.81%. Cofepris, the regulatory authority in Mexico, has made great efforts to contribute to the growth of the pharmaceutical market. There have been policy changes for both generic and innovative medications and increased cooperation with other countries to establish regulations that improve the sector's competitiveness. **The low cost of labor and strong**

[215] Fitch Pharmaceutical sector report - Ukraine
[216] Mordor intelligence Global API market report
[217] Mordor intelligence Global API market report

domestic market have driven the growth of the API market. US sanctions on Chinese imports and growing differences between the two governments have benefitted Mexico, as many manufacturing units have shifted to the country. **Mexico offers an established supply chain integration with the US. Manufacturers enjoy low labor costs and a large pool of laborers**. **This has resulted in foreign companies investing in Mexico for R&D of various APIs.**

South Africa[218]

The API market in South Africa was valued at USD 0.8b in 2020 and is expected to reach USD 1.1b by 2026 at a CAGR of 5.8%. Major constraints identified include small local markets, the lack of skilled laborers and an export-averse culture that has prevented regional manufacturers from achieving the economies of scale essential to survive in the global market and reduce the cost of pharmaceutical products. The South African Department of Trade and Industry has improved intellectual property regulations to increase the local production of APIs, support domestic drug makers and create export opportunities for manufacturers.

The government has maintained a cost-conscious drug procurement stance for a long time, focusing on low-cost generic drugs and the API industry. Similarly, the government has introduced plans for compulsory licensing, somewhat limiting the market potential for innovators. The approval process for drugs suffers from long delays, resulting in a backlog of new products.

Local industry is strictly regulated in terms of pricing controls and price ceilings. South African drug pricing system is based on a single exit price (SEP)--the maximum price that API and drug manufacturers can sell their drugs in the domestic market. This previously hurt local drug makers due to the weakening of South African currency, subsequently increasing the cost of imported raw materials used in the manufacturing process.

Saudi Arabia[219]

The API market in Saudi Arabia was valued at USD 1.6b in 2020 and is expected to reach USD 2.3b by 2026 at a CAGR of 6.4%.A gradual shift toward low-cost generics and strong market penetration by global pharmaceutical sector players are expected to increase competition in the domestic market. This will lead to a bi-polar market dominated by branded patented drugs and ingredients on one hand and low-cost generic APIs on the other.

As a result, the barriers to market entry become more challenging. Several local companies hold significant market share and are playing an important role in the Saudi API market. Companies such as Banaja Saudi, Spimaco, Tabuk Pharmaceutical Manufacturing and Al-Jazeera **Pharmaceutical industries started as distributors for branded drugs but have gradually developed their capabilities, eventually establishing local manufacturing facilities.** In addition, several domestic players have created partnerships and joint ventures with global pharmaceutical manufacturer players supported by various government-sponsored incentive schemes aimed at promoting local manufacturing. Domestic players are mostly focused on branded generics and API manufacturing.

United Arab Emirates (UAE) [220]

The UAE's API market is growing rapidly. Population growth and lifestyle changes have been catalysts for the growing geriatric population. This, in turn, is expected to stimulate demand for healthcare services, especially geriatric care.

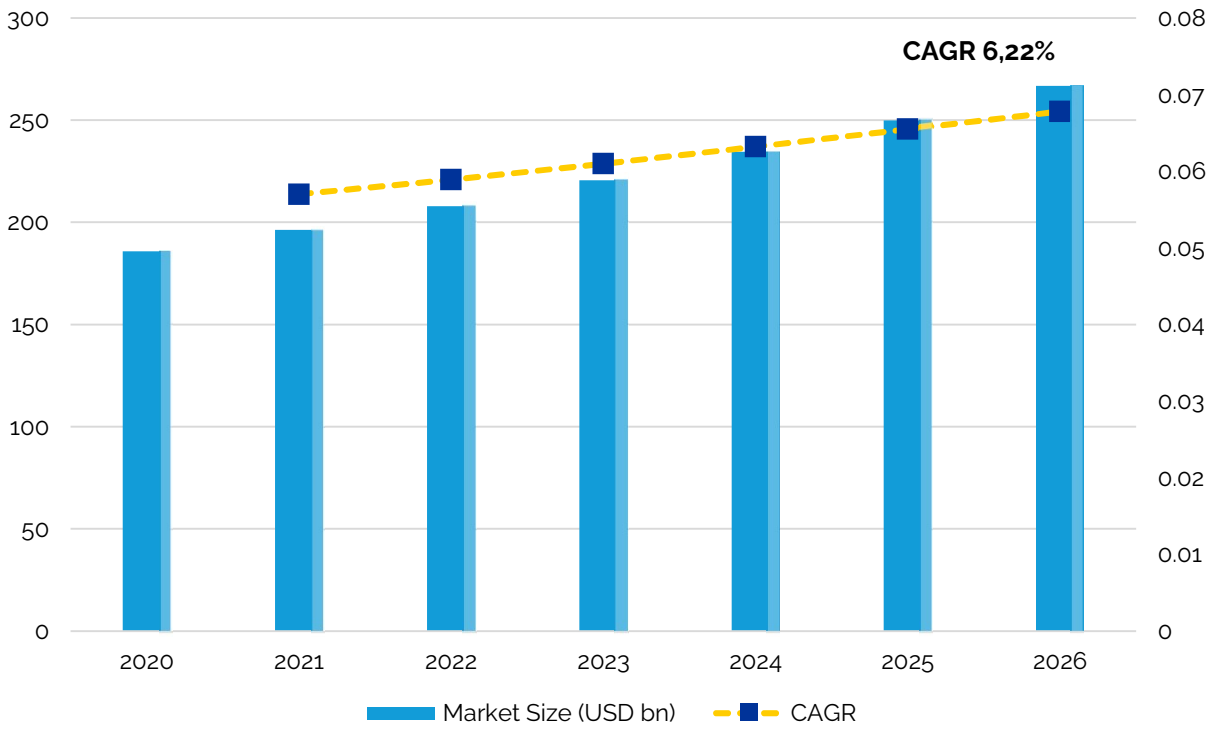
[218] Ibid
[219] Ibid
[220] Mordor intelligence Global API market report

As the healthcare and pharmaceutical markets continue to grow in the UAE, **the local drug manufacturing market is expected to strengthen its activities and boost the growth of the API market.**

The API market in UAE was valued at USD 0.9b in 2020 and is expected to reach USD 1.3b by 2026 at a CAGR of 6%. Due to changes in lifestyle habits, chronic conditions such as cardiovascular diseases, cancer and diabetes are prevalent in the region. The UAE has also emerged as a hub for medical tourism in the Middle East region due to fewer restrictions and an established medical infrastructure in the country. The growth in medical tourism has led to an expansion in local API manufacturing. The UAE government has developed a number of incentives to encourage local manufacturing and domestic API production. The UAE also has a workforce experienced in manufacturing APIs for the domestic market and the Middle East region.

6.5.2 API market trends [221]

Figure 93: Global API market 2020-2026, USD billion



The global API market is expected to grow approximately by **45% from 2020 to 2026, with the CAGR 6,22%** (Figure 93)

[221] Ibid

Figure 94: Revenue share by indicator

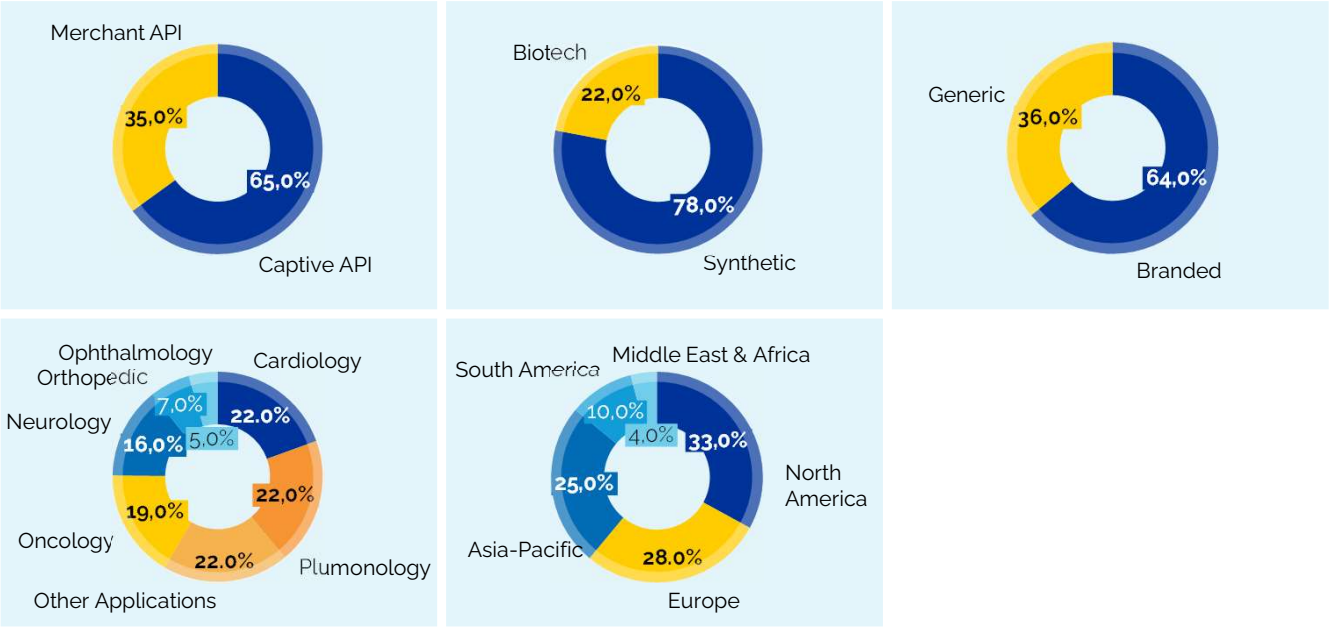
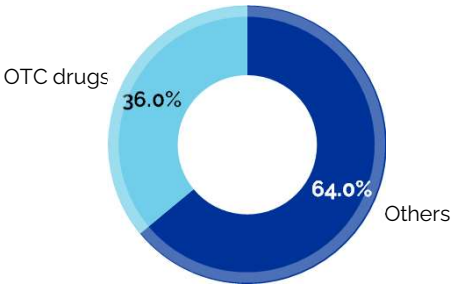


Figure 95: API for OTC drugs share, 2020 [222]



Based on manufacturer type, the captive manufacturing segment accounted for a 65% market share in 2020 and is expected to hold a 64% market share in 2026. (Figure 94) The increasing prevalence of outsourcing is a major reason behind the slowing pace of growth. The segment is expected to grow at a CAGR of 7.2% in the forecast period.

Based on synthesis type, synthetic APIs - that are also known as small molecules - accounted for a 73% market share in 2020 and is expected to hold a 72% market share in 2026. The segment is expected to register a CAGR of 5.9% in the forecast period.

Based on drug type, over-the-counter drugs is the largest segment and accounted for a 36% market share in 2020 and is expected to hold a 36% market share in 2026. (Figure 95) The segment is expected to grow at a CAGR of 5.9%. Even though the over-the-counter drugs segment accounts for a majority share, the market will decline due to stricter regulations on the sale of drugs without a prescription. Based on geography, the Asia-Pacific region is the largest region. It accounted for a 40% market share in 2020 and is expected to hold a 41% market share in 2026. The Asia-Pacific region will remain a manufacturing hub for APIs in the forecast period. It is expected to grow at a CAGR of 6.4%. Innovation and R&D capabilities of manufacturers will help them to sustain themselves in the market. Current trends such as the increase in the demand for biopharmaceuticals and naturally derived APIs are expected to boost the growth of the market.

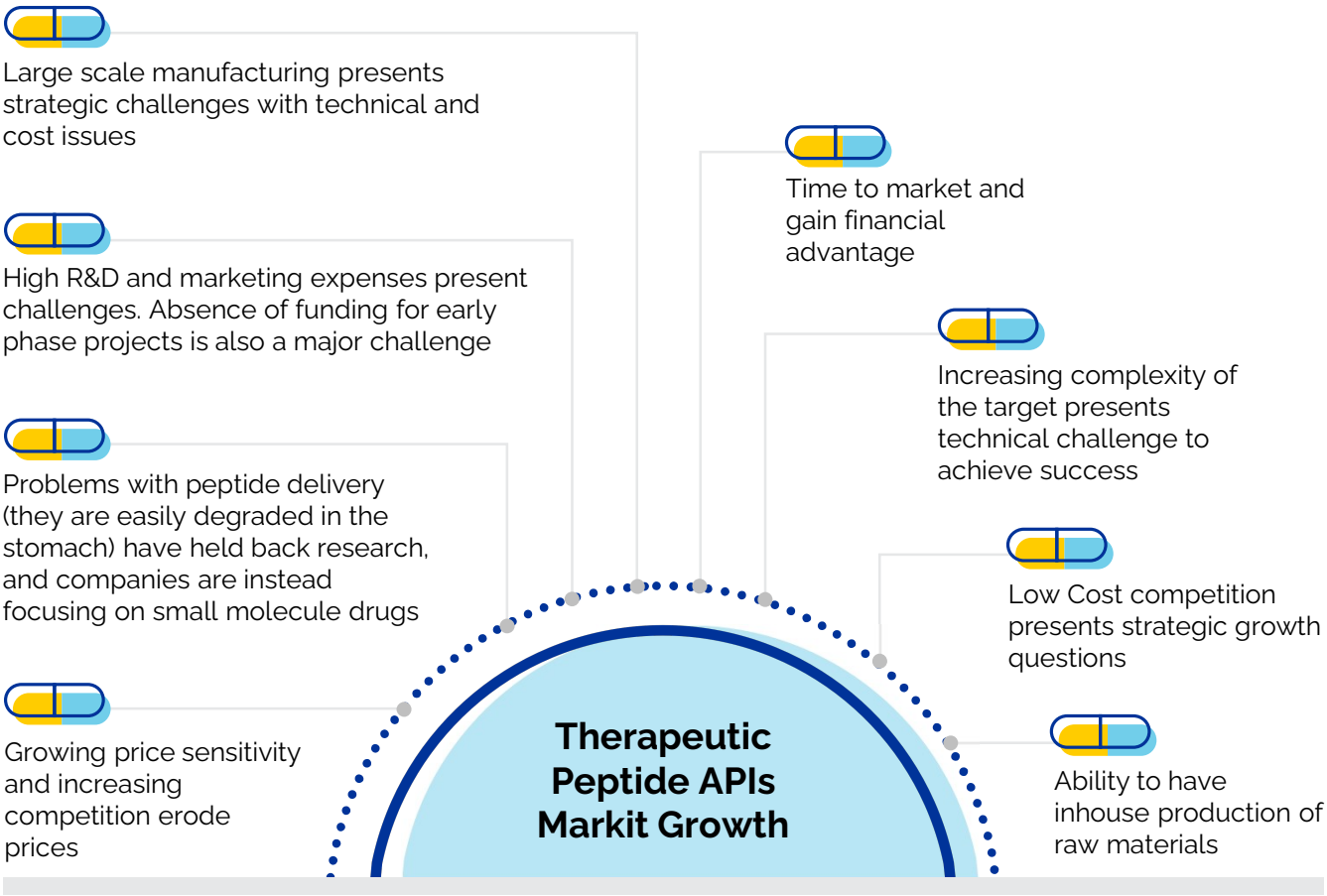
[222] Mordor intelligence Global API market report

Peptide APIs: Peptides are increasingly used as APIs. A peptide is a compound of two or more amino acids in which the carboxyl group of one is united with the amino group of another. Peptide APIs are **more stable and hence allow manufacturers to produce them in larger quantities**. With a greater supply of peptide APIs available, pharmaceutical companies can develop new and more effective drug treatments for the larger market. Some peptides can pass through cell membranes and deliver drugs that fight chronic diseases affecting the cardiovascular, respiratory, gastrointestinal and nervous systems. Peptide APIs are less toxic and do not accumulate in tissue, thus making them more effective in low doses. Peptides are short-lived. Therefore, they have to be continuously monitored.

Major **drivers** fueling the **growth** of peptide APIs market include:

- Technologies for cost-effective manufacturing;
- Advances in genomics and proteomics;
- Low toxicity and high potency;
- Modern and sophisticated formulation techniques;
- Outsourcing by pharmaceutical companies;
- Major R&D activities in early stages.

Figure 96: Therapeutic Peptide APIs market growth trends [223]



[223] Transperancy research - Peptide Therapeutics Market Trends

6.5.3 API cost structure

Sample cost structure for API firms is made based on financial statements of companies that are engaged in the sector: Solara active pharma sciences, Hovione, TEVA pharmaceuticals.

Figure 97: Sample cost structure for API firm in 2021, USD million[224]

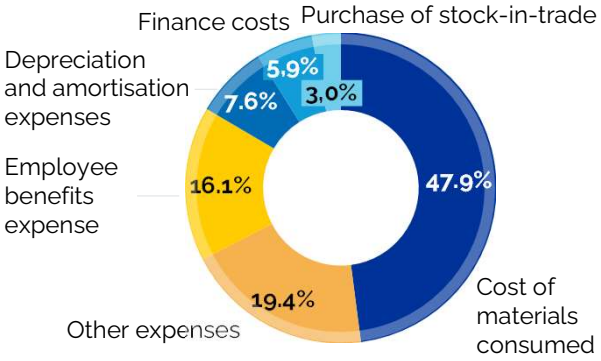
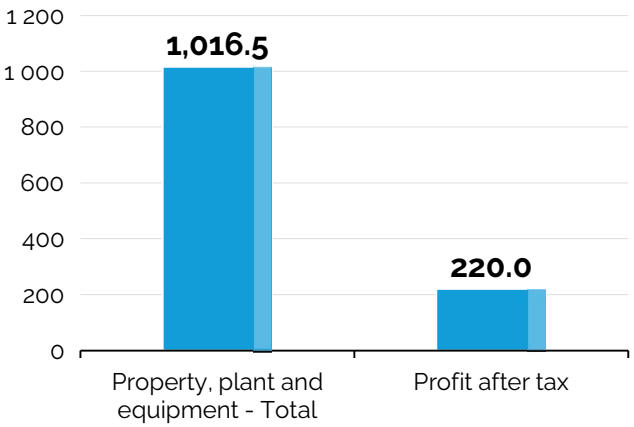


Figure 98: PPE and net income of a sample API company[225]



In 2021, compensation fees accounted for 16.1% of the cost structure (Figure 97). Less than one-fifth goes to employees. As such, the main added value resulting from the production of APIs is clearly concentrated in production technologies and raw materials, not in human capital.

In 2021, Plant Property Equipment (PPE) was equal to USD 1.02m, while profit after tax profit was USD 220,000 (Figure 98). Thus, the cost of the selected fixed assets will be fully paid off in 4.5 years from ongoing work. As a result, it can be concluded that the production of API is capital-intensive.

6.5.4 Market evaluation and potential[226]

Armenian domestic consumption of APIs can be calculated by looking at the top selling molecules. **In 2021, sodium, moxifloxacin, ciprofloxacin and dexamethasone covered 46% of the total local Armenian market in USD among domestic producers.**

While estimating the market for API consumption, we calculated each of this product's weight of active substances and the share and weight of APIs on each domestic product sold in this group. Then, we took the total weight of each API in this molecule and multiplied it by the average world market cost of this API, which resulted the following.

The total cost of sodium API consumed for local sales in 2021 was almost USD 25,000. The total cost of moxifloxacin was USD 24,000 and ciprofloxacin and dexamethasone were USD 7,500. The total cost of domestically sold local products will be evaluated as the average cost of these three APIs multiplied by the remaining market size. The total domestically consumed API market was calculated to be USD 370,000. Considering that 75% of pharmaceutical products are produced for export, total **API consumption could well be estimated as almost USD 1.5m.**

[224] https://solara.co.in/wp-content/uploads/2021/08/Annual%20Report%202020%20-%2021.pdf
[225] Ibid
[226] IQVIA Armenian retail market data

Armenia currently has no API production facilities and imports 100% of APIs. We estimate that **the local demand for key APIs** could be **covered by internal production**. Local companies have invested in API development, but at foreign production plants. Within the region, only Russia and Ukraine have API production among post-Soviet countries.

The current demand for APIs in Russia is more than USD 1.7b. Local producers cover less than 15% of domestic demand. Russia is currently suffering from a lack of APIs for local producers of medicines due to sanctions and logistics problems.

Armenia occupies a special niche in the development of APIs. During the Soviet era, six R&D institutes and all R&D facilities within state universities were actively involved in the development of APIs that were used in the production of medicines. These institutes continue to operate today, developing and patenting new APIs and driving pioneering research in various areas of cardiovascular, oncological, neuropsychiatric, infectious, and neurodegenerative diseases. At the same time, much of the infrastructure is obsolete.

The use of APIs has expanded globally peptides are cost effective to manufacture and thus have potential in developing countries due to the requirements of early-stage R&D This niche could serve as a platform for Armenia to enter global API markets..

API consumption could well be estimated as almost USD 1.5m

Armenia currently has no API production facilities and imports 100% of APIs

The local demand for key APIs covered by internal production

The current demand for APIs in Russia is more than USD 1.7b

Armenia occupies a special niche in the development of APIs

The use of APIs has expanded globally

6.5.5 SWOT analysis for the Armenian API sub-sector

Figure 99: SWOT analysis for the Armenian API sub-sector

Sub-sector summary: CRO/CMO

The CRO/CMO market has been driven by the growing need for state-of-the-art processes and production technologies. The global CRO/CMO market is valued at USD 160b in 2020, and expected to reach USD 237b by 2026 at a CAGR of 6.5%

Eastern Europe is turning out to be a CMO destination, attributing to superior intellectual property rights (IPR) laws, unlike the Asia-Pacific region, which lacks proper IPR protection. Pharmaceutical suppliers are also taking advantage of the many benefits that central European countries offer. Czech Republic, Slovakia, Hungary, Poland, Romania, Bulgaria, and the three Balkan states of Croatia, Serbia and Slovenia are leading the surge in European pharmaceutical contract manufacturing and active pharmaceutical ingredient (API sourcing). In the CIS region, CRO and CMO sectors are limited to 100 CRO companies located in capital cities and enjoy the benefits of low-cost and highly qualified workers

Armenia currently has no CMO production facilities but has successful experience in CRO development. Development of CRO/CMO in Armenia will provide possibilities of using technologies of multinational companies on its territory and provide services for foreign companies. CMOs have been consolidating as a means of improving profitability in the competitive market. Through consolidation, large CMOs can expand their geographical presence and penetrate niche markets. Small CMOs, meanwhile, can use the technical expertise and resources of larger CMOs and Armenia could do the same, using technologies of multinational companies on its territory. Business models followed by CROs are putting affordable highly qualified workforce that are present in Armenia as a considerable advantage in the current market scenario.

6.6 Overview of CRO/CMO sub-sector

CROs are popular because they offer a more cost-effective solution for firms seeking to produce new medicines for large and niche markets alike. **By outsourcing research to CROs, the costs of conducting a trial are reduced massively**, as the firm will not need the infrastructure, space or manpower to run trials or conduct research themselves. Before CROs became an established method of pursuing approval for a drug, many companies would only take action when there was a sense of guaranteed approval for large markets. **This has made research into new medicines a much more feasible and affordable** prospect for the average firm, reducing their general overhead costs.

CMOs also serve other firms within the pharmaceutical sector on a contractual basis. Instead of providing research services, **CMOs offer comprehensive drug development and manufacturing services.** Again, this assists the client company with scalability and allows them to focus on more important areas of their business, such as research or marketing. Alternatively, pharmaceutical firms may outsource drug manufacturing work to a CMO if they lack the expertise or facilities required to produce the quantity and/or form of a drug that is needed to perform pre-clinical and clinical trials. The demand for services that CMOs offer has resulted in fast growth for the CMO industry over the last decade, and this will continue as the need for CMOs increases.

F**or both clinical and commercial manufacturing, many pharmaceutical companies view CMOs as a source of profitability**, as it is more cost-effective to outsource to CMOs. The growing need for state-of-the-art methods and production techniques that have proven highly effective in meeting regulatory requirements is the most important factor driving the expansion of CMOs in the pharmaceutical sector. Owing to the growing number of pharmaceutical companies, the CRO market has the potential to grow. Paying attention to these companies' needs and meeting them in time could be lucrative for CDMOs.

Global CDMO market
USD 160b in 2020

Forecast:
USD 237b by 2026

- CMOs and CROs are consolidating as a means of enhancing profitability in the competitive market. Through consolidation, the large CMOs could expand their geographical presence and penetrate multiple markets.
- The most significant factor boosting the growth of the sub-sector in the pharmaceutical sector is the growing need for robust processes and production technologies that have proven highly effective in meeting regulatory requirements.
- There is also a tendency among pharmaceutical companies to outsource idea generation, and early discovery work, such as basic research, target identification, validation, and hit discovery, to third-party organisations.

[228] Mordor Intelligence - Global Pharmaceutical Contract Development and Manufacturing Organisation (CDMO) Market (2021-2026)

6.6.1 Overview of target countries: CRO/CMO

Russia [229]

Most CROs in Russia are involved in clinical trials. While multinational pharmaceutical firms will continue to favour developed Western markets for early stage (Phase 0 or Phase I) trials, they are increasingly looking to emerging markets for high-volume later stage trials, primarily due to lower costs. According to the Chief Executive Officer (CEO) of Synergy, a **CRO, lower investigator salaries and local CRO rates provide savings of up to 78% in direct costs compared to the US or EU**. In addition, while there are a large number of issues with Russia's healthcare system, in terms of restricted access to services in more rural areas, the presence of many large regional or city hospitals allows short enrolment periods, as many patients can be enrolled in the same trial at the same hospital.

More than 20 CRO companies are present in Russia, including X7 Research, Synteract, Syneos Health, SanaClis, PPD, OCT Clinical, MB Quest, Labcorp Drug Development, IQVIA, IPHARMA LLC, ACROSS Global and others. Most are located in western part of the country.

The Russian Government **has supported CMOs by introducing tender limitations for pharmaceutical products** – Third product is out rule, it is forecasted that it could be even strengthened to the rule Second one is out that may be launched in the nearest future. These tender limitations do not apply to EAEU countries. **Due to these rules, pharmaceutical companies need to produce products in cooperation with local companies or create new local plants..** The regulations have affected contract manufacturing and contract packaging organizations importing to or producing drugs in Russia. Some companies, however, including Takeda, Abbott, Pfizer and others, have already cut most of their investments in local production due to sanctions. Russia has the potential to develop CMOs and CROs, as it can offer lower costs than Western countries.

Kazakhstan [230]

Domestic pharmaceutical manufacturing, while relatively basic, is expanding rapidly thanks to imports and efforts to supply the hi-tech and innovative end of the market. However, significant quantities of basic medicines are still imported from other CIS countries, India and China, though these volumes have fallen in recent years. Foreign direct investment in the domestic medicines industry, on the other hand, is growing. In July 2018, two major European drug makers, Servier and Roche, committed to making investments in Kazakhstan.

Servier® signed an agreement on the transfer of pharmaceutical production technology and the coordination of an investment strategy for the localization of medicines.

In addition to these commitments, **a tender favoring domestically produced medicines was launched in July 2018**. The state-owned pharmaceutical procurement and distribution firm that provides medicines for the state's provision of free medical care, SK-Pharmacy, announced that this new tender will provide drug makers with a guaranteed market for their products for 10 years. The tender was related to SK-Pharmacy's complete list of free medicines, which included 398 compounds and 2,838 products.

According to the tender, drug makers must establish a production facility or modernize an existing facility in line with international standards within two years. This development will lead to further investments in the country's domestic pharmaceutical sector.

[229] Fitch Pharmaceutical sector report – Russia
[230] Fitch Pharmaceutical sector report – Kazakhstan

Brazil [231]

As the primary recipient of foreign direct investment in Latin America, Brazil has emerged as a global manufacturing hub for pharmaceutical contract companies. In 2019, **Brazil held the largest market share (24.9% in the pharmaceutical contract manufacturing market in Latin America.** Due to its comparative advantages, **such as low manufacturing costs and the presence of numerous Good Manufacturing Practice GMP-certified plants, the pharmaceutical companies are interested in entering the Brazilian market, thereby widening the scope of the contract manufacturing industry in the country**. Due to lower investments in R&D within the pharmaceutical sector, Brazil is expected to have significant scope for contract service providers over the forecast period.

Mexico [232]

Mexico is the second-largest market for pharmaceutical contract manufacturing in Latin America. Contract manufacturing has opened up a huge opportunity for Mexican companies and is rife with benefits. **Indian pharmaceutical companies are leading the way in the development of generic drugs in Mexico and are heavily investing in the country.** This has supported the steady growth of pharmaceutical contract manufacturing in Mexico and suggests that the ROI will be promising.

South Africa [233]

South Africa is the largest CMO market in Africa. Some of the major factors responsible for South Africa's attractive pharmaceutical contract manufacturing are its well-established and stable markets and high investment turnover. The tax structures and duties in South Africa, however, pose challenges to foreign companies that want to enter the market. On the other hand, increasing governmental support and initiatives taken to support innovation in drug development are expected to bolster the opportunities available in the country.

The main driver of the rapid growth of the South African pharmaceutical sector has been the availability of cost-effective and skilled labor, high-quality infrastructure and the introduction of the South African Health Products Regulatory Authority (SAHPRA). Most local drug manufacturers and distributors are controlled by international pharmaceutical firms. Growth within the region is also attributed to the expansion of public-private partnerships in the region to increase the accessibility of advanced healthcare facilities.

Nigeria [234]

Nigeria is one of the most promising and rapidly growing pharmaceutical manufacturing regions in West Africa, **with more than 150 pharmaceutical formulation-manufacturing facilities.** The Nigerian pharmaceutical contract manufacturing industry has been witnessing healthy growth. The major drivers of the growth in pharmaceutical contract manufacturing are the low costs, increasing demand of biological production, favorable government regulations and patent expirations.

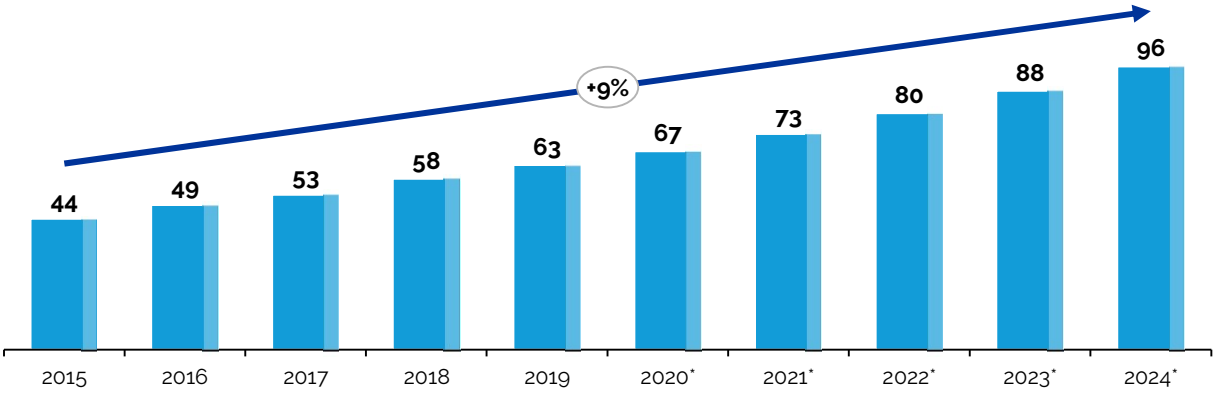
Contract manufacturing has emerged as the best option to avoid uncertainty **and pitfalls associated with the manufacturing of pharmaceutical products in Nigeria. Growing regional trade and investments, as Nigerian companies expand their footprint into Africa**, are augmenting the growth potential of the Nigerian CMO industry.

[231] Mordor intelligence - Global CDMO market overview
[232] Ibid
[233] Mordor intelligence - Global CDMO market overview
[234] Ibid

Eastern Europe is turning out to be a CMO destination, **attributing to superior intellectual property rights (IPR) laws, unlike the Asia-Pacific region, which lacks proper IPR protection**. Pharmaceutical suppliers are also taking advantage of the many benefits that central European countries offer. **Czech Republic, Slovakia, Hungary, Poland, Romania, Bulgaria, and the three Balkan states of Croatia, Serbia and Slovenia are leading the surge in European pharmaceutical contract manufacturing and active pharmaceutical ingredient (API sourcing).** These countries are developing a specialized area of operations and a mature product and service portfolio. **In the CIS region, CRO and CMO sectors are limited. 100 CRO companies are located in capital cities and enjoy the benefits of low-cost and highly qualified workers**.

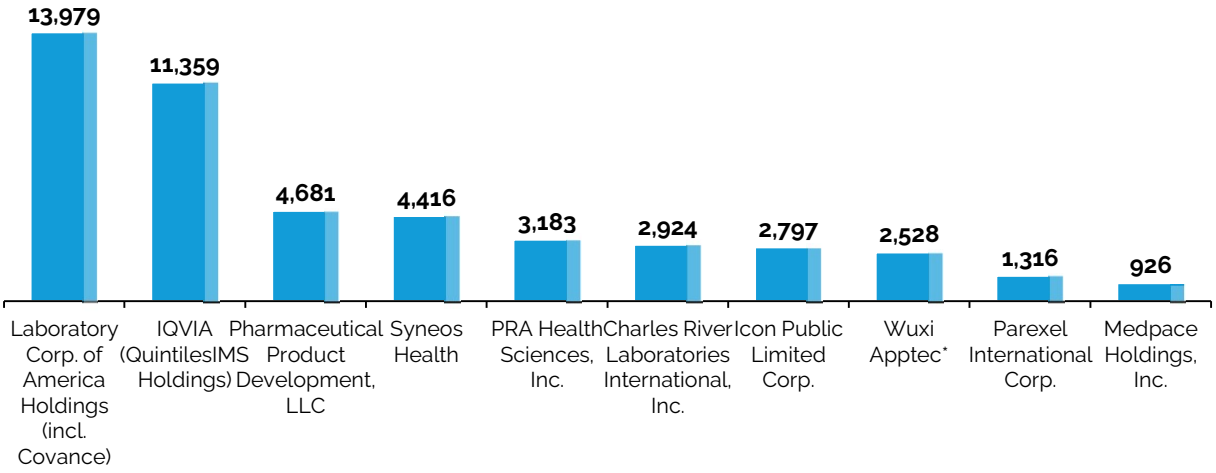
Market trends: CRO

Figure 100: Total global CRO market, 2015-2024 (USD b) [235]



The global CRO market was valued at USD 44.3b in 2015 and is projected to reach USD 96b in 2024. **CAGR is expected to be steady at 9% through 2024**. (Figure 100)

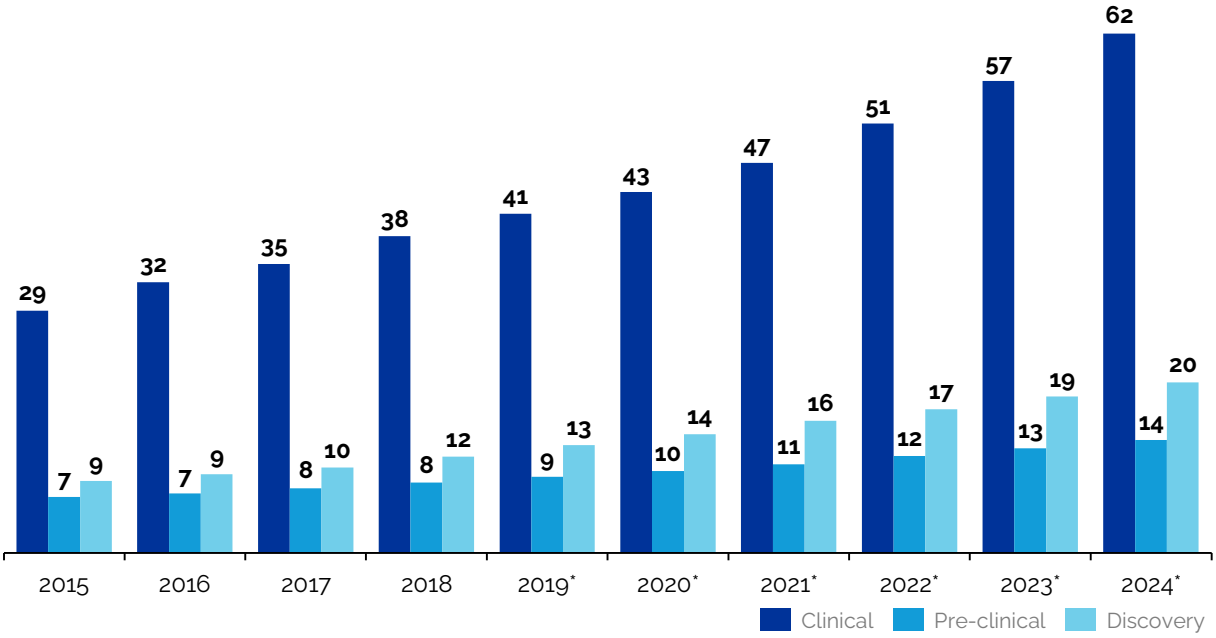
Figure 101: Leading global contract research organisations based on revenue 2020 (USD million) [236]



The two largest companies in the CRO market by revenue are Laboratory Corporation of America Holdings and IQVIA (Quintiles IMS Holdings) (Figure 101). In 2020, **IQVIA generated USD 11.4b in revenue, while Laboratory Corp. of America Holdings generated USD 14b**. The third largest company in the market, Pharmaceutical Product Development, LLC, had revenues of USD 4.7b in 2020.

[235] Statista- CRO market dynamics
[236] Statista

Figure 102: Global pharma CRO market, 2015-2024, by pre-clinical, clinical and discovery (USD b)[237]



The **clinical sector is the largest sector in the global CRO market**. (Figure 102) In 2015, the sector was valued at USD 29b By 2024, it is projected to reach USD 62.4b. From 2015 to 2024, growth is expected to average 114%. **The preclinical sector will reach USD 14b by 2024 at 101% growth**, while the discovery sector will reach USD 20b at 137% growth over the same period.

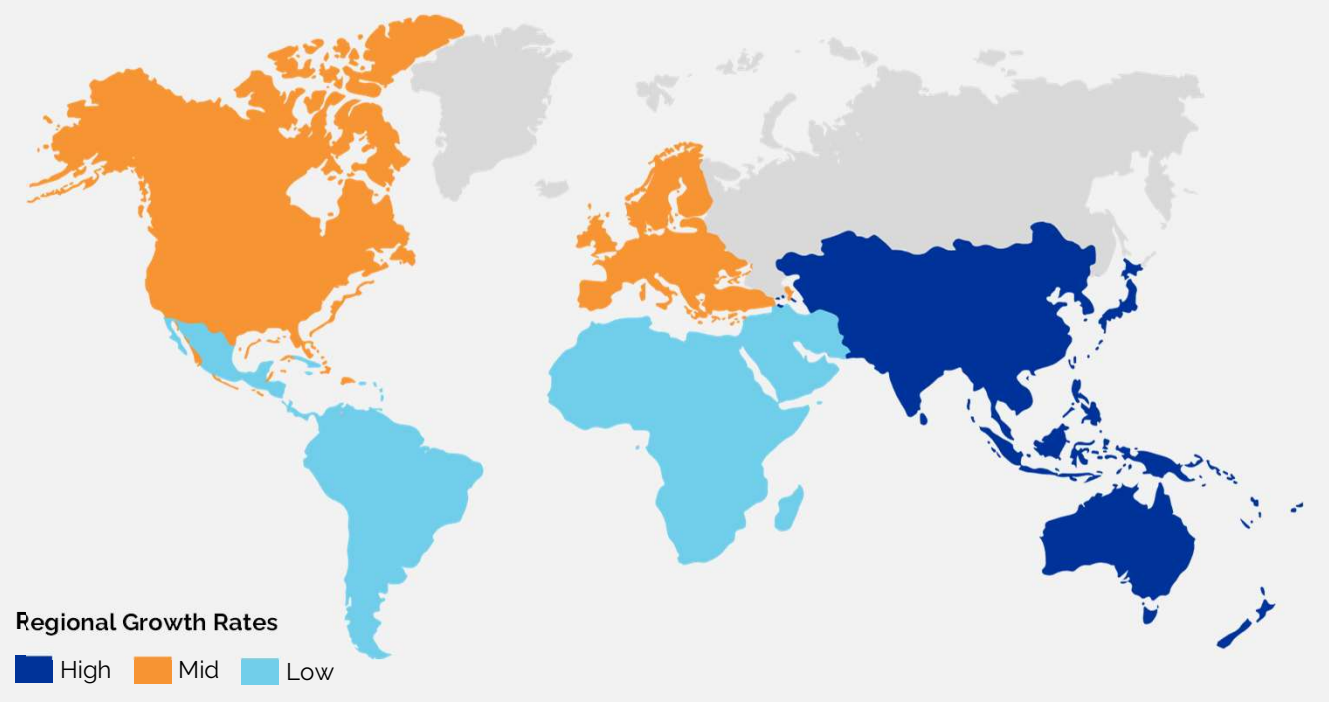
Table 10: Market trends, b USD: CMO [238]

Pharmaceutical CMO Market: Revenue in USD billion, by Geography, 2019 – 2026

Geography	2019	2020	2021	2022	2023	2024	2025	2026	CAGR (%)
North America	42.5	45.1	47.9	50.8	53.4	56.0	58.3	60.3	**4.7%**
Europe	29.2	30.8	32.5	34.1	35.7	37.0	38.0	39.1	**3.8%**
Asia Pacific	33.4	36.9	40.9	45.0	49.4	53.8	58.3	62.5	**8.9%**
Latin America	2.2	2.3	2.4	2.5	2.6	2.6	2.7	2.7	**2.7%**
MENA	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.0	**4.4%**

[237] Statista
[238] Mordor intelligence - Global CDMO market overview

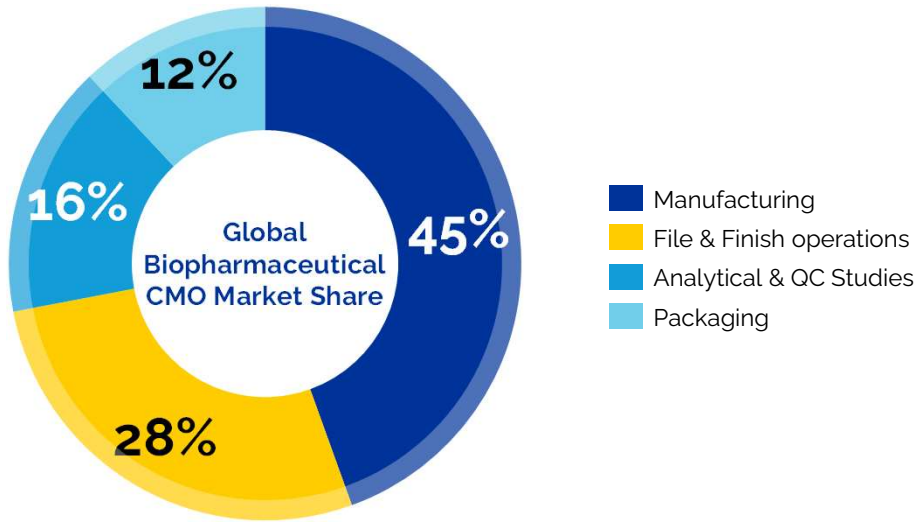
Figure 103: Pharmaceutical CMO Market – Growth Rate by Region (2021 – 2026)



Source: Mordor Intelligence

North America is a largest CMO market (Table 10), valued at USD 45b in 2020 and forecasted to grow by USD 60,3b by 2026. **Asia-Pacific is the fastest growing market** (Figure 103) with CAGR of 8.9% and forecasted to become the largest CMO market in the world by 2026 generating revenues of more than USD 62b per annum.

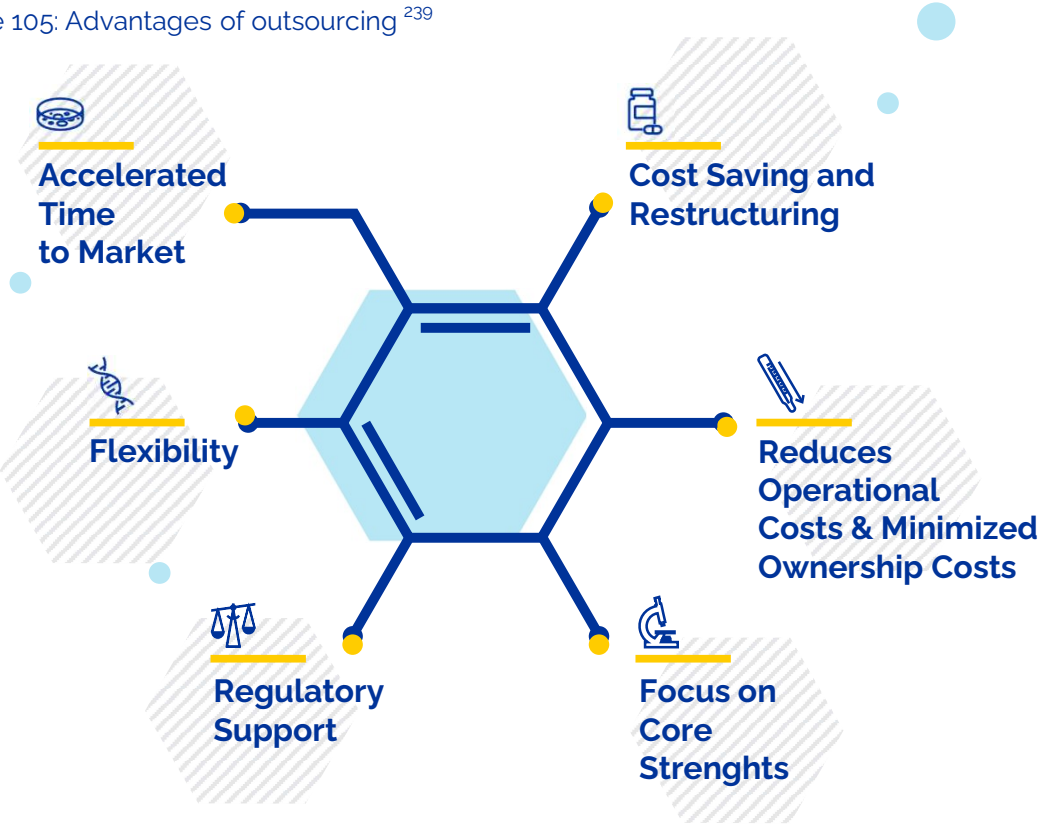
Figure 104: Global Biopharmaceutical CMO Market Share, By service 2020



The manufacturing segment held the highest market share in 2020. (Figure 104) Across the forecast period, lucrative growth is expected thanks to the **increasing number of contract manufacturing projects being awarded to CMOs across the globe**. For instance, Novartis announced that it has signed an initial contract manufacturing agreement to support the production of the Pfizer-BioNTech Covid-19 vaccine. This agreement will allow Novartis to use its aseptic manufacturing facilities in Stein, Switzerland, to support production.

The manufacturing segment is **facing with processing complex operation that relies on cutting edge technology**. Currently, several small-scale biotechnology companies lack in-house manufacturing facilities. Hence, to **continue the production of biologics** via downstream processing, these companies tend to **outsource their operations to the CMOs**. On the other hand, the fill and finish operations segment will witness considerable growth during the forecast period. A **growing number of launches** pertaining to biologics has simultaneously **stimulated demand for fill and finish services** as well. Moreover, increasing initiatives by CMOs to enhance their fill and finish operations has further sparked segmental growth.

Figure 105: Advantages of outsourcing [239]



CMOs allow companies to manufacture APIs **without increasing their overhead costs** (Figure 105). In the manufacturing process, CMOs follow the guidelines of the outsourcing company. In contrast, CDMOs manufacture and develop the drug during the contractual period. The research and development of APIs in CDMOs services are offered additionally. Patient centricity, risk-based monitoring, digitization of clinical trials, and analytics have an impact on clinical outsourcing. In the future, **outsourcing decisions will be influenced by patients' experiences with vendors and CROs**. Vendors that provide platforms to effectively integrate data from multiple systems into a central decision-making tool are also expected to witness demand.

The need for flexibility in study designs and new drug supply requirements can influence decision-making, and more outsourcing work may come to smaller vendors and CROs that have better overall predictive performance analytics. CMOs and CDMOs will continue to be the strategic and integral parts of the global supply process.
The shift to biologics, personalized medicine and specialized, often low-volume, small molecules is creating a shortage in manufacturing capacity. **CMOs and CDMOs streamline the supply chain with better managing capacity, improved efficiency and reduced time to market. CDMOs are expanding to become full-service providers and "true partners" that can offer a wider variety of capabilities.**

[239] Mordor intelligence - Global API market overview

6.6.2 CRO/CMO cost structure

Sample cost structure for CMO firms is made based on the financial statements of companies that are engaged in the sector: Cambrex, Patheon, Catalent.

Figure 106: Net income and PP&E of a sample CMO company77

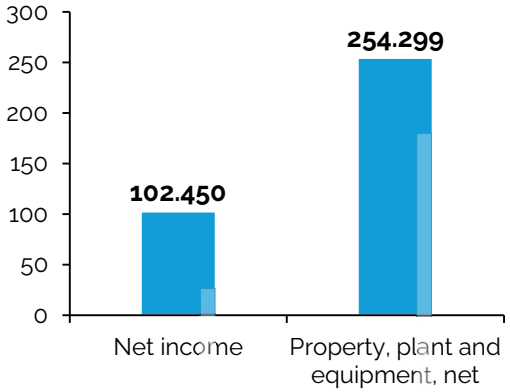
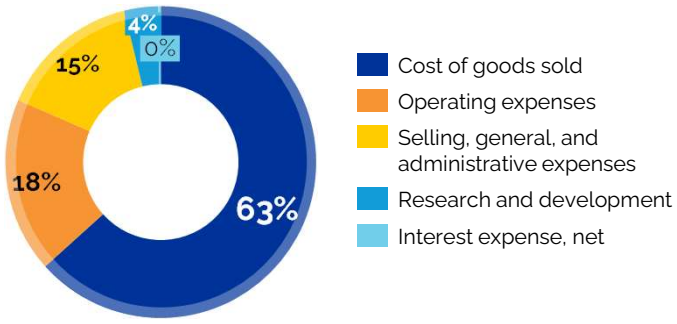


Figure 107[240] : Sample cost structure for CRO firm in 2021, USD



R&D expenses account for ~4% of the total, while the cost of goods sold account for 63.4%. Compared with other sub-sectors, operating expenses (18.2%) account for a significant share of the cost structure at CMOs. (Figure 107). In 2017, expenses on PPE was USD 254,299, while net income was USD 102,450. (Figure 106) Compared with other sub-sectors, CMO is a capital-intensive sector where the main asset is PPE.

CRO cost structure

Sample cost structure for CRO firms is made on the basis of financial statements of companies that are engaged in the sector: Syneos Health, Covance, Parexel.

Figure 108: PP&E and net income of a sample API company[225]

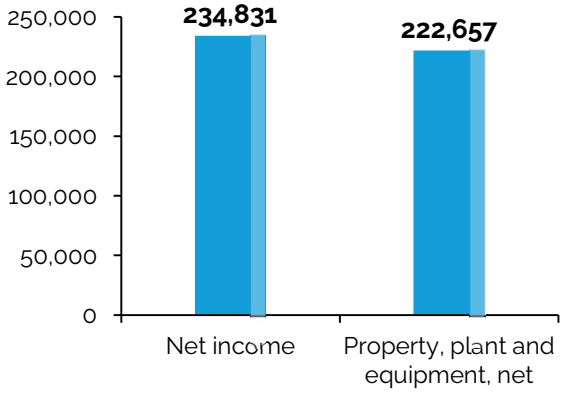
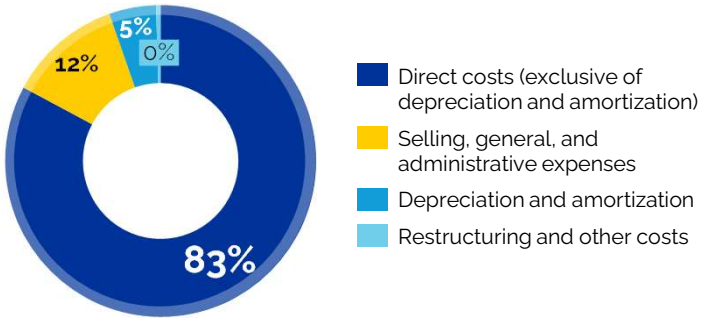


Figure 109[241] : Sample cost structure for CRO firm in 2021, USD



Direct costs account for 82.8% of the total (this is the highest figure among the sub-sectors). (Figure 109) This item among other expenses includes compensation fees. This fact is related to the model of the CRO sector, where the main company asset is human capital.

In 2021, net income was higher than property and equipment (USD 234,831 and USD 222,657 respectively) (Figure 108). In the CRO sector, the main assets are human capital and technology, which are not fixed assets.

[240] Mordor intelligence - Global API market overview
[241] https://www.investor.syneoshealth.com/financials/annual-reports

6.6.3 Market evaluation and potential

The global pharmaceutical **CDMO market was valued at USD 160.12b in 2020 and is expected to reach USD 237b by 2026 at a CAGR of 6.5%.**

The **Russian market in 2021 is expected to be USD 810m and forecasted to grow by almost USD 1b at a CAGR of 8.5% by 2023**. The main growth driver has been the significant support from the government for local producers and limitations introduced for tenders. **These limitations do not apply to EAEU countries, so Armenia could find great opportunities.**

In the global market, Armenia already has a representative office of a Chinese-Indian CRO company named Clinchoice, which was founded in 2015. The company has more than 400 employees, including life science professionals, medical doctors, biochemists, pharmacists, statisticians and linguists. Around 98% of their operations are geared towards exports.

The company is planning expansion to expand to Gyumri in order to enter the Georgian market. The company organizes continuous professional development of their employees in-house by leveraging on network firms' knowledge and experience.

The biggest factor driving the growth of CMOs in the pharmaceutical sector is the growing need for state-of-the-art processes and production technologies, which have proven to be highly effective in meeting regulatory requirements.

CMOs have been consolidating as a means of improving profitability in the competitive market. Through consolidation, large CMOs can expand their geographical presence and penetrate niche markets. Small CMOs, meanwhile, can use the technical expertise and resources of larger CMOs and Armenia could do the same, using technologies of multinational companies on its territory.

In recent years**, R&D costs have considerably increased** owing to several factors ranging from regional and international regulatory constraints to the global economy, global R&D spending in the pharmaceutical and biotechnology sector shows no signs of a slowdown. **CROs are a solution for continuing development of R&D.**

Business models followed by CROs **are putting affordable high qualified workforce that are present in Armenia as a considerable advantage** in the current market scenario. Currently, CROs either run in a preferred provider model or make strategic alliance partnerships with pharmaceutical companies. **In the preferred provider model,** the pharmaceutical company or the developer may get an exclusive price for CRO services in exchange for guaranteeing a large part of the work to be outsourced to the CRO. **In case of a strategic alliance,** a whole range of tasks will be carried by the CROs, allowing both parties to be involved in a more linear partnership, sharing their common business together. This model goes beyond contractual commitments, creating a deeper sense of collaboration and providing valuable experience to CROs.

6.6.4 SWOT analysis for the Armenian CMO / CRO sub-sector

Figure 110: SWOT analysis for the Armenian CMO / CRO sub-sector

6.7 Socio-economic impact

Social and economic impact of chosen sub-sectors

Potential sub-sector development and **impact creation** are the two pillars for our approach to **socio-economic impact analysis.** These pillars have been used to evaluate factors like **GDP per capita** – GDP per capita has been tested to evaluate impact of increasing development of the chosen sub-sectors on the household incomes. Gross Domestic Product (GDP) data was used as the indicator to test it. **Life expectancy** - has been tested to see whether the countries with higher life expectancies have better developed pharmaceutical sub-sectors. Life expectancy data was used as the indicator to test this hypothesis. **Human Development Index** (HDI) - defines the level of possessing a long and healthy life, knowledge and a decent standard of living through the main indicators of developments valid for a country's population. The reason to use this variable in our hypothesis was related to the idea to test whether the countries with higher HDI scores have higher level of development of the chosen pharmaceutical sub-sectors. We used world HDI data as an indicator to test this hypothesis. Similarly, **Private health expenditure per capita** - was tested to understand if the countries with higher domestic private health expenditure allocate a higher budget for private investment in healthcare. Full list of countries for evaluation of socio-economic impact are listed in **Annex 11**

Value of clinical trials per capita in 2020 was used to determine the correlation **of clinical trials** with socioeconomic indicators in:

40 countries from High income group

30 countries from the Upper middle-income group

23 countries from Lower middle-income group

2 countries from Low-income group

To determine the correlation **of generics** with socioeconomic indicators we used and applied the **share of generics in 2020** in the following countries:

23 countries from High income group

9 countries from the Upper middle-income group

1 country from Lower middle-income group

R&D expenditure per capita in the following countries was used to determine the correlation **of R&D** with socioeconomic indicators:

20 countries from High income group

3 countries from the Upper middle-income group

To determine the correlation **of API** with socioeconomic indicators, **API export per capita** data was used from the following countries:

7 countries from High income group

4 countries from the Upper middle-income group

1 country from Lower middle-income group

To determine the correlation of **CROs** with socioeconomic indicators, **CROs per capita** data was used from the following countries

36 countries from High income group

21 countries from the Upper middle-income group;

12 countries from Lower middle-income group

The **correlation value defines** the **magnitude of relation** between variables within the range of -1 and 1, a negative correlation from -1 to 0 and positive correlation from 0 to 1. In this respect, **higher correlation value indicates greater relation between variable and clinical trials development.** Factors with a **correlation value of above 0.5 shows a strong direct relationship** and **below -0.5 shows a strong opposite relationship** within the chosen sub-sector. Factors with a correlation value between 0,5 and -0,5 do not show strong correlation and can not be used for impact assessment.

Table 11: Correlation between Clinical trials and socio-economic indicators

	CT per Capita	GDP per Capita	HDI	Life Expectancy	Private Health Expenditure per Capita
CT per Capita	1				
GDP per Capita	0,73	1			
HDI	0,69	0,76	1		
Life Expectancy	0,58	0,68	0,88	1	
Private Health Expenditure per Capita	0,53	0,75	0,54	0,50	1

In the table above**, all variables** that were selected for this analysis **depict a positive correlation with clinical trials** development. GDP per capita and HDI demonstrated the highest correlation with clinical trials development. Life expectancy and private health expenditure per capita also have a correlation higher than 0,5 and can be used for proving our hypothesis that the **number of clinical trials per capita have a positive impact on growth** of all the factors:

- GDP per capita
- HDI
- Life expectancy
- Private Health expenditures per Capita

Table 12: Correlation between Generics share and socio-economic indicators

	Share of Generic, %	HDI	Life Expectancy	GDP per Capita	Private Health Expenditure per Capita
Share of Generic, %	1				
HDI	-0,72	1			
Life Expectancy	-0,71	0,88	1		
GDP per Capita	-0,58	0,87	0,75	1	
Private Health Expenditure per Capita	-0,35	0,51	0,48	0,70	1

In the table above, **all the variables** that were selected for this analysis **depicted negative correlation** with the **share of Generics**. Life expectancy, human development index and GDP per capita have sufficient correlation and will be used for testing our hypothesis that **higher share of Generics impacts**:

- GDP growth per capita
- HDI
- Life expectancy

Table 13: Correlation between API and socio-economic indicators

	API export (tones per 1.000.000 Capita)	GDP per Capita	Private Health Expenditure per Capita	Life Expectancy	HDI
API export (tones per 1.000.000 Capita)	1				
GDP per Capita	0,79	1			
Private Health Expenditure per Capita	0,68	0,82	1		
Expectancy	0,56	0,71	0,42	1	
HDI	0,53	0,83	0,53	0,68	1

In the table above, **all variables** for this analysis **depicted positive correlation** with **API export** (tones per 1.000.000 people). However, gross domestic product per capita and private health expenditure per capita demonstrated the highest correlation with clinical trials development. Mean years of life expectancy and human development index also had a correlation of higher than 0,5 and will be used for testing our hypothesis on the **number of API export** (tones per 1.000.000 people) and its **impact** on:

- GDP per capita
- HDI
- Life expectancy
- Private Health expenditures per Capita

Table 14: Correlation between R&D expenditure and socio-economic indicators

	R&D expenditure per Capita, $	Private Health Expenditure per Capita	GDP per Capita	HDI	Life Expectancy
R&D expenditure per capita, $	1				
Private Health Expenditure per Capita	0,87	1			
GDP per Capita	0,59	0,69	1		
HDI	0,44	0,51	0,88	1	
Life Expectancy	0,35	0,47	0,66	0,80	1

In the table above, **all selected variables** depicted a **positive correlation** with R&D expenditures per capita. However, private health expenditure per capita and GDP per capita demonstrated a correlation of above 0,5 while HDI and life expectancy showed a correlation of lower than 0,5. and will be used for testing our hypothesis that **R&D increases the impact on:**

- Growth of GDP
- Private Health Expenditure per Capita

Table 15: Correlation between number of CRO s and socio-economic indicators

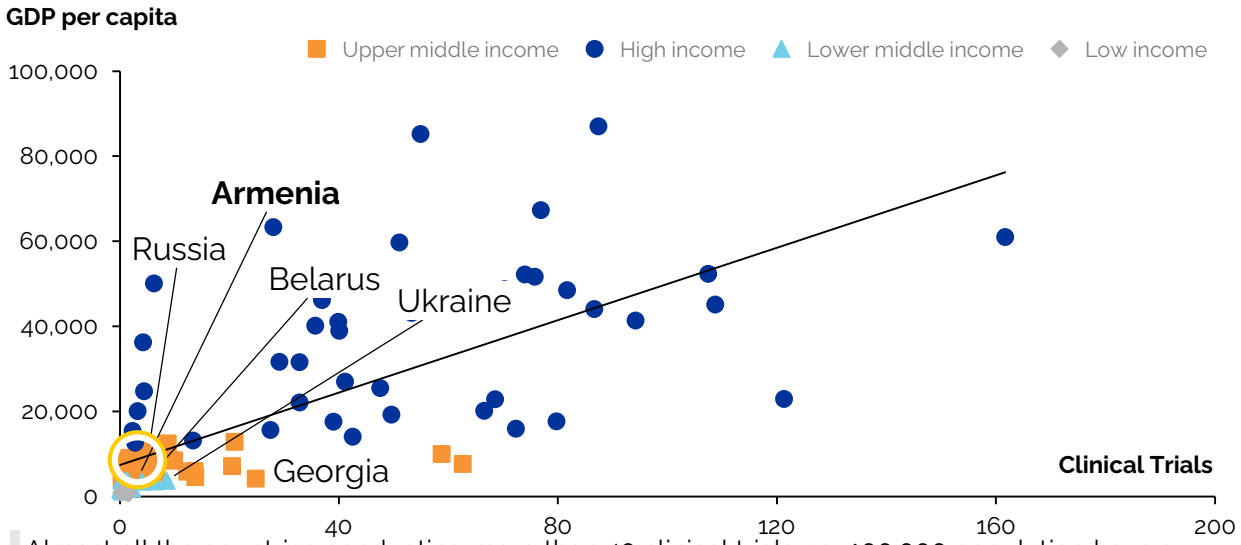
	CROs per 1.000.000 Capita	HDI	GDP Per Capita	Life Expectancy	Private Health Expenditure per Capita
CROs per 1.000.000 Capita	1				
HDI	0,52	1			
GDP per Capita	0,44	0,79	1		
Life Expectancy	0,38	0,84	0,70	1	
Private Health Expenditure per Capita	0,32	0,51	0,75	0,44	1

In the table above, **all selected variables** depicted a **positive correlation** with number of CROs (per 1.000.000 people) . However, only HDI demonstrated a sufficient correlation of above 0,5. Other factors have correlation lower than 0,5 and will not be used for testing our hypothesis on the **number of CROs** (per 1.000.000 people) per capita and its **impact on HDI**.

Impact on GDP per Capita

Hypothesis: with an increase in **clinical trials**, GDP per capita is expected to increase **1**

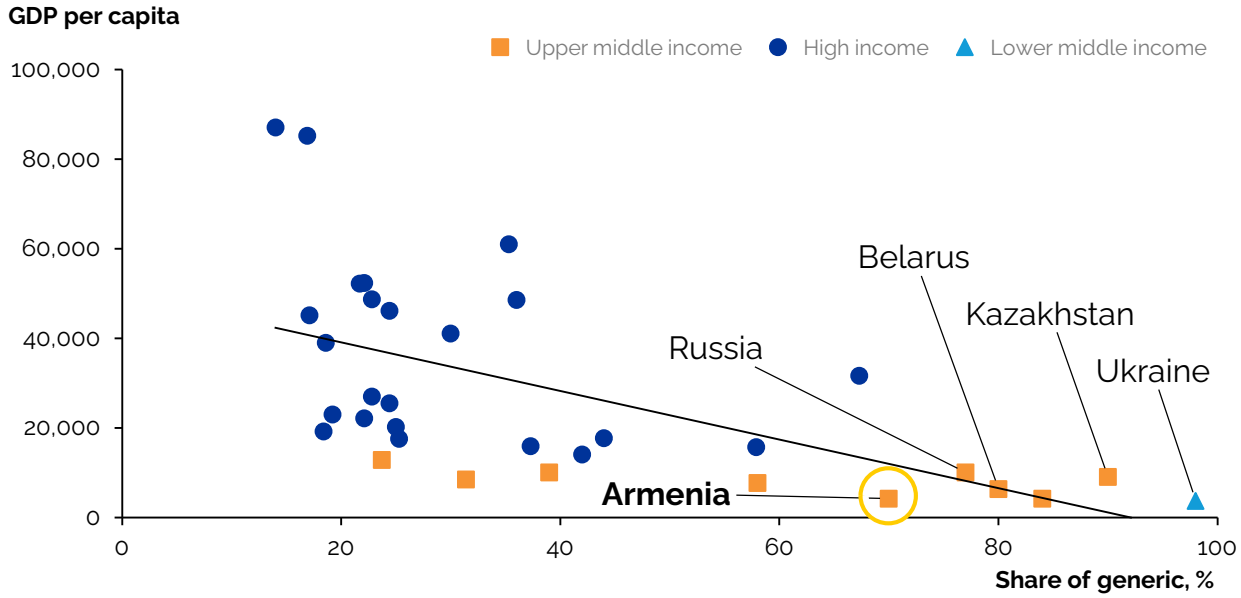
Figure 111: Number of Clinical Trials



Almost all the countries conducting more than 40 clinical trials per 100.000 population have a GDP per capita higher than USD 20,000 and countries conducting less than 40 clinical trials per 100'000 population have a GDP per capita lower than USD 20,000 and belong to the lower middle income and low-income groups of countries.

Hypothesis: With an increase in **share of generics**, GDP per capita is expected to increase **2**

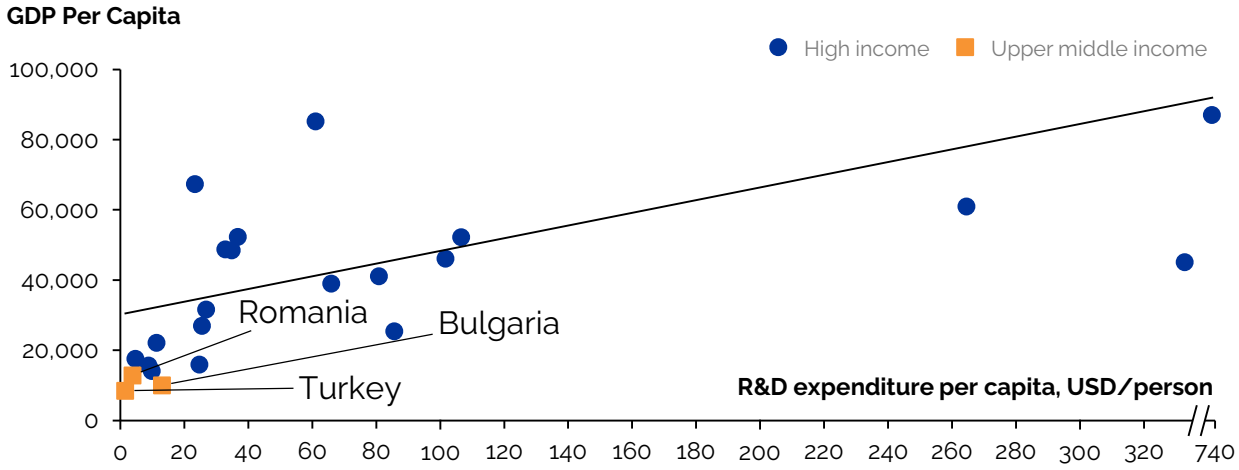
Figure 112: Share of Generics



Countries with the share of generics less than 20% have a GDP per capita of more than USD 20,000, and countries with the share of generics higher than 60% have a GDP per capita of less than USD 10,000. There is direct opposite correlation with increasing share of generics and GDP per Capita.

Hypothesis: With an increase in **R&D expenditure** per Capita, GDP per Capita is expected to increase **3**

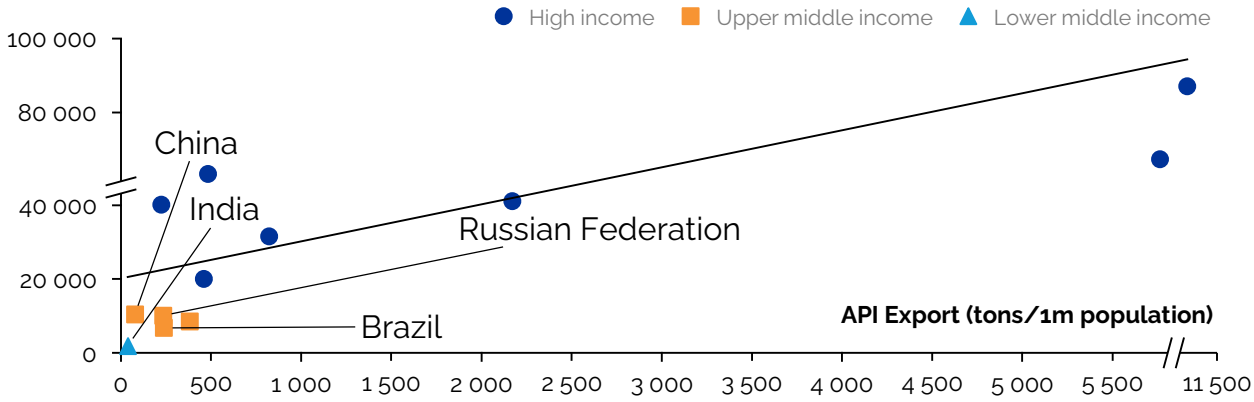
Figure 113: R&D expenditures



Graph confirms the hypothesis, that countries with R&D expenditure per capita higher than USD 50 have a GDP per capita higher than USD 40,000 and almost all countries with R&D expenditure per capita lower than USD 50 have a GDP per capita of lower than USD 30,000.

Hypothesis: With an increase of **API exports**, GDP per Capita is expected to increase **4**

Figure 114: API exports



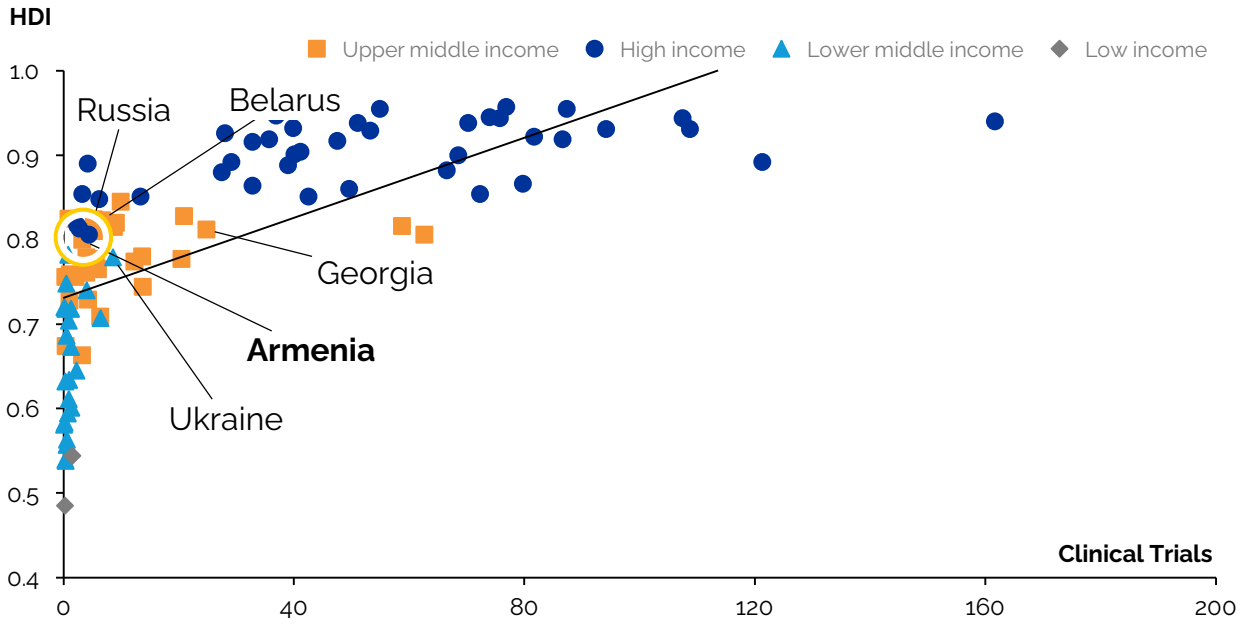
Graph confirms the hypothesis, that countries exporting APIs of more than 1000 tonnes have a higher GDP per capita of USD 30,000 and most of the countries exporting lesser APIs than 500 tonnes have a GDP of USD 20,000 and lower. The related countries belong to upper and lower-middle income groups of countries.

As a result, we see a developed pharmaceutical industry, new jobs and improved living standards

Impact on HDI

Hypothesis: With an increase in **clinical trials**, HDI is expected to increase **1**

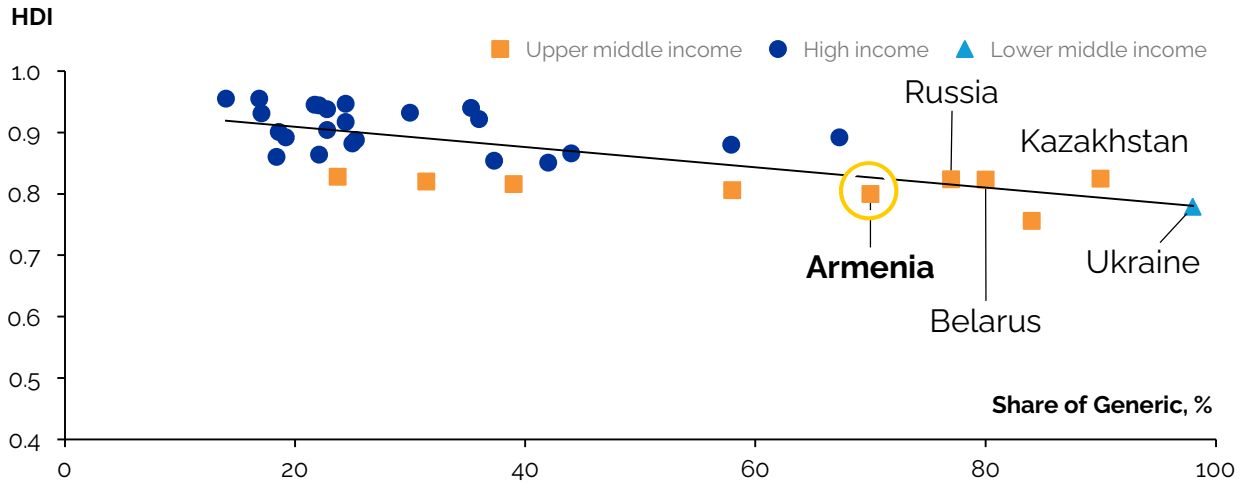
Figure 115: Number of Clinical Trials



Graph confirms the hypothesis, that countries conducting more than 40 clinical trials per 100'000 population have a HDI higher than 0,9 and countries conducting less than 40 clinical trials per 100'000 population have a HDI between 0,6 and 0,8 (belong to upper-middle income and lower middle-income groups of countries).

Hypothesis: With an increase in **share of generics**, HDI is expected to increase **2**

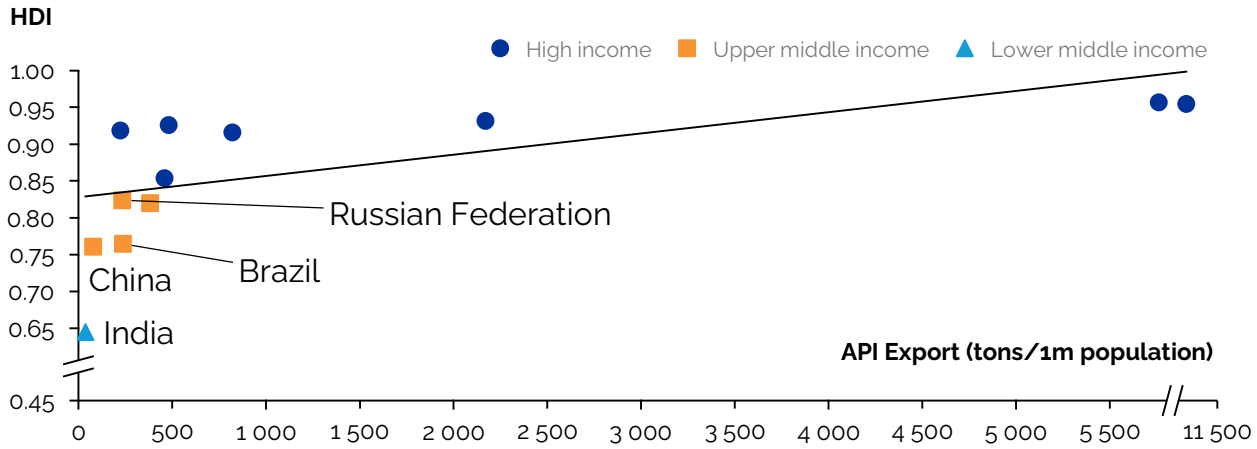
Figure 116: Share of Generics



The graph does not confirm our hypothesis. Countries with the share of Generics less than 20% have a HDI higher than 0,9 and almost all countries whose share of Generics is higher than 60% have a HDI less 0,85. There is direct opposite correlation between increasing share of Generics HDI.

Hypothesis: With an increase of **API exports**, HDI is expected to increase **3**

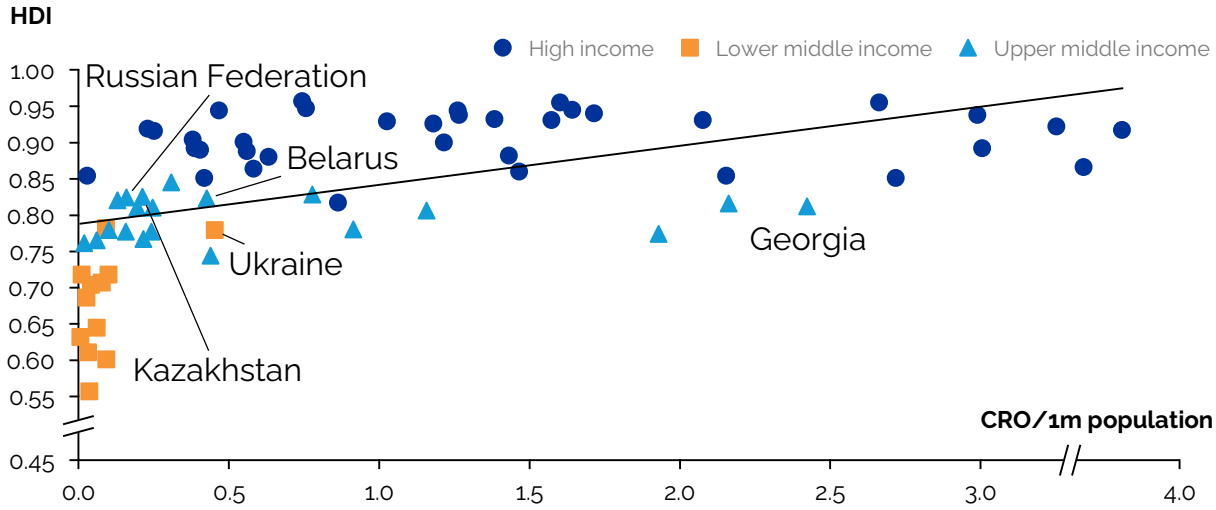
Figure 117: API Exports



The graph confirms our hypothesis that countries exporting APIs of more than 500 tonnes have a higher HDI and most of the countries exporting lesser APIs than 500 tonnes have a lower HDI of 0,85. There is direct correlation with volume of exported APIs and increased HDI

Hypothesis: With an increase in **number of CROs**, HDI level is expected to increase **4**

Figure 118: Number of CROs



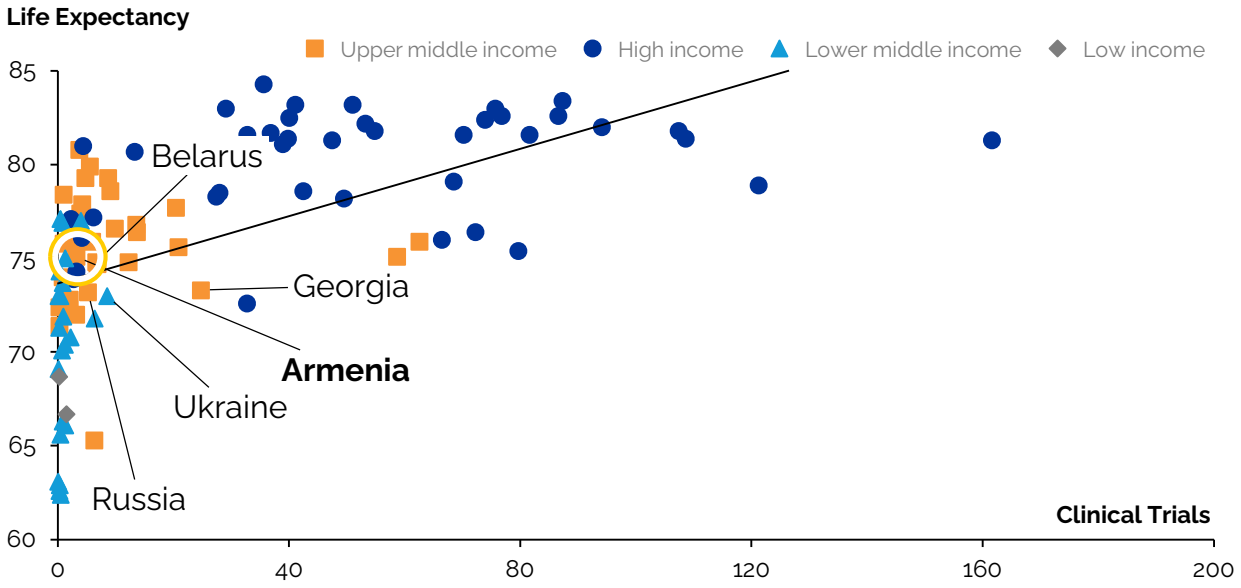
The graph confirms our hypothesis that most of the countries with a higher than 1 CRO show a higher HDI of 0,9 and above. There is direct correlation with increasing number of CROs (per 1.000.000 people) and increasing HDI level.

As a result, we engage communities, increase their level of education, quality of life, GNI and achieve improved life expectancy

Impact on Life Expectancy

Hypothesis: With an increase in **clinical trials** per capita, life expectancy is expected to increase **1**

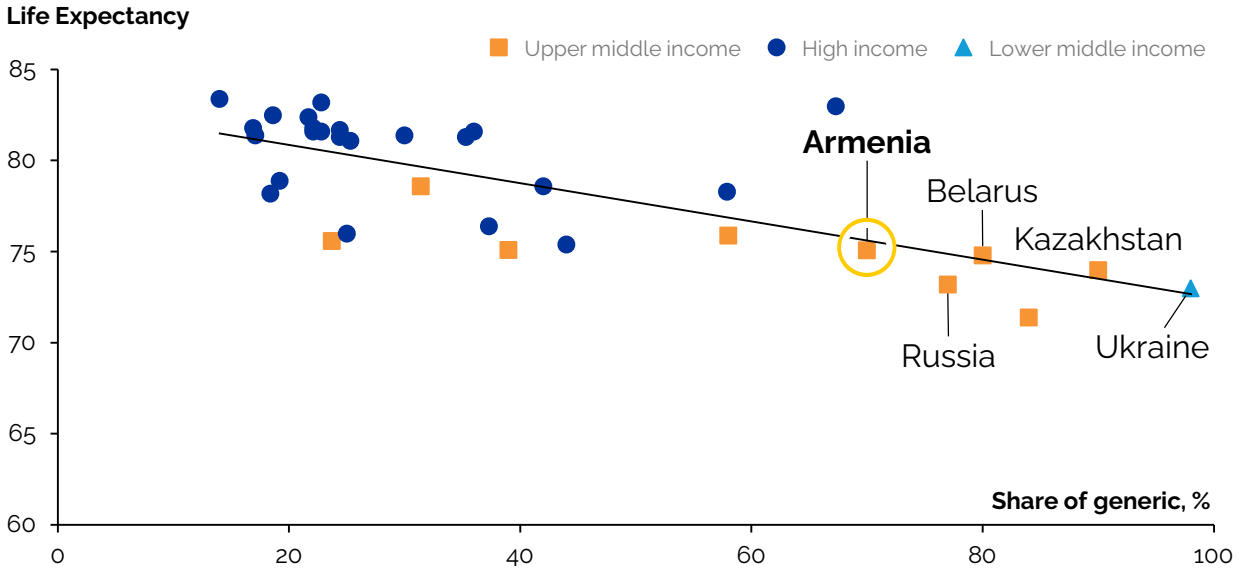
Figure 119: Number of Clinical Trials



The graph confirms our hypothesis that countries conducting more than 40 clinical trials per 100'000 population have a life expectancy higher than 80y and almost all countries that conduct less than 40 clinical trials per 100'000 have a life expectancy level of less than 75y.

Hypothesis: With an increase in **share of Generics**, life expectancy level is expected to increase **2**

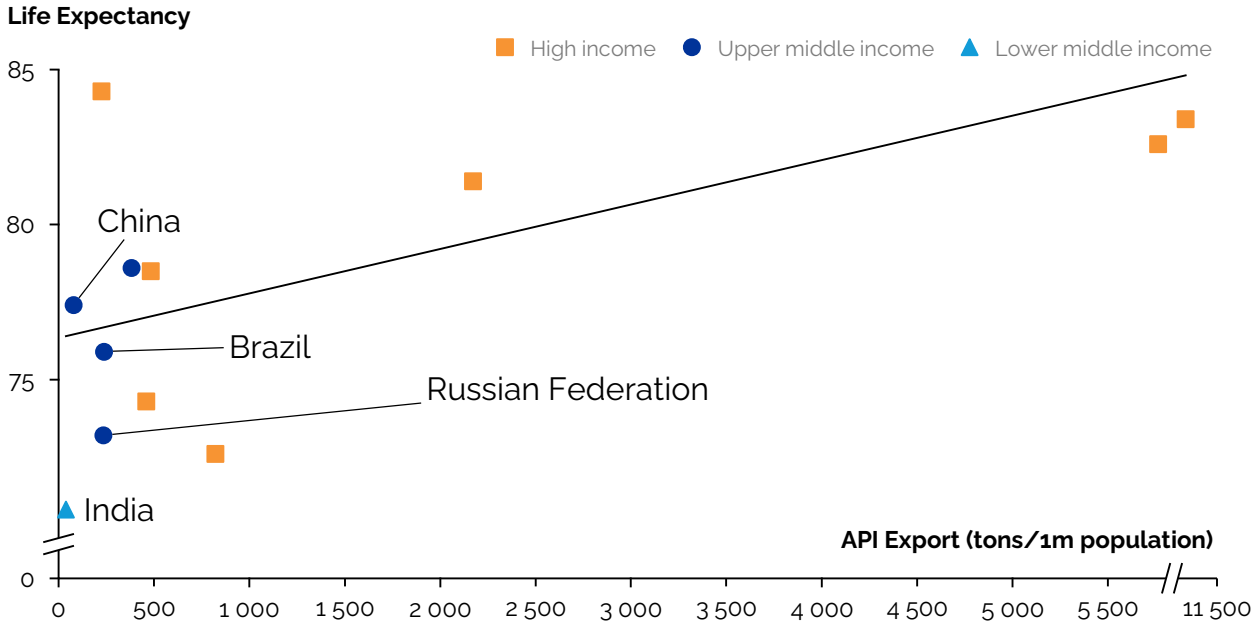
Figure 120: Share of Generics



Graph does not confirm our hypothesis and there is a opposite correlation with increasing share of Generics and life expectancy.

Hypothesis: With an increase of **API exports**, Life expectancy level is expected to increase **3**

Figure 121: API Exports



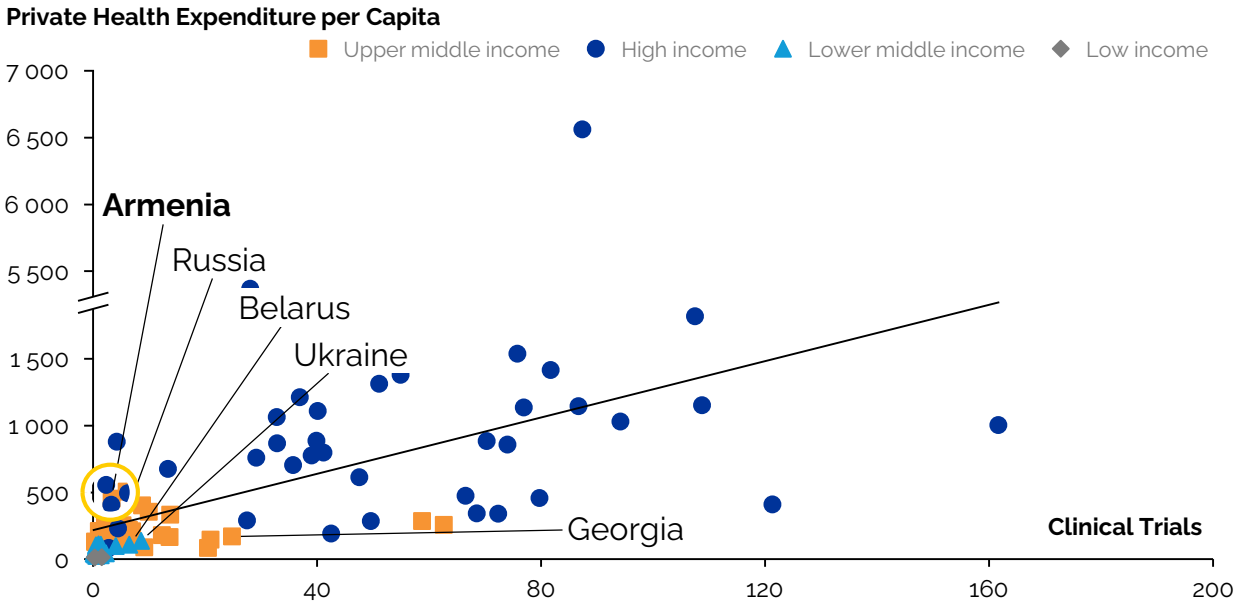
The graph confirms our hypothesis and there is a direct correlation with the increasing number of exported APIs and an increasing in life expectancy.

As a result, we get improved quality of healthcare, availability & emergence of contemporary technologies

Impact on Private Health Expenditure (PHE) per capita

Hypothesis: With an increase in **clinical trials**, PHE per capita is expected to increase **1**

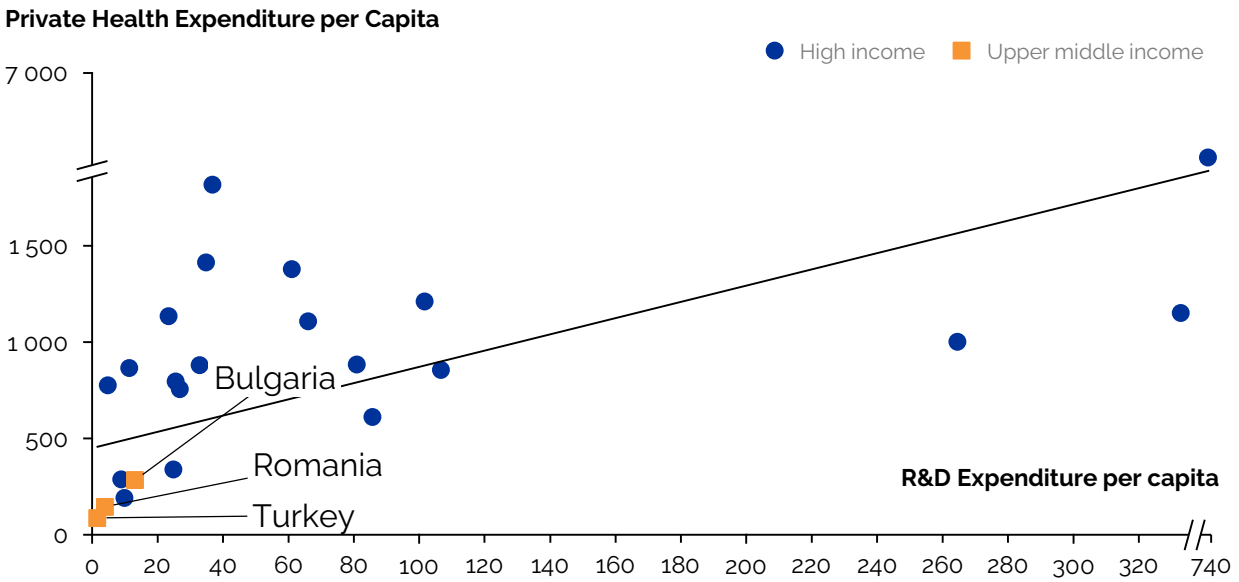
Figure 122: Number of Clinical Trials



The graph confirms our hypothesis and there is direct correlation with the increasing number of clinical trials and private health expenditure per capita level.

Hypothesis: With an increase in **R&D expenditure**, PHE per capita is expected to increase **2**

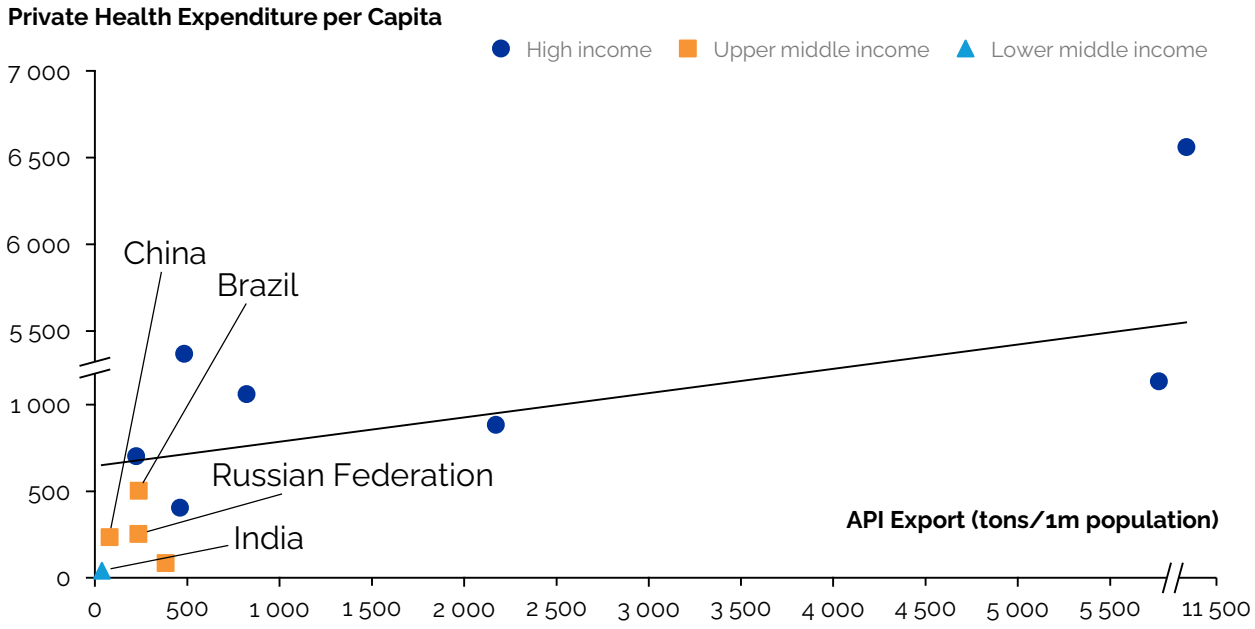
Figure 123: R&D Expenditure



The graph confirms our hypothesis and there is a direct correlation with increasing R&D expenditure per capita and private health expenditure per Capita.

Hypothesis: With an increase of **API exports**, PHE per capita is expected to increase **3**

Figure 124: API Exports



The graph confirms our hypothesis and there is a direct correlation with an increasing in the number of exported APIs and increased private health expenditure per capita.

Conclusions:

- Clinical trials and API sub-sectors have the highest socio-economic impact out of the chosen sub-sectors in the form of growing GDP per capita, an increase in HDI and life expectancy while increasing private investments in Healthcare industry.
- Developing this sub-sectors will lead to the development of the pharmaceutical industry, by creating jobs and attracting highly qualified specialists, leading to improved quality of life.

Table 16: Socio-economic impact correlation with sub-sectors

	Clinical trials	API	R&D	CRO	Generics
GDP per capita	0,73	0,79	0,59	0,44	-0,58
HDI	0,69	0,53	0,44	0,52	-0,72
Life Expectancy	0,58	0,56	0,35	0,38	-0,71
PHE per capita	0,53	0,68	0,87	0,32	-0,35

- The R&D sub-sector also shows a high level of correlation with the growth of GDP per capita and private health expenditures and will facilitate partnership with foreign companies and help develop the health care industry.
- CRO sub-sector does not have a significant correlation with most of the socio-economic factors, while having a low level of correlation only with the HDI.
- Generics sub-sector shows an opposite correlation with key socio-economic factors and in the long-term does not develop the pharmaceutical industry sufficiently. On the contrary, Generics increase the accessibility of medicines for the population in the short-term. High share of Generics is common in Upper- and lower-income group countries.

6.8 Additional opportunities

6.8.1 Reference Standards

The pharmaceutical reference standard (also known as a physical standard, certified reference material or reference material) is a standard substance developed in accordance with the international guidance to produce reference standards (ISO Guide 34, ISO/IEC 17025:2005, etc.), which **serves as the basis for the assessment of similar substances**.

Increased requirements for product purity along with identification of inherent impurities that may be highly toxic or have side effects have recently **put the issue of standardization methods at the top of the agenda**. The pharmaceutical sector uses the pharmaceutical reference standard to this end.

These standards are produced in small vials and used as a calibration sample thus allowing manufacturers of pharmaceuticals to test their products for conformity to the standards. **Reference materials are critical for pharmaceutical manufacturers to ensure safe and effective drug material production.** They are primarily employed in API quantification, elemental impurity identification and end-product sterility determination.

Depending on the test procedure, the reference standards can be primary or secondary. Additionally, the reference standards are divided into the following categories:

International	**Interstate (regional)**	**Pharmacopoeia**	**Enterprise**

A **primary standard** is a standard shown to have suitable properties for its intended use (the demonstration of suitability is made without comparison to existing reference standards).

A **secondary standard** is one that is established by reference to a primary standard.

An **international standard** is one whose activity is measured in International Units (IUs). The equivalence of International Units (IUs) of the international standard is approved by the WHO.

An **interstate (regional) standard** is a reference standard within the European Union or Eurasian Economic Union recognized in accordance with the established rules and applied in the member states that recognize it. An **enterprise standard** is a reference standard that is duly approved by an enterprise head and applied in accordance with the policies and regulations of the approving enterprise. They are established using international or pharmacopoeia reference standards and generally represent secondary standards.

Depending on the type of substance/substances that make up the content of a reference standard, they fall into chemical, biological and herbal reference standards.

A **chemical reference standard (substance)** is a chemical substance, or a mixture of chemical substances intended for use as prescribed in individual monographs or regulatory documents, as well as certain general monographs. The content of a specific substance in the chemical reference standard is expressed as a percentage with some exceptions (as a rule, antibiotics) where the quantitative content is expressed in IUs. The latter are secondary standards established by reference to international standards. A **biological reference standard** is a biological substance, or a mixture of biological substances intended for use as

prescribed in individual monographs or regulatory documents, as well as certain general monographs. Biological reference standards are either primary standards or secondary standards established by reference to International Reference Standards. Their activity is usually expressed in IUs. Other assigned values may also be used such as viral titre or bacterial number.

An **herbal reference standard** is herbal substance or a mixture of herbal substances. For medicinal herbs and herbal pharmaceuticals, the reference standard may be a biologically active herbal substance (a known active constituent), an active and/or inactive marker substance (a chemical substance used to identify and/or quantify basic substances), or a standard herb or extract. The latter must be identified using reference standards of biologically active substances or marker substances.

Reference Standards are Used for:

- quantitative assays of pharmaceutical substances and pharmaceutical preparations, tests for purity and compensation and control solution tests;
- qualitative analysis (for example, identification and assessment of the suitability for use as tracking substances in chromatography-based methods);
- specific tests (for example, as reference standards for calibration and verification of equipment operation, as authentic visual reference standards, as reference standards for melting point determination and particle count).

In the context of manufacturing and the development of new pharmaceuticals, the demand for reference standards and materials for new pharmaceuticals is growing.

The importance of reference standards has increased. The standards market is expected to **grow at a CAGR of 6.8% to reach USD 2.66b by 2027**. **Growth is mainly driven by increasing safety concerns in the food and pharmaceutical sector.**

The Standards market: expected to grow at a **CAGR of 6.8%**	**Forecast:** **USD 2.66b by 2027**

The recent Covid-19 outbreak contributed to innovation and the development of new products in the standards space.

The growing number of ISO/ IEC 17025 accreditations suggests that the demand for reliable and traceable results in the pharmaceutical business is on the rise. Responding to increased market requirements, manufacturers of reference standards have made investments in new product development.

The Asia-Pacific region is set to become the fastest growing regional market. The Asia-Pacific growth will be fueled by the expanding pharmaceutical sector and new government initiatives. Untapped opportunities in the Asia-Pacific healthcare sector coupled with advances in pharmaceutical and biological science and development of infrastructure hold vast potential to support the growth of the reference standards market in the Asia-Pacific region.

Overview of target countries: Standards development

Europe

Reference standards distributed by the European Directorate for the Quality of Medicines & Healthcare (EDQM). The EDQM supplies chemical reference substances (CRS), herbal reference standards (HRS) and biological reference preparations (BRP) as well as reference spectra for the tests and assays to be **carried out in accordance with the official methods prescribed in the European Pharmacopoeia**.

US

The US Pharmacopeia (USP) includes over **6,800 quality standards for medicines**, both chemical and biologic, active pharmaceutical ingredients and excipients (inactive ingredients). It is the most comprehensive source in the world for quality standards and it is used in over 150 countries worldwide and integrated into the laws of more than 40 countries.

Global (WHO)

The International Pharmacopoeia of reference standards stands apart. Reference standards developed and used in accordance with the International Pharmacopoeia are called the International Chemical Reference Substances (ICRS). The EDQM also develops reference standards required for quality control. **ICRS are intended to be used as primary standards for tests of pharmaceuticals in accordance with the International Pharmacopoeia or to calibrate secondary standards.**

Unlike reference standards in the European and US Pharmacopoeia, the reference standards in the International Pharmacopoeia are supplied with reference documentation. For reference standards in the European Pharmacopoeia, batch validity statements and leaflets have been developed to share relevant information. For reference standards in the US Pharmacopoeia, USP Certificates are available, but they do not contain any analytical data.

Reference documentation for WHO reference standards contains the largest amount of analytical data with quantitative and qualitative data about reference standards. In addition to chemical pharmaceutical reference standards, the World Health Organization produces the International Standards for Antibiotics (ISA) and biological standards by the WHO Expert Committee on Biological Standardization (ECBS). **These two sets of reference standards are mainly used for the calibration of secondary standards for national and regional use. India, China, etc**.

EAEU

The EAEU currently does not have any licensed standard producers aside from international patents. In most cases, non-licensed standards or reference standards **from the European Union or the US are used**. As an EAEU member, **Armenia can become a potential producer of regional reference standards**. Due to the absence of barriers between the EAEU countries and the fact that reference standards, unlike pharmaceuticals, are not registered or otherwise licensed for import, the production of reference standards in Armenia could be profitable.

6.8.2 Certification

Since the regulations of GxP are global, every company manufacturing life sciences products is affected by it. Therefore, meeting the GxP requirements is highly important. Some of the GxPs are important for the life cycle of products.

1. **Good Manufacturing Practices (GMP):** GMPs are the guidelines recommended by agencies for the authorization and control of manufacturing of products such as drugs, medical devices, APIs, etc. Adhering to these guidelines assures the agencies about the quality of the products and that the manufacturers have taken every possible measure to ensure the safety of the product.
2. **Good Clinical Practices (GCP):** GCPs are international quality standards set by the ICH that state the clinical trial regulations for the products that involve testing on human subjects. The standards outline the requirements of the clinical trial and the roles and responsibilities of the officials involved. The GCPs ensure that no human experiments are performed just for the sake of medical advancement.
3. **Good Laboratory Practices (GLP):** These are the standards set by the FDA for non-clinical laboratory tests and studies conducted for assessing the safety and efficacy of the product. GLPs define the framework for a non-clinical study and state how they should be performed, evaluated, reported, etc.

As the global economy recovers, GxP (GMP) regulation testing is likely to grow significantly. **Global GxP (GMP) regulation testing market was USD 10,1b in 2021, with a change of % between 2021 and 2022. The global GxP (GMP) regulation testing market will reach USD 20.5b in 2028, growing at a CAGR of 10.7%.**

The Principles of GLP are managerial quality control systems covering the organizational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived). The OECD Principles of GLP are followed by test facilities carrying out studies to be submitted to receiving authorities for the purposes of assessing the health and environmental safety of chemicals and chemical products that may also be of natural or biological origin and, in some circumstances, may be living organisms.

GMP describes the minimum standard that medicine manufacturers must meet in their production processes. The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonizing GMP activities at the EU level.

GxP guidelines focus on:

- Traceability: The ability to reconstruct the development history of a drug or medical device.
- Accountability: The ability to resolve who has contributed what to the development and when.
- Data Integrity (DI): The reliability of data generated by the system.

GxP compliance is divided into five main elements. The '5 Ps' are:

1. **People**
   Highly skilled and valued for the work they do
   a. Have definite roles and responsibilities
   b. Follow all procedures
2. **Procedures**
   a. Properly documented and recorded covering all critical processes
   b. Ensure deviations are thoroughly investigated and reported
3. **Products**
   a. Include specifications for raw materials, components, intermediate and finished products
   b. Follow methods for packing, testing, sampling, status control, stability testing and records
4. **Premises & equipment**
   a. Enable proper cleaning and avoid cross-contamination
   b. Validated and calibrated in accordance with procedures, schedules and records
5. **Processes**
   a. Completely established, consistent and documented
   b. Identify critical steps
   c. Have robust change control procedures

Table 17: Number of issued GMP certificates and GLP certified test facilities by countries

Country	Number of issues GMP certificates[244]	Number of GLP Certified Test Facilities	National responsible monitoring authorities[245]
India	**1060**	**50**	National GLP Compliance Monitoring Authority (NGCMA), Department of Science and Technology
Germany	**2211**	**151**	German GLP Federal Bureau
Czech Republic	**1770**	**19**	State Institute for Drug Control
Hungary	**578**	**87**	National Institute of Pharmacy and Nutrition
Netherlands	**403**	**150**	Health and Young Care Inspectorate
United Kingdom	**1.322**	**105**	Medicines and Healthcare products Regulatory Agency

[244] http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
[245] https://www.oecd.org/chemicalsafety/testing/linkstonationalwebsitesongoodlaboratorypractice.htm

In 2019, the Armenian GMP inspectorate reviewed the Averse production site in Georgia. In 2021, they reviewed 15 production sites (three Gilead sites, three Roche sites, six Pfizer sites, one Pharmex Ukraine site, one Berlin-Chemie site and Genetic Italy). All the sites received confirmation of GMP certificates issued by the relevant authorities in the manufacturer's country.

6 **Pfizer** sites

3 **Gilead** sites

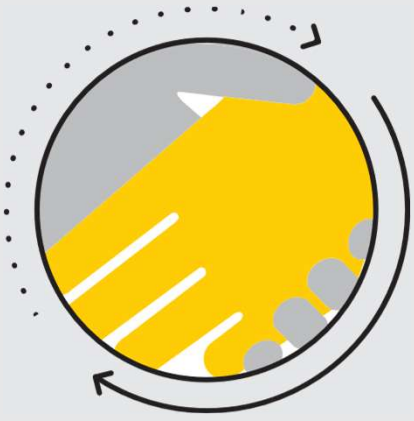
3 **Roche** sites

1 **Berlin-Chemie**

1 **Pharmex Ukraine** site

1 **Genetic Italy**

7 Potential investors



Potential investors

The table presented in Annex 12 contains information about big pharmaceutical companies operating in the EAEU market which can be interested in investing in Armenia and entities who have already done some investments in the EAEU pharmaceutical sector.
The sample includes large pharmaceutical companies with their own investment or venture funds; sovereign funds; private equity funds and firms or investment firms that help implement FDI in the Pharma segment.

Name/Country of incorporation column indicates the name of the Company and countries where the Company invests based on investment portfolio (companies and countries of their presence)[246].

Type of organization column indicates the form of organization of the Company.

Sub-sector/segment column indicates the priority areas for investing in other countries for example Clinical trial, Research & Development, API, Generic etc. There is an expert assessment based on the Company's own statements, investment portfolio, investment presentation or investment reports.

Investment destinations column shows the main destinations and areas for investment in general, without detailing by country (US, Europe, Asia-Pacific, etc.)

Rationale column indicates key points related to the investment process: description, type of activity, basic principles of investment, foreign companies that are interested in the Company in the field of investment.

Relevant qualifying information column indicates more detailed and fundamentally significant points related to the FDI process.

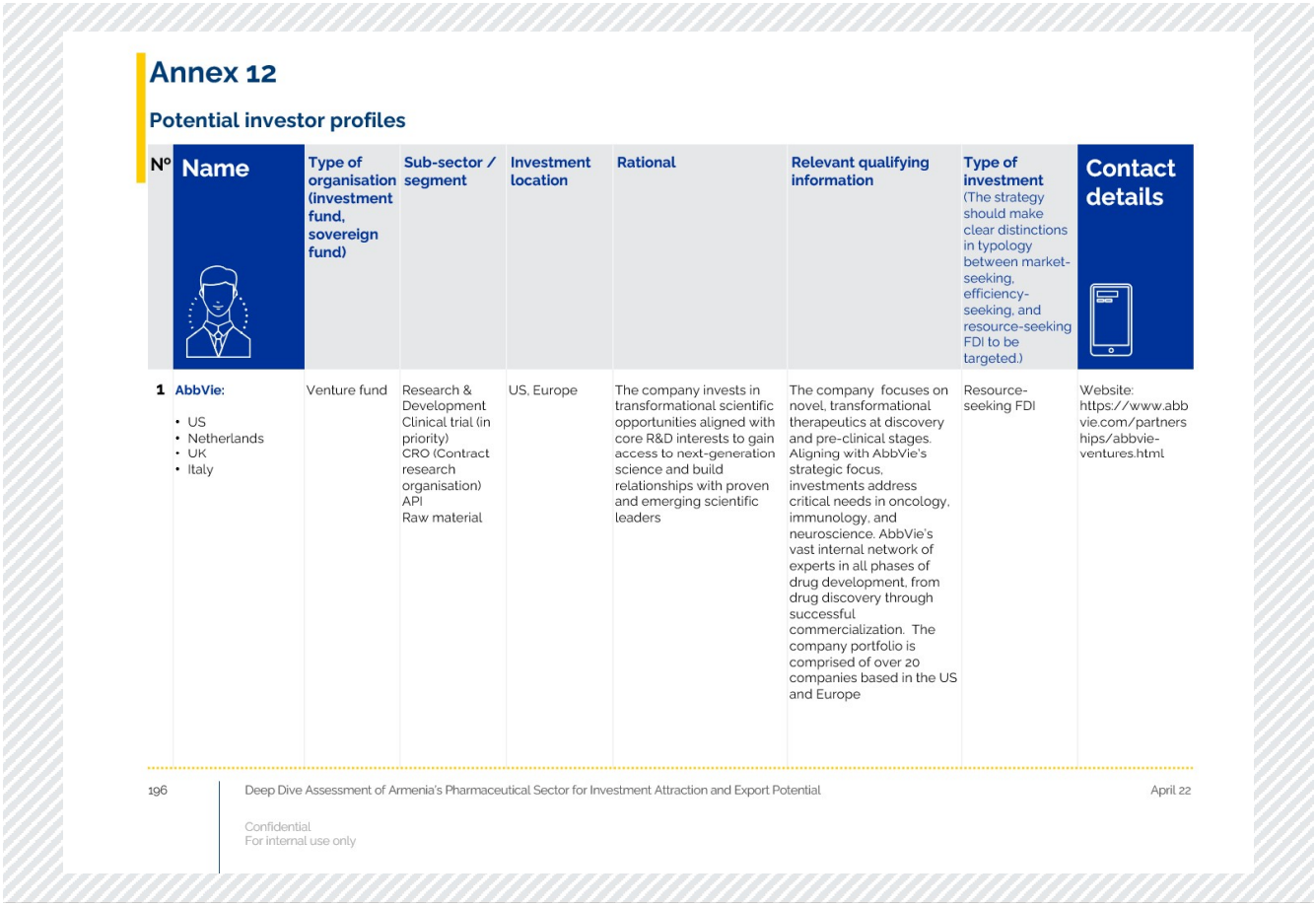
[246] For example, the investment portfolio of *Novartis*: https://www.nvfund.com/#OurPortfolio

Type of investment column provides an expert assessment of the Company's investment strategy in other countries based on investment portfolio data, investment presentation, analysis of investment reports or annual reports of the Company:

- **Market-seeking FDI** strategy aim to find new markets (countries) for manufacturing and distribution products or expansion of the Company's global presence[247].
- **Efficiency-seeking FDI** strategy aims to find new markets (countries) to improve the quality of products: in-depth research, new clinical trials, the search for new technologies to produce products, etc[248].
- **Resource-seeking FDI** strategy aims to find new resources to strengthen the Company's global position and expand production (for example search for new commodity markets (raw materials for production), export markets, human resources (highly qualified specialists)[249].

«?» is given in a specific case when it is difficult to identify the Company's investment strategy.

Contact details column indicates the Company's general website or investment portal.



Annex 12

Potential investor profiles

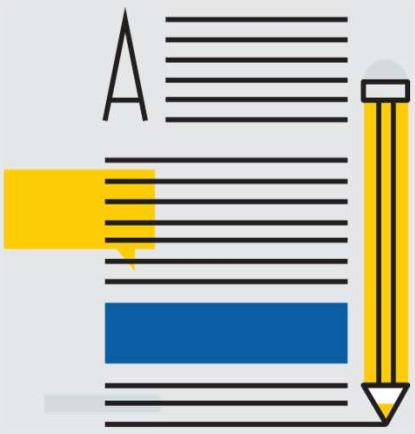
№	Name	Type of organisation (investment fund, sovereign fund)	Sub-sector / segment	Investment location	Rational	Relevant qualifying information	Type of investment (The strategy should make clear distinctions in typology between market-seeking, efficiency-seeking, and resource-seeking FDI to be targeted.)	Contact details
1	**AbbVie:** • US • Netherlands • UK • Italy	Venture fund	Research & Development Clinical trial (in priority) CRO (Contract research organisation) API Raw material	US, Europe	The company invests in transformational scientific opportunities aligned with core R&D interests to gain access to next-generation science and build relationships with proven and emerging scientific leaders	The company focuses on novel, transformational therapeutics at discovery and pre-clinical stages. Aligning with AbbVie's strategic focus, investments address critical needs in oncology, immunology, and neuroscience. AbbVie's vast internal network of experts in all phases of drug development, from drug discovery through successful commercialization. The company portfolio is comprised of over 20 companies based in the US and Europe	Resource-seeking FDI	Website: https://www.abbvie.com/partnerships/abbvie-ventures.html

[247] For example, the investment strategy of *Moderna Inc.*: https://s29.q4cdn.com/745959723/files/doc_news/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates-2022.pdf

[248] For example, the investment strategy of CDH VGC: https://www.cdhfund.com/index.php/a/lists/catid/170/

[249] For example, the investment strategy of GlaxoSmithKline PLC: https://www.gsk.com/media/7050/gsk-investor-update_23-06-21.pdf

8 Sub-sector choice and concluding remarks



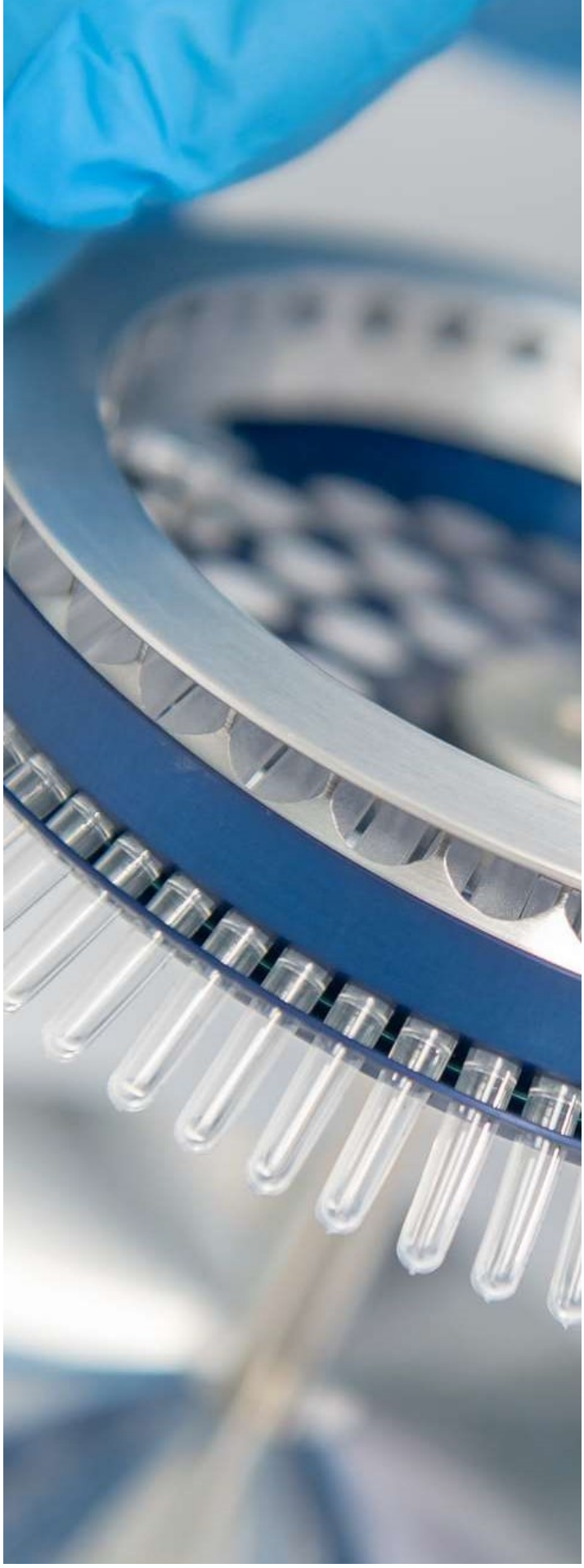
Sub-sector choice and concluding remarks

Production of Generic drugs has one of the biggest potentials in Armenia, both for local and international markets, specially for the post-soviet countries including Russia **and is valued at 160 m USD annually**. Current established trade operations with post-soviet countries and increasing export/import trends for generics will help to develop this sub-sector in Armenia. Apart from the currently established partnerships with foreign companies and institutions, **an available scientific foundation and necessary workforce will largely contribute to the development of this sub-sector.**

Costs, creation of modern facilities and diversified but niche product portfolio are the **key factors in creating a competitive landscape for the Generic drugs market**. The product portfolio should include OTC and prescribed (Rx) drugs (anti-psoriasis, standard solutions, anti-acne medications, ace-inhibitors, anti-rheumatics) that contribute to a big share in EAEU RX drugs market and will have a huge demand in the growing Russian and regional hospital market.

The Government of Armenia is already taking strategic steps like **curtailing certain import taxes and customs duty for imported equipment** to **develop the Generics sub-sector by identifying it as a priority sub-sector**. This sub-sector has a proven potential for FDI mobility and development of the pharmaceutical and the healthcare industry while **increasing access to affordable drugs.**

In the long-term, **Good Distribution Practice (GDP) certified warehouses, a common legislation with EAEU will also contribute to developing the sector** as well as **increase exports to the EAEU countries.**



Considering the COGS factor for locally produced Generics, producers should focus on increasing volumes per stock keeping units (SKU) per site and closely integrate commercial and technical operations. **Armenia, specifically could choose a path where it produces new Generic drugs in high volumes but limits the SKU while concentrating on growing product categories for OTC and R_X products in the EAEU countries.**

Localization or contract manufacturing of Generic drugs in partnership with leading companies **will help utilize the expertise and technologies of the market leaders and produce large volumes with attractive COGS** for the EAEU market and allow the foreign companies from sanctioned countries to freely sell their products in the given market.

Another potential sector to invest in Armenia is research and development. R&D in the pharmaceutical industry was **globally valued at almost 17 b USD in 2021** and is **expected to increase to 24 b USD by 2025**, with a **CAGR of 7.84%.** While the government still invests very little, the private sector covers most of the investments in R&D. **Armenia's key factors in creating a competitive landscape in the pharmaceutical industry are its vast R&D resources and human capital** in specialties like biochemistry, molecular genetics and microbiology. Armenian researchers have a significant number of joint international publications, driven in part by the country's diaspora networks. Burdened by the current sanctions, the Russian government continues to invest in research and development in the pharmaceutical industries and is increasingly looking for alternative partners and geographies to extend its activities in the region.

The ultimate goal of drug development is to bring a new compound with proven therapeutic effect to the market. In this context, the transition from preclinical research to clinical stages marks a critical turning point, as it nears the new medicinal product to the market. With the promise of marketing authorization, though far ahead in the road, hanging on the horizon, the approval of a clinical trial usually attracts investors and leads to a respectable revenue generation.

Valued at 250 m USD, the **clinical trials market in EAEU is forecasted to grow** significantly as a result of the supranational registration of drugs in the EAEU by 2025. In 2020, 94% of the EAEU clinical trials market was shared jointly by Russia and Belarus. This share is expected to decrease considering the sanctions on Russia and Belarus, again paving the path for Armenia. While Russia has the largest share of the clinical trials market in the EAEU, emerging economies like Belarus, Moldova and Georgia, the Czech Republic and Serbia are clearly focusing on this sub-sector. **Clinical trials** sub-sector has a big potential in Armenia. **With low human capital costs, prevalence of more than 90 rare and genetic diseases and a developed legislative and scientific oversight base, growing prevalence of chronic disorders, increasing demand for advanced treatments and innovative drug development, developing countries like Armenia could well position itself in the clinical trials market** absorbing a substantial part of the growing EAEU clinical trials market. By **partnering with global clinical research organisations**, Armenia could expand its **participation in global clinical trials** and prioritize profitable areas such as rare genetic diseases, respiratory, infectious diseases, ophthalmology, pain management, anesthesia, as well as in the Phase III clinical trials. Despite lack of an immediate local demand for clinical trials and increasing demand for generic drugs, accounting for 70% of the total retail pharmaceutical market, potentially, **Armenia could absorb a part of the growing EAEU clinical trials market by prioritizing profitable areas** such as respiratory, anti-infective, ophthalmology and pain/anaesthesia, as well as participating and partnering with global players, especially in the

financially attractive Phase III trials. 70% of the costs of clinical trials are workforce-related and Armenia with its cost-effective, qualified workforce could offer **relevant advantage over its regional competitors.**

Overcoming one of the **biggest restraining factor of GLP certified laboratories** is the **key task before the sector** and should be immediately addressed in a detailed strategy that will not only lay down a targeted short/mid/and long-term recommendations for the pharma sector development but also streamline the process of new drug registration, introduction of regulatory measures to support local producers, support marketing activities abroad to increase trust towards Armenian pharmaceutical products and create a conducive environment for promotion of raw materials development.

Association of Manufacturers of Pharmaceuticals of Armenia, within the framework of the Government's Program of Activities designed for 2021-2026 has developed a set of recommendations, aimed at development for the pharmaceutical industry as a priority sector of the economy. The comprehensive list of recommendations is presented in **Annex 10.**

Annexes

Annex 1

List of respondents

1. Ministry of Health
2. Scientific Centre of Drug and Medical Technology Expertise
3. Institute of Molecular Biology (National Academy of Sciences of the RA)
4. Scientific and Production Center "Armbiotechnology" (National Academy of Sciences of the RA)
5. Drug Manufacturers association
6. Union on Manufacturers and Businessmen of Armenia
7. Gedeon Richter
8. Arpimed
9. Esco-Pharm
10. Leykoalex
11. Liqvor Pharmaceuticals
12. Medical Horizon
13. Bio-Chem
14. Azad Pharmaceuticals
15. Clinchoice
16. Armenikum

Annex 2

The legislative framework for the import and export of medicines in Armenia

1. Law of Armenia of 17 May 2016 "On Medicines"
2. Armenian Government Resolution No. 202-N of 28 February 2019 "On the Approval of the Procedure for the Import into Armenia and the export from Armenia of medicines, substances, medical plant raw materials and pharmaceutical products under Investigation, the Procedure for the Examination of Imports and Exports, as well as the List of Necessary Documents and On the Invalidation of Armenian Government Resolution No. 581 of 20 September 2000."
3. Rules for the Formation and Maintenance of the Unified Register" approved by Eurasian Economic Commission Board Order No. 177 of 22 December 2015.
4. Regulations on the Import into the Customs territory of the EAEU and Export from the Customs Territory of the EAEU of Narcotic Drugs, Psychotropic Substances and their Precursors."[250]

[258] Annex No. 10 to EEC Board Decision No. 30 of 21 April 2015 On Non-Tariff Regulation Measures"

Annex 3

The state registration

1. Ministry of Health of Armenia Order No. 31-N of 10 June 2019 "On the Approval of the Form of the Certificate of State Registration of Medicines, the Structure and Procedure for Maintaining the Register of Registered Medicines, and the Procedure for Determining the Prescription Status of Medicines and its Revision in Armenia" and the cancellation of Order No. 123-N of 7 February 2006.
2. Armenian Law "On Medicines".
3. Armenian Law "On Licensing".
4. Armenian Law "On Narcotic Drugs and Psychotropic Substances".
5. Armenian Law "On Medical Care and Public Services".
6. Armenian Government Resolution No. 162-N of 28 February 2019 "On the Approval of the Procedure for State Registration and Re-Registration of Medicines, Extension of the Validity period of the Certificate, as well as Refusal of Registration, Re-Registration of Medicines and Extension of the Validity period of the Certificate, Suspension and Cancellation of Registration, Examination Procedure in these Cases, as Well as the Submission and Examination of Post-registration Changes and a List of Necessary Documents, a List of Changes that do not Require New Registration, the Procedure for Conducting Pharmaceutical Inspections and Recognising Reports of the Competent Authorities of other Countries and on the Invalidation of Armenian Government Decree No. 347 of 25 April 2001".
7. Armenian Government Resolution No. 166-N of 28 February 2019 "On the Approval of Payment Amounts for Expertise in the State Regulation of the Circulation of Medicines".
8. Armenian Government Resolution No. 168-N of 28 February 2019 On the Approval of the Procedure for Issuing a Permit for Conducting Clinical Trials, the Procedure for Conducting an Examination for this Purpose and the List of Necessary Documents, and on the Invalidation of Armenian Government Resolution No. 63 of 24 January 2002."
9. Armenian Government Decision No. 867 of 29 June 2002 "On the Approval of Procedures for Licensing the Production of Medicines, Pharmacy Practice, Medical Care and Services, as well as Curricula of Secondary and Higher Medical Education and Approval of the Form."
10. Armenian Government Decision No. 1129-N of 21 August 2003 "On the Approval of the List of Narcotic Drugs, Psychotropic Substances and Their Precursors Subject to Control in Armenia".
11. Ministry of Health of Armenia Order No. 07-N of 13 April 2018 "On the Approval of the List of Essential Medicines of the Republic of Armenia" and Ministry of Health of Armenia Order No. 14-N of 31 May 2018 about amendments.
12. Armenian Government Resolution No. 281-N of 18 March 2011 "On the Approval of Licensing Procedures for the Production, Export, Import or Wholesale of Narcotic Drugs or Psychotropic Substances or Their Precursors".
13. Armenian Government Resolution No. 172-A of 23 February 2017 "On the Definition of an International Professional Organisation Provided for by the Law on Medicines of Armenia".
14. Armenian Government Resolution No. 716-n of 23 June 2017 "On the Approval of the List of Pharmacopeias Operating in Armenia"
15. EAEU Decision No. 88 of 3 November 2016 "On the Approval of the Requirements for the Instructions for the Medical Use of Medicines and the General Characteristics of Medicines for Medical Use."
16. EAEU Decision No. 76 of 3 November 2016 "On the Approval of Requirements for Labelling for Medical Use and Veterinary Medicines."
17. EAEU Recommendation No. 13 of 23 April 2019 "On the Rules for the Compilation of Grouping Names of Medicines".

18. EAEU Recommendation No. 2 of 29 January 2019 “On the Guidelines for the Selection of Trade Names of Medicines”.
19. EEC Decision No. 151 of 7 September 2018 “On the Approval of the Guidelines for the Preparation of a Regulatory Document on the Quality of a Medical Product”.
20. EAEU Decision No. 9 of 30 January 2020 “On Amendments to the Rules for Registration and Examination of Medicines for Medical Use”.
21. General Technical Document (ED) on the rules of the EAEU.
22. Application form for registration of medicines according to the rules of the EAEU (updated on 21 December 2020).
23. EAEU Decision No. 78 of 3 November 2016 “On the Rules of Registration and Examination of Medicines for Medical Use and EAEU Decision No. 55 of 14 June 2018 ‘On Amendments to EAEU Decision No. 78 of 3 November 2016’”.

Annex 4

Armenian legal and regulatory framework on GMP

1. Law of the Republic Armenia of 17 May 2016 "On Medicines" (Article 3, 16, 18, 21, 22 and 24)
2. Armenian Government Decision No. 1089-N of 26 September 2013 On the Approval of the Procedure for Monitoring Compliance with the Rules of Good Manufacturing Practice and Issuance of a Certificate of GMP in the Republic of Armenia".
3. At the same time, 20 draft regulations were developed, amended and approved by resolutions and orders issued by the Armenian Government and Ministry of Health. Armenia has introduced legal norms necessary for the functioning of proper systems for the production and distribution of medicines in accordance with international standards.
4. Eurasian Economic Commission Council Decision No. 77 of 3 November 2016 "On the Approval of the Rules of Good Manufacturing Practice of the Eurasian Economic Union".

Annex 5

EEC regulations on the production and quality control of medicines

1. Eurasian Economic Commission Council Decision No. 77 of 3 November 2016 "On the Approval of the Rules of Good Manufacturing Practice of the Eurasian Economic Union".
2. Eurasian Economic Commission Council Decision No. 80 of 3 November 2016 "On the Approval of the Rules of Good Distribution Practice within the Framework of the Eurasian Economic Union".
3. Eurasian Economic Commission Council Decision No. 15 of 26 January 2018 "On the Approval of the Rules of Good Practice in the Cultivation, Collection, Processing and Storage of Raw Materials of Plant Origin"
4. Eurasian Economic Commission Council Decision No. 93 of 3 November 2016 "On the Recognition of the Results of the Inspection of the Production of Medicines".
5. Eurasian Economic Commission Council Decision No. 82 of 3 November 2016 "On the Approval of the General Requirements for the Quality System of Pharmaceutical Inspectorates of the Member States of the Eurasian Economic Union".
6. Eurasian Economic Commission Council Decision No. 83 of 3 November 2016 "On the Approval of the Rules for Conducting Pharmaceutical Inspections".
7. Eurasian Economic Commission Council Decision No. 91 of 3 November 2016 "On the Approval of the Procedure for Ensuring Joint Pharmaceutical Inspections".
8. Eurasian Economic Commission Council Decision No. 73 of 3 November 2016 "On the Procedure for the Certification of Authorised Persons of Manufacturers of Medicines".
9. Eurasian Economic Commission Council Decision No. 74 of 3 November 2016 "On the Approval of the Procedure for the Formation and Maintenance of the Register of Authorised Persons of Manufacturers of Medicines of the Eurasian Economic Union".
10. Eurasian Economic Commission Council Decision No. 76 of 3 November 2016 "On the Approval of Requirements for Labelling of Medicines for Medical Use and Veterinary Medicines'.
11. Eurasian Economic Commission Board Decision No. 1 of 14 January 2020 "On the Approval of the Guidelines for Establishing Permissible Limits of Health Effects in Order to Identify Risks in the Production of Medicines on Common Production (Technological) Lines".
12. Eurasian Economic Commission Board Recommendation No. 3 of 29 January 2019 "On the Guidelines for the Production of Finished Dosage Forms of Medicines".
13. Eurasian Economic Commission Board Recommendation No. 19 of 26 September 2017 "On the Guidelines for the Validation of the Production Process of Medicines for Medical Use".
14. Eurasian Economic Commission Board Recommendation No. 31 of 13 December 2017 "On the Requirements for Water for Pharmaceutical Use in the Production of Medicines".
15. Eurasian Economic Commission Board Recommendation No. 6 of 10 May 2018 "On the Quality Gidelines for Medical Herbal Preparations".
16. Eurasian Economic Commission Board Recommendation of No. 17 of 7 September 2018 On the Guidelines for the Quality of Medicines for Inhalation and Nasal Medicines".
17. Eurasian Economic Commission Board Recommendation No. 6 of 12 February 2019 "On the Guidelines for the Selection of Tests and Acceptance Criteria for Drawing up Specifications for Medical Plant Raw Materials, Herbal Pharmaceutical Substances (Treatments based on Medical Plant Raw Materials) and Medical Plant Treatments".

Annex 6

The legislative framework for sales, transportation and storage

1. Rules of Good Distribution Practice of the EAEU.
2. Armenian Government Resolution No. 156-N of 28 February 2019 On the Approval of the Inspection Procedure for the Certification of Suppliers and Issuance of a Certificate of Good Distribution Practice, the Procedure for Conducting an Examination for Licensing the Wholesale Sale of Medicines and a List of Necessary Documents" (Appendix 1 GMP).
3. The Rules of Good Distribution Practice of the EAEU were approved by Eurasian Economic Commission Council Decision No. 80 of 3 November 2016.

Annex 7

Armenian legal norms for supporting the production and distribution of medicines in accordance with international standards

1. Armenian Government Resolution No. 1603-N of 15 November 2010 "On the Approval of the Rules of GMP of medicines".
2. Armenian Government Resolution No. 734-N of 26 May 2011 On the Approval of the Schedule for the Implementation of the Rules for the GMP of Medicines in the Republic of Armenia for the Implementation of Reforms in the Field of Circulation of Medicines".
3. Ministry of Health of Armenia Order No. 1069-A of 2 June 2011 On the Establishment of an Expert Department of Good manufacturing practice, Good Distribution Practice as Part of the Scientific Centre of Drug and Medical Technology Expertise".
4. Ministry of Health of Armenia Order No. 1324-A of 8 July 2011 "On the Approval of an Application for Membership in Relevant International Organisations (World Health Organisation Certificate of pharmaceutical product, Scheme of cooperation of pharmaceutical inspections, etc.)."
5. Ministry of Health of Armenia Order No. 1325-A of 8 July 2011 "On the Approval of the Programme and the List of Necessary Regulations of the Quality Management System (standard operating procedures, template, designation of responsible person for the quality, etc.) of the GMP/GMP Expert Department of the Scientific Centre of Drug and Medical Technology Expertise of the Ministry of Health of Armenia.
6. Ministry of Health of Armenia Order No. 2237-A of 15 November 2011 "On the Approval of the Inspection Procedure and Inspection Report Substances".
7. Ministry of Health of Armenia Order No. 2283-A of 22 November 2011 On the Approval of the List of Standard Procedures and Guidelines for the Implementation of a Quality Management System Required for the Activities of the GMP/GMP Examination Department of Medicines and Medical Technology Examination Centre of the Ministry of Health of the Republic of Armenia".
8. Ministry of Health of Armenia Order No. 303-A of 24 February 2012 On the Procedure for Termination (Recall) of Circulation of Medicines, ther Medical Products, Biologically Active Food Additives (Recall) in Armenia and n the Notification of Recall Alarm andonfirmation of Recall of Information."
9. Ministry of Health of Armenia Order No. 5-N of 7 February 2012 "On the Amendments to the Ministry of Health of Armenia Order No. 123-N of 7 February 2006."
10. Ministry of Health of Armenia Order No. 1395-A of 15 June 2012 "On Cooperation, Information Exchange and Joint Monitoring of International Organisations of the Centre for Expertise of Medicines and Medical Technologies".
11. Armenian Government Resolution No. 1239-N of 20 September 2012 "On Amendments and Additions to Armenian Government Resolution No. 867 of 29 June 2002".
12. Armenian Government Decision No. 1089-N of 26 September 2013 "On the Approval of the Procedure for Monitoring Compliance with the Rules of Good Manufacturing Practice and Issuance of a Certificate of GMP in Armenia".
13. Ministry of Health of Armenia Order No. 18-N of 20 May 2013 "On the Approval of the Procedure for the Collection and Destruction of Products that do not Correspond to the Quality of Medicines Established by the Legislation of Armenia in the Manufacturing of Medicines".
14. Ministry of Health of Armenia Order No. 189-A of 6 February 2014 "On the Approval of the Maximum Amount of Payment for Monitoring Compliance of the Production of Medicines and Medicinal Products in Armenia with the rules of GMP".

15. Ministry of Health of Armenia Order No. 1613-A 8 July 2014 On the Approval of Requirements on GMP Specialists in Armenia, including qualifications and training".
16. Ministry of Health of Armenia Order No. 24-N of 17 May 2017 "On the Approval of the GMP Rules".
17. Ministry of Health of Armenia Order No. 32-N of 14 June 2017 On the Approval of the GMP Rules".
18. Ministry of Health of Armenia Order No. 28-N 7 June 2017 "On Determining the Requirements on Qualified Individuals Engaged in the Production of Medicines".
19. Armenian Government Resolution No. 105-N of 8 February 2018 "On Amendments to Armenian Government Resolution No. 867 of 29 June 2002".
20. Armenian Government Resolution No. 166-N of 28 February 2019 "On the Establishment of Fees for Conducting Examinations for the State Regulation of the Circulation of Medicines".
21. Armenian Government Resolution No. 162-N of 28 February 2019 "On Adopting the Rules on the State Registration, Re-registration and Extension of the Term of Medical Product Certificates, as well as on the Refusal to Register, Re-register or Extend the Term of the Certificate, the Suspension of Registration or Withdrawal Thereof, the Rules for Carrying Out Assessments for These Purposes, as well as the Rules on the Submission and Assessment of Post-registration Changes, the List of Required Documents, the List of Changes to Registered Medicinal Products that do not Require New Registration, the Rules on the Inspection and Recognition of Inspection Reports Issued by the Competent Authorities of Other Countries and in Armenia, and on Repealing Armenian Government Decree No. 347 of 25 April 2001".
22. Armenian Government Resolution No. 199-N of 28 February2019 "On Adopting the Rules of Compliance Inspection with the Requirements of Good Manufacturing Practice of Medicinal Products and Pharmaceutical Substances, the Issuance of Good Manufacturing Practice Certificates, Assessment Rules for the Purpose of Licensing the Manufacturing of Medicinal Products and the List of Necessary Documents, as well as On the of Armenian Government Decree No. 1603-N of 25 November2010 and Armenian Government Decree No. 1089-N of 23 September 2013".
23. Armenian Government Resolution No. 202-N of 28 February 2019 "On Adopting the Rules on the Importation to Armenia and exportation from Armenia of Medicinal Products, Active Substances, Herbal Substances and Investigational Medicinal Products, the Rules on the Assessment for the Purpose of Importation and Exportation and the List of Necessary Documents, as well as On the Repeal of Armenian Government Decree No. 581 of 20 September 2000".
24. Armenian Government Resolution No. 164-N of 28 February 2019 "On Adopting Procedures in Armenia Related to the Rapid Alert, Termination of Circulation and Recall of Nonregistered, Non-conforming, Expired, De-registered or Suspended Medicinal Products, Counterfeit Medicinal Products, Active Substance, Herbal Substances, Investigational Medicinal Products and Medicinal Products imported in violation of Armenian legislation."
25. Armenian Government Resolution No. 156-N of 28 February 2019 "On Adopting the Rules of Inspection in the Scope of Distributor Certification and Issuance Good Distribution Practice Certificates, the Assessment Rule for the Purpose of Licensing Wholesale Medicinal Products and the List of Necessary Documents in Armenia".
26. Armenian Government Resolution No. 150-N of 28 February 2019 "On the Designation of a Body Responsible for the Organisation of Assessments and Inspections for the State Regulation of the Circulation of Medicinal Products.
27. Ministry of Health of Armenia Order No. 01-N of 16 January 2020 "On Determining the Requirements for the Person Responsible for GMP".

Annex 8

The legislative framework for conducting clinical trials in Armenia

1. Law of the Republic of Armenia of 17 May 2016 "On Medicines"
2. Armenian Government Resolution No. 168-N of 28 February 2019 "On the Approval of the Procedure for Issuing a Permit for Conducting Clinical trials, the Procedure for Conducting an Examination for this Purpose and the List of Necessary Documents and On the Annulment of Armenian Government Resolution No. 63 of 24 January 2002."
3. Rules of Good Clinical Practice of the Eurasian Economic Union" (Good Clinical Practice; GCP) approved by Eurasian Economic Commission Council Decision No. 79 of 3 November 2016.**i**

Annex 9

The legislative framework for conducting pharmacovigilance in Armenia

1. Law of the Republic of Armenia "On Medicines"
2. "Rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union (Good pharmacovigilance practices, GVP)" approved by Eurasian Economic Commission Council Decision No. 87 of 3 November 2016.

Annex 10

Recommendations for legal and institutional reforms provided by the Association of Manufacturers of Pharmaceuticals of Armenia

1. Co-financing of expenses for registration of medicines and medical devices (items and equipment) of Armenian production abroad

   Co-financing the costs of registration of Armenian-made medicines 50/50 is the main instrument of state support for export promotion, taking into account the results of previous experience and thereby anticipating further export growth rates promotion

   .In 2013-2016, pharmaceutical companies received 50% of the co-financing of the costs of registering Armenian-made medicines abroad within the framework of co-financing programs from the sector Development Fund, as a result of which Armenian-made medicines were registered in *Georgia, Uzbekistan, Kyrgyzstan, Tajikistan, Belarus, Ukraine, Moldova, Yemen, Iraq, Vietnam, and Kuwait.*

2. Co-financing of the costs of registration of medicines of strategic importance (intended for the treatment of widespread diseases)

   At the same time, pharmaceutical companies will register medicines at new, higher tariffs (*see Appendix No. 1 to the Decision of the Government of the Republic of Armenia No. 166-N*). In this sense, a possible instrument of state support may be co-financing the costs of registration of medicines of strategic importance (provided for the treatment of widespread diseases), which will enable the manufacturer to ***register new medicines of strategic importance,*** expanding its range, thereby contributing to ensuring drug self-sufficiency.

   Addendum: Currently, within the framework of the working group on the efficiency policy of the EAEU, discussions are being completed on the approval of the list of medicines of strategic importance, which will be followed by appropriate additions in the legislative acts of the member states.

3. Co-financing of the costs of registration of medicines produced to meet the needs of the domestic market

   From July 1, 2021, after the transition to the unified procedure for drug registrations of the EAEU, domestic manufacturers undertake to register medicines in higher values than before.

   According to Annex 1 to the decision of the Government of the Republic of Armenia 166-N, united registration prices have been established, according to which the first registration of the EAEU is USD 4,900, instead of the previous USD 2,481. Currently, local manufacturers are expanding their activities in the single market, which has a number of advantages, however, there are medicines produced exclusively to meet the needs of the domestic market and do not have a tendency to export, these are, for example, liquids (iodine, hydrogen peroxide, ammonia solution), alcohols, drops, powders. registration of medicines specified in accordance with the EAEU regulations at the approved new prices is extremely unprofitable for the local manufacturer, logically, that he does not plan to export them to the member states, and the sale on the domestic market at best will make it possible to cover only the costs of registration., However, if these costs are also not covered by the manufacturer, the manufacturer will simply stop producing them, which will cause large volumes of imports.

   In connection with the above, we propose to subsidize 50% of the registration costs in accordance with the Uniform Rules of those medicines that are produced exclusively to meet the needs of the domestic market.

4. Co-financing 50% of companies' expenses for participation in international forums, exhibitions

   Forums and exhibitions promote both the exchange of experience, the establishment of a new partnership, and the expansion of export routes. As you know, the exhibition of pharmaceuticals and biotechnologies "IPhEB Russia 2021" was held in St. Petersburg from April 14 to April 16 this year. The grand opening of the exhibition was carried out by the Union of Manufacturers of Medicines of Armenia. Representatives of domestic pharmaceutical companies received visitors during the exhibition, familiarized themselves with the range of products, held meetings with colleagues, and reached agreements. An agreement was reached between the Union of Manufacturers of Medicines of the Republic of Armenia and the Armenian Medical Union of St. Petersburg on further cooperation within the framework of educational programs.

5. Co-financing of professional training in Armenia and abroad

   Between the company "Liqvor" and YSMU, the Institute of Pharmacy of YSU signed memorandums of cooperation this year. Within the framework of cooperation, students of the Faculty of Pharmacy of YSMU, the Institute of Pharmacy of YSU will undergo practical training, study the features of proper production and laboratory activities (GMP, GLP) and get acquainted with the process of organising production.

   The company has also established scholarships and a tuition compensation program for students of the Faculty of Pharmacy of YSMU, the Institute of Pharmacy of YSU with the highest academic performance. Azad Pharmaceuticals R&D Company in order to expand the laboratory, began to implement an annual retraining program for undergraduate and graduate students of organic chemistry, biology and related specialties who are motivated to engage in science. During the period of retraining, participants will receive a salary of USD 298 and upon completion they will be accepted into the laboratory of the main work. As part of the implementation of the program, the company has started cooperation with the Armenian-Russian University. Similar educational programs are also carried out by the company “Arpimed”. In the near future, the member companies of the Union of Manufacturers of Medicines of the Republic of Armenia within the framework of the Union are also planning cooperation with the International University of Eurasia within the framework of a new master's educational program, professional retraining. The noted cooperation aims not only to transfer theoretical knowledge to students, but also to give them the opportunity to gain experience in workshops, as a result, university graduates gain sufficient experience and have the opportunity to start working in pharmaceutical companies after graduation. In addition, the knowledge of specialists of pharmaceutical companies will be continuously re-equipped in accordance with the rapidly developing pace of science and technology. The Union previously had similar experience, having held a lecture with the participation of Dmitry Rozhdestvensky, Head of the Department of Regulation and Accreditation of the Circulation of Medicines and Medical Products of the Department of Technical Regulation and Accreditation of the EEC -bioequivalence and therefore, we propose to include in the development program of the sphere also a tool for co-financing professional retraining, providing financial assistance to the lectures of teachers invited from abroad in the Republic of Armenia, as well as the retraining of specialists sent abroad.

6. Co-financing of clinical trials of innovative products in Armenia

   Co-financing of clinical trials of innovative products in Armenia, easing the financial burden of manufacturers will enable the latter to start implementing the national innovation system in drug production.

   The Republic of Armenia belongs to developing countries, but it has the potential to develop innovative opportunities, and if the existing problems in the sphere are solved, it can achieve great success in the innovation sphere.

Innovative activity and innovative technologies are the main driving force of economic prosperity in the modern world. They not only provide an opportunity to improve the standard of living of the population, solve health and social problems, but also are the most important foundation of the geopolitical, military and economic power and independence of countries.

7. Co-financing of bioequivalence research in RA

Bioequivalence of the drug - determination of the degree of similarity of drugs by comparing the strength, size, speed and other factors of absorption of drugs containing the same dose.
The determination of bioequivalence involves a thorough study of two drugs: the standard and the researcher, pharmacokinetic parameters in vivo and their further comparison.
Currently, bioequivalence studies are conducted from the EAEU member states in Russia, Belarus and Kazakhstan, and in the Caucasus region Armenia is the only one who initiated bioequivalence studies so far. Taking into account the obligation to conduct bioequivalence studies of generics all over the world, pharmaceutical companies operating in Armenia are currently forced to conduct these studies abroad, having paid huge sums for it, having signed up for a queue several years ago.

Starting this year, bioequivalence studies for the registration of new medicines according to uniform rules should be conducted on the territory of the EAEU. This means that this process will require not only medicines produced on the territory of the EAEU, but also all generics that must be imported from third countries.
In each Member State, there is also no need to conduct a double bioequivalence examination, since the results of the examination of the Member states are mutually accepted and recognized throughout the Union.

Conducting bioequivalence research can have serious economic successes, in particular, as a result of the start of the process, internal financial resources will not be directed outside the country, but will remain inside the country and not only, since there will be an influx of financial resources from abroad, given the limited opportunities for conducting such research in the region, flexible pricing policy and incomparably lower values in the RA.
As a possible support tool, we propose to provide indirect co-financing, subsidizing 50% of the expenses of pharmaceutical companies operating in Armenia when conducting bioequivalence studies in the research complex of the Tonus-les company.

8. Provision of financial assistance in the production of generic (reproduced) medicines on its basis after the expiration of the patent period of patent medicines

Locally produced medicines account for 16% of the domestic market of medicines, this is the greatest threat to the country's economy, life and health of people, which manifested itself under martial law and continues to manifest itself during the state of emergency. In a state of war and emergency, when some people find it difficult or even impossible to import medicines, the problem of providing medicines leads to the collapse of the healthcare system. Therefore, in an era of challenges facing the world, and being a belligerent State, we must, if possible, ensure drug self-sufficiency within the country. The state, through possible financial instruments, should assist the local manufacturer in doubling the share of local production in the domestic market, bringing it to 50%, among which a significant number should be medicines included in the list of the main medicines of the Republic of Armenia. The main medicines that meet the requirements of the majority of the population in the field of health protection, and in any case should be in sufficient quantities, in appropriate dosage forms and doses.

Annex 11

Full list of countries for evaluation of socio-economic impact

Table 17: clinical trials

High income	Japan, Korea, Australia, Singapore, New Zealand, Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, Chile, Uruguay, Israel, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, United States, Canada
Upper middle income	Armenia, China, Thailand, Malaysia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Georgia, Kazakhstan, North Macedonia, Romania, Russia, Serbia, Turkey, Argentina, Brazil, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Mexico, Panama, Paraguay, Peru, Iraq, Jordan, Lebanon, South Africa
Lower middle income	Indonesia, Philippines, Viet Nam, Myanmar, Cambodia, Ukraine, Uzbekistan, El Salvador, Honduras, Algeria, Egypt, Morocco, Tunisia, India, Pakistan, Bangladesh, Sri Lanka, Angola, Cameroon, Cote d'Ivoire, Ghana, Kenya, Nigeria
Low income	Ethiopia, Uganda

Table 18: generics

High income	Austria, Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom
Upper middle income	Armenia, Azerbaijan, Belarus, Bulgaria, Kazakhstan, Romania, Russia, Serbia, Turkey
Lower middle income	Ukraine

Table 19: R&D

High income	Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom
Upper middle income	Bulgaria, Romania, Turkey

Table 20: API

High income	Japan, Korea, Norway, Switzerland, United Kingdom, Saudi Arabia, United States
Upper middle income	China, Russia, Brazil, Turkey
Lower middle income	India

Table 21: CROs

High income	Japan, Korea, Australia, Singapore, New Zealand, Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, Chile, Uruguay, Saudi Arabia, United Arab Emirates, United States, Canada
Upper middle income	China, Thailand, Malaysia, Belarus, Bosnia and Herzegovina, Bulgaria, Georgia, Kazakhstan, North Macedonia, Romania, Russia, Serbia, Turkey, Argentina, Brazil, Colombia, Costa Rica, Guatemala, Mexico, Peru, Lebanon
Lower middle income	Indonesia, Philippines, Viet Nam, Ukraine, Egypt, Morocco, India, Pakistan, Bangladesh, Sri Lanka, Ghana, Kenya

Annex 12

Potential investors profiles

Nº	Name	Type of organisation (investment fund, sovereign fund)	Sub-sector / segment	Investment location	Rational	Relevant qualifying information	Type of investment (The strategy should make clear distinctions in typology between market-seeking, efficiency-seeking, and resource-seeking FDI to be targeted)	Contact details
1	**AbbVie:** • US • Netherlands • UK • Italy	Venture fund	Research & Development Clinical trial (in priority) CRO (Contract research organisation) API Raw material	US, Europe	The company invests in transformational scientific opportunities aligned with core R&D interests to gain access to next-generation science and build relationships with proven and emerging scientific leaders	The company focuses on novel, transformational therapeutics at discovery and pre-clinical stages. Aligning with AbbVie's strategic focus, investments address critical needs in oncology, immunology, and neuroscience. AbbVie's vast internal network of experts in all phases of drug development, from drug discovery through successful commercialization. The company portfolio is comprised of over 20 companies based in the US and Europe	Resource-seeking FDI	Website: https://www.abbvie.com/partnerships/abbvie-ventures.html

2	**AbbVie:** • US • Netherlands • UK • Italy	Venture fund	Research & Development Clinical trial (in priority) CRO (Contract research organisation) API Raw material	US, Europe	The company invests in transformational scientific opportunities aligned with core R&D interests to gain access to next-generation science and build relationships with proven and emerging scientific leaders	USD 11.1B 2020 investment in R&D >350 Clinical Trials in over 20 tumour types: The Global Experts Centres Initiative is a research platform launched by Bristol Myers Squibb to accelerate oncology drug Development 350 investigators - 250 research projects: The II-ON (International Immuno-Oncology Network) is a global peer-to-peer collaboration between Bristol Myers Squibband academia that aims to advance cancer research and translational medicine	Efficiency-seeking FDI	Website: https://www.bms.com/assets/bms/us/en-us/pdf/global-access-report.pdf

3	**Amgen Inc.:** • ! US in focus • China (WuXiNextCode)	Venture fund	Research & Development (in priority) Clinical trial CMO	US, Europe	The company takes a long-term approach, deploying the full capabilities of the Johnson & Johnson family of companies, including discovery, clinical development, regulatory affairs, manufacturing and commercialization. The team includes leaders in the healthcare and technology communities, many with deep R&D experience. This gives the company the ability to understand our partners and provide the help they need.	The company invests across sectors—pharmaceuticals, medical devices and consumer healthcare—and at all stages, from seed-level startups to Series B and beyond USD 11bn 2019 investment in Pharmaceutical, Medical Devices and Consumer businesses	Efficiency-seeking FDI	Website: https://jnjinnovation.com/jjdc https://www.investor.jnj.com/annual-meeting-materials/2019-annual-report
4	**Pfizer:** • ! US focused primarily • Canada • EU • Japan (no data) • China (HD BIOSCIENCES) • South Korea (no data) • ! Russia (no further investment) • Israel • Lebanon (M2S)	Venture fund	Research & Development Clinical trial (in priority) API	US, Europe	The company takes a long-term approach, deploying the full capabilities of the Johnson & Johnson family of companies, including discovery, clinical development, regulatory affairs, manufacturing and commercialization. The team includes leaders in the healthcare and technology communities, many with deep R&D experience. This gives the company the ability to understand our partners and provide the help they need.	The company invests across sectors—pharmaceuticals, medical devices and consumer healthcare—and at all stages, from seed-level startups to Series B and beyond USD 11bn 2019 investment in Pharmaceutical, Medical Devices and Consumer businesses	Efficiency-seeking FDI	Website: https://jnjinnovation.com/jjdc https://www.investor.jnj.com/annual-meeting-materials/2019-annual-report

5	**Johnson & Johnson:** • US • Belgium • Brazil • China (no data) • France • Germany • India • Israel • Netherlands • Poland • Singapore • Sweden • Switzerland • UK	Investment fund	Research & Development Clinical trial API CMO (Contract manufacturing organisation)	US (in focus) Asia-Pacific region	Amgen can provide innovators access to deep expertise and strategic insights including: • Technical expertise across multiple therapeutic modalities • Strong biological and translational research • Extensive experience conducting large-scale clinical trials • Expertise in biologics manufacturing and drug delivery • Commercial infrastructure to market medicines globally Amgen seeks opportunities that match our strategy and expand our capabilities in oncology, immuno-oncology, cardiovascular, inammation, bone health, nephrology, metabolic disorders, and neuroscience. Technologies include discovery research, digital health, health IT and drug delivery. Amgen support innovation and build relationships in areas of great future promise complementing our strategic interest and supporting our therapeutic pipeline.	Amgen investments include therapeutics and technologies to support R&D and digital health / healthcare IT. Amgen invests in early and late stage companies including seed stage investments. Amgen typical size of investment is ~USD 5m with up to ~USD 15m reserved for the life of the company	Resource-seeking FDI Market-seeking FDI	Website: https://www.amgen.com/~/media/Themes/CorporateAffairs/amgen-com/amgen-com/downloads/amgen-ventures-overview.pdf

6	**Bayer:** • ! US and China are in focus • US • Canada • Germany • Israel • UK • China (no data)	Investment fund	Research & Development Clinical trial Raw Material Generic	US and China are in focus US (52%) EMEA (24%) Asia-Pacific (9%) China (8%) Japan (7%)	The company partners mostly in the field of biotech (and mostly in US and China)	The company is targeting to Significantly Expand our Presence in Select Areas of Oncology where One Blockbuster can Build a Franchise	Resource-seeking FDI	Website: https://www.bayer.com/sites/default/files/2021-10/Bayer%20AG%20-%20Investor%20Overview%20-%20October%202021.pdf https://leaps.bayer.com/companies
7	**Novartis:** • US • Canada • Israel • UK • Switzerland • Germany • Finland • France	Investment fund	Research & Development Clinical trial (in priority) API	US Europe Israel	Company primary focus is on the development of novel therapeutics and platforms. In our investments we look for unmet need and clinical impact, novel proprietary science and understanding of mechanism, management and board experience and capital efficiency in the program	The company invests in North America, Europe and Israel with approximately USD 750m under management in committed capital and more than 24 portfolio companies. We continue our strategy of making larger focused investments and anticipate total investments up to USD 30m per company over its life. The company makes equity investments in Biotechnology/Biopharma life sciences companies. Novartis Venture Fund is stage agnostic and engages in seed investments as well as later-stage investments. We typically lead or co-lead an investment and play an active role on company boards.	Efficiency-seeking FDI Resource-seeking FDI	Website: https://www.nvfund.com/#OurFund

8	**Fund Tinkoff NASDAQ Biotech:** • US • UK • Germany • Ireland • Netherlands • China (BeiGene Ltd) • Australia • Sweden • France • Denmark • Belgium	Investment fund	Research & Development	US (86%) Europe (8%) Other countries (6%)	A dollar exchange-traded fund that invests in shares of 268 pharmaceutical and biotech companies from the US and other countries. The fund fully replicates the NASDAQ Biotechnology Total Return Index to track the total value of pharmaceutical and biotechnology stocks listed on the NASDAQ exchange.	Shares of 268 biotech companies with a market capitalization of at least USD 200m and an average daily trading volume of at least 100,000 shares.	Market-seeking FDI, Efficiency-seeking FDI	Website: https://www.tinkoff.ru/invest/analytics/capital/nasdaq-biotech/
9	**Sber - Biotechnology:** • US • Ireland • Germany	Investment fund	Research & Development	US Europe	The fund invests in shares of the foreign investment fund iShares Nasdaq Biotechnology ETF.	Structure by sectors: 76.6% - biotechnology 19.3% - biological sciences 2.3% - other 1.9% - pharmaceutical companies	Efficiency-seeking FDI, Market-seeking FDI	Website: https://www.sber-am.ru/individuals/fund/opif-fondov-sberbank-biotekhnologii/
10	**Fund VEB Ventures:** • Russia (Mircod) • India (Plan)	Investment fund	Research & Development MedTech BioTech	Russia India	The company of the VEB.RF Group is created to support high-tech projects through direct transactions and venture fund management. Among the priorities of VEB Ventures is the financing of companies through own funds, funds from private and state funds, as well as assistance to Russian start-ups in entering international markets.	VEB Ventures venture market helps venture market participants in the field of development institutions, technology entrepreneurs, investors, as well as other players - banks, corporations of various levels. VEB Ventures focuses on expert support of Russian business entering the international market.	Resource-seeking FDI, Efficiency-seeking FDI	Website: https://veb.ventures/ru/about/mission

11	**International Fund SOSV:** • US • Canada • Ireland • India • Argentina • UK • Ireland • Singapore (Vertical Oceans)	Venture fund	Research & Development Clinical trial	US Europe Latin America South Asia	SOSV is a global venture capital firm providing multi-stage investment to develop and scale our founders' big ideas for positive change. We invest in 150 companies every year through category-leading startup development programs. The company programs provide startups with seed capital, a specialised global staff of engineers, designers, and scientists to accelerate product development, mentors with deep market and technical expertise, and an unparalleled infrastructure of fully outfitted laboratory and maker spaces.	IndieBio is the leading startup development program for Life Sciences, devoted to funding and building startups dedicated toward solving humanity's most pressing problems with life itself.	Market-seeking FDI Resource-seeking FDI	Website: https://sosv.com/programs/
12	**Roche:** • US • UK • Latvia • Mexico • Switzerland • France • Spain • Denmark	Venture fund	Clinical trial	US Mexico Europe	The Roche Venture Fund invests to develop commercially successful innovative life science companies. The corporate venture fund of Roche, a global leader in bringing medicines and in vitro diagnostics to the benefit of patients.	A USD 799m evergreen fund. Invest in life science companies in pharmaceuticals, diagnostics and digital health. Focus on financial returns.	A USD 799m evergreen fund. Invest in life science companies in pharmaceuticals, diagnostics and digital health. Focus on financial returns.	https://www.roche.com/venturefund/

13	**Eli Lilly:** • US • UK • Australia	Venture fund	Research & Development Clinical trial	US Europe Asia-Pacific	Lilly Ventures is the venture capital firm responsible for life science investing in North America and Europe. Its primary goal is to facilitate the success of companies in its areas of focus through early to expansion stage investments and value-adding resources. Lilly Ventures currently has USD 200m under management and focuses on three major areas of interest. It partners actively with the management teams of its portfolio companies to realise the potential of their technologies.	Lilly Ventures has made 70 investments. Their most recent investment was on Oct 5, 2021, when IpiNovyx Bio raised USD 10M. Lilly Ventures has made 6 diversity investments. Their most recent diversity investment was on Dec 1, 2015, when Symic Biomedical raised USD 25m. 19 lead investments currently	Efficiency-seeking FDI	Website: https://investor.lilly.com/ https://www.crunchbase.com/organization/lilly-ventures/recent_investments

14	**Merck:** • US • Switzerland • Germany • France • Finland • UK	Venture fund	Research & Development API	US Europe	The fund has the mandate to invest in four focus areas: Healthcare, Life Sciences, Electronics and Frontier Tech and Sustainability, in alignment with the strategic interests of Merck KGaA, Darmstadt, Germany's business areas. The M Ventures Biotechnology team executes and manages investments across a broad range of Healthcare and Life Sciences opportunities.	In Healthcare, the company focuses on investments in emerging biotechnology companies that aim to develop differentiated products, platforms, modalities and/or technologies that have the potential to significantly improve patient outcomes. In Life Sciences, the company is instrumental in building world class Life Science companies that develop tools, technologies and/or services that have the potential to make academic and industrial research, chemical/biotech manufacturing or other biotechnology applications. The M Ventures Technology team executes and manages investments across a broad range of Electronics, Frontier Technology and Sustainability focused opportunities.	Efficiency-seeking FDI Resource-seeking FDI	Website:https://www.m-ventures.com/us

15	**Novo Nordisk:** • US • Switzerland • UK • Netherlands • Austria • Singapore (Hummingbird) • Indonesia (Halodoc)	Venture fund	Research & Development API	US Europe Asia-Pacific	The company strives to invest in companies that develop innovative drugs, medical devices and diagnostics. Novo Ventures executed 79 investments in 2020 and among its exits were 9 initial public offerings (IPOs). By the end of 2020, the Novo Ventures Investment Portfolio included 68 companies.	The company primarily invests in biotechnology and medical technology. Within biotech NN primarily invests in companies with clinical stage compounds. In medtech - in commercial stage companies.	Efficiency-seeking FDI	https://www.novoholdings.dk/investments/ventures/
16	**Ironwood Pharmaceuticals Inc.:** • US (with AbbVie) • Canada (with AbbVie) • Mexico (with AbbVie) • Ireland (with AbbVie) • UK (with AbbVie) • China (with AstraZeneca) (LINZESS)) • Hong Kong (with AstraZeneca) (LINZESS)) • Japan (with AstraZeneca) (LINZESS))	Investment fund	Clinical trial	US Europe Asia-Pacific	Ironwood is focused on delivering differentiated medicines to patients with GI diseases and generating returns for shareholders.	Ironwood Pharmaceuticals has raised a total of USD 634m in funding over 10 rounds. Their latest funding was raised on Sep 26, 2016	Efficiency-seeking FDI	Website: https://investor.ironwoodpharma.com/home/default.aspx https://www.crunchbase.com/organization/ironwood-pharmaceuticals/company_financials

17	**Dynavax Technologies Corp.:** • France • UK • India (Biological E Ltd) • China (Clover Biopharmaceuti-cals) • Taiwan (Medigen Vaccine Biologics Corporation)	Investment fund	Research & Development Clinical trial	Europe Asia-Pacific	Dynavax is a commercial stage biopharmaceutical company built on the foundation of experience and expertise in vaccine development and commercialization.	Dynavax Technologies has raised a total of USD 1bn in funding over 15 rounds. Their latest funding was raised on May 11, 2021	Efficiency-seeking FDI Resource-seeking FDI	Website: https://investors.dynavax.com/static-files/6e046557-2a31-4635-bd67-7 99c74e594b1 https://investors.dynavax.com/ https://www.crunchbase.com/organization/dynavax-technologies/company_financials
18	**Novavax:** • Czech Republic (Novavax CZ) • India (Serum Institute) • South Korea (SK bioscience) • Japan (Takeda) • Spain • Canada • Poland • Sweden • Denmark	Investment fund	Research & Development Clinical trial	Europe Asia-Pacific	Novavax, Inc. is a clinical-stage vaccine company committed to delivering products to prevent a broad range of infectious diseases. The company's nanoparticles and technology are the foundation for innovation that improves global health through safe and effective vaccines.	Main products for the attention of potential investors: Primary Vaccination Booster Vaccination Pediatric Vaccination Omicron Variant Vaccine Novavax has raised a total of USD 2.4bn in funding over 7 rounds. Their latest funding was raised on Jul 7, 2020.	Efficiency-seeking FDI Market-seeking FDI	Website: https://ir.novavax.com/ https://www.novavax.com/sites/default/files/2022-02/NVAX-Corporate-Investor-Deck_Jan2022.pdf

19	**GlaxoSmithKline PLC (GSK):** • US • China (Shingrix)	Investment fund	Research & Development Clinical trial	US Europe (?) Asia-Pacific	IGSK is a science-led healthcare company that aims to deliver growth and improving returns to shareholders through the development of innovative pharmaceutical, vaccine and consumer healthcare products	The company plans to increase targeted investment in R&D, to build on and invest behind our top line momentum for key growth drivers and to deliver the demerger of Consumer Healthcare business in mid-year. Vaccines sales are expected to grow at a low teens percentage at CER for the year as a whole.	Efficiency-seeking FDI Resource-seeking FDI	Website: https://www.gsk.com/en-gb/investors/ https://www.gsk.com/media/7050/gsk-investor-update_23-06-21.pdf
20	**Sanofi SA:** • US • Netherlands • Denmark • UK	Venture fund	Research & Development Clinical trial API	US Europe	Sanofi ventures are investors in top tier biotherapeutic and digital health entrepreneurs. The company partners with management on their boards and makes equity investments.	The company provides a low-cost, self-sustaining vehicle enabling parent companies to engage with the early stage innovation ecosystem when companies are too risky or early to in-licence or acquire.	Efficiency-seeking FDI Resource-seeking FDI Market-Seeking FDI	Website: https://www.sanofiventures.com/

21	**Takeda Pharmaceutical Co. Ltd.:** • US • Canada • Belgium • Japan (Seed Supply; ReboRNA; Noile-Immune Biotech; GENVaxUSD Gen Ahead Bio; FIMECS; Chordia Therapeutics; ARTham) • Israel • Spain • UK • Netherlands • France • Australia	Investment fund Venture fund	Research & Development	US Canada Europe Asia-Pacific	Takeda Ventures focuses on high-calibre therapeutic and platform based opportunities around the world. The company invests in early-stage opportunities that complement Takeda's pipeline and products.	The mission of the company is to create strategic growth opportunities by investing and nurturing Innovative Life Science Companies in areas aligned with Takeda's R&D focuses which include; Oncology, Gastroenterology, Neuroscience, and Rare Disease. The aim is to access and support therapeutic and platform innovation working closely with academic innovators, entrepreneurs and investors. The company invests in seeds or syndicated venture investing providing to the companies access to the resources of a multinational pharmaceutical company.	Efficiency-seeking FDI Market-seeking FDI	Website: https://www.takeda.com/investors/ https://www.takeda.com/what-we-do/research-and-development/takeda-ventures/
22	**Pharma Mar:** • US • EU • Japan (Mondelis, Zepzelca, Aplidin)	Venture fund	Research & Development	Europe (in priority) US Japan	PharmaMar is a fully integrated Spanish biotech/pharmaceutical. The company takes its inspiration for discovery of oncology medicines from the sea. The company does basic research to identify drug candidates, conduct pre-clinical work, and clinical trials.	Main approach to investors and shareholders: the company is transparent in communications, accommodates investor and shareholder requests, releases material news on a timely and equitable basis, and is proactive in reaching out when there are situations that require context.	Resource-seeking FDI Market-seeking FDI	Website: https://pharmamar.com/en/investors/

23	**Moderna Inc.:** • Italy • France • Germany • Spain • UK • Switzerland	Investment fund	Research & Development Clinical trial	US Europe	Moderna's mission is to deliver on the promise of messenger ribonucleic acid (mRNA) science to create a new generation of transformative medicines for patients. The company platform plays an important role in supporting a rapid response to the global pandemic, and our Covid-19 Vaccine is now authorised for use in more than 35 countries.	Moderna's corporate responsibility strategy considers the needs and priorities of our key stakeholders and the five focus areas where we can have a positive impact today and in the future. Moderna increased its 2022 signed advance purchase agreements to approximately USD 19bn, with additional signed options of approximately USD 3bn; numerous discussions ongoing with governments for the fall of 2022 and 2023. Company now has 44 programs in development.	Market-seeking FDI	Website: https://s29.q4cdn.com/745959723/files/doc_news/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates-2022.pdf https://investors.modernatx.com/overview/default.aspx
24	**BioNTech SE:** • US • Canada • Germany • UK • Switzerland	Investment fund	Research & Development Clinical trial API	US, Canada Europe	The company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of biopharmaceuticals. The company offers diagnostic products and drug discovery services for other therapeutic areas, including infectious diseases, allergies and autoimmune disorders	BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.	Efficiency-seeking FDI	Website: https://investors.biontech.de/

25	**Abbott Laboratories:** • US • Canada • EU • India (CFR Pharmaceuticals) • Russia (Veropharm) • Chilie (CFR Pharmaceuticals) • Mexico (Grupo Casa Saba) • Brazilia (Hypermarcas)	Investment fund	Research & Development Clinical trial API Generic	US, Canada Europe Latin America Asia-Pacific	The company is creating the future of healthcare through life-changing technologies (cardiovascular care, diabetes care etc.), products, diagnostics, nutrition products and branded generic medicines. Abbott is poised to deliver top-tier growth, expanding margins, strong cash flow and increasing returns to shareholders.	100% focused on emerging markets: Leading positions in India, Russia and Latin America Strategic priorities: • Strengthening local presence and capabilities • Market-specific innovation • Building locally-relevant portfolios in key therapeutic areas	Resource-seeking FDI Market-seeking FDI Efficiency-seeking FDI	Website: https://www.abbott.com/investors.html https://dam.abbott.com/en-us/documents/pdfs/investors/our-strategy/2016_Abbott_Overview.pdf
26	**Novus Capital:** • US (with Torreya Partners) (no data) • UK (with Torreya Partners) (no data) • Bulgaria (with Mane Capital) (no data) • India (with Torreya Partners) (no data) • CIS countries (with Baltic Partners) (no data) • Baltic States (with Baltic Partners) (no data) • Russia (Geropharm; DIALAB; ASNA GROUP; Salvim LLC; Active Component; Materia Medica; Akvion; Diod; ALSI Pharma; Unipharm)	Investment fund (M&A transactions)	Pharmaceutical industry (M&A)	US Europe	Novus Capital specialises in M&A transactions for mid-cap companies specialised in pharmaceutical and technology sectors as well as work in media, logistics and fast moving consumer goods (FMCG) sectors. Novus Capital leadership team brings decades of expertise in investment, debt and equity capital markets, deal flow and relationships.	Investment criteria: Enterprise Value of USD 500m to USD 1.5bn Consideration of ESG Factors Operating Stability with Significant Growth Potential Leadership Position in its Industry Unrealized Potential for Shareholder Value Creation Has the Potential to Grow Through Further Acquisition Opportunities Innovate Within an Existing Market Has a Committed and Capable Management Team	Efficiency-seeking FDI Market-seeking FDI	Website: http://www.novuscapital.ru

27	**Rothschild & Co (HRA pharma):** • US • EU	Private equity fund	Research & Development Clinical trial	US Europe	HRA Pharma is an innovative OTC pharma company with leading positions in Europe and in the US. HRA Pharma is a European leader in emergency contraception.	HRA Pharma also acquired several category-leading products, in particular two global leaders: Compeed, the leading blister treatment products and Mederma, the US category-leading scar-care treatment. HRA Pharma also holds a strong and successful global franchise in the therapeutic area of rare endocrine diseases, with a particular focus on Cushing syndrome.	Market-seeking FDI	https://www.hra-pharma.com/
28	**Russia-China Investment Fund (RCIF):** • UK • Russia (no data) • China (Biren Technology; Changyang Technology)	Private equity fund	Research & Development API	Europe China Russia	The purpose of the Fund is to invest in projects on the territory of Russia and abroad, the implementation of which has an economically significant effect on the development of cooperation between the two countries. The Fund's strategic investors are large public and private corporations in China	! The priorities for the Fund are projects in the field of energy, transport infrastructure, logistics and agriculture	Market-seeking FDI	http://rcif.com/

29	**Global Emerging Markets ("GEM"):** • US • Canada • UK • Poland • Sweden • France • Israel	Investment fund	Research & Development Clinical trial API	US Europe Israe	GEM is a USD 3.4bn alternative investment group that manages a diverse set of Investment vehicles focused on emerging markets across the world. GEM acquires majority stakes in operating companies by recapitalizing balance sheets, executing management or leveraged buyouts, carving out assets, or outright acquisition of controlling shareholders' interests with equity.	GEM prefers to partner with management teams and operators and with them execute strategic plans and create value. Minority Investments Past Minority Investments Control Investments	Efficiency-seeking FDI, Market-seeking FDI	https://www.gemny.com/
30	**Russia-Japan Investment Fund (RJIF):** Russia (Evotech-Mirai Genomics; Doctis)	Investment fund	Clinical trials CPO	Russia Japan	RJIF is an investment fund that aims to generate competitive returns by investing in projects.	Priority fields: Pharma and healthcare Smart cities Ecology Energy Technology Creation of pharmaceutical industries and the participation of Japanese companies in the modernization of the Russian system of healthcare is a priority.	Market-seeking FDI	https://www.crunchbase.com/organization/russia-japan-investment-fund

31	**New Investment Holding:** Russia (Nearmedic; Binnopharm Group; Medsi; Sistema Biotech)	Investment fund	Clinical trials CPO CMO	Russia	Joint venture between Sberbank and AFK Sistema that aims to invest in medicine and pharmaceutical manufacturing.	Priority fields: Pharmaceuticals Medical centres Biotechnology	Market-seeking FDI, Efficiency-seeking FDI, Resource-seeking FDI	https://www.tadviser.ru/index.php/%D0%9A%D0%BE%D0%BC%D0%BF%D0%B0%D0%BD%D0%B8%D1%8F:%D0%9D%D0%BE%D0%B2%D1%8B%D0%B9_%D0%98%D0%BD%D0%B2%D0%B5%D1%81%D1%82%D0%B8%D1%86%D0%B8%D0%BE%D0%BD%D0%BD%D1%8B%D0%B9_%D0%A5%D0%BE%D0%BB%D0%B4%D0%B8%D0%BD%D0%B3
32	**Russian Direct Investment Fund (RDIF):** • Russia (Geropharm; R-Pharm) • India (Gland Pharma Ltd)	Sovereign fund	Research & Development Clinical trial	Russia	RDIF makes direct investments in leading and promising Russian companies together with leading investors. Sovereign investment fund with a reserved capital of USD 10bn under management.	Over the past two years, the Fund's activities have been largely focused on ensuring global epidemiological safety - fight against the new coronavirus infection in more than 70 countries around the world. In particular, RDIF is the main investor in test systems for detecting coronavirus infection, an antiviral drug, as well as in the Russian vaccines Sputnik V and Sputnik Light.	Efficiency-seeking FDI	https://rdif.ru/About/

33	**Georgia Capital LLC:** Georgia (Mega Lab; Pharmadepot; GPC)	Investment fund	Research & Development (Diagnostics laboratories)	Georgia	Georgia Capital capitalises with its robust corporate governance on the fast-growing Georgian economy across the last decade, having access to capital and management. Georgia Capital focuses on larger scale investment opportunities in Georgia.	Healthcare Services business, managed by GHG, is the largest market participant in the healthcare services industry: Hospitals segment Clinics segment Diagnostics laboratories Retail pharmacy	Efficiency-seeking FDI, Market-seeking FDI	https://georgiacapital.ge/about/ataglance
34	**Eight roads:** • US • Israel • EU • China (ABC Biomedical; BetterLife Medical; Bioregen; B-one; Nanos Medical; RedPine; Innovent; Geneseption; Senna) • India (Trivitron Healthcare; Xcyton; CyplaHealth; Eywa; Richcore) • Japan (J-Pharma; Metcela, Pormedtec)	Venture fund	Research & Development Clinical trial API	US Europe Asia-Pacific Israel	The platform provides entrepreneurs with access to a global ecosystem, to leverage and learn from.	The company has partnerships with over 300 companies and investment teams across Asia, Europe and the US..	Resource-seeking FDI Market-seeking FDI	https://eightroads.com/en/

35	**AVISTA:** • US • Canada • Belgium • Sweden • Denmark • France • Switzerland	Investment fund (firm?)	Research & Development Clinical trial API Generics	US Europe	Avista focuses on investing in and growing healthcare companies. The company industry expertise and proactive value-added investment approach.	Avista focuses on mid-sized companies concentrated in the following healthcare sub-sectors: outsourced pharma & medtech services, consumer healthcare, medical devices & technology, specialty & generic pharmaceuticals, distribution & services, and healthcare technology.	Efficiency-seeking FDI Resource-seeking FDI	https://avistacap.com/
36	**DEERFIELD:** • US • Canada • Australia • Switzerland	Investment fund (firm?)	Clinical trial API	US Europe Asia-Pacific	Deerfield works across the healthcare ecosystem, connecting people, capital, ideas, and technology.	Providing value beyond capital, Deerfield generally maintains a combined portfolio of more than 200 private and public investments across the life science, medical device, diagnostic, digital health and health service industries at all stages of evolution from start-up to mature company.	Efficiency-seeking FDI	https://deerfield.com/about-deerfield

37	**CVC Capital partners:** • US • France • Greece • UK • Finland • Italy • Spain • India (HealthCare Global Enterprises) • Indonesia (Siloam International Hospitals) • China (Xi'an Yikang Pharmacy)	Private equity fund	Clinical trial Research & Development Medical facilities	US Europe Asia-Pacific	CVC invests in high quality businesses across Europe, the Americas and Asia with competitive leadership positions and works with their management teams to create sustainable long-term value.	CVC's European and Americas private equity strategy is focused on control or co-control investments in market-leading businesses across these regions. Typical enterprise values are between USD 571m and USD 5.7bn+ CVC's Asia private equity strategy is focused on control, co-control and structured minority investments in high quality businesses in core consumer and services sectors across Asia. Typical enterprise values are between USD 250m and USD 1.5bn.	Market-seeking FDI	https://www.cvc.com/about/our-firm
38	**Hillhouse Capital:** China (Asia-Pacific)	Investment fund (firm?)	Research & Development	Asia-Pacific	Hillhouse is a significant partner to global institutional investors as well as to non-profit foundations that support meaningful causes such as the arts and music, scientific discovery and poverty alleviation.	The company works hand-in-hand with our entrepreneurs to build growth-oriented solutions from the ground up. One of the main priority fields is biotechnology.	Efficiency-seeking FDI	https://www.hillhouseinvestment.com/about/

39	**CDH VGC:** China (Harbour BioMed; I-Mab Biopharma; Kanghong Pharm; Alltech; YZY Med; Zhenghai Bio) Singapore (Luye)	Venture fund	Research & Development Clinical trial Medical facilities	Asia-Pacific	CDH's value-driven private equity approach with a "venture" perspective to invest in dynamic, fast-growing companies that are driving the upgrading of China's domestic consumption-led economy. Currently, the company manages two active VGC funds and three legacy venture funds, with cumulative assets under management of USD 2.6bn.	CDH VGC uses a research-driven investment approach to create opportunities in sectors that are expected to benefit from China's continued growth and shift from a fixed-asset investment-led economy to a domestic consumption-led economy. More specifically, CDH VGC focuses on investments in consumer and healthcare sectors	Efficiency-seeking FDI	https://www.cdhfund.com/index.php/a/lists/catid/170/
40	**ChrysCapital:** India (Corona Remedies; Curatio Healthcare; Intas Pharmaceuticals; Mankind Pharmaceuticals; Torrent Pharma)	Private equity firm	Research & Development Clinical trial	India	Leading India focused private equity firm with deep experience and a proven track record. Partnership model: Collaborate with entrepreneurs and business groups to add sustainable value. Key approach: Minority as well as control deals, ranging from USD 25m - USD 250m; ability to syndicate larger deals.	Sector focused: business services, financial services, healthcare and life science, consumer goods.	Efficiency-seeking FDI	http://www.chryscapital.com/

41	**CITIC CAPITAL:** China (Buchang Pharma)	Investment firm	Research & Development Clinical trial	China	CITIC Capital Holdings Limited ("CITIC Capital") is an alternative investment management and advisory company. The firm manages over USD 17bn of capital through its multi-asset class platform covering private equity, real estate, structured investment & finance, asset management, and special situations. The firm combines a deep knowledge of the Chinese business and financial markets with world-class investment expertise to create value for its investors.	CITIC Capital has over 150 portfolio companies that span 11 sectors	Efficiency-seeking FDI	http://www.citiccapital.com/SitePages/home-eng.aspx
42	**BainCapital:** US	Venture fund	Clinical trial Research & Development API CRO	US	BainCapital partners with disruptive founders to accelerate their ideas to market. Company focuses on founders passionate about transforming major industries, ranging from SaaS, infrastructure software and security to fintech and healthcare to commerce and consumer tech	Investments range from USD 1m of seed capital through USD 100m of growth equity.	Market-seeking FDI	https://www.baincapitalventures.com/

43	**EyePoint Pharmaceuticals:** US	Investment fund	Research & Development Clinical trial	US	EyePoint Pharmaceuticals, Inc. is a pharmaceutical company committed to developing and commercialising innovative therapeutics to help improve the lives of patients with serious eye disorders.	Cash Position and Growing Revenues with Strong Cash Runway: USD 210m+ of cash and investments on December 31, 2021 USD 39m of debt on December 31, 2021 USD 35m of net product revenues year to date December 31, 2021, a 70% increase over full-year 2020	Efficiency-seeking FDI	http://investors.eyepointpharma.com/static-files/9381ec68-b3e0-42c9-ae8a-5e604846b14d http://investors.eyepointpharma.com/
44	**Russia Venture Company (RVC):** Russia (R-Pharm; PharmMed Innovations)	Sovereign fund	Research & Development Clinical trial API	Russia	RVC invests in venture funds focused on investments in Russian technology companies. RVC's strategy involves careful selection of new funds and investment based on a co-investment model.	RVC adheres to the principle of diversification and control of the level of risks in terms of the number, stage and focus of funds, as well as the mandatory presence of co-investors in each of the funds with the participation of RVC. Priority fields in pharmacy: • pharmaceuticals • biotechnology	Efficiency-seeking FDI	https://rvc.ru/
45	**AstraZeneca:** • US • EU • CIS Countries (Russia, Ukraine, Belarus) • Balkans (Serbia)	Investment fund	Research & Development Clinical trial API	US Europe Asia-Pacific	The company's R&D and Commercial functions have been organised to accelerate decision making and the launches of new medicines across our main disease areas: Oncology; BioPharmaceuticals (including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology); and Rare Disease.	The Company's capital allocation priorities include investing in the business and pipeline, maintaining a strong, investment-grade credit rating, potential value-enhancing business development opportunities, and supporting the progressive dividend policy.	Efficiency-seeking FDI Market-seeking FDI	https://www.astrazeneca.com/investor-relations/key-facts.html

46	**TrueNorth:** • India (Anthem Biosciences Private Limited; Biocon Biologics; Integrace; KIMSHEALTH; Trivitron) • UAE (Aster DM Healthcare) • Russia (Cloudnine)	Private equity firm	Research & Development Clinical trial	India UAE Russia	The firm was founded with a vision towards investing in mid-sized, profitable, India-centric businesses, and transforming them into world-class industry leaders that are predicated on a strong value system.	The company investment strategy identifies fast growing and structurally attractive segments that either address the needs of domestic consumers or leverage India's strengths to service the global markets.	Efficiency-seeking FDI	https://www.truenorth.co.in/
47	**Eir Ventures:** • US • Sweden • Netherlands • Denmark	Venture fund	Research & Development Clinical trial	US Europe	Eir Ventures is a life sciences venture capital fund investing in private companies with stellar entrepreneurs developing transformative therapeutic approaches. The company management expertise, strategic thinking and our extensive networks to drive healthcare innovation to the benefit of patients, healthcare systems and investors.	The company represents a unique investment opportunity with high return potential due to an imbalance between the abundance of medical innovation and the scarcity of professional capital. Mission: Invest prudently and passionately Foster enduring partnerships Create customer-centric experiences	Efficiency-seeking FDI	https://eirventures.eu/
48	**Apollo Health Ventures:** • US • Switzerland • Germany • UK • Netherlands	Venture fund	Research & Development Clinical trial	US Europe	Apollo Health Ventures develops interventions with the potential to prevent or reverse age-related diseases and extend healthy human lifespan.	Key priority: innovative biotechnology and health-tech.	Efficiency-seeking FDI	https://www.apollo.vc/

49	**Public investment fund:** UK	Sovereign fund	API	UK Asia-Pacific	The Public Investment Fund is the sovereign wealth fund of Saudi Arabia. It is among the largest sovereign wealth funds in the world with total estimated assets of at least USD 500bn.	Locally, PIF drives strategic and sustainable diversification in line with Vision 2030 objectives and is supporting key sectors through investment opportunities, unlocking growth potential in the private sector. Internationally, PIF invests in a diversified portfolio across a range of asset classes.	Efficiency-seeking FDI	https://www.pif.gov.sa/en/Pages/OurInvestments-Global.aspx
50	**RA Capital Management:** • US • Hong Kong (Kira Pharmaceuticals) • Canada • Sweden • Denmark • UK • Switzerland • Belgium • Germany • Israel	Venture fund	API Research & Development Clinical trial	US (in priority) Europe Asia-Pacific	Evidence-Based Investing in Healthcare & Life Sciences. RA Capital Management is dedicated to evidence-based investing in public and private healthcare and life science companies developing drugs, medical devices, diagnostics, services, and research tools..	The firm's portfolio of private and public companies spans the globe and most therapeutic areas across all stages from discovery through commercialization. The company helps build and launch a company and finances it for academics, entrepreneurs, or executives and scientific leaders, using the expertise of an internal research unit known as TechAtlas, a dedicated venture capital team and experienced internal incubator entrepreneurs.	Market-seeking FDI	https://www.racap.com/

51	**OrbiMed:** • US • India (Advanced Enzymes; Asian Institute of Medical Sciences) • China (Star) • Hong Kong (Insilico Medicine) • Israel • Germany • Ireland • France • UK	Investment fund	Research & Development API	US Europe Asia-Pacific Israel	OrbiMed is a healthcare-dedicated investment firm focusing on biopharmaceuticals to medical devices and diagnostics.	OrbiMed has raised a total of USD 8.6bn across 14 funds, their latest being OrbiMed Private Investments VIII. This fund was announced on Mar 1, 2021 and raised a total of USD 1.5bn.	Efficiency-seeking FDI Market-seeking FDI	https://www.orbimed.com/
52	**Alexandria Venture Investments:** US	Venture platform	CRO API	US	Alexandria owns, operates, and develops collaborative life science, agtech, and technology campuses in the top urban innovation clusters in North America.	Company invests in seed-, early-, and growth-stage companies accelerating discoveries across a range of emerging technologies and novel modalities, including: Cell and Gene Therapies, Single-Cell Genomics, Epigenetics, Synthetic Biology, In Silico Drug Discovery, Biomanufacturing, Climate Tech, Precision Farming, Crop Protection.	Efficiency-seeking FDI	https://www.are.com/venture-investments.html

53	**KRKA:** • Slovenia • Croatia • Russia (no data) • Austria • Luxemburg • Poland	Investment fund	Generic	US Europe	Krka pursues the strategic objective of developing our generic pharmaceuticals by investing in research and development, and in our production and distribution centres around the world.	Krka will continue investing, because we are aware this is the only way to make progress. In Slovenia, Croatia and Russia, several projects have been launched. Also the company invests in construction and development of control centres that is currently Krka's most substantial investment.	Market-seeking FDI	https://www.krka.biz/en/
54	**Industrial Development Fund:** Russia (Nita-Pharm; Nearmedic; Amedart)	Sovereign fund	Research & Development Clinical trial	Russia	The company acts as a guarantor of the regulatory landscape, modernization of the production platform, a set of measures to support domestic manufacturers, and the emergence of its own competitive product.		Resource-seeking FDI	https://frprf.ru/