Sector Scan
Foreign Direct Investment in Pharmaceuticals and Healthcare in Armenia

September 2021

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Abbreviations

AI	Artificial intelligence
API	Active pharmaceutical ingredient
CAGR	Compound annual growth rate
CIS	Commonwealth of Independent States
CMO	Contract manufacturing outsourcing
CRO	Contract research organization
EA	Enterprise Armenia
EAEU	Eurasian Economic Union
ECA	East Europe and Central Asia
FDI	Foreign direct investment
GMP	Good manufacturing practices
GoA	Government of Armenia
GVC	Global value chain
IPA	Investment promotion agency
IPI	Investment promotion intermediary
LLDC	Landlocked developing country
M&A	Mergers and acquisitions
MNCs	Multinational companies
NACE	Statistical Classification of Economic Activities in the European Community
NEMs	Non-equity (or non-ownership) modes of international production
OOPS	Out-of-pocket spending
PPP	Public-private partnerships
RA	Republic of Armenia
R&D	Research and development
SCDMTE	Scientific Centre of Drug and Medical Technologies Expertise
SEZ	Special economic zone
WBG	World Bank Group

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Executive Summary[1]

The Role and Importance of Foreign Direct Investment (FDI)

1. **Foreign direct investment (FDI) in the Armenian healthcare sector can play a catalytic role in developing the country's economy.** As elsewhere, FDI is seen as a source of additional capital, jobs, skills, international market knowledge, and technology that are normally unavailable domestically; FDI is also a means to upgrade Armenia's production practices and disseminate innovations.

2. The COVID-19 pandemic has placed an unprecedented strain on health systems across the globe. **For Armenia, FDI can be a tool that could help improve the resilience and accessibility of its health system**. While this report touches upon the topic, it was not commissioned primarily to assess public financial-management bottlenecks in health-services delivery. FDI can be a part of the solution only in healthcare subsectors that are commercially viable or paid for by social health insurance.

3. **Companies invest in foreign countries to make profit.** Yet, the underlying rationales for establishing foreign subsidiaries are usually more complex. To grasp business opportunities outside its home country, a firm's decision-making process, designed to deliver its "international strategy", usually starts with identifying the business goals of investing abroad. Broadly speaking, FDI has three core motives:
   - **Resources:** the firm is seeking specific resources that can be obtained at a lower cost than in the home country or other countries (if, obtainable at all).
   - **Market:** the firm wants to exploit a foreign market, which is of some appeal to it. For example, by producing drug excipients or insulin in Armenia, which are currently imported.
   - **Efficiency:** the firm seeks access to export markets from a base offering competitive cost-effective and productive features; for example, contract pharmaceutical research.

   Market-seeking motivations and strategies dominate private firms' activities in healthcare infrastructure construction and domestic healthcare services, while efficiency-seeking firms seek to exploit the tradability of their healthcare goods and services.

4. **The healthcare sector includes two main industry groups: healthcare equipment and services and pharmaceuticals, biotech and life sciences.** This report's main focus is pharmaceuticals, biotech and life sciences, both identified by the

1 The Executive Summary summarizes the main sector-scan findings, conclusions, and recommendations. All figures and references contained in the executive summary are fully sourced in the main body of the report.

Government of Armenia (GoA) as priority sectors in its national export-led industrial development policy. Investment in healthcare infrastructure and professional services (for example, construction activities or operation and management of healthcare facilities, hospitals, and other medical services) often involves forms of private sector investment other than FDI, such as public-private partnerships (PPPs) and institutional investments.

5. **The value of FDI in the healthcare sector is usually lower than in other sectors.** In 2019, for example, the pharmaceutical sector was responsible for only 3 percent of all FDI projects, and 1 percent of all new jobs created by FDI in Europe. Similarly, in Armenia the pharmaceutical sector accounted for less than 2 percent of total FDI inflows during the period from 2014 to 2017. The pharmaceutical industry is geographically concentrated – globally, it contributes at least 5 percent of GDP in only 4 percent of countries. The opportunity for countries to participate in pharmaceutical global value chains (GVCs) is thus lower because of low pre-existing domestic production capacity. A similar trend of low levels of outsourcing and offshoring also applies to manufacturing of medical devices (complex therapeutic devices and capital medical equipment in particular).

6. **The pharmaceutical sector's prevailing mode of FDI is cross-border mergers and acquisitions (M&A).** While in 2018-2019 the sector was not ranked among the top 10 in value terms of newly announced greenfield FDI projects, it ranked first in value terms of net cross-border M&A; and the only sector with positive year-on-year growth in value terms.

7. **The sector supply chain involves two main stages: production of active pharmaceutical ingredients (APIs) and production of formulations.** While APIs are largely synthesized, extracted, or isolated in low-cost, high-volume manufacturing countries (India and China are responsible for over 60 percent of global API production), formulated drug products are typically manufactured nearer to their end markets.

8. **A common characteristic of the sector is a medium degree of internationalization.** In contrast to many other sectors (for example, the textile and apparel industry), the pharmaceutical GVC has specific requirements in terms of quality controls, high importance of intellectual property, and reliance on tacit knowledge. As a result, a general international production configuration applied to the pharmaceutical sector is that of a "global hub and spokes" model, with a short value chain, and few steps, if any, between high value-added upstream activities and the production and packaging of medication close to markets, geographic distribution of value-added product, and high governance This limits participation of many countries in the global pharmaceutical GVCs.

9. **Contract manufacturing outsourcing (CMO) and use of private contract research organizations (CROs)** are now a common feature of operations of most large multinational pharmaceutical companies. The pharmaceutical value chain is made up of

many connected components that have been significantly decentralized (outsourced) and optimized to reduce the cost of production and distribution.

10. **Attracting new FDI to the healthcare (pharmaceutical) sector: governments can influence investors' site selection decisions (to some extent).** Companies seeking to expand internationally will often compare several possible locations against a set of predetermined criteria to objectively determine the best investment location. Criteria may be quantitative and qualitative and typically cover aspects like access to markets, operating costs, transportation and logistics, various risk assessments and other factors. Investors will benchmark Armenia against other potential locations before making a final choice of location.

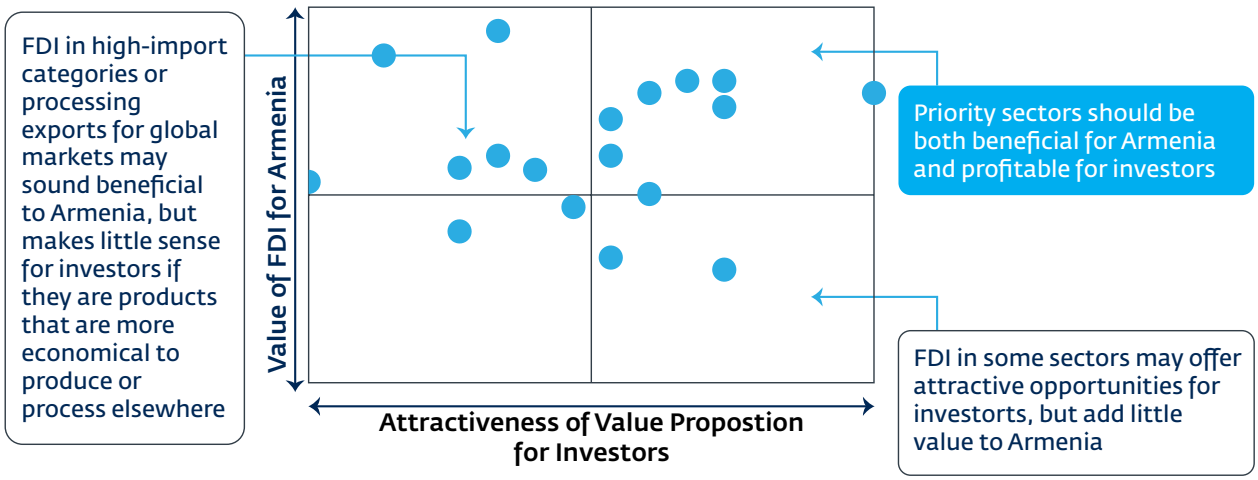
11. **Continuous improvement of Armenia's investment climate is critical to attract new FDI.** In the long term, the GoA can improve a country's competitiveness to attract new FDI by improving its investment climate, infrastructure, work force, and by giving policy support for targeted sectors. In the short term, the government can improve its chances by making sure that Armenia is on the lists of possible investment locations by ensuring that potential investors have access to the most complete and positively framed information possible. Proactive investor targeting seeks to accomplish this by seeking out and directly identifying and engaging investors with high potential to get interested in Armenia.

12. **Proactive investor targeting in the healthcare (pharmaceutical) sector requires identifying competitive subsectors that might be best placed to attract new investments.** Without well planned and proactive targeting, Armenia surrenders some of the little influence a government can wield over investor site selection decisions. This can lead to government allocation of land or other assets being driven by unsolicited proposals from investors of suboptimal merit. Targeting, if planned and delivered properly, can provide the GoA with some influence over the types of investment attracted. Successful or not, it will provide valuable insight into what Armenia can do to improve its attractiveness to foreign investors. Without proactive outreach, Armenia's investment promotion depends on investors to "make the first move."

13. **Armenia has a professional institutional capacity for investment promotion; the mandate of a national investment promotion agency (IPA) is being carried out by Enterprise Armenia,** in part, to mount investor outreach campaigns and engage in targeted promotional efforts in selected subsectors. This, in turn, will call for stronger sector insights and knowledge on the part of the agency staff.

Assessing Armenia's Competitive Strengths for FDI in the Healthcare (Pharmaceutical) Sector

14. **The IFC "Economic Growth" Project-supported sector scan seeks to identify healthcare subsectors with the most investment potential and resulting development impact, making them the most productive focus for a targeted FDI outreach campaign.** The IFC project team applied a well-developed methodology to review a range of existing healthcare subsectors to identify those where FDI could add most value to Armenia and in which Armenia has a strong value proposition to offer investors.



15. **The sector scan considered six subsectors that attract efficiency-seeking FDI.** Five subsectors are linked to pharmaceutical value-chain activities (production of APIs, production of original and generic pharmaceutical products, CMO, and CRO), and one subsector (medical devices and supplies) related to healthcare goods manufacturing. Subsectors that attract primarily market-driven FDI (such as healthcare services) and typically do not require government investment promotion effort were left out.

16. **Costs, opportunities, and challenges of each subsector vary.** The primary sources of information for the sector scan were existing sector studies and interviews with sector stakeholders–existing investors, both domestic and foreign, sector associations, public institutions, and independent experts. Information on the costs, market and export opportunities, import and quality challenges, etc. were analyzed to assess the extent to which additional FDI in a given subsector would add value to Armenia and the extent to which investment in the sector offered an attractive proposition to foreign investors

(including market assessment and competitive supply conditions). The full sector-scan report below provides a detailed assessment for each of the subsector value-chain segments.

The following table sets out the main criteria used in the assessment and describes the scoring methodology to compare the potential of the various subsectors.

To what extent:	Score	Evidence
1. Will additional FDI in this sector add value to Armenia?		
● Will new investors add value that is not already provided by local producers and existing investors?	1-5	● Quantity and quality of existing producers, SMEs, and investors already operating in the sector; impact of new investors on local SMEs in the sector.
● Will new investors create additional jobs?	1-5	● Potential jobs generated by new investments in the sector.
● Will new investors increase opportunities for domestic firms to supply goods/services to foreign investors?	1-5	● Improved opportunities for domestic firms to supply their goods/services to foreign investors and improved incomes generated by new investments in this sector.
● Will new investors create increased export revenues or reduce imports?	1-5	● Potential export revenues or reduced imports generated by investments in the sector.
● Will new investors improve performance of the value chain as a whole?	1-5	● Potential impact on other parts of the value chain (improved inputs or improved sales opportunities for domestic suppliers).
SUBTOTAL	**5-25**	
2. Does investment in this sector offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply, and prices) attractive?		
● Are the local and regional markets attractive?	1-5	● Demand, supply, and price trends in Armenia and neighbouring countries (EAEU market, in particular).
● Is the global market attractive?	1-5	● Demand, supply, and price trends in major global markets.
Does Armenia offer competitive supply conditions for investors in this sector?		
● Does Armenia have competitive natural endowments (raw materials, location, etc.)?	1-5	● Availability of suitable raw materials, proximity to key markets, etc.
● Does Armenia have competitive infrastructure?	1-5	● Availability and cost of power, transport, manufacturing sites, etc.
● Does Armenia have competitive skills and support services?	1-5	● Availability and productivity of suitable workforce and support services.
● Does Armenia offer a conducive business (regulatory/institutional) environment?	1-5	● Absence of regulatory of institutional barriers that might deter investors or hinder their performance.
SUBTOTAL	**6-30**	
Evaluation key:	5=very positive	4=positive	3=neutral	2=negative	1=very negative

The main assessment criteria reflects both FDI motivation (that is, benefits from access to market, resources or efficiencies that drive firms to invest abroad) and the value the investment could potentially add to Armenia.

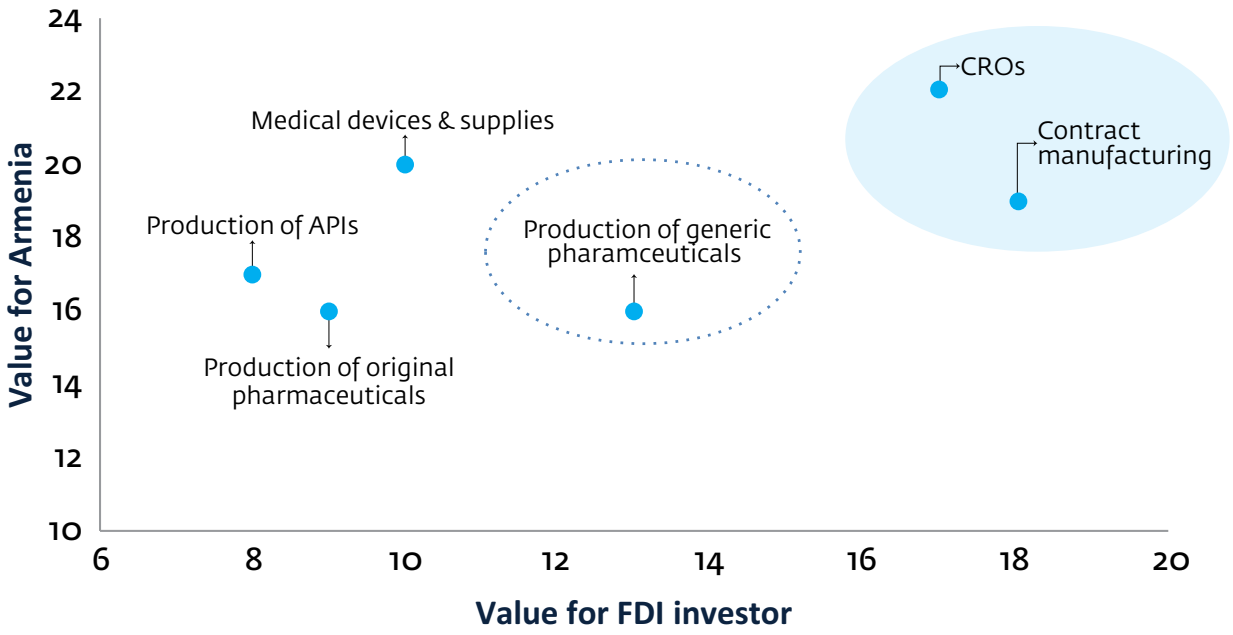
Sector-Scan Results

17. **Overall, the two subsectors** with the best investment proposition are linked to outsourcing/offshoring:

- **Contract research operations (CROs)**
- **Contract manufacturing operations (CMOs).**

These subsectors have some recent investment track record (both domestic and diaspora-linked investment), do not expose potential FDI to large capital investment risks, are export oriented, could build on existing Armenian experience of domestic firms, and seem to be internationally competitive. None of the remaining reviewed subsectors currently presents a strong enough value proposition for immediate substantial greenfield FDI. Enterprise Armenia could, however, probe into FDI drivers of generic pharmaceuticals production by contacting and interviewing foreign MNCs in this subsector to seek industry insight into key site-selection criteria. Understanding what value Armenia currently provides to potential FDI investors is a first step to further investment climate upgrading.

In some of these subsectors, particularly in areas that add value to existing low-value domestic production—for instance in API or medical devices and supplies manufacturing—while FDI would be very valuable for Armenia, the investment proposition for foreign investors is weak.



It should be noted that the subsector selection priorities described here are purely for the purpose of investor outreach. This conclusion is not meant to replace sector priorities set by any other Government strategy or goals, for instance an SME or a healthcare sector-development strategy. It is not necessarily related to institutional investors' prioritization either, as there may be other investment opportunities in these subsectors for PPP, start-up, or equity investment.

18. While investment propositions can be defined for at least two of the subsectors, there is **still a need for investment climate improvement** to remove some of the impediments identified by the private sector. In particular, the healthcare sector (pharmaceuticals) is concerned about availability of skilled labour (a critical site-selection criterion for CROs) and access to the EAEU market (Russia, in particular) for pharmaceuticals produced in Armenia. The GoA will also need to address the perception of Armenia, which may be perceived as an unsafe and high-risk country due to the recent conflict in Nagorno-Karabakh and the resulting political turmoil.

19. **Armenian diaspora can be an interesting resource to tap into.** Diaspora seed capital is likely behind some of the existing investment projects in the sector already. However, the diaspora or diaspora-backed initiatives (for example, FAST Foundation) can help the government obtain expert opinion and direct industry insight into the sector and provide critical feedback on the country's international competitiveness for FDI in the healthcare sector. This is important since entrepreneurs and sponsors of local origin are prospering in various parts of the world and can bridge the needs of the country for economic development of the sector. The government should create a special advisory council consisting of members from both in-country and international communities.

20. The ongoing **COVID-19 pandemic has spotlighted bottlenecks in the international healthcare equipment and medicines supply chains.** MNCs in healthcare industries have faced short-term supply-chain disruptions and, in the future, will likely opt for greater geographical diversification and other strategies to make their supply chains more resilient. However, the chances that Armenia will benefit from these new investment opportunities are not high.

21. **FDI alone is unlikely to improve resilience of Armenia's healthcare**. The country is in need of healthcare system reform reducing out-of-pocket payments and improving healthcare access as a prerequisite for the private sector to consider domestic market investment opportunities that are commercially viable and/or paid for by the health insurance system. The government also needs to evaluate how the local talent pool is being created and how academia is training youth so that the private sector can absorb them into high-tech roles. It is important to create a vibrant education system that is geared towards applied R&D and to discuss how to retain talent from leaving the country.

22. Although institutional assessment of **Enterprise Armenia** has not been a part of the report, the agency will **need to appoint a sector specialist to lead promotion efforts** on the basis of an agreed business plan. Russia and India could be initial target countries for investment promotion in the CMO subsector. The IPA will need to obtain additional data and industry insight in the CRO sector, in particular into the nature of research contracted to Armenia, consumption (export) markets, and operational bottlenecks.

23. There is a **special investment advocacy role for the GoA which needs to closely follow pharmaceutical sector policy development in Russia,** the largest regional market for Armenia-based producers. As Russia has introduced a number of policies protecting or prioritizing domestic producers, the GoA needs to ensure that, under the EAEU rules, these policies extend to Armenia-based producers. A similar effort will be needed when overseeing the implementation of the EAEU rules on drug registration harmonization.

Sector-Scan Summary/IFC Armenia Project Next Steps

24. The IFC project assessed Armenia's competitiveness in the healthcare (pharmaceutical) sector for foreign direct investment (FDI) to **identify subsectors that offer the most potential for foreign investment** in Armenia.

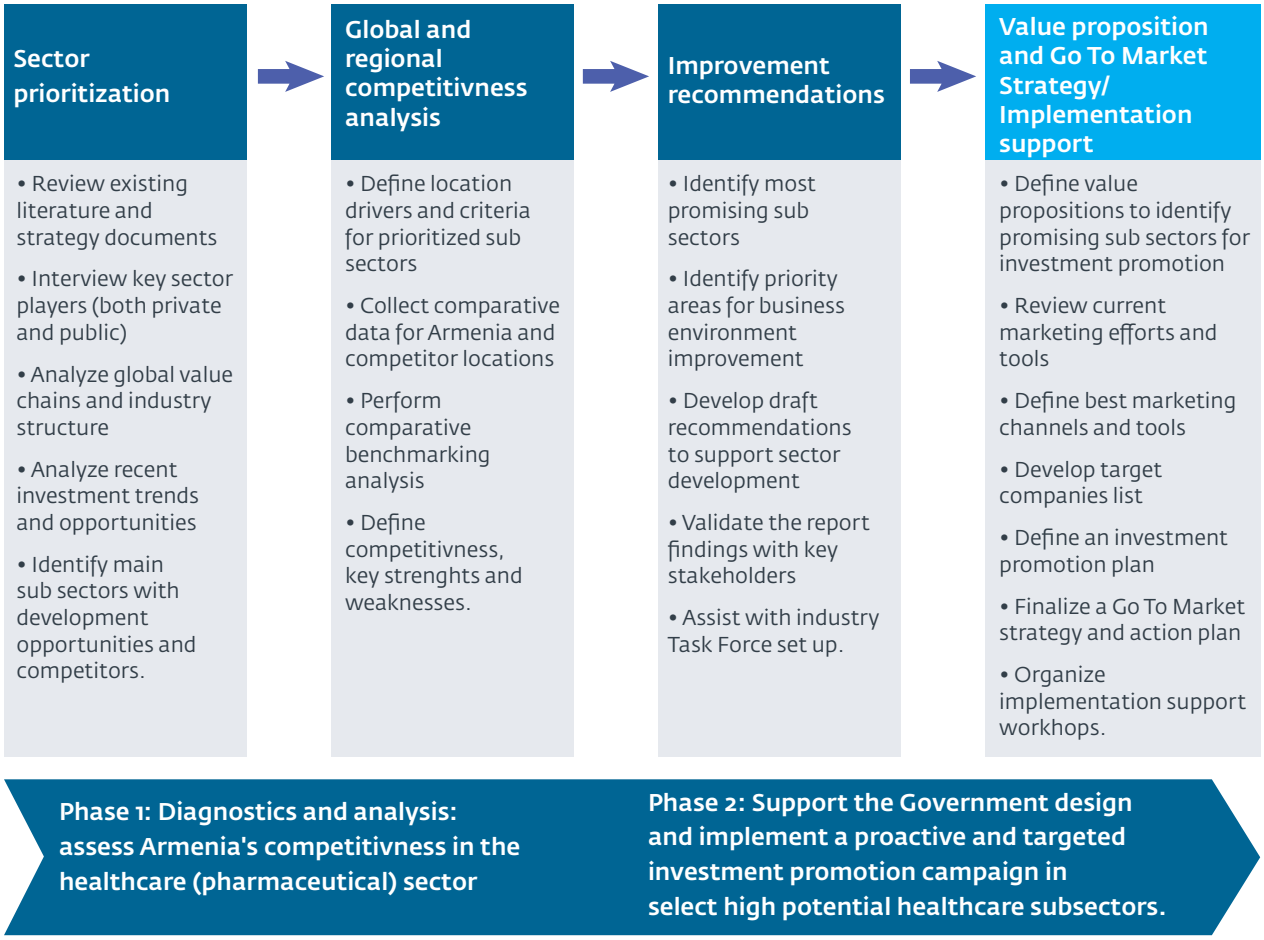
25. First, we reviewed the available and most up-to-date literature and analysis of **trends shaping corporate investment behavior** in the healthcare and pharmaceutical sectors to ascertain how the sector is developing globally and gain insight into how FDI activity for different subsectors will develop in the medium and longer term.

26. We then analyzed current FDI trends in the Healthcare and Pharmaceutical sectors globally, and in the European region and Armenia, to identify sectors expected to generate international investment projects.

27. Next, we analyzed the c**urrent Healthcare and Pharmaceutical sector in Armenia** to gain understanding of the local sector-specific business environment and to identify any special cluster strengths and opportunities that may be relevant to selecting subsectors and candidates for further analysis. During this phase we extensively interviewed representatives of the Armenia's private healthcare and pharmaceutical sector and also public stakeholders (for example, Ministry of Health, Ministry of Economy, Scientific Centre for Drug and Medical Technology Expertise, Association of Pharma Producers).

28. This approach combined an in-depth **analysis of the demand side of FDI with a review of the supply side** (Armenia's business environment) to arrive at a well-informed prioritization matrix that synthesised the findings and drew

conclusions on the sector's investment impediments. On concluding this phase, we identified priority areas for business environment improvement.



29. The **conclusions and recommendations of the analysis were validated** during two separate rounds of stakeholder meetings to finalize the sector-scan report.

30. As part of the next steps, the project will perform the following tasks:
    a. Develop the investment guide as the value proposition for the analyzed subsectors
    b. Review current marketing efforts and tools
    c. Define marketing materials
    d. Develop target companies list
    e. Define an investment promotion action plan
    f. Finalize a Go-To-Market Strategy and action plan.

31. As one of IFC's recommendations as a key first step in operationalizing the findings of the sector scan, EA will initiate a sector Task Force in the Armenian pharmaceutical sector comprising representatives from the Armenian Ministry of Healthcare, the Ministry of Economy, the Scientific Centre for Drug and Medical Technology Expertise, sector associations, and other stakeholders. The Task Force will help coordinate investment promotion efforts in the healthcare (pharmaceutical) sector.

2. Introduction

2.1. Introductory note

Since the peaceful revolution of 2018, the Government of Armenia (GoA) has set the path towards sustained democracy and good governance. The authorities are determined to fight poverty and unemployment through a structural transformation led by high-tech activities supported by the modernization of traditional ones. Plans to improve the business environment, increase investment, including foreign direct investment (FDI), and fight corruption have been announced. As in many countries, FDI is seen as a potentially transformative force. It could be a source of additional capital, jobs, skills, international market knowledge, and technology that are unavailable domestically; it could help to upgrade Armenia's production practices and disseminate innovation.

Definition of FDI

Foreign direct investment (FDI) is an investment made by a company or individual in one country in business interests in another country – either in whole or in part - in the form of either establishing business operations or acquiring business assets in the other country, such as ownership or controlling interest in a foreign company. FDI is defined as direct investor's ownership of 10% or more of the voting power in the direct investment enterprise.

Foreign direct investments can be made in a variety of ways, including the opening of a subsidiary or associate company in a foreign country, acquiring a controlling interest in an existing foreign company, or by means of a merger or joint venture with a foreign company. See Annex 1 additional FDI terminology and principles.

This report is tasked to assess the prospects for FDI in the healthcare industry, with a particular focus on the pharmaceutical sector, which has been identified by the government as a national export-led industrial development policy priority sector.[2] It was commissioned during the fall of 2020 by IFC, in collaboration with the GoA, to identify which subsectors in healthcare offer most potential for FDI in Armenia, particularly for efficiency-seeking foreign firms exploiting the tradability of healthcare goods and services. As this report was drafted during the ongoing COVID-19 pandemic, which has placed unprecedented strain on health systems across the globe, it also attempts to explore if FDI can improve resilience and accessibility of Armenia's health system?

The report coincides with the early stages of implementation of IFC 3.0. IFC's FY19-23 Country Strategy has identified healthcare as a key sector for intervention, both for advisory services and private healthcare investment. The prominence of the healthcare sector is only likely to increase during the Country Strategy implementation, given the impact the ongoing COVID-19 pandemic has had on health system capacity to supply health centers and hospitals

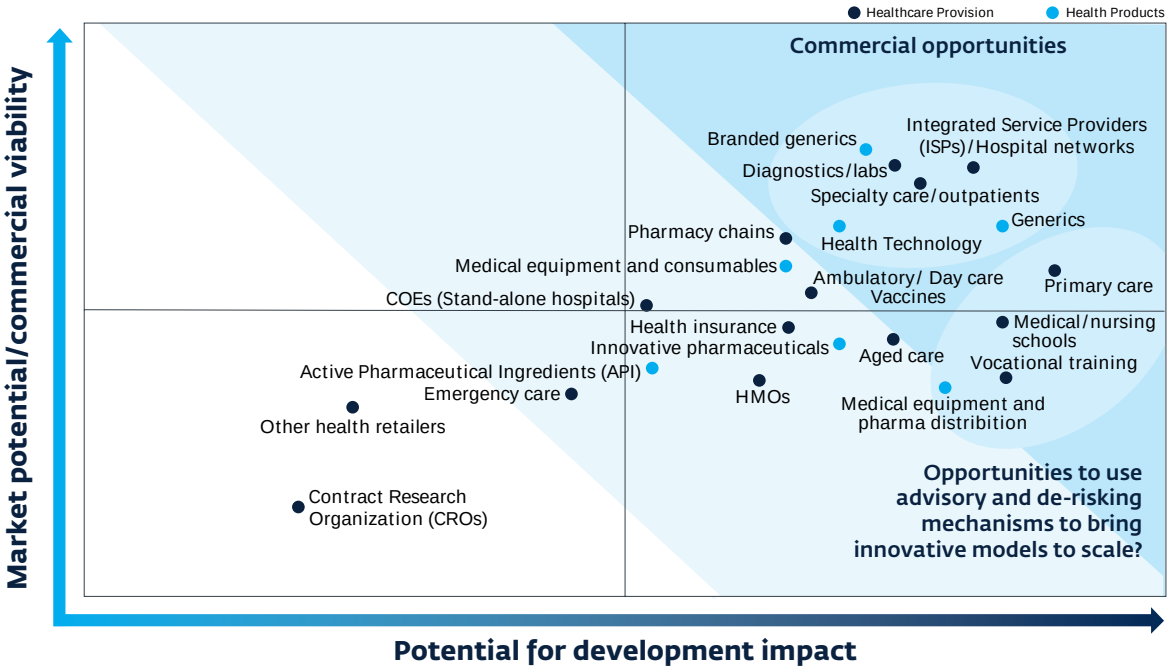
2 Ministry of Economy (2011), Strategy of Export-led Industrial Policy of Republic of Armenia, retrieved from www.mineconomy.am/en/page/97

with enough beds, medical equipment, personal protective equipment, and COVID-19 tests, in addition to maintaining routine health services. The pressure on Armenia's health budget due to the COVID-19 pandemic has created additional public financial management bottlenecks in health service delivery, particularly to the unfinished universal health coverage agenda.[3]

While the report was not originally conceived to provide analytical background for IFC's investments, it can provide some additional analytical data to the IFC investment team.

However, the sector-scan methodology used in the report to prioritize healthcare subsectors for efficiency-seeking FDI and final sector selection, do not necessarily match sectors identified by the IFC investment team. The FDI sector scan focuses primarily on subsectors where Armenia's business environment provides an internationally competitive match for FDI demand, while IFC's sector segmentation focuses on subsectors that help achieve the Sustainable Development Goals and are commercially viable or paid for by social health insurance (Figure 1).

***Figure 1:** Key areas for institutional investment in private health sector*



Source: Based on **IFC Guide for Investors in Private Health Care in Emerging Markets**

This report already incorporates comments and feedback provided by the IFC Advisory and by the GoA (Ministry of Economy, Ministry of Health, and investment promotion agency, in particular). It can, however, be further extended to include more analytical data needed by the IFC investment team, if required.

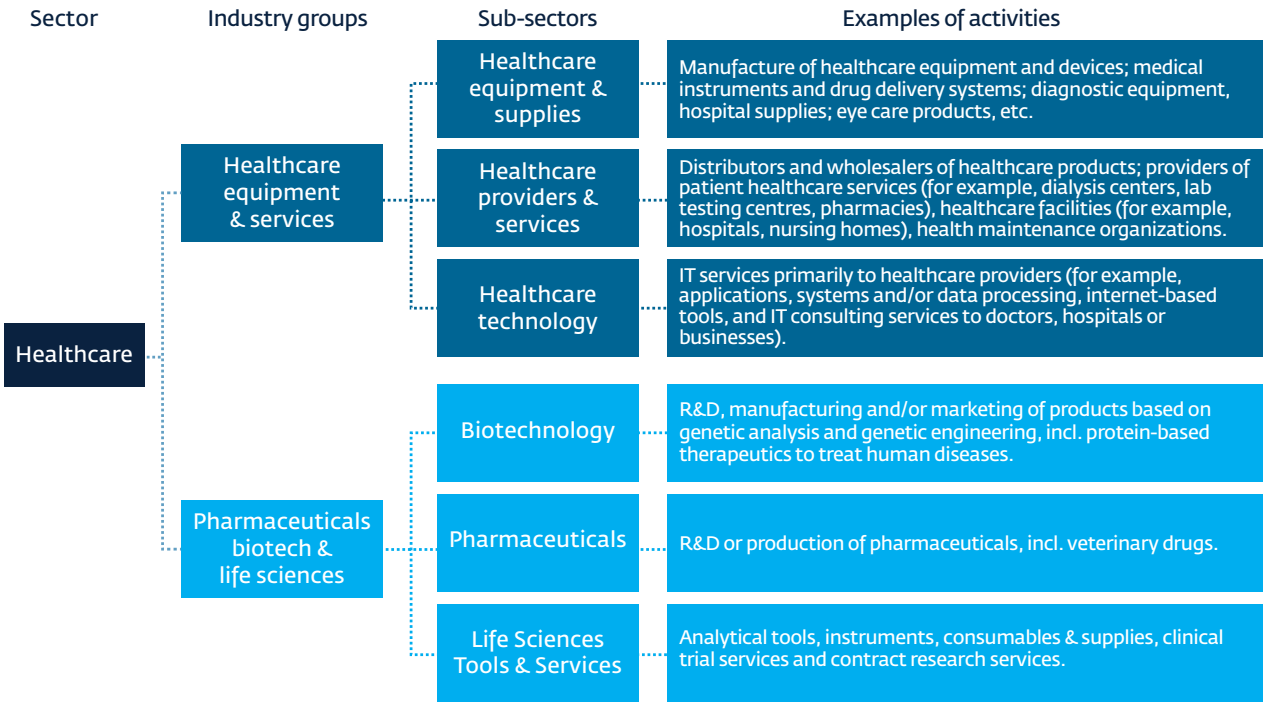
3 Chukwuma, Adanna; Gurazada, Srinivas; Jain, Manoj; Tsaturyan, Saro; Khcheyan, Makich. 2020. FinHealth Armenia: Reforming Public Financial Management to Improve Health Service Delivery. World Bank, 2020; retrieved at **https://openknowledge.worldbank.org/handle/10986/34747.**

2.2. Healthcare Sector Classification

Potential FDI opportunities in any sector or subsector need to consider both (a) attractiveness of value proposition for investors and (b) the value that can be generated for Armenia. This report finds a low track record for FDI in the healthcare sector, suggesting that the sector's value proposition for foreign investors has been weak, and that the investment climate needs to improve to promote its growth. The enormous international competition for FDI and recent global health crisis caused by COVID-19 further complicates investment attraction efforts. Attracting "first movers" always takes more reform and promotion effort by governments than just focusing on investors who are already in the country.

The healthcare sector entails two main industry groups: healthcare equipment and services, and pharmaceuticals; and biotech and life sciences (Pharm, Bio & Life Sci) (Figure 2). While many healthcare activities are limited to domestic markets (for example, patient healthcare services or retail distribution of pharmaceuticals) and hence will attract only market-seeking FDI, other healthcare products and services are exportable (for example, R&D services; production of pharmaceuticals, medical devices, or hospital supplies). This report primarily deals with the Pharm, Bio & Life Sci sector, as this sector is given strategic importance by policy makers and is export oriented. However, it will also briefly discuss investment prospects and Armenia's competitiveness in the remaining healthcare subsectors.

***Figure 2:** Healthcare sector classification*



Source: Global Industry Classification Standard (GICS)

Although the sector scan has identified two subsectors that could offer a viable investment proposition for potential foreign investors, no reviewed subsectors currently demonstrates features strong enough to motivate FDI into a large-scale greenfield project in the short-term. The risks and benefits associated with targeting potential opportunities therefore need to be acknowledged and assessed carefully.

The policy implication is that the government could preferably conduct a broader sector review to design a new support framework for domestic producers in the pharmaceutical sector. Many reforms, some of which can be derived from this report, are needed to nurture local investment to ensure opportunities for more value addition and job creation. All these efforts will contribute to prospective investment attraction efforts in the medium to long-term as they will contribute to the overall value proposition of the sector. A more robust and export-oriented domestic pharmaceutical sector has better chances for local firms to attract a foreign joint-venture partner or bid for non-equity investment modes for international production (NEMs).

Another implication is that Armenia's investment promotion agency (IPA)—Enterprise Armenia—would need to have an appropriate operational model, resources, and capacity aligned with the new focus on the promising sectors. Otherwise, the recommendations of the sector scan will not lead to the final and most important part, which is implementation.

3. FDI and the Healthcare Sector

3.1. FDI Motivation

Understanding the motivation that leads to FDI decisions is critical for investment promotion. Companies invest in foreign countries to make greater profits. Yet the underlying rationale for establishing foreign subsidiaries is invariably more complex. To grasp business opportunities outside their home country, a firm's decision-making process, designed to deliver its "international strategy", usually starts with identification of the business goals to be achieved by investing abroad. Broadly speaking, FDI can be motivated by three core motives:

- **Resources:** the firm is seeking specific resources that can be obtained at a lower cost than in the home country or other countries (if, obtainable at all).
- **Market:** the firm wants to exploit a foreign market, which is of some appeal to it. For example, by producing drug excipients or insulin in Armenia, which are currently imported.
- **Efficiency:** the firm seeks access to export markets from a base offering competitive cost-effective and productive features; for example, contract pharmaceutical research.

Companies seeking to expand internationally will often compare several possible locations against a set of predetermined criteria to arrive at an objective determination of the best investment location for them. Criteria may be quantitative and qualitative and typically cover aspects of doing business like access to markets, operating costs, transportation and logistics, assessment of various risks and many other factors. Investors will benchmark Armenia against other potential locations before making their final location choice. By understanding this process, the government can–to some extent–influence investors' site selection decisions.

3.2. FDI Trends in Armenia

Since its transition to a market economy in the 1990s, Armenia has received very modest amounts of FDI with annual inflows not surpassing $50 million during the first decade and remaining at an average annual level of $150 million until 2005. In the latter half of the 2000s, however, inflows began to increase, peaking in 2008 ($925 million).[4]

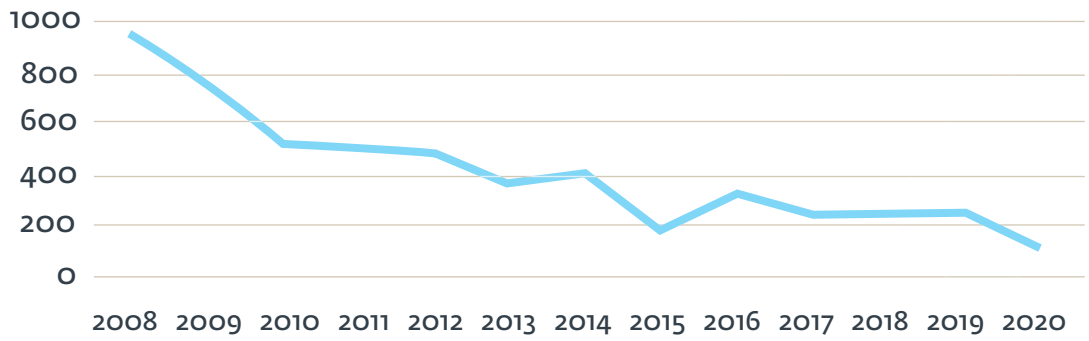
Classified as a landlocked developing country (LLDC),[5] Armenia has been largely bypassed by FDI, which in LLDCs typically focuses on natural

4 National Bank of Armenia, Balance of Payments

5 United Nations Conference on Trade and Development List of Land-locked Developing Countries. Retrieved from: **https://unctad.org/topic/landlocked-developing-countries/list-of-LLDCs**

resources. With respect to infrastructure development, as in many other LLDCs, investor interest goes beyond pure FDI deals and embraces other forms of involvement, especially public-private partnerships (PPPs). Armenia, too, relied on PPP to develop, for instance, a hydropower project worth $250 million at Vorotan. Recent FDI inflows have mostly stagnated (figure 3) due to, what has been described in some reports, as a "wait-and-see" attitude among investors,[6] due to disputes affecting headline projects with foreign investment (Amulsar Gold Project). The global COVID-19 pandemics further impacted FDI inflow; in 2020, FDI inflow shrank to $117 million.[7]

***Figure 3:** FDI inflow in Armenia (in million dollars)*



Source: UNCTAD, World Investment Reports 2014–2021

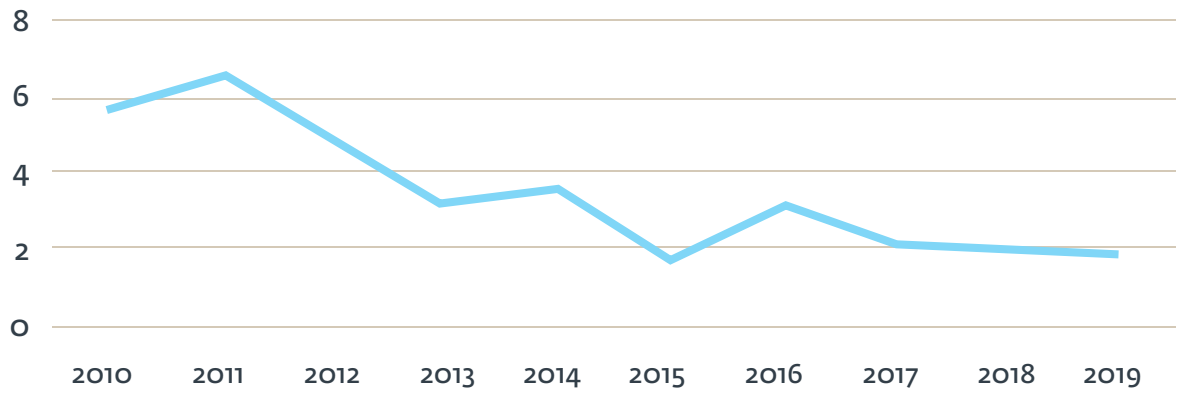
The largest foreign investors in Armenia are those that have acquired interests in the telecommunications, mining, energy, air transportation, and financial sectors. The privatization of Yerevan's largest hotels, two historic brandy factories, the Zvartnots International (Yerevan) and Shirak (Gyumri) Airports, the telecommunications network, several mining assets, and much of the energy generation and distribution accounts for the bulk of foreign commercial presence in Armenia.

FDI flows as percentage of gross fixed capital formation have never reached the 2008 pre-crisis annual average (20 percent) and currently run at 11,8 percent (2019), suggesting that FDI had lost its previous eminence in Armenia's economy. Similarly, net FDI inflows as a percentage of GDP have been in downturn since 2011 and dropped to 1,86 percent in 2019 (figure 4). For comparison, the world average in 2019 based on 177 countries was 4.08 percent.

6 UNCTAD (2019), Investment Policy Review of Armenia, November 2019

7 UNCTAD (2021), World Investment Report 2021

***Figure 4:** FDI, net inflows (% of GDP)*



Source: www.theglobaleconomy.com/armenia/foreign_direct_investment

Russia, Greece, Cyprus, and Germany are the four major investors in Armenia, although significant investments are also made by the members of the Armenian diaspora (nearly 7 million people). There is no record kept about the amount of diaspora FDI; some diaspora-originated FDI may be in fact portfolio investment in Armenia, which was later transformed into productive direct investment. The number of announced new greenfield FDI projects decreased in 2019, as did the value of announced greenfield investment projects. In common with many countries, data for 2020 show a massive slide in FDI performance (figure 5).

***Figure 5:** FDI overview*

FDI	2017	2018	2019	2020
FDI inward flow (million dollars)	251	254	255	117
FDI stock (million dollars)	4,753	5,512	5,664	5,246
Number of greenfield investments	14	15	9	...
Value of announced greenfield Investment projects (million dollars)	651	544	185	40

Source: World Investment Report 2021 (Country Factsheet, retrieved at https://unctad.org/system/files/non-official-document/wir_fs_am_en.pdf).

The share of efficiency-seeking FDI remains very low (<5 percent of total FDI). To a certain degree, the geographic position of Armenia constrains its ability to expand its economy through trade and to take part in the international production systems of MNCs. All goods must transit through Georgia due to border restrictions imposed by Turkey and Azerbaijan. In addition, one of the main export routes, the Verkhniy Lars border crossing

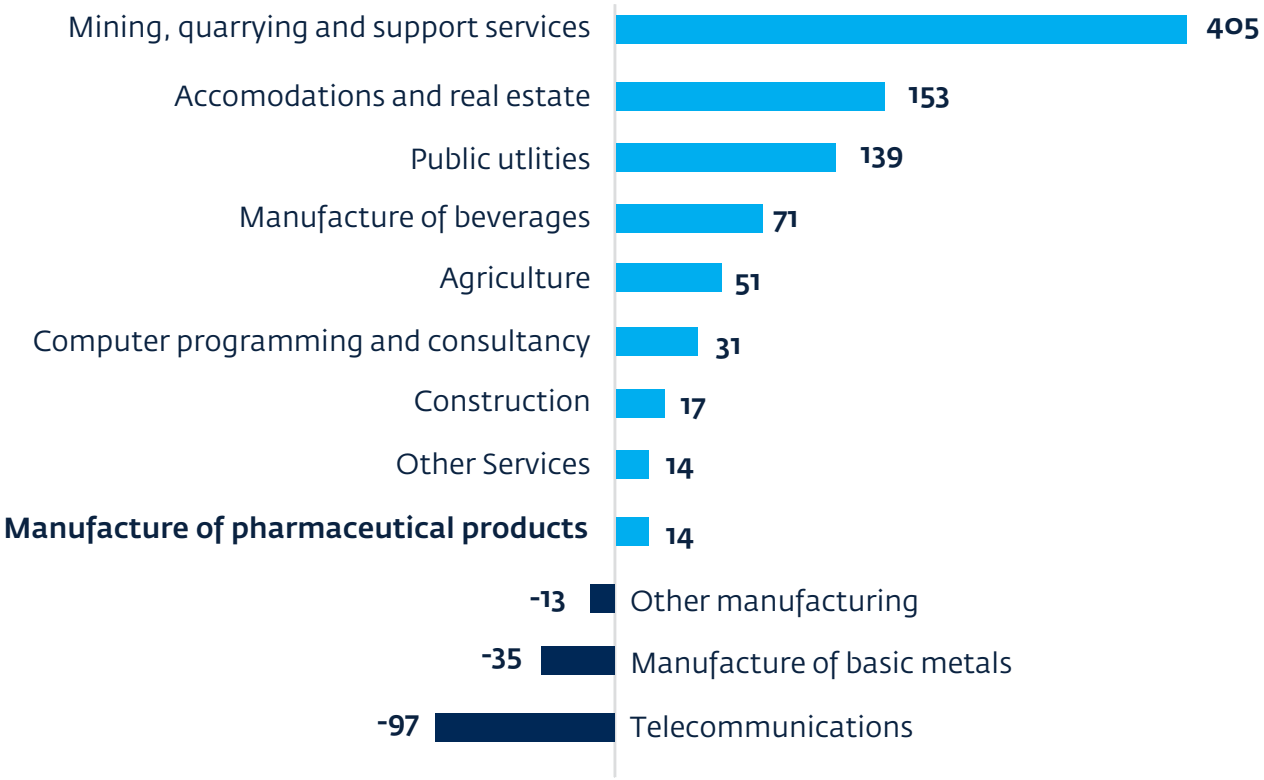
between Georgia and the Russian Federation, becomes often impracticable due to the weather conditions (when snow or rain impede transit), while exports through the Georgian ports on the Black Sea are affected by unreliable ferry schedules.[8]

For distant markets, access to sea is critical because land transport costs are much higher than those of shipping by sea. In the case of Armenia, where most exports of goods go to Russian markets, road transport is a viable option to sea transport, yet transport costs, along with border crossing and transit customs clearance capacities, remain an issue.

3.3. FDI in Pharm, Bio & Life Sci sector

FDI inflows in the pharmaceutical sector in Armenia have been negligible (figure 6). During 2014-2017, it accounted for less than 2 percent of total capital FDI inflows ($14 million).

***Figure 6:** Cumulative FDI inflows to Armenia (2014-2017 (million dollars)*



Source: UNCTAD (2019), Investment Policy Review of Armenia, November 2019

8 UNCTAD (2019), Investment Policy Review of Armenia, November 2019

Interestingly, the Financial Times fDi Markets, the most comprehensive online database of cross-border greenfield investments available, registers only one FDI project in Armenia's pharmaceutical sector during 2003-2020 (a Latvian company investing <$500,000), suggesting either low visibility of FDI projects or insignificant size of greenfield projects. The low investment in Armenia may also be due to strong manufacturing investments and EU-approved plants installed elsewhere in the Eastern Europe and Central Asia (ECA) region; in countries with a large talent pool, readymade infrastructure, and a developed system of regulatory approvals. Over the past five years, the whole ECA region attracted 72 FDI greenfield projects in the pharmaceutical sector, with Russia accounting for almost half of them (figure 7).

Figure 7: Number of recorded FDI greenfield projects in the pharmaceutical sector in ECA/CE region

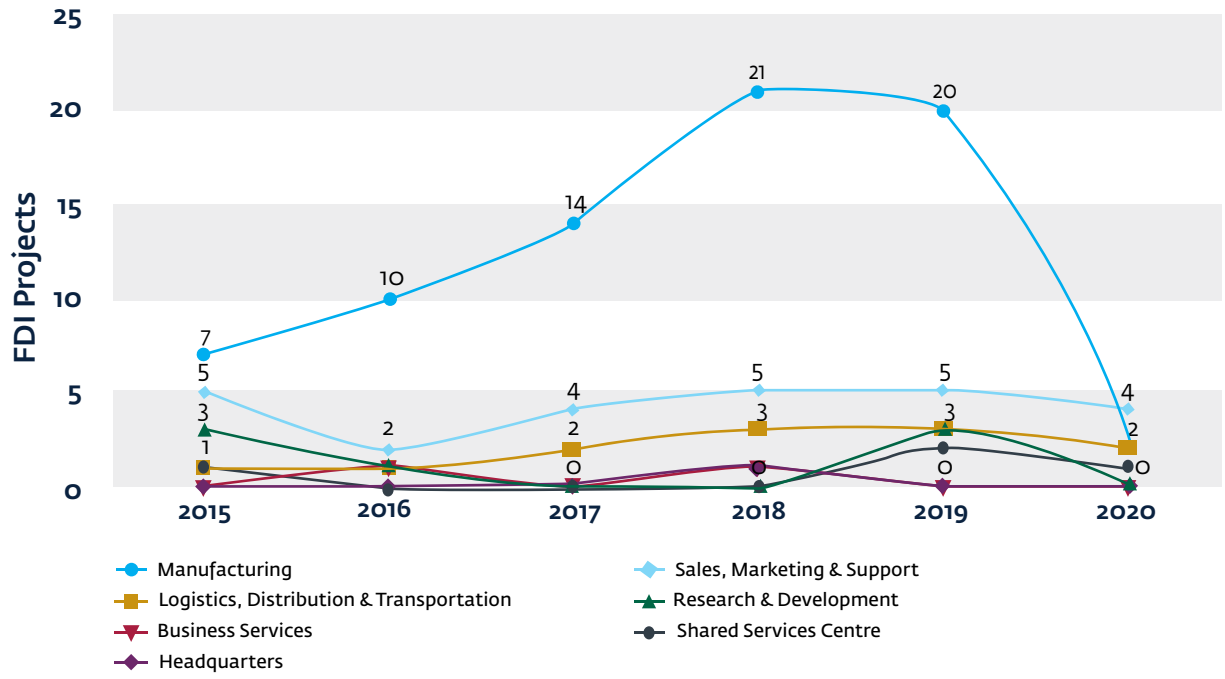
Country	Number of greenfield projects/ companies	Value of FDI (million dollars)	Number of created jobs
ECA region			
Russia	32 / 27	1 172	4 777
Uzbekistan	10 / 10	146	2 347
Kazakhstan	8 / 8	297	1 090
Serbia	7 / 5	81	578
Azerbaijan	6 / 6	307	980
Ukraine	3 / 3	29	119
Albania	2 / 2	8	23
Bosnia-Herzegovina	2 / 2	18	160
Belarus	1 / 1	1	3
Kyrgyzstan	1 / 1	3	25
TOTAL	**72 / 65**	**2 063**	**10 102**
Central European Region*			
Poland	21 / 20	194	942
Hungary	13 / 11	244	749
Turkey	9 / 8	161	928
Romania	5 / 5	73	641
Croatia	4 / 4	56	222
Bulgaria	3 / 2	41	330
TOTAL	**55 / 50**	**769**	**3 812**

Source: fDi Markets (data for Jan 2015 – Aug 2020), * incl. Turkey

Most pharmaceutical FDI projects in the ECA and Central Europe (CE) regions are in manufacturing (74 projects), followed by sales and marketing (25) and logistics and distribution (12). Only a few projects were in R&D (7), business services (4), or shared service centres (4). While the number of manufacturing projects dropped sharply in 2020 (most likely due to COVID-19 health and economic crises), the number of service-based projects did not change much (figure 8).

FDI in the pharmaceutical sector in ECA and CE regions comes mostly from the U.K., the U.S., Germany, France, and India. While there is no project recorded in the neighbouring Georgia, there are 6 FDI projects in Azerbaijan, with investment from Iran, India, Switzerland, Jordan, and Russia.

***Figure 8:** Pharmaceutical FDI projects in ECA & CE regions by business activity*



Source: fDi Markets (data for Jan 2015 – Aug 2020)

Armenia's small share of FDI in pharmaceuticals is, however, not unusual. There were 164 new FDI projects in the pharmaceutical industry registered in Europe in 2019. The pharmaceutical sector was responsible for 3 percent of all FDI projects and 1 percent of all new jobs created by FDI (figure 9). In 2020, the number of new projects in the sector increased to 265 (5 percent of all FDI projects), however the increase was driven by unique COVID-19 circumstances; due to businesses catering to surges in demand for vaccines, treatments, and personal protection equipment.[9]

9 E&Y European Investment Monitor (EIM), 2021, retrieved at **www.ey.com/en_gl/attractiveness/21/foreign-investors-back-europe-but-is-europe-back**

***Figure 9:** Top 15 FDI sectors in Europe in 2019 (projects and job creation)*

Top 15 sectors	Number of FDI Projects 2019	Market share (number of projects 2019)	Job creation 2019	Market share (number of jobs 2019)
Digital	1,219	19%	41,025	15%
Business services	774	12%	25,601	9%
Transportation manufacturers and suppliers	472	7%	64,460	23%
Machinery and equipment	535	8%	16,512	6%
Finance	367	6%	6,126	2%
Agri-food business	377	6%	11,392	4%
Transportation and logistics	414	6%	22,183	8%
Chemicals and plastics	283	4%	6,955	3%
Electronics and IT	274	4%	16,741	6%
Utility Supply	130	2%	2,964	1%
Metals	108	2%	4,834	2%
Pharmaceuticals	164	3%	3,921	1%
Raw materials	153	2%	2,788	1%
Textile, clothing and leather	111	2%	9,027	3%
Research and scientific instruments	184	3%	6,249	2%
Other	847	13%	34,157	12%
Total	6,412	100%	274,935	100%

Source: E&Y European Investment Monitor (EIM), 2020, retrieved at www.ey.com/en_gl/attractiveness/20/how-can-europe-reset-the-investment-agenda-now-to-rebuild-its-future

The pharmaceutical sector's prevailing mode of FDI is cross-border M&A. While in 2018-2019 the sector has not ranked among the top 10 sectors in value terms of newly announced FDI greenfield projects, it was the No. 1 sector in value terms of net cross-border M&A and the only sector with positive year-on-year growth rate in value terms (figure 10).

***Figure 10:** Value and number of net cross-border M&As (by sector, 2018-2019)*

Sector/Industry	Value (Billions of dollars) 2018	2019	Growth rate (%)	Number 2018	2019	Growth rate (%)
Total	**816**	**491**	**-40**	6821	6575	-4
Primary	39	34	-14	307	410	1
Manufacturing	307	243	-21	1599	1531	-4
Services	470	215	-54	4816	4634	-4
Top 10 industries in value terms:						
Pharmaceuticals, medicinal chemicals and botanical products	58	98	70	182	180	-1
Business activities	87	66	-24	1327	1156	-13
Financial and insurance activities	108	48	-55	599	565	-6
Chemicals and chemical products	119	35	-71	153	152	-4
Mining, quarrying and petroleum	38	32	-16	329	336	2
Information and communication	116	21	-82	1173	1210	3
Computer, electronic, optical products and electrical equipment	42	21	-51	257	264	3
Transportation and storage	46	20	-57	229	249	9
Food, beverages and tobacco	55	19	-65	205	177	-14
Trade	35	13	-62	501	509	2

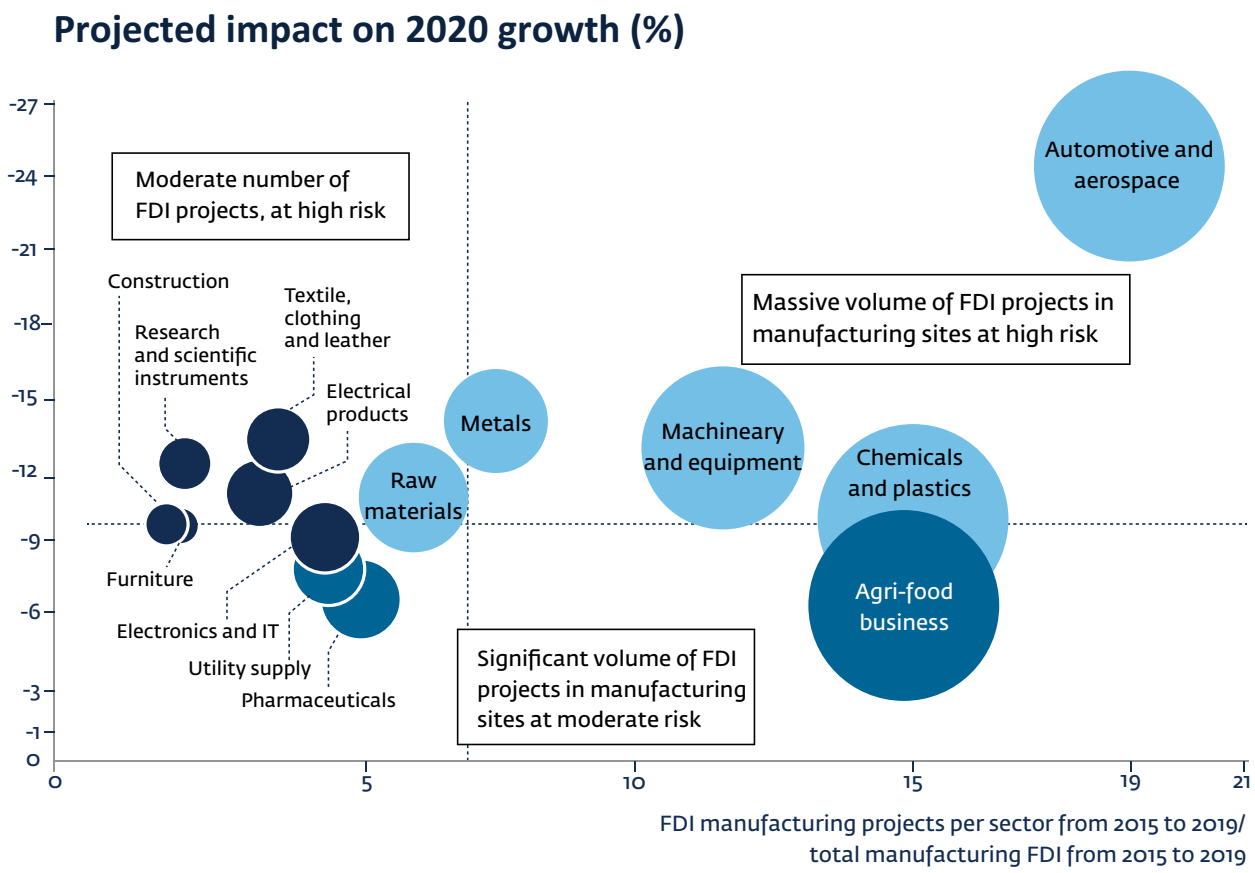
Source: World Investment Report 2020, UNCTAD

A detailed look at pharmaceutical FDI in the ECA region confirms this trend. Out of 38 FDI pharmaceutical projects that launched in Russia and Azerbaijan within the last five years, 30 percent were joint-ventures with a local producer, 25 percent was expansion of existing manufacturing facilities, 15 percent was sales and marketing. The remaining 30 percent were new greenfield manufacturing projects, a majority originating outside traditional West European countries, but from India (Hetero Drugs, Sun Pharma, Cadila Pharmaceuticals, Lupin, Star Company, PSK Pharma, ZEE Laboratories).

3.4. Impact of the COVID-19 Crisis on FDI

The COVID-19 crisis impacted the pharmaceutical industry less than other sectors. At the global level, M&A deal values in the pharmaceutical industry fell by 46 percent, but pharma remained the second largest M&A beneficiary due to deals in North America. An estimated $17 billion worth of acquisitions was made by Europe's largest pharmaceutical companies, such as Novartis (Switzerland), Sanofi (France), UCB (Belgium), and Roche (Switzerland) in the U.S. The sector appears resilient for now and is hit much less than other manufacturing FDI sectors (figure 11).

***Figure 11:** Projected sector growth and risk to manufacturing FDI projects*



Source: E&Y European Investment Monitor (EIM), 2020, retrieved at www.ey.com/en_gl/attractiveness/20/how-can-europe-reset-the-investment-agenda-now-to-rebuild-its-future

Global FDI flows show significantly different patterns before and after the start of the pandemic.

In 2019, global FDI flows rose modestly, following sizable declines registered in 2017 and 2018. At $1.54 trillion, inflows were 3 percent up. They remained below the average of the last 10 years and some 25 percent off the peak value of 2015. The rise in FDI was mainly the result of higher flows to developed economies.

Flows to transition economies also increased, while those to developing economies declined marginally. FDI stock increased by 11 percent, reaching $36 trillion on the back of rising valuations in global capital markets and higher multinational enterprises' profitability in 2019.[10]

Global FDI flows in 2020 were under severe pressure due to the COVID-19 pandemic (figure 12). Global FDI flows dropped by 35 percent to $1 trillion, from $1.5 trillion in 2019.

10 World Investment Report 2020, UNCTAD, available at https://unctad.org/system/files/official-document/wir2020_en.pdf

***Figure 12:** Global FDI flows in 2020*

Cross-border M&A

Cross-border M&A values reached $475 billion in 2020. The 13 percent decline in developed countries, which account for about 80 percent of global transactions, was checked by the continuation of M&A activity in digital industries. In the second half of the year, cross-border M&A partly recovered, although the recovery was concentrated in developed economies.

Greenfield FDI

The value of greenfield investment project announcements–an indicator of future FDI trends–was $564 billion in 2020. Developing economies saw a much bigger fall (-44 percent) than developed economies (-16 percent), reflecting their more limited capacity to roll out economic support packages. Greenfield investment in the transition economies fell by 58 percent. In larger recipients of greenfield investment such as Kazakhstan (-86 percent), Russia (-68 percent) and Serbia (-72 percent), the decline was even steeper, indicating a major slowdown in future investment intentions.

Source: World Investment Report 2021, UNCTAD

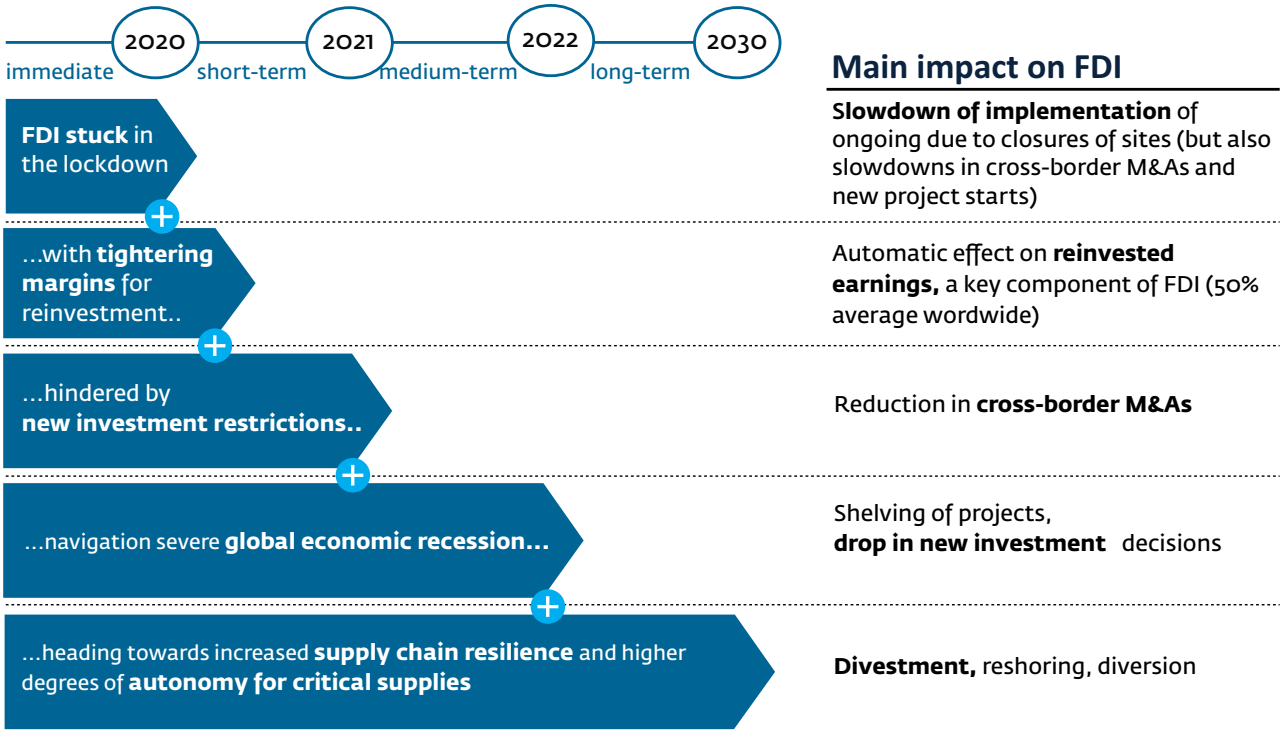
All components of FDI were down. The overall contraction in new project activity, combined with a slowdown in cross-border M&As, led to a decline in equity investment flows by more than 50 percent. The impact of the pandemic on global FDI was concentrated in the first half of 2020. In the second half, cross-border M&As and international project finance deals largely recovered. But greenfield investment–more important for developing countries–continued its negative trend throughout 2020 and into the first quarter of 2021.[11]

While the COVID-19 crisis has already had immediate effects on FDI, it can also have potentially lasting consequences through a transmission mechanism (figure 13). In the healthcare sector, the pandemic has brought about some serious disruptions and interruptions to the pharmaceutical supply chain, which will likely lead to re-examination of the value chain to build flexibility where needed for future pharmaceutical companies' success.[12] We are increasingly seeing a huge shift towards local manufacturing as pharma and health security has become increasingly important due to the crisis.

11 World Investment Report 2021, UNCTAD, available at **https://unctad.org/system/files/official-document/wir2021_en.pdf**

12 Alex Jung: COVID-19: risks and resiliency in the drug supply chain, E&Y, accessible at **www.ey.com/en_us/strategy-transactions/covid-19-risks-and-resiliency-in-the-drug-supply-chain.**

Figure 13: Impact of the pandemic on FDI: transmission mechanism



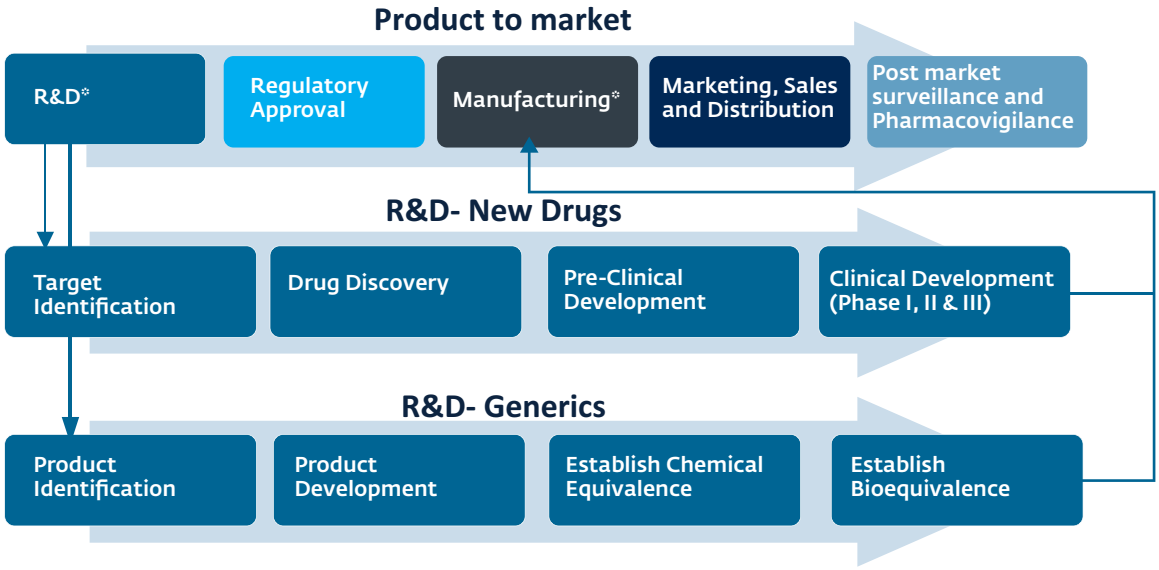
Source: World Investment Report 2020, UNCTAD; retrieved at https://unctad.org/system/files/official-document/wir2020_en.pdf

3.5. Pharmaceutical Sector Value-Chain and International Production Trends

A supply chain is the means by which a company transfers its products from development to the marketplace to sell them and generate a profit. It includes all the organizational, operational, and value-adding activities needed to manufacture those products and get them to the customer. So, for a pharma company, it covers everything from new product development through to delivery to the hospital, retail pharmacy or patient.

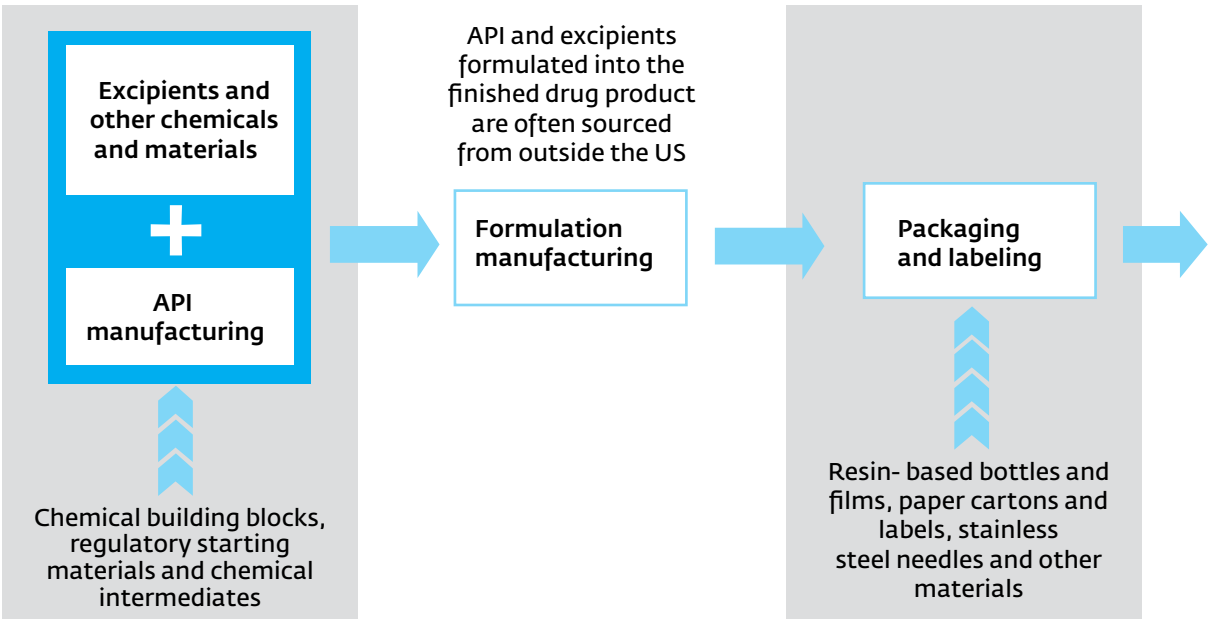
It starts with R&D activities needed for product development. These are organized in a way which either leads to full-scale production of a new drug involving expensive and time-consuming clinical trials (new drugs/brands) or development of chemically and biologically equivalent copies of innovative products after their patent protection has expired (generic drugs/generics) (figure 14).

Figure 14: Pharmaceutical sector value chain



The pharmaceutical manufacturing supply chain involves two main stages. The first is the production of active pharmaceutical ingredients (APIs). These are the key ingredients of drugs, which produce the intended effects. API production is chemical-intensive, involving reactors for drug substance manufacture. The second stage is a physical process known as formulations production. Substances known as excipients are combined with APIs to turn a drug into a consumable form, such as a tablet, liquid, capsule, cream, ointment. or injectable. (figure 15).

Figure 15: Pharmaceutical sector material procurement and manufacturing



While APIs are largely synthesized, fermented, extracted, or isolated in low-cost, high-volume manufacturing countries (India and China are responsible for over 60 percent of global API production),[13] formulated drug products are typically manufactured in a geographic region nearer to their ultimate end market. Beyond the APIs and excipients that are necessary for the production and distribution of drugs is packaging, often made outside the ultimate end market too. Packaging and labels rely on components like resin-based bottles and films, paper cartons and labels, stainless steel needles, and other materials required to safely contain, transport, and administer medication.

The pharmaceutical value chain is made up of many connected components that have been significantly decentralized and optimized to reduce the cost of production and distribution. Like in many other sectors, new international production patterns have emerged in the pharmaceutical sector.

As a result of the growing demand for generic medicines and biologics, the capital-intensive nature of the business, and complex manufacturing requirements, many pharmaceutical companies have identified potential profitability in contract manufacturing outsourcing (CMO) for both clinical and commercial stage manufacturing. CMO is now a common feature of formulation manufacturing for many pharmaceutical MNCs.[14]

To stay competitive and flexible in a world of exponentially growing knowledge and increasingly sophisticated technologies, pharmaceutical companies are nowadays also increasingly outsourcing research activities to academic and private contract research organizations (CROs). The R&D tasks that firms choose to outsource include a wide spectrum of activities from basic research to late-stage development: genetic engineering, target validation, assay development, hit exploration, and lead optimization. CROs are also typically involved in assessment of biological safety and efficacy of drug entities in in-vitro and animal models or in pharmacokinetic studies.

The pharmaceutical industry is geographically concentrated–globally, it contributes at least 5 percent of GDP in only 4 percent of countries (figure 16). The opportunity for countries to participate in pharmaceutical GVCs is thus small because of the low pre-existing domestic production capacity.

13 APIs – Global market report - Edition 2019

14 In pharmaceuticals, the trend to outsource production stages along the pharmaceutical value chain in their home markets is leading MNCs to adopt the same lean model globally. For example, as part of Pfizer's outsourcing strategy, the company manages approximately 150 contract manufacturers around the world.

***Figure 16:** Key dimensions of international production*

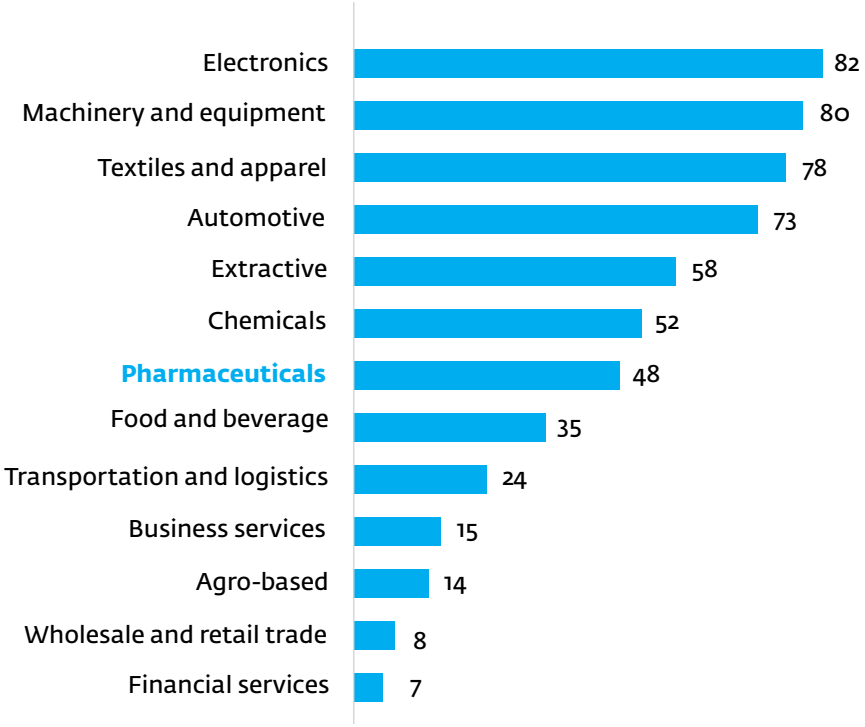
	Length/fragmentation of value chains		Geographical Distribution of value added			Governance of value chains	
	Steps	Distance	Concentration		Contribution	FDI intensity	NEM intensity
Sector/Industry	Number	Km	Number of countries accounting for 80% of value added in gross exports	Number of countries accounting for >0.5% of value added in gross exports	Share of countries in which contribution is >5% of GDP (%)	Share of countries in which contribution is >5% of GDP (%)	Share of countries in which contribution is >5% of GDP (%)
Primary							
Agro-based	1.9	1 484	29	34	30	0.2	3
Extractive	1.5	1 402	22	37	12	2.0	2
Manufacturing							
Food and beverage	2.4	1 971	23	35	24	1.4	3
Textiles and apparel	2.6	2 278	20	31	6	0.1	5
Pharmaceuticals	1.8	2 433	21	30	4	2.2	4
Chemicals	2.4	2 911	21	37	36	0.9	2
Automotive	2.8	2 789	12	22	6	0.5	2
Machinery and equipment	2.5	2 457	16	32	37	0.4	4
Electronics	2.6	2 990	14	30	37	0.2	4
Services							
Wholesale and retail trade	1.7	1 083	16	27	55	1.1	2
Transportation and logistics	1.9	1 935	28	41	18	0.8	4
Financial services	1.7	858	18	36	84		1
Business services	1.5	1 203	16	35	82	1.3	1
Median	**1.9**	**1 971**	**18**	**34**	**30**	**0.8**	**3**

Source: World Investment Report 2020, UNCTAD

Another common characteristic of the sector is a medium degree of internationalization (figure 17). In contrast to many other sectors (for example, the textile and apparel industry), the pharmaceutical global value chain (GVC) has specific requirements in terms of quality controls, high degree of intellectual property, and reliance on tacit knowledge. As a result, a general international production configuration applied to the pharmaceutical sector is that of a "global hub and spokes" model, with a short value chain, and few steps, if any, between high value-added upstream activities and the production and packaging of medication close to markets, geographic distribution of value-added product, and high governance. This limits participation of many countries in the global pharmaceutical GVCs.

15 World Investment Report 2020, UNCTAD; retrieved at **https://unctad.org/system/files/official-document/wir2020_en.pdf**

***Figure 17:** Degree of internalization of selected industries (gross exports as share of output, %)*



Source: World Investment Report 2020, UNCTAD

4. Investor Targeting

Investor targeting—that is, proactively reaching out to investors identified as being desirable and likely to invest and presenting them with tailored business cases to help them select a given location—is the main proactive element of any country's wider investment promotion strategy. Companies seeking to expand internationally are likely to compare several possible locations against a set of predetermined criteria to arrive at the best investment location for them. In general, criteria used by investors to compare locations for investment in any sector may be both quantitative and qualitative, typically covering aspects of doing business like access to markets, operating costs, various forms of risk, and quality of life.

In the long term, the Government of Armenia can improve the country's competitiveness by improving its investment climate, infrastructure, workforce, and policy support for attractive sectors. In the short term, the government can improve its chances by making sure that Armenia makes it onto potential investors' lists of possible investment locations and potential investors have access to the most complete and positively framed information possible. Targeting seeks to accomplish these two tasks by seeking out and directly engaging investors identified as having high potential interest in a particular location.

Without well planned and proactive targeting, the country surrenders some of the little influence a government can wield over investor site-selection decisions, and government allocation of valuable land assets may be driven by unsolicited proposals from investors of suboptimal merit. Targeting, if planned and delivered properly, can provide the Government of Armenia with some influence over the types of investment attracted, and whether successful or not, it invariably provides valuable insights into what Armenia can do to improve its attractiveness to investors.

Without proactive outreach, Armenia's investment promotion depends on investors to "make the first move." However, many developing countries suffer from poor images or weak investment track records and may not be considered by the most attractive investors. These countries struggle to attract capital, jobs, technology, skills, and international business connections. Global evidence shows that outreach may be the only way for these countries to attract sufficient interest from potential investors who would otherwise not consider their locations.

Strategic targeting is generally regarded as the most effective method for the promotion of FDI, regardless of the economic background of the country. Empirical evidence demonstrates that targeting has been successful, both in small regions and large countries, in emerging and mature economies, and by investment promotion agencies (IPAs) regardless of budget size.[16]

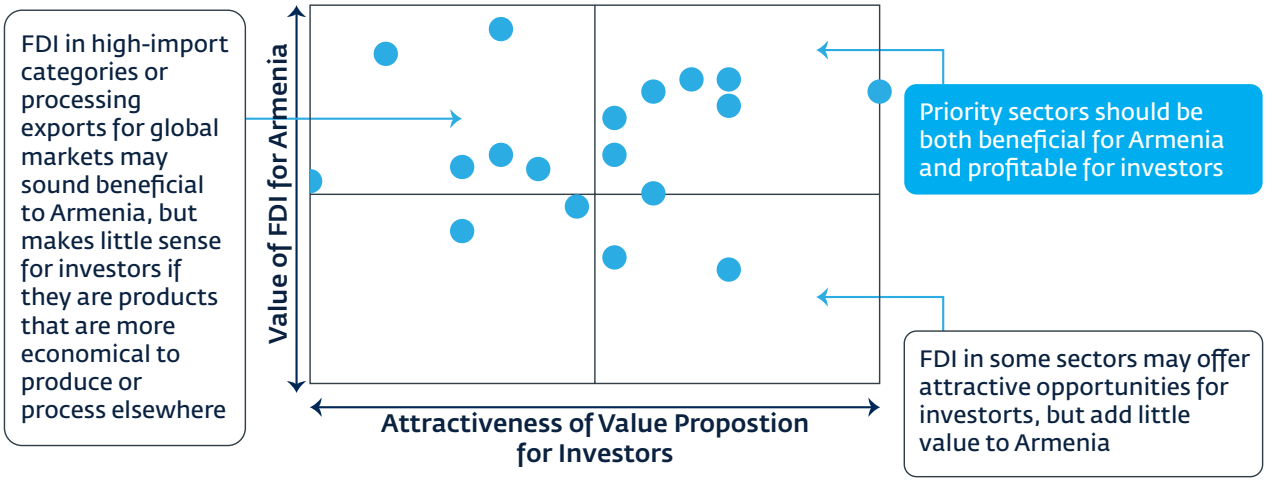
16 See, for instance, Harding, T. and Javorcik, B. S. (2011), Roll Out the Red Carpet and They Will Come: Investment Promotion and FDI Inflows. The Economic Journal, 121: 1445–1476.

4.1. Sector Scan–a Tool for Identification of Competitive Subsectors for FDI

This report describes the results of a review of pharmaceutical subsector competitiveness for FDI (known as a "sector scan") undertaken by the World Bank Group. The sector scan attempts to identify those pharma subsectors that have both sufficient competitiveness to attract FDI and are likely to bring the desired development impact, considering the current conditions in the international economy and Armenia. The scan is the first step towards investor targeting. By selecting the pharmaceutical subsectors where FDI will add most value to Armenia and in which Armenia has a strong-value proposition to offer investors, the outcome of the sector scan is to provide Enterprise Armenia with a list of subsectors that the agency may target through proactive outreach (figure 18).

As a principle, the priority sectors for promoting FDI should always be those that offer the most value to Armenia and the most value to investors (top right quadrant of chart). While attracting FDI into sectors that have high imports or that have the potential to export to regional and global markets may sound beneficial to Armenia, investing in those sectors could make little economic sense for investors, for example if they have products that are more economical to produce or process elsewhere (that is, the commercial economics of the project do not stack up). On the other hand, FDI in some sectors may offer attractive opportunities for investors, but add little value to Armenia in terms of jobs or exports, in line with national development objectives, or could lead to crowding-out domestic investment.

***Figure 18:** Illustrative example of framework for selecting priority sectors*



The following methodological framework was used to evaluate and select priority pharmaceutical subsectors for FDI promotion and reflect government objectives for FDI attraction and to ensure that Armenia is a competitive location:

***Figure 19:** Sector-scan methodological framework*

To what extent:	Score	Evidence
1. Will additional FDI in this sector add value to Armenia?		
• Will new investors add value that is not already provided by local producers & existing investors?	1-5	• Quantity and quality of existing producers, SMEs, and investors already operating in the sector; impact of new investors on local SMEs in the sector.
• Will new investors create additional jobs?	1-5	• Potential jobs generated by new investments in the sector.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	1-5	• Improved opportunities for domestic firms to supply their goods/services to foreign investors and improved incomes generated by new investments in this sector.
• Will new investors create increased export revenues or reduce imports?	1-5	• Potential export revenues or reduced imports generated by investments in the sector.
• Will new investors improve performance of the value chain as a whole?	1-5	• Potential impact on other parts of the value chain (improved inputs or improved sales opportunities for domestic suppliers).
SUBTOTAL	**5-25**	
2.Does investment in this sector offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply and prices) attractive?		
• Are the local and regional markets attractive?	1-5	• Demand, supply and price trends in Armenia and neighboring countries.
• Is the global market attractive?	1-5	• Demand, supply, and price trends in major global markets.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)?	1-5	• Availability of suitable raw materials, proximity to key markets, etc.
• Does Armenia have competitive infrastructure?	1-5	• Availability and cost of power, transport, manufacturing sites, etc.
• Does Armenia have competitive skills and support services?	1-5	• Availability and productivity of suitable workforce and support services.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	1-5	• Absence of regulatory of institutional barriers that might deter investors or hinder their performance.
SUBTOTAL	**6-30**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

4.2. Selection of competitive subsectors

The pharmaceutical sector is at the core of the sector scan as this sector has been given a strategic importance by the policy makers and is export oriented. This sector-scan report has considered the following 5+1 value chain subsectors for a detailed analysis:

1. **Production of APIs**
2. **Production of original pharmaceutical products**
3. **Production of generic pharmaceutical products**
4. **Contract manufacturing outsourcing (CMO)**
5. **Contract pharmaceutical research (CRO)**

+

6. **Medical devices & supplies manufacturing.**

The first five subsectors reflect the pharmaceutical sector value-chain activities; the last subsector was added to test Armenia's opportunities to attract FDI in a health-related manufacturing sector outside pharmaceuticals. As there are no biotechnology companies manufacturing products based on genetic analysis and genetic engineering, including protein-based therapeutics (for example, insulin production) in Armenia, this subsector has been left out too. Other subsectors, which attract primarily market-driven FDI (such as healthcare services) and do not require intensive investment promotion, were left out. The sector selection does not mirror the selection of commercially viable sectors identified by IFC Sector Deep Dive - Health[17] as there are different investment drivers for efficiency-seeking FDI and for commercially viable projects sought after by IFC's investment team.

Some subsectors can be classified under different industry headlines. Healthcare technologies, for instance, provide IT services primarily to healthcare providers (for example, applications, systems and/or data processing, internet-based tools, and IT consulting services to doctors, hospitals, or businesses) and have already been included in a recent ICT sector scan.[18] Effective investment promotion needs to focus on sectors in which Armenia represents a viable location in competition with other locations.

The subsector review and analysis is based on interviews with a cross-section of policy-makers, investors, and other stakeholders and existing studies of the value-chain needs and opportunities (see annex 2 for a full list of interviewed experts and private sector representatives).

17 See IFC Strategy and Business Update FY20-FY22 (page 50), available at **https://documents1.worldbank.org/curated/en/567541556555433909/pdf/IFC-Strategy-and-Business-Outlook-Update-FY20-FY22-Gearing-up-to-Deliver-IFC-3-0-at-Scale.pdf**

18 World Bank 2020, Armenia's FDI competitiveness in the ICT sector (IBM-Plant Location International report)

5. Sector-Scan Results

5.1. Production of APIs

In 2018, the global API market size was valued at $162 billion, and this is expected to grow at a CAGR of 5.7 percent from 2020 to 2027. This rise can be attributed to increased occurrence of chronic diseases, technology advances in API manufacturing and increasing significance of generic drugs (patent-expired blockbuster drugs). APIs are either produced in-house for the internal consumption of a pharmaceutical company or by specialized API producers. The revenue of the in-house API manufacturing segment has declined in the past few years due to outsourcing of API production. A high degree of competition and reduced profitability are the key factors attributed to the increased preference for outsourcing API production.[19]

APIs are largely synthesized, fermented, extracted, or isolated in low-cost, high-volume manufacturing countries; the main production hub is concentrated in the Asia-Pacific region, primarily in India, China, and Taiwan (India and China are responsible for over 60 percent of global API production).[20] China, in particular, has been emerging as the global API production centre with bulk APIs costing approximately a third of Indian manufactured APIs. There are several factors behind Chinese achievements in production and export of APIs: the country has successfully developed cost-effective technologies, acquired an advantageous edge with large-scale manufacturing operations, cheap and shared utilities, along with supportive government policies, including highly subsidized pricing of APIs. This has resulted in the shutting down of some domestic API manufacturing facilities in India. Indian firms have gradually disengaged from the production of APIs as the capital investments did not yield higher returns.[21]

API production requires cost-efficient access to raw materials or chemical product manufacturers and often entails sophisticated chemical manufacturing processes that are subject to high-quality assurance standards and good manufacturing practices (GMP).

Leading players operating in the global API market are:[22]

- **Teva Pharmaceutical Industries Ltd.**
- **Sun Pharmaceutical Industries Ltd.**

19 Active Pharmaceutical Ingredients (API) Market - Industry Trends and Forecast to 2027, Vision Research Reports, retrieved from **www.mynewsdesk.com/se/pnewswire/pressreleases/active-pharmaceutical-ingredients-api-market-2020-size-global-trends-comprehensive-research-study-development-status-opportunities-future-dot-dot-dot-3034140**

20 APIs – Global market report - Edition 2019

21 Future of Pharmaceutical industry in India, September 2020, Observer Research Foundation, retrieved from **www.orfonline.org/expert-speak/future-of-pharmaceutical-industry-in-india.**

22 Active Pharmaceutical Ingredients (API) Market 2020 Size, Global Trends, Comprehensive Research Study, Development Status, Opportunities, Future Plans, Competitive Landscape and Growth by Forecast 2027, Vision Research Reports, September 2020

- **Aurobindo Pharma**
- **Boehringer Ingelheim GmbH**
- **Merck & Co., Inc.**
- **Novartis AG**
- **BASF SE**
- **F. Hoffmann-La Roche Ltd**
- **Bayer AG.**

There are no API producers in Armenia and local pharmaceuticals producers depend entirely on imports from traditional API production hubs (China, India) and also from the EU, the U.S., or Russia. FDI in the API subsector would, therefore, add considerable value to the domestic pharmaceutical value chain and improve its performance as a whole. The country, however, does not provide competitive supply conditions. The economy of API production depends on three key factors: access to primary raw materials, a highly developed synthetic chemical industry base and talent pool, and easy and cost-efficient access to main regional/global transport routes for trade in bulk materials. Armenia is not internationally competitive in any of these three areas and does not provide a viable investment proposition for MNCs in API production subsectors. This conclusion has been shared by all private sector representatives interviewed during the data collection phase.

Production of APIs		
To what extent:	**Score**	**Evidence**
Will additional FDI in production of APIs add value to Armenia?		
• Will new investors add value that is not already provided by local producers and existing investors?	5	• New FDI would add considerable value as the domestic APIs production is non-existent and local producers fully depend on imports.
• Will new investors create additional jobs?	2	• API production is a moderately labour-intensive production; new jobs will be created. However, for a substantial employment impact FDI would need to operate on a larger scale, which is unlikely given the existing input constraints.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	1	• New entrants would not generate new supplier opportunities as API production is one of the upstream activities with little supplier inputs apart from raw materials.
• Will new investors create increased export revenues or reduce imports?	4	• New FDI could positively impact trade balance as Armenia is highly dependent on API imports.
• Will new investors improve the performance of the value chain as a whole?	5	• Additional FDI could positively impact the whole value chain as it would bring in new elements to the value chain, which are currently missing.
SUBTOTAL	**17**	

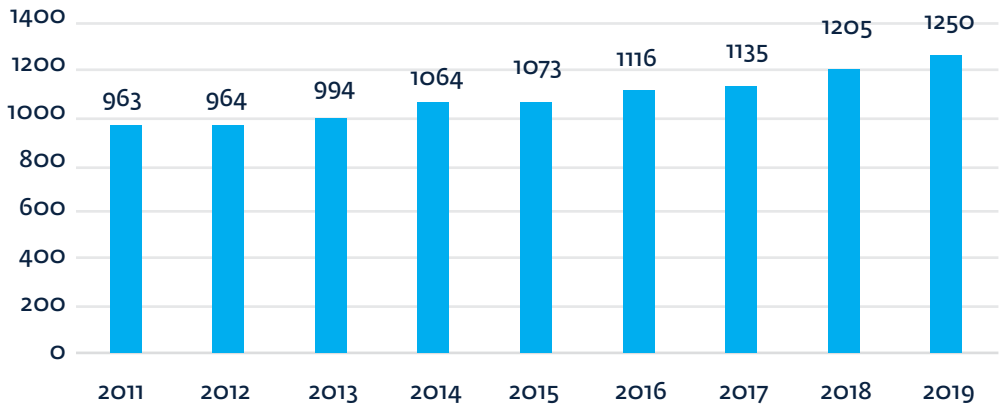
Does investment in production of APIs offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply, and prices) attractive?		
• Are the local and regional markets attractive?	1	• Domestic market is too small; regional (EAEU) market provides more business opportunities but also faces higher competition from existing global producers. Production in Russia rather than in Armenia may provide additional benefits to foreign investors wishing to serve the EAEU market.
• Is the global market attractive?	1	• The global market is increasing and provides new business opportunities; the Asia Pacific market for APIs is projected to expand faster than elsewhere. Armenia's limited transport options, high transport cost of high-volume bulk cargo and trade costs make the investment proposition to serve global markets out of Armenia unrealistic.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)?	1	• Insufficient raw materials resources and basic chemical production preclude FDI.
• Does Armenia have competitive infrastructure?	1	• High transport costs due to poor country connectivity increases operation costs.
• Does Armenia have competitive skills and supportive services?	2	• Limited skill base for a large scale FDI operations.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	2	• There are no specific investment and regulatory incentives for API producers in place in Armenia.
SUBTOTAL	**8**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

5.2. Production of Original Pharmaceutical Products

In 2019 the worldwide pharmaceutical market was worth nearly $1.3 trillion (figure 20), with 4 to 5 percent growth globally; the top 10 pharma companies accounted for around a third of sales ($393 billion)[23]. Global spending is expected to exceed $1.5 trillion by 2023 as the market grows in mid-single digits.

23 World Preview 2019, Outlook to 2024, EvaluatePharma (2019), retrieved from https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf.

***Figure 20:** Revenue of the worldwide pharmaceutical market (in billion dollars)*



Source: Pharmaceutical market: worldwide revenue 2001-2019, retrieved from www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001

The COVID-19 pandemic has crippled several sectors such as transportation and non-food retailing, However, the pharmaceutical sector has been cashing in on continued demand for the development and supply of treatments by healthcare systems around the world. While the pandemic has changed the way healthcare is delivered and has resulted in a surge in online healthcare and remote consultation, global drug sales are expected to rise too. Some analysts predict a growth rate twice as high as the average of the market over the last decade.[24] Despite these positive predictions, the global pharmaceutical sector is experiencing price pressure from multiple governments, which are curbing healthcare costs through price regulations. This affects overall profit margins for pharmaceutical operations.

There is little investment motivation for purely domestic market-seeking FDI in the pharmaceutical sector in Armenia. Armenia's pharmaceutical market does not offer many revenue generation opportunities for MNC pharmaceutical firms on account of its small market size (population of 2.96 million) and unfavourable demographic trends. Although the share of population aged 65 and over is set to rise in Armenia from 10 percent to almost 20 percent of the population by 2030, the total population is thereafter expected to shrink by about 10 percent down to 2.7 million by 2050.[25] Importing original pharmaceutical products is, therefore, almost always a more economical option for market entry than FDI.

In addition to the small market size, Armenia also displays a low propensity for healthcare and pharmaceutical spending. Armenia's public health financing is among the lowest in the region (figure 23); household out-of-pocket spending (OOPS) is the predominant source of

24 See, for instance, sector overview by Euler Hermes, accessible at **https://www.eulerhermes.com/en_global/economic-research/sector-reports/pharmaceuticals.html**

25 Future Armenia: Connect, Compete, Prosper (World Bank Group/Systematic Country Diagnostic, Nov. 2017)

financing for health in the country (figure 21, 22), with approximately $300 being the annual health spending per capita.[26]

***Figure 21:** Sources of health expenditure*

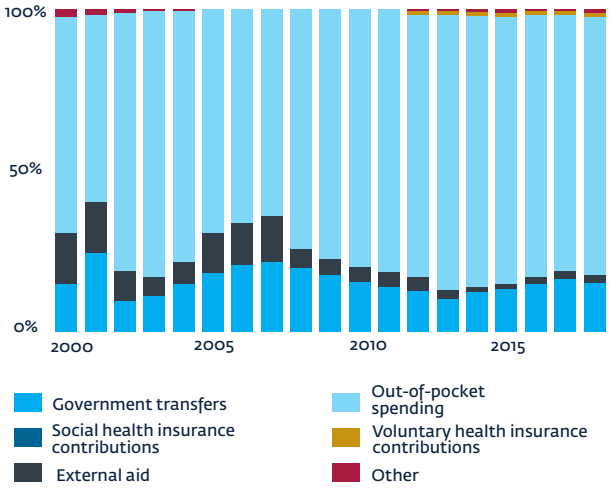


***Figure 22:** Government vs. out-of-pocket health spending per capita (constant dollar)*

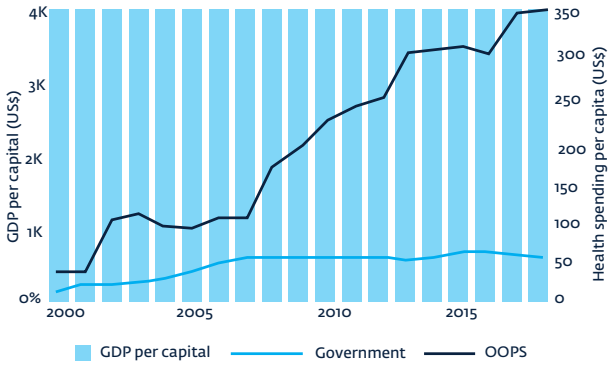
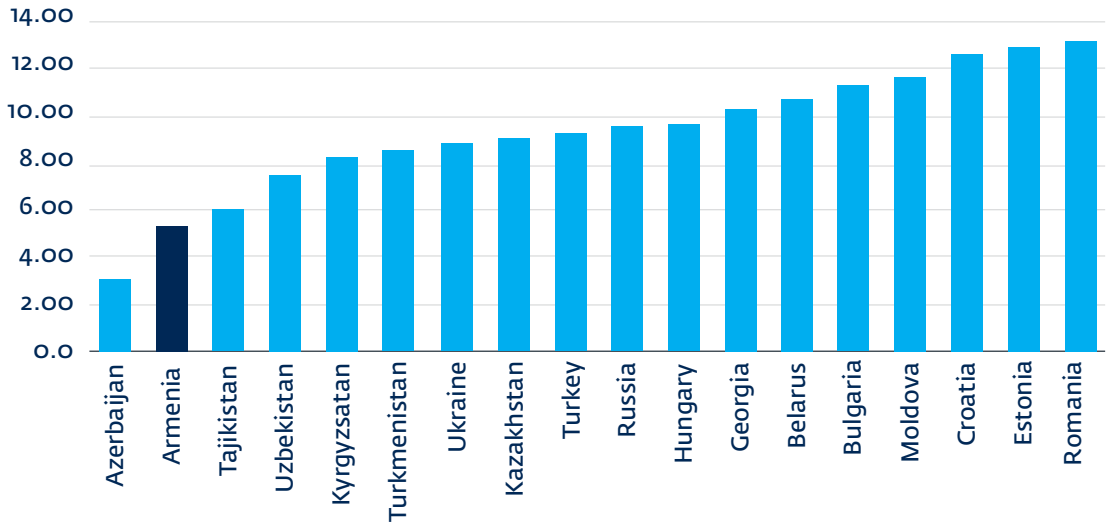


***Figure 23:** Health's share of government expenditures, selected countries (2018)*



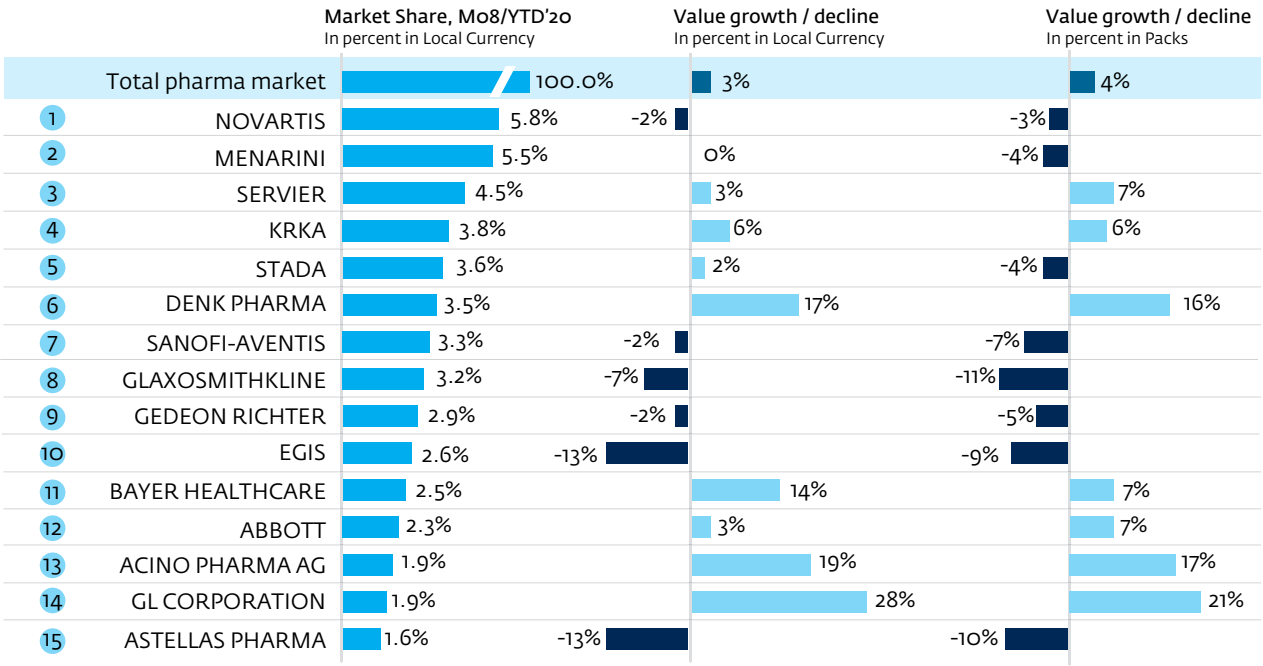
Source: WHO, Global Health Expenditure Database 2020

26 Lavado, R., Hayrapetyan, S., and Kharazyan, S. 2018. "Expansion of the Benefits Package: The Experience of Armenia". Universal Health Care Coverage Series No. 27, World Bank Group, Washington, DC.

Following the lead of some of its regional peers, Armenia is looking to implement a compulsory health insurance system (universal health coverage) to replace its current model. It is hoped that this system will increase efficiency of healthcare funds, enable greater access to healthcare services and medicines, and potentially increase market attractiveness to pharmaceutical producers. There is, however, no clear implementation timeline for the introduction of the universal health coverage system.

There is no original pharmaceuticals production in Armenia. Unlike the capital-light IT industry, the Armenian pharmaceutical industry does not have access to the deep pools of risk capital needed to innovate in this sector (where a single new drug can take 10 years and a billion dollars to reach market) and the skills needed for innovative pharmaceuticals production. The market is served either by imports of original drugs produced by MNCs or by domestic production of generics. Foreign imports have the largest share of the domestic pharmaceutical sales market–the top 15 pharmaceutical companies cover half of the domestic market (figure 24).

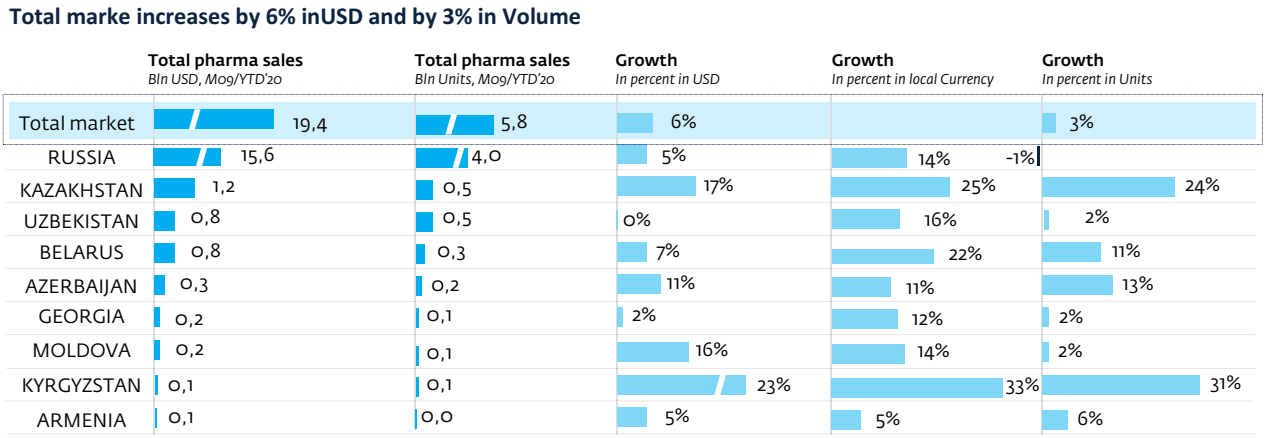
***Figure 24:** Top 15 corporations on Armenia market (January–August 2020)*



Source: Russia and CIS pharma market growth in September 2020, IQVIA; retrieved from www.iqvia.com/locations/russia/library/presentations/september-2020-russia-and-cis-pharma-market-growth

A regional market could be a better investment driver. With a population of nearly 240 million, the Eurasian Economic Union (EAEU) and Commonwealth of Independent States (CIS) represent an important market for the pharmaceutical sector. Russia as the largest market in the region (80 percent of total pharma sales), is viewed by the industry as a priority growth market that has enjoyed a continued growth over the past decade without slowing during the COVID-19 pandemic (figure 25).[27]

***Figure 25:** Pharmaceutical market in EAEU / CIS countries (Jan – Sep 2020; value in billion dollars)*



Source: Russia and CIS pharma market growth in September 2020, IQVIA; retrieved at www.iqvia.com/-/media/iqvia/pdfs/russia/facts/september-2020-facts-from-iqvia.pdf.

Market growth prospects remain positive, although the EAEU pharmaceutical industry will face multiple conflicting demographic factors (decreasing fertility rates and specific migratory dynamics on one hand and, on the other, rapidly ageing populations with higher incidences of non-contagious chronic diseases and conditions such as cardiovascular disease, obesity and type-2 diabetes). At the same time, the pharmaceutical industry in the region is considered the most complex as it involves complicated legal, regulatory, and marketing factors.[28,29]

27 Figures exclude sales of parapharmaceuticals (food supplements). Total sales including parapharmaceuticals reached $25 billion in 2019. In January to September, market size grew 10.6 percent in RUB terms, faster than in dollar terms. Source: Deloitte CIS Research Center (2020): Russian Pharmaceutical Market Trends 2020; retrieved at www2.deloitte.com/content/dam/Deloitte/ru/Documents/life-sciences-health-care/russian-rharmaceutical-market-trends-2020.pdf.

28 Trademarks in the medical sphere: practice, examination and obstacles for registration in Russia, Ukraine and the CIS. European Pharmaceutical Review, 20 July 2020, accessible at www.europeanpharmaceuticalreview.com/article/122618/trademarks-in-the-medical-sphere-practice-examination-and-obstacles-for-registration-in-russia-ukraine-and-the-cis

29 FIAC survey: foreign business in Russia, October 2020, accessible at https://assets.ey.com/content/dam/ey-sites/ey-com/en_ru/news/2020/10/ey-fiac-survey-2020-eng.pdf

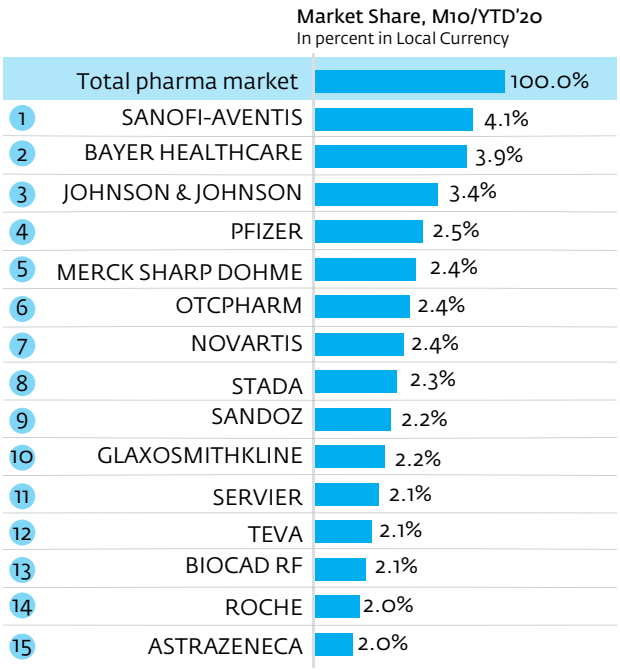
Yet the Russian and CIS markets also face stronger competition from generic drug producers. Of 15 top global pharma companies (figure 26), only eight rank among the 15 top pharma companies in the Russian market, with a total market share of about 20 percent (figure 27). The Financial Times fDi Markets database of cross-border greenfield investments registers 23 FDI projects in the ECA region between 2015 and 2020 from seven of the top pharma companies (all FDI went to Russia), suggesting that even for a large regional market imports, NEMs, rather than FDI, may be a preferred market access choice for large pharmaceutical MNCs.

***Figure 26:** Top global pharma companies by revenues (billion dollars, 2020)*

Rank	Company	Revenues
1	Johnson & Johnson	60.11
2	Roche	31.62
3	Pfizer	23.83
4	Novartis	23.63
5	Merck	22.93
6	GlaxoSmithKline	21.47
7	Bristol Myers Squibb	20.35
8	Sanofi	20.03
9	Abbvie	19.04
10	Abbott	15.05
11	Astra Zeneca	12.63
12	Amgen	11.80
13	Eli Lilly	11.36
14	Gilead	10.53
15	Novo Nordisk	10.00

Source: IQVIA, October 2020

***Figure 27:** Top 15 pharma companies in the Russian market (Jan– Oct 2020)*



Source: iPharmaCentre, October 2020

Pharmaceutical biotechnology is another growing subsector in which the principles of biotechnology are applied to the development of drugs. A majority of therapeutic drugs in the current market are bioformulations, such as antibodies, nucleic acid products, vaccines and protein-based therapeutics to treat human diseases. Similar to original pharmaceuticals, there are no biotechnology (or biosimilars) producers in Armenia. Unlike existing generics production, the missing biotechnology/ biosimilars production means there are very limited skills for production of pharmaceutical biotechnology in Armenia.

The most recent operational and development trends in pharmaceuticals production focus on improving profitability, either by exploring more lucrative business opportunities (such as biosimilars) or by implementing cost-efficient measures to reduce overall costs (figure 28).

***Figure 28:** Recent pharmaceutical sector trends*

Industry 4.0 in manufacturing

Adoption of disruptive Industry 4.0 technologies offers a potential solution to sector streamlining and cost reduction, such as setting up intelligent factories with highly integrated, flexible IT and manufacturing systems. This type of investment allows companies to increase productivity, by implementing a higher level of automation and control on human intervention, while scaling-up production through data-driven program management.

Biosimilars to gain further ground

Production of biosimilars (medicines that are made from living microorganisms found in plant or animal cells) is expected to be spurred by the loss of patent protection for bestselling biologics. Industry reports indicate 66 innovator biologics are due to come off-patent between 2020 and 2025. Consequently, it is expected there will be an increasing number of biosimilar production in the coming years. This is especially lucrative, as this type of product is mostly destined to premium, high-value-added drugs.

Pharmaceutical companies to restructure in search of cost efficiency

Pharmaceutical companies are continuing to reduce overall costs, by reducing staff, refocusing R&D, closing manufacturing plants, and divesting poorly-performing or sub-scale businesses. These savings are expected to be used to re-stock pipelines with promising new drug candidates.

Artificial Intelligence (AI) to be implemented in R&D

AI will increase drug development efficiency by streamlining research efforts. The predictive and analytical powers of AI are expected to enable companies to make smarter, faster, and more strategic decisions, by collecting and aggregating disparate data sets and identifying patterns, which in turn will generate more insights.

Mergers and Acquisitions (M&A)

M&A will be driven by a need to consolidate a highly fragmented business sector. Large pharmaceutical companies continue to outsource more of their manufacturing activity and want to simplify the outsourced manufacturing supply chain by having larger integrated suppliers. Investors, fuelled by the continued availability of relatively low-cost finance, will see this as an opportunity to be the consolidator in an evolving, long-term successful business sector.

Source: Euromonitor International, Ltd. 2019

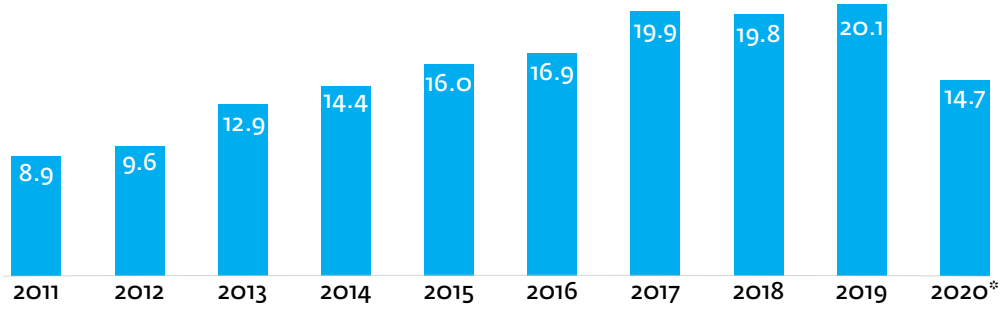
Armenia does not provide a competitive production landscape that would fit these future trends. The absence of original pharmaceutical producers and companies operating in biotechnology precludes M&As and FDI in production of biosimilars. Use of traditional industry production technologies does not meet the sector expected future needs either.

Production of original pharmaceutical products		
To what extent:	**Score**	**Evidence**
Will additional FDI in production of original pharmaceutical products add value to Armenia?		
• Will new investors add value that is not already provided by local producers and existing investors?	4	• New FDI would add value as the domestic pharmaceutical production focuses solely on production of generic pharmaceuticals.
• Will new investors create additional jobs?	3	• Pharmaceutical production is a moderately labour-intensive sector; new jobs will be created. However, unless R&D activities are part of the FDI operation, the jobs created will not necessarily require qualified labour.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	2	• New entrants would not generate new supplier opportunities as there is no domestic production of API, excipients, or pharmaceutical packaging materials.
• Will new investors create increased export revenues or reduce imports?	4	• New FDI could positively impact trade balance as domestic production would lead to import substitution.
• Will new investors improve the performance of the value chain as a whole?	3	• Additional FDI in manufacturing of original pharmaceutical products would not bring about a major improvement of the value chain, as the production methods do not differ much from generics production.
SUBTOTAL	**16**	
Does investment in production of original pharmaceutical products offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply and prices) attractive?		
• Are the local and regional markets attractive?	2	• Domestic market is too small; regional (EAEU) market provides more business opportunities but also faces higher competition from generics pharmaceuticals producers. Production in Russia rather than in Armenia may provide additional market access benefits to foreign investors wishing to service the EAEU market.
• Is the global market attractive?	1	• The global market is increasing and provides new business opportunities; the Asia Pacific market for APIs is projected to expand faster than elsewhere. Armenia's limited transport options, high transport cost of high-volume bulk cargo and trade costs make the investment proposition to serve global markets out of Armenia unrealistic.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)?	1	• With no local API production, all production inputs must be imported.
• Does Armenia have competitive infrastructure?	1	• High transport costs due to poor country connectivity increases operation costs.
• Does Armenia have competitive skills and supportive services?	2	• With no local original pharmaceutical production and small pharma labour market, advanced skills needed for original pharmaceutical production are likely to be missing.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	2	• There are no specific investment and regulatory incentives for pharmaceutical producers in place in Armenia.
SUBTOTAL	**9**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

5.3. Production of Generic Pharmaceutical Products

Armenia's generic pharmaceutical sector is a dynamic, yet small, sector of the Armenian economy. While pharmaceutical sector output has more than doubled over the past decade (figure 29), reaching $20.1 million in 2019, manufacture of basic pharmaceutical products and pharmaceutical preparations accounted for only 0.3 to 0.6 percent of total industrial output (figure 30). [30]

***Figure 29:** Annual pharmaceutical sector output (in current prices, million dollars)*



Source: Statistical Committee of RA, Volume of industrial production by types of economic activity (NACE 2, 2011-2020), retrieved from www.armstat.am/file/doc/99520473.xls.
Legend: * data for January to August, 2020

***Figure 30:** Pharmaceutical sector output 2011–2020 (in current prices)*

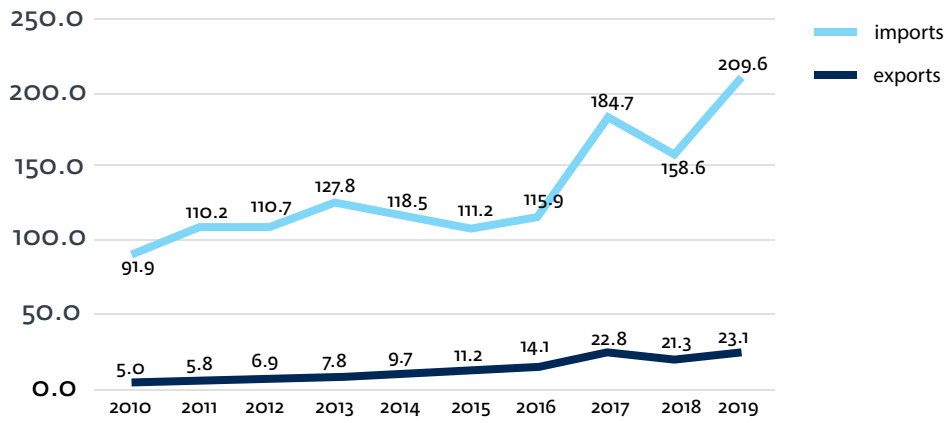
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020*
Annual pharma sector output (in million dollars)	8,9	9,6	12,9	14,4	16,0	16,9	19,9	19,8	20,1	14,7
Share of pharma sector in total industrial output (%)	0,34	0,34	0,43	0,46	0,57	0,56	0,53	0,50	0,47	0,67

Source: Statistical Committee of RA, Volume of industrial production by types of economic activity (NACE 2, 2011-2020), retrieved from www.armstat.am/file/doc/99520473.xls.
Legend: * data for January to August, 2020

30 The ongoing health crisis due to the COVID-19 pandemic does not seem to have negatively impacted the Armenian pharmaceutical sector so far. The average monthly sector output for the first eight months of 2020 was $1.83 million compared to $1.5 million during the same period in 2019.

The industry produces a small range of generic drugs, mostly for the domestic market. Exports of pharmaceuticals were $23.1 million in 2019, mostly to Russia and other EAEU countries. Imports of pharmaceuticals (including APIs), however, was tenfold higher at $209.6 million (figure 31).[31] Higher exports than domestic sector output suggest that total exports are inclusive of a certain volume of re-exports. The Association of Armenian pharmaceutical producers (ArPharMa) says exports in 2019 were approximately 50 percent of domestic pharma sector output ($10.3 million exports/$20.1 million pharma sector output).

***Figure 31:** Pharmaceutical sector imports and exports (million dollars)*



Source: Statistical Committee of RA, retrieved at https://armstatbank.am/pxweb/en/ArmStatBank

As of November 2020, 23 companies held manufacturing authorizations from the Scientific Centre of Drug and Medical Technologies Expertise in Armenia, including some food supplement producers and pharmacies with little or no mass production of pharmaceutical products (figure 32).[32]

***Figure 32:** List of companies operating in the generics pharmaceuticals sector in Armenia*

Manufacture of generic pharmaceuticals[1]				
1.	Arpimed	https://arpimed.am	GMP certified	Producer of medicines, prophylactic and medical, antiseptic and disinfecting solutions, diagnostic and cosmetic preparations
2.	Arsanit	www.arsanit.am	GMP certified	Manufacturer of liquid and gel forms of medicine, production of antiseptics, nasal drops and sprays, keratolytics, etc.

31 Armenian national statistics follows the established NACE four-digit sector classification, under which it reports sector data for manufacture of basic pharmaceutical products (NACE 21.1.) and manufacture of pharmaceutical preparations (NACE 21.2.), without distinguishing the type of pharmaceuticals (original vs. generics) produced/traded.

32 **http://www.pharm.am/attachments/article/287/Manufactures.pdf**

3.	Esco-Pharm	www.escopharm.am	GMP certified	Producer of almost 60 types of non-sterile products, creams and ointments, liquids, tinctures, oils, powders, skincare products
4.	LEYKOALEX	https://leykoalex.am		Producer of powder, oil and liquid medications
5.	Liqvor Pharmaceuticals	https://liqvor.com/en	GMP certified	Producer of infusion solutions; currently produces more than 50 sterile liquid medications (intravenous infusion, ophthalmic, injection segments)
6.	Medical Horizon	www.medicalhorizon.am	GMP certified	Armenia's sole producer of suppositories; producer of 17 types of products (analgesics, antipyretics, infectious diseases, gynaecology, aqueous solutions, gastrointestinal tract, vitamins and supplements)
7.	Pharma Tech	www.pharmatech.am	GMP certified	Producer of intravenous solutions of various types and volumes, as well as five different eye drops
8.	T-Pharma	http://t-pharma.am	GMP certified	Producer of five groups of drugs (analgesic, antipyretic and anti-inflammatory formulations; anti-allergy and anti-histamine drugs; anticoagulants; antifungal drugs and proton pump inhibitors)
9.	Tonus-Les	www.tonusles.am	GMP certified	Contract manufacturer of medicines and biologically active supplements
10.	Yerevan Chemical-Pharmaceutical	https://www.multigroup.am/en/company/yerevan-chemical-pharmaceutical-firm-ojsc.html		Producer of injection and galenic preparations (over 100 different drugs)

Legend: [1] Companies included in the table are those that hold manufacturing authorization from the Scientific Centre of Drug and Medical Technologies Expertise and are engaged in mass production of pharmaceutical products. Excluded are food supplement producers and companies with little or no mass production of pharmaceutical products (for example, pharmacies).

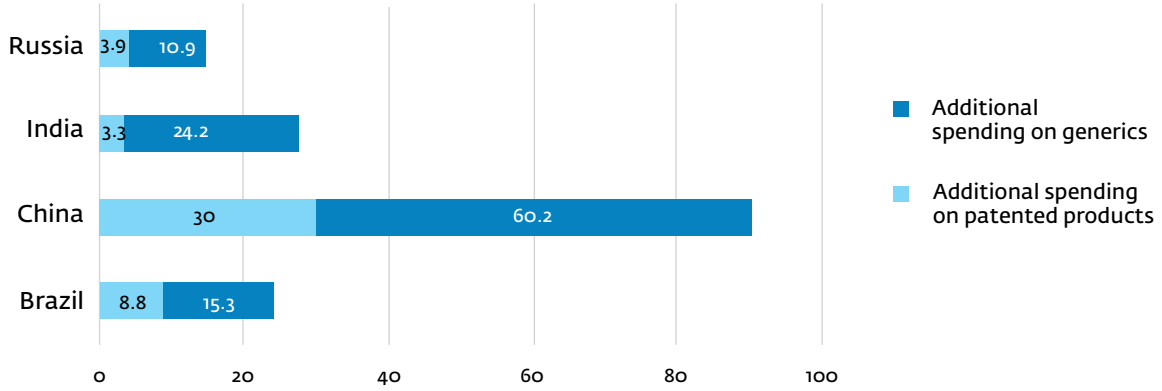
There are noticeable differences between the size of operation of individual producers of pharmaceutical products. Domestic production is dominated by three main drug makers: Liqvor, Arpimed, and PharmaTech. One producer alone, Liqvor, accounts for 40 per cent of all pharmaceutical exports.[33]

The main export markets for Armenian producers are the growth markets of EAEU and CIS countries where expenditure on medicines is rising far faster than in the traditional developed economies as economic expansion and better access to healthcare drive up demand. The growth economies, however, also vary in terms

33 UNCTAD (2019), Investment Policy Review of Armenia, November 2019

of the treatments they need, and their ability and willingness to pay for new medicines. Generally, the growth countries lack the financial power to reward innovation, hence most of the projected increase in pharmaceutical sales in these countries over the next decade is expected to come from generics rather than patented products (figure 33).[34]

Figure 33: Generics: the main driver in pharmaceutical sales in the growth economies *(all sales in billion dollars)*



Source: Pharma 2020: From Vision to Decision, PwC series

The growth markets include three tiers of the so-called "pharmerging" markets.[35] Tier I countries, which includes China, dominated the global pharmerging market because of higher government healthcare spending. However, Tier II countries, which include India, Brazil, and Russia, are projected to grow significantly, owing to rapidly increasing aging populations, a rise in consumer awareness, favourable government policies, and modernization of healthcare infrastructure in these countries. Tier III countries (Poland, Argentina, Turkey, Mexico, Venezuela, Romania, Saudi Arabia, Colombia, Vietnam, South Africa, Algeria, Thailand, Indonesia, Egypt, Pakistan, Nigeria, and Ukraine) hold the least market share among pharmerging countries. However, they are estimated to grow substantially over the forecast period.

Generics produced in Armenia are currently exported to one Tier II country (Russia), and some Tier III countries (Vietnam, Ukraine).

FDI in generic pharmaceutical production is largely driven by M&As, which allows MNCs' inorganic growth parallel to technological innovations and product extensions. Industry

34 Pharma 2020: From Vision to Decision, PwC series, accessible at **www.pwc.com/pharma2020.**

35 Pharmerging markets are defined as those countries having a per capita GDP threshold of $25,000 and more than $1 billion spending growth from 2012 to 2016. Thus, pharmerging markets includes 21 countries that are further categorized in Tier I, Tier II, Tier III countries based on IMS-defined parameters and macroeconomic factors and respective pharmaceutical market forecasts.

analysts expect M&As to intensify the market in near future.[36] Recent FDI data from the ECA region support this trend; most new FDI pharmaceutical projects. started in Russia and Azerbaijan in the last five years, were established as joint-venture operations with local producers (figure 34). The majority of new greenfield manufacturing projects came from Indian generics producers. Given its production track record (the global leader in generics production) and investment track record in the ECA region, India and its key generic drugs manufacturers could become one of the priority countries for Armenia's investment promotion effort (figure 35). Even though Armenia may not immediately meet Indian firms' site-selection criteria, these companies can provide valuable feedback to Enterprise Armenia as to where the country currently falls short of industry expectations.

***Figure 34:** Selected Indian FDI projects in the pharmaceutical sector in ECA region*

Company	FDI project
Sun Pharmaceutical	Acquisition of JSC Biosintez/Russia
	Greenfield investment/Azerbaijan
Aurobindo Pharma	Acquisition of OJSC Diod/Russia
Cadila Pharmaceuticals	Greenfield investment (TBC drugs)/Russia
Hetero Drugs	Greenfield investment (oncological and HIV drugs)/Russia
Lupin Ltd	Acquisition of JSC Bio-com/Russia
Star Company	Greenfield investment (lysine production)
PSK Pharma	Greenfield investment (asthma medications)
ZEE Laboratories	Greenfield investment (oncological and hepatitis C drugs)
Dr. Reddy's Laboratories	Joint-venture with R-Pharm/Russia
Advanced Pharmaceuticals	Greenfield investment (TBC, HIV, hepatitis drugs)/Russia

36 Pharma 2020: From Vision to Decision, PwC series, accessible at **www.pwc.com/pharma2020.**

***Figure 35:** Top 10 listed pharmaceutical companies in India by market capitalization*

Rank	Company	Market capitalization (in million dollars/June 2020)
1.	Sun Pharmaceutical	116 415
2.	Dr. Reddy's Laboratories	66 596
3.	Divi's Laboratories	61 282
4.	Cipla	51 645
5.	Aurobindo Pharma	46 043
6.	Torrent Pharmaceuticals	42 753
7.	Lupin Ltd	41 747
8.	Zydus Cadila Healthcare	37 422
9.	Abbott India	33 915
10.	Alkem Laboratories	27 807

Source: Moneycontrol, retrieved at www.moneycontrol.com/stocks/marketinfo/marketcap/bse/pharmaceuticals-drugs.html

Armenia's free access to the EAEU market, and opportunities stemming from production cost differences between Armenia and Russia—EAEU's main market—is the investment proposition for Indian producers. Access to the Russian market, in particular, is a strong selling point, as pharmaceuticals produced in Armenia meet the strict localization rules introduced in Russia under the government's policy to support local pharmaceutical production Pharma, 2020.[37]

From December 31, 2020, the authorization of all new pharmaceuticals in Russia can be conducted based solely on EAEU rules (figure 36). Since the first application was filed in March 2018 in Kazakhstan,

***Figure 36:** EAEU drug registration harmonization*

After Decision No. 78 of the Board Eurasian Economic Commission on November 3, 2016, the "Rules" for registration and expert review of drugs for medical use within the EAEU were approved and came into force on May 6, 2017.

Medicines registered under the "Rules" can be offered for sale throughout the EAEU without any registration procedures in each member state. In particular, the "Rules" provide two procedures for registration of medicines:

1) Mutual recognition: the registration is first conducted in the reference state of the applicant's choice, then in states of recognition at the applicant's request'.

2) Decentralized procedure: the registration is conducted simultaneously in several member states in which an applications are filed, one of which is chosen as the reference state.

In addition, for medicines registered in member states under individual national requirements before December 31, 2020, it will be necessary to complete a Bringing into Compliance procedure to align with EAEU requirements by December 31, 2025.

In case the product was registered before December 31, 2020 and marketed in at least three member states for five years, an unlimited MA will be issued, after approval through the above-mentioned procedure.

Source: www.regulatorypharmanet.com/eaeu.

37 In March 2019 the program 'Development of the Pharmaceutical and Medical Industry' (Pharma 2020) was extended until 2024, and new targets have been added with respect to ensuring the competitiveness of the pharmaceutical industry in Russia. At the same time, preparatory works for a new program (Pharma 2030) have already been underway.

only 63 pharmaceutical products have been authorized through the EAEU procedure. By December 31, 2025, all pharmaceuticals authorized under national regulation is expected to be brought in line with EAEU Rules.[38] The functioning of the common pharma market will, therefore, be fully implemented no earlier than 2026.

Production in Armenia can also help foreign drug producers to meet the Russian rules to participate in public tenders; foreign drugs are not allowed for tenders and auctions in Russia, unless submissions include two or more drugs produced in Russia or the EAEU countries.

Apart from strengthening market presence, M&A with existing Armenian producers will allow foreign investors to access already approved facilities outside their country of origin. In 2013 Armenia introduced a system of compulsory GMP certification; by the end of 2020 most local generics producers have European GMP compliant plants (figure 32).

Production of generic pharmaceutical products		
To what extent:	**Score**	**Evidence**
Will additional FDI in production of generic pharmaceutical products add value to Armenia?		
• Will new investors add value that is not already provided by local producers and existing investors?	3	• FDI may bring new technologies and production and organizational innovations, which are not yet accessible to domestic producers.
• Will new investors create additional jobs?	4	• Pharmaceutical production is a moderately labour-intensive sector; new jobs will be created. However, unless R&D activities are part of the FDI operation, the jobs created will not necessarily require qualified labour.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	3	• New entrants will not generate new supplier opportunities, but could bring new market opportunities, in particular for M&A types of FDI.
• Will new investors create increased export revenues or reduce imports?	3	• New FDI will have only limited impact on the trade balance, as domestic production of generics does not lead to major import substitution.
• Will new investors improve the performance of the value chain as a whole?	3	• Additional FDI in manufacturing of original pharmaceutical products would not bring about a major improvement of the value chain, as production methods for generics production are already established in Armenia.
SUBTOTAL	**16**	

38 Yuriev, E. et al.: The pharmaceutical intellectual property and competition law review: Russia chapter. Herbert Smith Freehils, December 2020, retrieved from **www.herbertsmithfreehills.com/lang-ru/latest-thinking/the-pharmaceutical-intellectual-property-and-competition-law-review-russia-chapter**

Does investment in production of generic pharmaceutical products offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply and prices) attractive?		
• Are the local and regional markets attractive?	3	• Domestic market is not attractive, import of drugs will most likely always be a more economical way of market access compared to FDI. The regional EAEU market provides a considerably better investment proposition as production in Armenia would allow preferential access to the largest regional market (Russia).
• Is the global market attractive?	1	• The global market is growing and provides new business opportunities; yet Armenia's limited transport options, absence of APIs, production costs, and infrastructure that is not on par with global production centers of generic pharmaceuticals, make the investment proposition to service global markets out of Armenia unrealistic.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)?	1	• With no local API production, all production inputs must be imported.
• Does Armenia have competitive infrastructure?	3	• Experience of the existing domestic generic pharma sector proves that it is possible to access export markets despite the country's poor connectivity and high transport costs. Missing physical infrastructure for greenfield projects may be a negative signal for investors.
• Does Armenia have competitive skills and support services?	3	• With no local original pharmaceutical production and small pharma labour market, advanced skills needed for original pharmaceutical production are likely be missing.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	2	• Unlike in Russia, there are no specific investment and regulatory incentives in place for pharmaceutical producers in Armenia.
SUBTOTAL	**13**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

FDI in generic pharmaceutical products is plausible on two accounts—the experience of domestic generic pharma firms proves that the industry can produce and export generic pharmaceutical products that are, both in price and quality, competitive in international markets, despite the country's poor connectivity and transport costs. Production costs in Armenia are higher than in some global production hubs (for example, India) but lower than in key export markets, for example, Russia or the EU (for detailed analysis of Armenia's international competitiveness in the efficiency-seeking FDI of the pharmaceutical sector, see the following chapter on contract manufacturing outsourcing). Some domestic producers are also open to the idea of M&A with foreign firms. M&As have been the prevailing mode of FDI entry in the pharmaceutical sector globally and some MNCs may see a possibility of geographical diversification by entering into a M&A deal with Armenian manufacturers. At the same time, the size and production capacities of individual Armenian producers may be seen as too small by MNCs to consider a market entry via M&A.

5.4. Contract Manufacturing Outsourcing (CMO)

As described earlier, the pharmaceuticals industry—like many other sectors—continues to optimize operations and increase profitability by engaging in various non-equity modes of production (NEM), for example, production under license or contract manufacturing (CMO).

The use of NEMs is optional for MNCs, the choice between ownership and partnership is analogous to a "make or buy" decision. For example, a pharmaceutical firm can either build its own plant to serve an overseas market or grant a license to a local manufacturer to do so. Alternatively, it can outsource a part (or the whole) of its production to a specialized CMO firm. NEMs and FDI operations can be developed in parallel. CMOs provide highly valuable services by offering additional manufacturing capacity, access to specialty capabilities, and potential cost advantages over in-house manufacturing.

According to a recent review of the outsourced manufacturing sector, overall CMO market penetration reached 26 percent in 2019 and will increase to 29 percent by 2023. The CMO sector is predicted to grow at a GACR of 6.8 percent, outpacing growth in the underlying pharmaceutical market. The likelihood of a project being outsourced very much depends on the scale of the MNC. In 2017, just 20 percent of newly approved drugs were outsourced by big pharma, whereas about 80 percent of manufacturing for small companies was outsourced. Small and medium-sized companies therefore often dominate the customer list for CMOs.[39]

The global CMO market is highly fragmented with over 1,000 companies active in the sector. Companies generating less than $50 million in annual revenue represent over two-thirds of all CMOs; the top 10 companies hold less than 20 percent market share. China is becoming the most attractive country for outsourcing. However, the majority of CMOs operating in China offer mainly API and bulk drug products manufacturing for approved branded and generic drugs rather than a small batch production.

In volume terms, generic products are estimated to represent nearly 90 percent of drugs dispensed, but generate less than 20 percent of pharmaceutical market sales. For the CMO sector however, generics generate a similar level of commercial revenue to original pharmaceutical products.

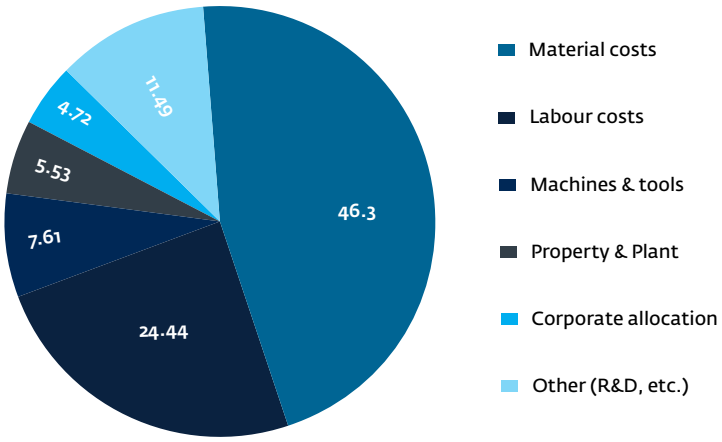
Given the overall small size of the pharmaceutical sector in Armenia, there seems to be no discernible CMO sector. However, anecdotal evidence, collected during the interviews with local producers, suggests that some manufacturers operate in a contract manufacturing mode, serving Russian pharmaceutical companies. Whether this is just local pharma companies selling spare manufacturing capacity or whether CMO is a dedicated business model pursued by some

39 Outsourced Pharmaceutical Manufacturing 2020: Current Trends and Future Prospects, Result Healthcare, 2020; retrieved from https://resultshealthcare.com/wp-content/uploads/2019/11/Outsourced-Pharmaceutical-Manufacturing-2020-White-Paper_Results-Healthcare.pdf

local producers is unclear. None of the interviewed companies indicated operations in other NEM production modes, pharma in-licensing.

Lower production costs are one of the primary drivers for CMOs (or any efficiency-driven FDI, for that matter). Understanding the cost structure in the pharmaceutical sector helps to identify the potential sources of Armenia's international FDI competitiveness (figure 37).

Figure 37: Cost structure of pharmaceutical manufacturing (%)



Source: St. Gallen Report 2006[40]

MATERIALS COSTS

Direct and indirect material costs are by far the largest cost item of any pharmaceutical manufacturing plant. APIs as well as excipients are exclusively sourced from third-party producers outside Armenia and imported. Input materials are the largest cost item of domestic production—during interviews, local producers confirmed that over 50 percent of their total production costs is linked to APIs and excipients. Absence of raw materials and intermediary suppliers needed for API manufacturing makes Armenia dependent on material imports and excludes import substitution-motivated FDI.

LABOUR COSTS AND SKILLS

Labour costs are central for efficiency-seeking FDI and international production networks. In the pharmaceutical sector, direct labour costs account for approximately 13 percent of total manufacturing costs; indirect labour costs add another 12 percent.[41]

Generally, Armenia has labour cost advantages, particularly for skilled staff. Average salaries are similar to those paid elsewhere in the EAUE countries and the close geographical region, except for the higher remuneration in Russia and lower in Kyrgyzstan. Armenia's market wage cost advantage is more pronounced in comparison with some of the EU. CEE member states (Bulgaria and Romania), however, it is on a par or even higher than some of global pharmaceutical production centres, such as India or Pakistan (figure 38). Anecdotal evidence collected during company interviews suggests that salaries in the pharmaceutical sector are higher than overall average (in the range of $500 to 700 for production line operators, and $1000 to 2000 for skilled, highly qualified staff).

40 St. Gallen Report: International Benchmarking Study: Operational Excellence in the Pharmaceutical Industry. University of St. Gallen & APV 2006.

41 Ibid.

***Figure 38:** Monthly earnings in manufacturing, by country comparison (in dollars, 2020)*

EAEU		Regional countries		Pharmaceutical sector manufacturing countries	
Armenia	381	Azerbaijan	414	India	437
Belarus	497	Georgia	399	China	1071
Kazakhstan	492	Ukraine	430	Pakistan	171
Kyrgyzstan	231	Bulgaria	842		
Russia	638	Romania	1317		

Source: 2020 CEIC DATA; retrieved at https://www.ceicdata.com/en/indicator/monthly-earnings.

While comparable international data for skilled, highly qualified staff in the pharmaceutical industry are not available, Armenia's international competitiveness is likely to be more pronounced for qualified labour than for unskilled staff. The availability of skilled pharma talent is a key success factor, and without this, it is very difficult to develop and incubate a high-tech industry like pharma in Armenia.

However, Armenia ranks less well when pay and productivity are combined. It ranks 54 on the "Pay and Productivity" sub-indicator of global competitiveness rankings, suggesting an issue with labour productivity. By comparison, Russia's ranking on this sub-indicator (37) is much better than its overall labour ranking (62).[42]

Skills needed for advanced pharmaceutical research or manufacturing are underdeveloped. Companies interviewed for this report consistently pointed out the need for training and qualification upgrade of pharmaceutical sector specialists. Introducing quality management systems and good practices in the pharmaceutical industry (GMP/good manufacturing practices, etc.) helped to develop sector human capital, however, the overall labour pool is still rather limited. Most Armenian production companies operating in the pharmaceutical market are small to medium-sized, employing from 30 to 100 workers. The overall size of the pharmaceutical manufacturing labour pool is less than 1000 people.[43] Information on industry employment breakdown by qualification/skills is not available.

While Armenia has a long history of educational excellence in science and technology, the industry representatives interviewed for this report described a skills mismatch between market needs (in particular skills required in advanced pharmaceutical technologies and original R&D) and labour market supply.

42 The Global Competitiveness Report 2019, WEF 2019; retrieved at www3.weforum.org/docs/WEF_TheGlobalCompetitivenessReport2019.pdf.

43 The retail segment of the pharma market (pharmacies) employs an additional 3300 workers.

Twelve state and private universities and colleges in Armenia offer education in pharmacy or related chemical technologies, with a total annual output of 100 to 150 graduates.[44] The ability of these graduates to get education with "applied private sector-ready" skills is very important as an entry point for talent into the private sector.

REGULATORY/MARKET-ACCESS COSTS

EAEU membership allows Armenia-based producers better access to its large internal market of 180 million people. However, Armenian production still makes only around 0.2 percent of the EAEU's total pharma production.[45]

Joining the EAEU also resulted in higher import tariffs for Armenia, which previously had more advantageous free-trade agreement conditions, in particular for import of high-tech technologies.[46] Producers based in one of the EAEU member states are afforded tariff protection by the common external tariff applied to all union's imports from all sources. Pharmaceutical products imported from the EU are subject to 3.95 percent tariff, imports from Turkey to 4.2 percent tariff.[47] Overall, the protective effect is moderate, but the single market is very large relative to Armenia's size.

Tax policies of EAEU members are inconsistent (figure 39). This is due to the volatile geopolitical situation and global oil price levels that limit opportunities for tax cuts in Russia. While the tax competition among EAEU member states is escalating, Armenia maintains its competitive advantage of 0 percent statutory insurance payments with direct impact on total labour costs.

***Figure 39:** Tax rates in the EAEU member states (2019)*

Country	Corporate tax	VAT	Income tax	Insurance payments
Armenia	20	20	9-15	0
Belarus	10-25	10-20	13	29
Kazakhstan	10-20	12	10	9,5
Kyrgyzstan	20	12	10-20	>17
Russia	20	20	13	22

Source: Keysets, B., Cher nova, V.: A Monetary Union within the EAEU: Problems and prospects, Spacious, Vol. 41 (Issue 01), 2020.

44 Based on data provided in Pharmaceutical Guide Armenia, 2014

45 Armenia Pharmaceutical Country Report 2019, UPHARMA, retrieved at www.upharma-c.com/en/news/218-armenia-pharmaceutical-country-report-2019

46 The Eurasian Economic Union. Analysis from a trade policy perspective, Berlin Economics, 2017

47 Source: UN Comtrade, simple average external tariffs on pharmaceutical products (HS code: 30)

Since the Armenian industry offers skilled staff at much lower cost than in developed countries, but not considerably lower than in some traditional production hubs (such as India), it is unlikely to be enough to create a significant shift towards more efficiency-seeking FDI. The investment proposition for top CMOs (figure 40) to start new greenfield operations in Armenia is hard to define.

The labour cost differential, however, may be sufficient for local firms to engage in CMO, in particular for Russia-based clients. The advancing unification of the internal EAEU market and mutual recognition or common regulation of medicine approvals could enlarge the niche market for non-equity mode of investment.

Figure 40: *Top CMOs*

- Catalent Inc.
- Recipharm AB
- Jubilant Life Sciences Ltd.
- Patheon Inc.
- Boehringer Ingelheim Group
- Pfizer Centre Source
- Aenova Holding GmbH
- Famar SA
- Baxter Biopharma Solutions
- Lonza Group
- Dr. Reddy's Laboratories
- Almac
- Vetter

At the same time, it is fair to mention that cheaper running costs are not always the primary motive for CMO in the pharmaceutical sector. Technological capability and access to specialized technologies is often the most important differentiator when selecting a CMO.[48] Further work is required to fully assess the regional competitive landscape of CMO to understand how the Armenian CMO business could compete and if it would be viable. CMOs can require a lot of continuous investment and huge R&D spending to ensure they keep their client pipeline and production capacities full. This requires massive infrastructure and continuous regulatory and quality upgrades and ongoing capex investment.

This in turn, requires domestic Armenian firms to continuously improve their international competitiveness by technological upgrading and production specialization, rather than relying on existing cost differentials, as well as access to a locally well-developed talent pool, both of which seem to be lacking at the present moment. It also calls for the government to design a tailored policy that will support domestic firms in their technological development. Last, but not least, Enterprise Armenia needs to explore, along with the private sector, how the government can assist domestic producers to secure investment by CMOs.

48 2017 NICE insight CDMO Outsourcing survey, retrieved at **https://www.pharma-iq.com/manufacturing/articles/top-10-medical-contract-manufacturing.**

Contract manufacturing outsourcing (CMO)		
To what extent:	**Score**	**Evidence**
Will additional FDI in contract manufacturing of pharmaceutical products add value to Armenia?		
• Will new investors add value that is not already provided by local producers & existing investors?	4	• CMO may bring new technologies and production and organizational innovations, which are not yet accessible to domestic producers.
• Will new investors create additional jobs?	3	• Medium. CMO could lead to creation of new jobs in case it involves adding new technologies and expanding existing production capacities.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	5	• CMO is by definition a direct business opportunity for domestic firms who provide manufacturing services and capacities to foreign pharmaceutical firms.
• Will new investors create increased export revenues or reduce imports?	5	• CMO outputs are likely to be 100% export oriented, the growth of the CMO sector will positively impact balance of trade.
• Will new investors improve the performance of the value chain as a whole?	2	• CMO would likely not bring about a major improvement of the value chain, CMO production methods are already established in Armenia. It could, however, push domestic companies to technologically upgrade their operations.
SUBTOTAL	**19**	
Does investment in contract manufacturing of pharmaceutical products offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply and prices) attractive?		
• Are the local and regional markets attractive?	4	• Domestic market is not attractive, however Russia-based pharmaceutical companies may find the cost differential sufficiently competitive to outsource some manufacturing activities to Armenia.
• Is the global market attractive?	1	• Although the global market is growing, Armenia is unlikely to be competitive with the traditional low-cost manufacturing Asia-Pacific hubs.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)?	2	• Although all production inputs must be imported, the cost differential may still be sufficient to keep Armenia competitive for CMO.
• Does Armenia have competitive infrastructure?	4	• Experience of existing domestic pharma sector proves that it is possible to export high value-to-weight pharmaceuticals products without logistics issues of conventional manufacturing.
• Does Armenia have competitive skills and support services?	5	• Yes, the existing domestic pharma sector has the skills required for CMO.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	2	• Unlike in Russia, there are no specific investment and regulatory incentives for pharmaceutical producers in Armenia.
SUBTOTAL	**18**	

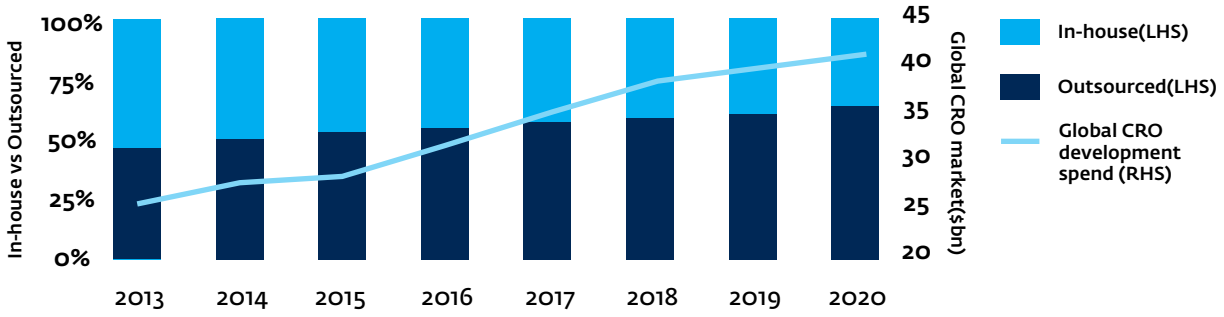
Evaluation key: 5=very positive 4=positive 3=neutral 2=negative 1=very negative

5.5. Contract Pharmaceutical Research (CRO)

Outsourcing research to academic and private contract research organizations (CROs) is another way pharmaceutical firms stay competitive and flexible in a world of exponentially growing knowledge and increasingly sophisticated technologies. CROs support drug manufacturers on their road to discover and approve drugs of the future by absorbing some of the clinical stage's burdens. Data research, project management, tests, trials that are run post approval, pre-clinical, and clinical are just some of the activities covered.

The CRO market is considerably smaller than the CMO market; of the total contract development and manufacturing outsourcing (COMO), market, nearly 90 percent comprises the commercial CMO market. Yet the CRO industry has grown steadily in recent years. In 2018, the value of global CRO services was estimated at $37 billion. In the period of 2018 to 2024, the market is estimated to grow at 8.2 percent CAGR as demand for robust clinical services grows and sponsors continue to invest in R&D. In 2013, outsourcing represented over 47 percent of clinical development spend, which increased to over 60 percent by 2020 (figure 41).[49]

***Figure 41:** Global CRO market and penetration rates*

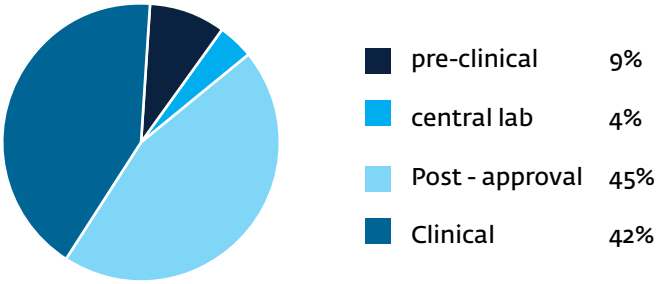


Source: CRO Sector: M&A drivers and market trends, Result Healthcare, 2019

The CRO market covers several main segments alongside the drug development and approval process: drug discovery, pre-clinical research, clinical trials, new drug application review, post-approval studies. The clinical and post-approval stages are the most complex and regulatory-intense stages of development; these are the stages at which pharma companies require the most input from specialist outsourced providers, which is reflected in the market size of the respective stages (figure 42).

49 CRO Sector: M&A drivers and market trends, Result Healthcare, 2019, retrieved at https://resultshealthcare.com/wp-content/uploads/2019/07/CRO-sector-MA-drivers-and-market-trends-Results-Healthcare.pdf

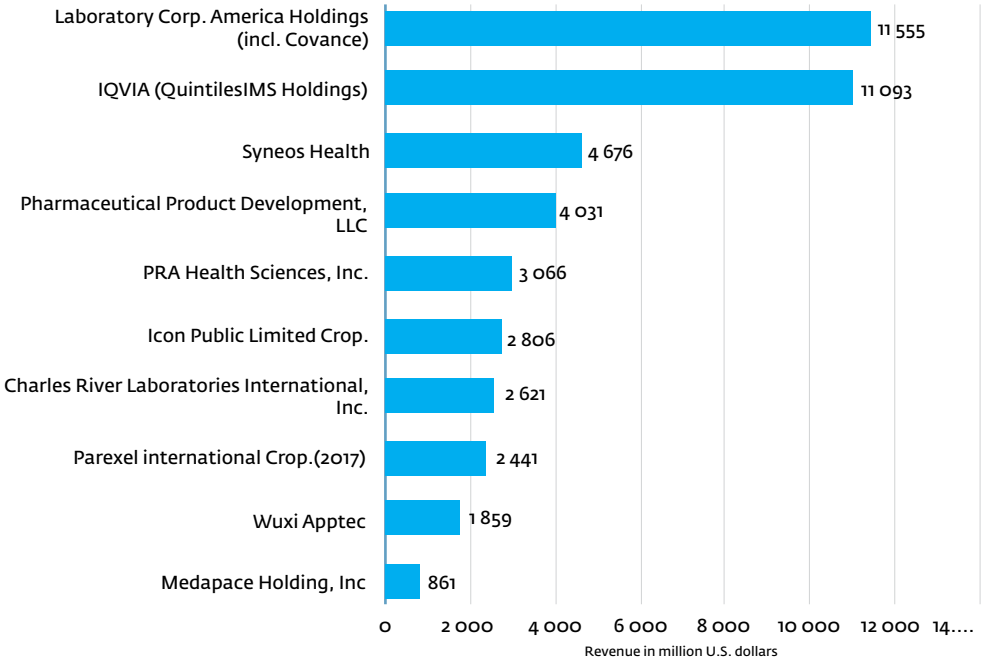
***Figure 42:** CRO market size by function*



Source: CRO Sector: M&A drivers and market trends, Result Healthcare, 2019

In contrast to the highly fragmented CMO market, the CRO market has undergone significant consolidation in recent years, as critical mass and geographic spread facilitates the running of multicenter global clinical trials. The CRO market is skewed far more heavily towards a few large players—the top 10 companies have a combined market share of over 60 percent (figure 43). Outside the top 10 CROs, the industry landscape is vastly fragmented, comprising a handful of large, global, full-service CROs and several hundred small and medium sized, defined-service providers.

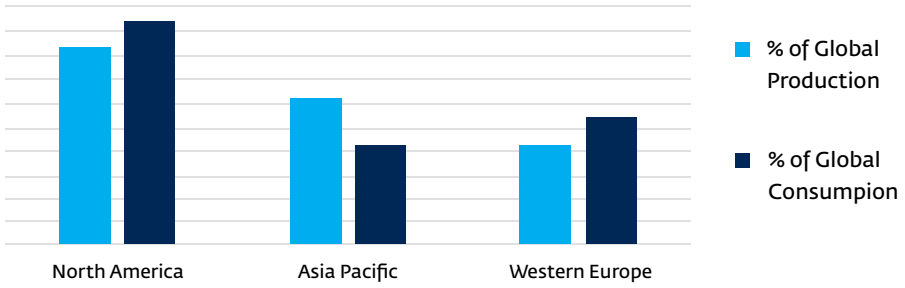
***Figure 43:** Top 10 CRO firms by revenue (2019)*



Source: Statista 2020, retrieved at www.statista.com/statistics/732804/top-clinical-research-organizations-by-revenue

North America is both the largest CRO production and consumption center due to the presence of many pharmaceutical companies. Approximately one-third of the total CRO production is in Asia Pacific, where the consumption market is smaller but where Western companies increasingly outsource their research activities to contain costs. In Western Europe, as in North America, the relation between the production and consumption markets is the reverse of that in Asia Pacific, at 27 percent of global consumption against 21 percent of global production. The difference here is also due to R&D outsourcing to emerging economy suppliers by Western European drug manufacturers (figure 44).[50]

***Figure 44:** CRO production and consumption by regions*



Source: The Rapid Growth of the CRO Industry: Analysis & Forecasts, The Business Research Company, 2018

Most recently, the demand for outsourcing services has moved from traditional markets for CRO outsourcing in Eastern Europe and Latin America to China. The main reason for this shift has consistently been the cost—but increasingly also technological—advantage, as the cost of conducting clinical trials in China (or Indonesia and India) is considerably low. This is changing somewhat in China due to higher labour costs, but the government and industry are trying to climb the value chain via investment in high technology, thereby still maintaining China's international attractiveness. The governments in Asia-Pacific countries are increasingly spending on healthcare. Thus, clinical outsourcing is correspondingly seen as an effective way for innovative drugs to gain early market access.[51] The sector development is largely driven by M&As and private equity investment.

Several CROs operate in Armenia (figure 45). Most are small local CRO operations providing regulatory affairs services or a variety of post-marketing surveillance services. However, there has also been some FDI in this subsector

50 The Rapid Growth of the CRO Industry: Analysis & Forecasts, The Business Research Company, 2018; retrieved at **https://blog.marketresearch.com/the-rapid-growth-of-the-cro-industry-analysis-and-forecats.**

51 **www.gminsights.com/pressrelease/contract-research-organization-cro-market**

and there are at least two foreign firms serving global markets: Azad Pharmaceuticals (Swiss investment), which performs R&D on new formulations of drug compounds, and ClinChoice (formerly FMD K&L), a Chinese/U.S. company that provides data management services to the industry and employs around 200 healthcare professionals.

***Figure 45:** List of CRO firms in Armenia*

Life sciences tools and services			
1.	ClinChoice LLC (ex FMD K&L Europe)	www.klserv.com	Clinical research, medical writers, pharmaceutical safety, biometrics
2.	AZAD Pharmaceuticals	www.azad.ch	R&D in complex generic APIs, niche generic drug products, and selected generic plus formulations
3.	Tonus-Les	www.tonusles.am	Clinical trial management and monitoring, project and site management, pharmacovigilance and clinical drug safety management, medical writing, and regulatory affairs services
4.	The Gurus	https://thegurus.am	Clinical Data Management, Statistical Programming, Biostatistics, Pharmacovigilance, CRM Development
5.	Soleil Partout	http://cro.am	Organization of multicentre international clinical studies in Armenia, services in the field of marketing authorization
6.	NoyMed	https://noymed.com	Biostatistics, Data Management and SAS Programming to pharmaceutical, biotechnology, and medical device industries worldwide
7.	AmberCRO	www.amber-cro.com/about	Monitoring, regulatory, contract negotiation and brokerage activities, IP/medical device, and other project supply imports
8.	Crocus Medical	www.crocusmedical.com	Clinical services, recruitment and outsourcing, laboratory services
9.	Atlant Clinical	www.atlantclinical.com/offices	International clinical trials

An existing—though modest—FDI track record suggests that there are opportunities for attracting investment in this sector in collaboration with universities and research institutes. Armenia could provide a meaningful investment proposition to foreign CROs. The country offers a compelling combination of highly skilled professionals at competitive

cost to a large global industry. Investors based in Armenia can benefit from the EAEU membership; for instance, in conducting bio-equivalency tests of drugs going to the EAEU market. Since 2010 Russia has been selective about recognizing the results of bio-equivalency tests done outside Russia; tests done in India, which accounts for about 70 percent of the global market, are not usually accepted due to quality issues. Armenia can thus become a cost-effective alternative for tests done in Europe and Russia.

The scaling up of professional labour might be an ultimate constraint, probably requiring up to 2,000 professionals per $100 million of exports.[52] Some of the more complex skills (for example, biostatistics programming in SAS software) are not included in standard university curricula and companies must invest additional funds in training and re-training. Some companies already report that increasing private sector demand for highly skilled CRO labor and limited supply of new graduates leads to salary cost increases and poaching of skilled staff from one company by another (internal brain drain).

While availability of advanced English language skills is seen by the private sector as a competitive advantage over some other established CRO locations (for example, China), low international brand awareness and recognition of Armenia as a CRO destination is regarded as a competitive disadvantage.

Contract pharmaceutical research (CROs)		
To what extent:	**Score**	**Evidence**
Will additional FDI in contract pharmaceutical research (CROs) add value to Armenia?		
• Will new investors add value that is not already provided by local producers and existing investors?	5	• Yes. Large CRO firms would add considerable value to the overall sector as they bring high value-added specialized services that improve overall sector level of know-how and skills.
• Will new investors create additional jobs?	4	• Yes. Although initial CRO operations may generate less jobs than in manufacturing, development jobs usually require higher qualifications and provide better remuneration than jobs in manufacturing.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	3	• CROs may not create direct opportunities for domestic producers but would generate potential for cooperation with academia and research institutions.
• Will new investors create increased export revenues or reduce imports?	5	• CRO outputs are likely to be 100% export oriented, the growth of the CRO sector will positively impact the overall balance of trade/payment.
• Will new investors improve the performance of the value chain as a whole?	5	• CROs would bring about a major improvement of the value chain as they add development activities to the value chain, which is currently limited mostly to generics manufacturing.
SUBTOTAL	**22**	

52 UNCTAD (2019), Investment Policy Review of Armenia, November 2019

Does investment in contract pharmaceutical research (CROs) offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply, and prices) attractive?		
• Are the local and regional markets attractive?	2	• Domestic market is not attractive, regional market limited to EAEU/CIS countries, does not provide as many opportunities as wider regional market (Europe)
• Is the global market attractive?	4	• Yes, the global market is growing and CRO services are not geographically restrained by transport distances and trade costs like manufacturing. Armenia may be able to position itself in a CRO niche segment and provide services globally.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments?	3	• The CRO subsector does not require any critical natural endowments that would limit incoming FDI. Trade in services is considerably easier than trade in goods.
• Does Armenia have competitive infrastructure?	3	Basic life science technology and IT infrastructure needed for CRO activities is in place, CRO firms would likely need to import some additional equipment and technologies for selected advanced CRO activities.
• Does Armenia have competitive skills and support services?	3	• Yes, existing CRO firms did not indicate labour market related issues, although staff usually required some additional training. The scaling up of professional labour might be an ultimate constraint for large headcount operations.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	2	• Although there are no specific investment and regulatory incentives for CRO firms in Armenia, the sector is less incentive sensitive than manufacturing, so, tax incentives may not be required since tax exposure can easily be optimized by the MNC.
SUBTOTAL	**17**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

It is unlikely that corporate tax incentives would be required by the private sector to stimulate investment since tax exposure can easily be optimized for work performed between related companies. International tax optimization by MNCs can, however, be detrimental to the domestic CRO sector, which cannot optimize in the same way and therefore will bear the full tax burden. A more detailed survey among existing CROs based in Armenia would help to provide a more detailed insight into the sector, in particular on labor skills and costs, CRO activities undertaken in Armenia, growth trends, CRO consumption countries (export), and operational bottlenecks.

5.6. Medical Devices Manufacturing

Medical devices represent, in several ways, a different subsector from pharmaceuticals. Medical devices have demonstrated more traditional manufacturing patterns similar to, for instance, the electronic industry, with diversified participation across a large number of MNCs focused on multiple end-markets.

Medical devices vary in technological complexity and capital and labour intensity in manufacturing. They differ in the degree of oversight and protection required by brands, and their offshoring has been uneven. The medical devices GVC until recently was characterized by vertical integration with relatively low degrees of outsourcing and offshoring. Medical devices can be placed in four key product categories (figure 46), with varying degrees of offshoring.

Figure 46: Medical devices classification

Disposables	Single-use products, such as catheters, tubing and syringes, which are cost-driven and subject to less stringent regulatory requirements. Their production was the first to be offshored.
Medical instruments	Multi-use products, such as forceps and surgical scissors, which are sterilized between uses on different patients.
Therapeutic devices	Highly diverse products that may be inserted in the human body (for example, orthopaedic implants, pacemakers, and hearing aids), which are subject to very high levels of international health and safety regulation and quality standards.
Capital equipment	Large, long-term investments for complex, single-purchase machines that can be used repeatedly over the years, such as magnetic resonance imaging equipment. Comparatively little offshoring of final production has occurred in these industries.

There are limited statistics on international FDI inflows in the medical devices subsector; data is usually included with several other categories (for example, equipment, chemicals and plastic, scientific instruments). Offshoring to a low-cost location is more common in the category of disposables and medical instruments, while therapeutic devices and capital equipment, in particular, display relatively low degrees of outsourcing and offshoring.

In 2019 the medical devices market size reached nearly $456.9 billion, having increased at a CAGR of 4.4 percent since 2015. The market declined by 3.2 percent in 2020, mainly due to the lockdowns imposed by governments across the world, which hindered the supply chain in the medical devices industry.[53] The market is expected to recover and grow at a CAGR of 6.1 percent from 2021 and reach $603.5 billion in 2023 due to increase in incidences of infectious

53 However, there is an exceptional increase in the manufacturing of ventilators used to treat COVID-19 patients.

and chronic diseases and growth in numbers of healthcare facilities. North America accounts for about 39 percent of production, and with the largest share of the global market.[54] The Asia-Pacific region is projected to account for 27 percent of the global medical device market in 2025. The four largest market share segments include in-vitro diagnostic, orthopaedic, and cardiovascular devices, and diagnostic imaging.[55] All 15 top medical devices producers are original brand manufacturing firms and share over 50 percent of the global market (figure 47). The low market fragmentation is due to the substantial investment required to develop new products and thus the need to protect intellectual property, together with the very strict regulatory environment in the sector.

***Figure 47:** Top global medical devices producers (by revenue, 2019)*

Company	Revenue (in billion dollars)	Country
Medtronic	30,55	Ireland
Johnson & Johnson	26,0	US
GE Healthcare	21,1	UK
Abbott Laboratories	19,95	US
Philips Healthcare	19,1	Netherlands
Fresenius Medical Care	19,0	Germany
Becton Dickinson	17,29	US
Siemens Healthineers	15,9	Germany
Cardinal Health	15,6	US
Stryker Corp	14,88	US
Danaher Corp	13,6	US
Baxter International Inc.	11,1	US
Boston Scientific	10,73	US
Essilor International	8,67	France
Zimmer Biomet	7,98	US

Source: Top Medical Device Companies in the World in 2020, retrieved at www.getreskilled.com/medical-device-companies

54 Medical Devices Global Market Opportunities and Strategies, The Business Research Company, July 2020; retrieved at www.thebusinessresearchcompany.com/report/medical-devices-market

55 Medical Devices Market, Fortune Business Inside, 2019; retrieved at www.fortunebusinessinsights.com/industry-reports/toc/medical-devices-market-100085

In Armenia, the medical devices sector is of indiscernible size. There are three domestic producers, all manufacturing low value-added disposables (figure 48). Medical instruments, therapeutic devices, and capital equipment are all imported as there are no domestic production capacities in these categories.

Figure 48: Medical devices producers in Armenia

1.	LEYKOALEX	https://leykoalex.am		Producer of healthcare and hospital supplies (analysis containers, napkins, cotton, syringes, drug boxes, gauze, canes, sheets, bandages, etc.)
2.	Lizin	www.lizin.am	GMP certified	Producer of medical ethanol
3.	Bio-Chem	www.bcdental.am	GMP certified	Manufacturer of endodontic dental materials for different purposes, antiseptic solutions for oral hygiene, disinfectants, therapeutic and other auxiliary dental materials.

FDI in the sector is unlikely, given the sector's offshoring has been concentrated in a limited number of countries where firms can ensure quality, regulatory compliance, and intellectual property protection. These include Costa Rica, the Dominican Republic, Ireland, Mexico, and Singapore. In many of these locations, special export-processing zones provide an additional layer of security for firms. There may be a niche market for FDI (or NEM) in the segment of disposables, provided producers can source at least some production inputs locally.

A recent report on Armenia's competitiveness in the ICT sector concludes that the sector of precision and optical instruments has low priority for investment promotion.[56] The main reasons for the sector's low international FDI competitiveness include low regional market share, inadequate match with local supply, and poor global trends. Similar reasons would apply to low competitiveness of the medical devices and instruments sector.

56 IBM-Plant Location International (2020): Armenia's FDI competitiveness in the ICT sector (unpublished report, property of WB/IFC).

Medical devices manufacturing		
To what extent:	**Score**	**Evidence**
Will additional FDI in medical devices add value to Armenia?		
• Will new investors add value that is not already provided by local producers and existing investors?	4	• Yes. The medical devices sector in Armenia is very small, new investors would add value to the whole sector as they are likely to bring new technologies and production innovation.
• Will new investors create additional jobs?	4	• Yes. Low-tech medical devices production (manufacture of disposables) is labour intensive, particularly in semi-skilled labour.
• Will new investors increase opportunities for domestic firms to supply their goods/ services to foreign investors?	3	• New investors could provide sourcing opportunities for domestic firms provided there are domestic producers in the subsector (particularly in inputs production).
• Will new investors create increased export revenues or reduce imports?	5	• Medical devices outputs are likely to be produced for export; investment would improve the balance of trade by both export and import substitution.
• Will new investors improve the performance of the value chain as a whole?	4	• Medical devices producers would likely improve the performance of the value chain as a whole as the sector is largely underdeveloped and depends on imports.
SUBTOTAL	**20**	
Does investment in medical devices offer an attractive proposition for foreign investors?		
Is the market (in terms of demand, supply and prices) attractive?		
• Are the local and regional markets attractive?	2	• Domestic market is too small, although part of the production can also be placed in Armenia. The regional (EAEU) market provides more business opportunities, however production in the low-tech segment (disposables) is also likely to face high competition from existing global producers.
• Is the global market attractive?	1	• The global market is increasing and provides new business opportunities; yet for the production of disposables, Armenia's limited transport options and high transport costs of high-volume bulk cargo make investment proposition to service global markets out of Armenia unrealistic.
Does Armenia offer competitive supply conditions for investors in this sector?		
• Does Armenia have competitive natural endowments (raw materials, location, etc.)	1	• Insufficient raw materials, resources, and basic inputs (for example, cotton) may make Armenia less competitive than other traditional low-cost production centres.
• Does Armenia have competitive infrastructure?	2	• High transport costs due to poor country connectivity increases operation costs.
• Does Armenia have competitive skills and supportive services?	3	• For high-tech medical devices production, Armenia does not have the required qualification profile; for semi-skilled operation there is sufficient labour supply.
• Does Armenia offer a conducive business (regulatory/institutional) environment?	1	• There are no specific investment and regulatory incentives for medical devices producers in Armenia.
SUBTOTAL	**10**	
Evaluation key: 5=very positive	4=positive	3=neutral 2=negative 1=very negative

5.7. Overall sector-scan results

Based on the sector-scan results the subsectors with the best investment proposition are linked to outsourcing/offshoring (figure 49):

- contract research operations (CROs)
- contract manufacturing (CMOs).

***Figure 49:** Summary of sector-scan assessment matrix*

Subsector	Value for Armenia						Value Proposition for Investors				
	Lack of existing investors	New jobs	Firms' income/ suppliers	Trade balance	Impact on value chain	Local market	Global market	Natural assets	Infra-structure	Skills and services	Business environ-ment
1.Production of APIs			17						8		
	5	2	1	4	5	1	1	1	1	2	2
2. Production of original pharmaceuticals			16						9		
	4	3	1	3	2	2	1	1	1	2	2
3. Production of generic pharmaceuticals			16						13		
	3	3	3	2	2	3	1	1	3	3	2
4. NEM—contract manufacturing			19						18		
	4	3	5	5	2	4	1	2	4	5	2
5. Contract pharmaceutical research (CROs)			22						17		
	5	4	3	5	5	2	4	3	3	3	2
6. Medical devices and supplies manufacturing			20						10		
	4	4	3	5	4	2	1	1	2	3	1

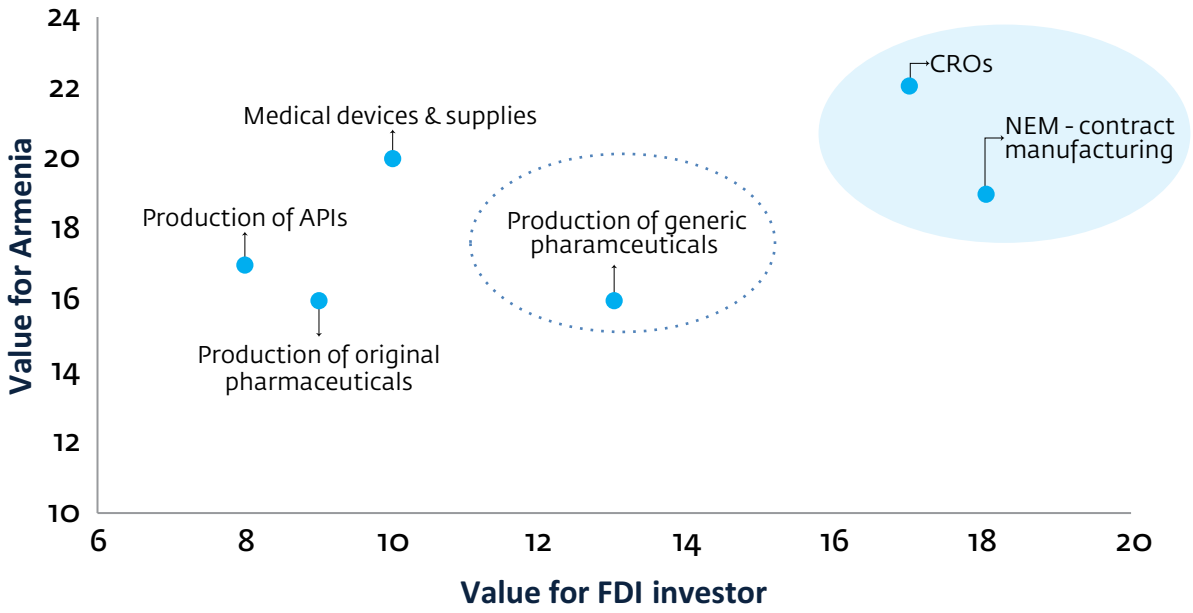
These subsectors have at least some recent investment track record (both domestic and diaspora-linked investment), do not expose potential FDI to large capital-investment risks, are export oriented and could build on existing Armenian experience.

They are the closest to priority sub-segments that could be promoted to foreign firms for greenfield or joint-venture investment. None of the other reviewed subsectors currently present strong enough value propositions for immediate substantial greenfield FDI. However, production of generic pharmaceuticals is a sector where Armenia may want to test the waters with MNCs to get a better insight into where the country meets/fails their site-selection criteria.

In some of the remaining subsectors (in particular, areas that add value to the

existing low-value domestic production, for instance in API or medical devices and supplies manufacturing), FDI would be very valuable for Armenia, yet the investment proposition for foreign investors is weak and economically not viable. The assessment for all six subsectors is summarized in figure 50.

***Figure 50:** Prioritization of target subsectors for proactive FDI promotion*



5.8. Sector-linked Investment Impediments

While the interviews undertaken with the private sector revealed some investment impediments, most were related to domestic producers with little or low relevance to potential FDI investors.

	Domestic firms	FDI firms
Financing	No particular impediments linked to investment or export financing. The companies have been able to finance their growth by internal finance or by debt financing. The sector has not indicated demand for loans with subsidized interest rates. While domestic firms ask for government co-financing of selected business activities (for example, costs involving drug registration in export markets, clinical trials undertaken in Armenia, staff training, and international marketing) or reduction of fees for registration of low-profit drugs, these are not critical barriers to sector development.	International expansion of MNCs does not depend on access to the host-country's financial markets. While financial incentives provided to FDI firms will improve profitability of their operations in Armenia, they are not a critical site-selection factor.

Human resources	Firms claim that while Armenia has skilled human resources, they usually lack adequate professional experience and need additional extensive training. The sector is also subject to international brain drain with some qualified medical doctors/pharmaceutical specialists leaving the country and working abroad (Russia) due to salary differences. An "Open Door" policy to attract qualified personnel from other countries (for example, Lebanon, Syria, Iran, CIS countries) to Armenia may help to improve labour market supply.	Foreign companies will face identical issues. Policy measures supporting skills development may include fiscal tools (for example, special tax advantages for in-house training and skills upgrading), financial measures (for example, training vouchers or programs supporting industry-academia cooperation), or regulatory incentives (for example, a smart visa program for highly skilled pharma/healthcare professionals). A small pool of highly qualified staff may be an investment impediment for expansion of the CRO sector. A recent UNCTAD investment policy review suggests that the country would need 2,000 professionals per $100 million of R&D revenue.[57] According to data provided by the industry association, the whole pharmaceutical sector in Armenia currently employs less than 1,000 professionals.
Regulatory environment	The introduction of GMP regulations to the sector and adoption of a new Law on Drugs led to human capital development and better market access for pharmaceuticals produced in Armenia, due to the improved quality certification. Nowadays, almost all local pharmaceutical producers hold EU-compliant GMP certification. Domestic firms agreed that further easing of import regulations, import duties, and taxes would improve export competitiveness. However, Armenia as a member state of EAEU is obliged to follow unified external trade tariffs and government policies likely cannot be adopted unilaterally. CRO firms sometimes face arbitrary customs' interpretation of import/export regulations, which could be a critical impediment for some CRO activities (for example, shipment of samples from clinical trials abroad).	One of Armenia's key unique selling propositions in the healthcare (pharma) sector is its free access to the internal markets of EAEU states. Domestic companies indicated that, despite continuing EAEU harmonization, there are still informal trade barriers and preferential treatment of domestic companies (in Russia, in particular) which limits market access for Armenian producers. These market access barriers would be a considerable investment impediment for foreign firms. GoA needs to closely follow EAEU harmonization progress and proactively intervene to guarantee free movement of healthcare (pharma) goods and services within the internal EAEU market. Intellectual property and industry-science linkages could potentially be seen by foreign investors as insufficient. Although not highlighted by local firms as a policy issue, various external assessment analyses indicate that Armenia's industry-science linkages are underdeveloped and innovation performance is weak.[58] Both intellectual property protection and strong industry-science linkages are seen as key prerequisites for both high value-added manufacturing of original pharmaceuticals and R&D activities.

57 IUNCTAD (2019), Investment Policy Review of Armenia, November 2019

58 World Bank (2015): Export-Led Industrial Development Strategy: Implementation Review and Recommendations on New Toolset

Market access	None of the domestic pharmaceutical companies seems to be exporting to the EU market. Firms claim that strict EU regulatory requirements and high cost of drug registration prevents them from entering the market. Despite undergoing sector rules harmonization within the EAEU market, domestic companies claim that entering Russian market is difficult due to frequent regulatory changes, high marketing costs, preferential treatment of domestic companies (for example, with regard to public procurement), and low prices of drugs on the list of essential medicines.	With regard to access to EU market, MNCs will not be limited by the same investment impediments as they are likely already supplying their goods and services to the EU market and have both the financial means and expertise to register new products. However, incomplete sector harmonization rules and existence of informal trade barriers with Russia is a major investment impediment for efficiency-seeking FDI. Access to Russian government procurement in pharmaceuticals could be a strong investment proposition to foreign investors in pharma manufacturing. Based on information provided by domestic firms, Russia has employed various forms of a protectionist agenda, with increased localization efforts, such as discriminatory tendering procedures and proposed compulsory licenses, to support domestic manufacturing. If Armenia is able to guarantee preferential access to Russian market and effectively circumvent the Russian preferential treatment of domestic producers by using the EAEU common market rules,[59] it could be a strong investment incentive for FDI in pharmaceutical manufacturing. Inability to conduct full-cycle production (including API) in Armenia or the EAEU is, however, a strong sector-linked investment impediment, which could deter FDI motivated by localization needs. One concrete example of missed investment opportunity, provided by one of the interviewees, is of certified laboratories for bioequivalence studies. There is currently no such laboratory in Armenia, given the small size of the domestic market and Russia's rule that only studies undertaken in Russian laboratories are recognized in Russia.

59 Producers of finished products and active pharmaceutical ingredients within the EAEU have a 20 per cent preference in public procurement.

5.9. General Investment Climate Impediments

Many factors affect Armenia's attractiveness to investors. While the focus of this paper is primarily on investment-climate issues related to investment in the healthcare (pharmaceutical) sector, most identified crosscutting investment-climate issues are relevant to other sectors as well.

Consistent with its free-trade stance, Armenia has been open to foreign investment since the early 1990s and offers foreign investors high standards of treatment and protection. However, several legal provisions and institutional impediments send contradicting signals to investors and are inconsistent with the liberal approach to investment adopted by the public administration.

POLITICAL, POLICY, AND REGULATORY UNCERTAINTY

Political uncertainty and instability negatively impact FDI flows. The recent Nagorno-Karabakh conflict and continuing ceasefire violations may have a negative impact on investors' perception of Armenia as an investment destination due to security and geopolitical risks. The result of recent parliamentary elections could, on the other hand, send out a positive signal to the investor community as the elections ended the post-war political crisis, which paralyzed relations with the private sector.

Companies interviewed during some of the previous sector scans reported that every time there is a transition of power in Armenia, the structure of government changes and so do government agencies and staff involved in policy regulations. The transition process is very often lengthy and leads to policy paralysis, inadequate government capacity, ineffective governance, and corruption, according to many respondents of the World Bank 2018 Country Opinion Survey.[60]

Absence of a policy document on the government's vision for development of the pharmaceutical (healthcare) sector does not encourage potential FDI investors to consider the country for investment. Firms interviewed for this report indicated they were not aware of any topical government policy document that would clearly indicate what conditions the government wants to improve to increase private sector investment and sector growth.

SHORTAGE OF SKILLS

Armenia has historically benefited from strong science education, and some universities have attracted international attention. However, a recent investment policy review points to skills shortages and mismatches.[61] While firms operating in pharma manufacturing did not identify any major labour market shortages, companies in the CRO subsector acknowledged that new hires usually require extensive training to be brought up-to-date on knowledge and skills. Improving supply of highly skilled and educated labour could be an important part of

60 World Bank Group (2019): FY19–FY23 Country partnership framework for the RA; retrieved at http://documents1.worldbank.org/curated/en/523501552357219076/pdf/armenia-cpf-fy19-fy23-february-27-final-update-3-4-19-03062019-636876792405788612.pdf

61 UNCTAD (2019), Investment Policy Review of Armenia, November 2019

the sector's value proposition enhancement. This includes improving conditions for foreign hiring. Unlike in ICT, food technologies, or finance, professionals with higher education in the pharmaceutical sector must undergo a standard (non fast-tracked) work permitting procedure.

Limited supply of skilled and educated workers and staff is a concern for any investor, regardless of its origin, but it is a critical investment site-selection criterion for foreign investors that could potentially discourage them from considering Armenia.

6. Conclusions and Recommendations

6.1. Subcontracting/Offshoring: the Most Likely Sources of FDI in the Healthcare Sector

FDI inflow patterns in the Armenian pharmaceutical sector are unlikely to differ substantially from established investment trends seen elsewhere in healthcare and pharmaceutical sectors (that is, most FDI in the form of mergers and acquisitions, non-equity participation of MNCs more frequent than greenfield FDI, MNCs revisiting global value chains to minimize dependency on imports of critical APIs). Although the sector scan identified two subsectors that could be viable investment propositions for potential foreign investors, none of the reviewed subsectors currently demonstrates features strong enough to motivate FDI into large-scale greenfield production in the short term. Investment is likely to be on the small-scale side, both in subcontracting (given the existing production capacities of Armenian firms) and in CRO (given the limiting availability of highly qualified labour). There should also be degree certifications in the pharma and life sciences studies with mandatory private sector fellowships and internships that allow a young talent pool and degree seekers to get exposure to the applied part of the industry and hone their skills accordingly. Setting up a teaching institute or department at some local universities could be an important catalyst for this.

The Armenian diaspora can be an interesting resource to tap into. Diaspora seed capital is likely behind some of the existing investment projects in the sector already. However, the diaspora or some of the diaspora backed initiatives (for example, FAST Foundation or SmartGateVC) may also help the government to obtain expert opinion and direct industry insight into the sector and provide critical feedback on the country's international competitiveness for FDI in the healthcare sector. Foreign-based diaspora can also provide recommendations on how best Armenia can extend its R&D capability and its small generics industry into larger scale manufacturing (figure 51). Diaspora can also provide views on how to attract more projects to Armenia's ICT sector related to healthcare (for example, health-tech start-up projects of Vineti and Macadamian).

***Figure 51:** Illustrative list of diaspora linked to healthcare sector*

Name	Position	LinkedIn contact
Noubar Afeyan	Chairman and co-founder at Moderna Therapeutics	www.linkedin.com/in/noubarafeyan
David Donabedian	Co-founder, CEO, and Director at Axial Therapeutics	www.linkedin.com/in/david-donabedian-73050a
Aleen Hosdaghian	Senior director of marketing at SUN Pharma	www.linkedin.com/in/aleen-c-hosdaghian-8169a17
Lilian Latchinian	Executive Director, Development Program Management at Incyte	www.linkedin.com/in/lilian-latchinian-ab98932
Andrew Kayserian	Associate Scientist at AstraZeneca	www.linkedin.com/in/andrewkayserian
Romic Eskandarian	Senior Director of Pharmaceutical Services at Adventist Health Glendale	www.linkedin.com/in/romic-eskandarianpharmd
Johnny El Chemmas	Healthcare Strategy and Business Development, previously at Omnicell and MedTech Innovator	www.linkedin.com/in/johnny-elchemmas
Sevan Kolejian	FDA Lead General Health Scientist	www.linkedin.com/in/sevankole-jian
Linda Simonian	Partner at A.S.A.P. Rx Corp.	www.linkedin.com/in/linda-simonian-pharm-d-733893102
Pogos TerStepanyan	Pharmacy Program Manager at MPI Pension & Health Plans	www.linkedin.com/in/pogos-terstepa-nyan-pharmd-bcgp-7b1838149
Hambardzum Kaghketsyan	Partner at SmartGateVC	www.linkedin.com/in/hambard-zum/

Courtesy of Daron Bedrosyan (World Bank)

Defining an investment proposition for FDI in the CRO subsector will require additional research into existing CRO activities in Armenia. Contracted research can include a host of activities which, in turn, will each require a specific set of skills (figure 52). Analyzing the existing scope of CRO operations will help assess Armenia's skills and qualifications and their impact on international competitiveness, to understand whether qualified staff is available to support expansion of CRO, and to define investment proposition for FDI. The findings can also guide the government in defining policy support measures, such as co-financing schemes for workforce training, international certification, etc.

***Figure 52:** List of CRO activities*

Initial drug discovery solutions	Biostatistics/biostatistics programming	Formulation assistance
Toxicology studies	Study and development program design and consulting	Database design and build
Bio-analytical services	Regulatory affairs	Data entry and validation
Central laboratory functions	Post-marketing surveillance services	Medicine and disease coding
Site monitoring	Bio-equivalency testing	Quality and metric reporting
Data-management services	Clinical trial patient recruitment	Validation programming
Vigilance	Clinical trial data management	Safety and efficacy summaries

6.2. Can FDI Improve the Resilience of Armenia's Healthcare?

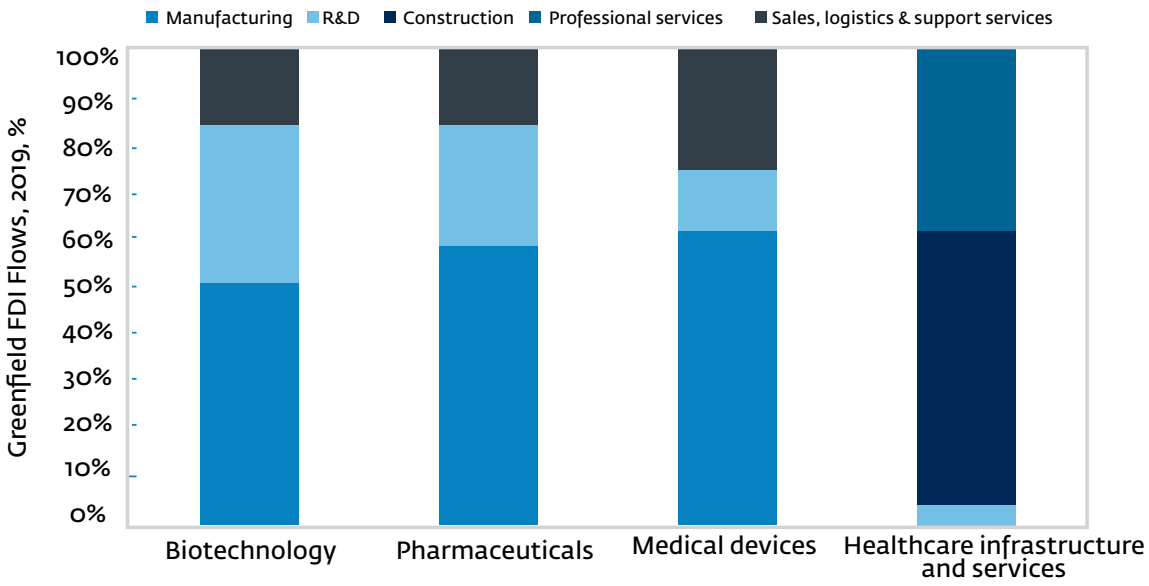
The ongoing COVID-19 pandemic has placed a spotlight on the bottlenecks in the international supply chains of healthcare equipment and medicines. MNCs in healthcare industries have faced short-term supply chain disruptions, similar to those in other industries, and have also been affected by emergency policy measures by national governments, including restrictive trade measures, tightened investment regulations, and general requisition measures to meet national needs. In the future, MNCs will likely opt for greater geographical diversification and other strategies to make their supply chains more resilient. This will lead to degrees of slack and redundancy (risk-management measures) as well as replication, with production of similar equipment across all major blocks.[62] This may create new investment opportunities, which are not necessarily motivated by the same traditional FDI drivers as in the pre-pandemic times (market access, cost optimization, and localization requirements). Unfortunately, Armenia is, for reasons analyzed above, unlikely to benefit from these new investment opportunities.

However, the pandemic has also put unprecedented strain on health systems across the globe and brought resilience of national health systems to the forefront of policy discussions. Could private provision of healthcare goods, infrastructure, and services, in particular by foreign investors, increase this resilience without deteriorating access to healthcare? A recent OECD report suggests that as an immediate response to the COVID-19 crisis, governments may want to consider alleviating administrative burdens on investors, providing additional fiscal incentives for producers of medical equipment, and incentives for conversion of production lines to essential medical goods needed to contain the pandemic.[63] However, while these measures may lead to new investment from existing firms

62 World Investment Report 2020, UNCTAD

in Armenia, they are unlikely to stimulate a new inflow of FDI in the sector. The key segments of the health sector—goods, infrastructure and services—are subject to different degrees of state regulation and private sector participation, with private investors, domestic and foreign, prevailing in manufacturing and distribution of medical goods and technologies, and the public sector often prevailing in health infrastructure and services. Market-seeking motivations and strategies dominate private firms' activities in healthcare services, while efficiency-seeking firms also exploit the tradability of healthcare goods (figure 53).

***Figure 53:** FDI in the health sector by activity*



Source: OECD (2020), retrieved at www.oecd.org/investment/Can-FDI-improve-the-resilience-of-health-systems.pdf

Given their different intrinsic sectoral characteristics, the key segments of the healthcare value chain attract clearly distinct foreign investment activities. Manufacturing investments dominate healthcare goods and technologies, followed by investments in R&D, and distribution activities. Unsurprisingly, foreign investments in healthcare infrastructure and services primarily involve construction activities and professional services (for example, operation and management of healthcare facilities, hospitals, and other medical services).[64]

63 OECD (2020): Can FDI improve the resilience of health systems? Policy note for discussion at the second session of the 2020 Roundtable on Investment and Sustainable Development; retrieved at **www.oecd.org/investment/Can-FDI-improve-the-resilience-of-health-systems.pdf**

64 OECD (2020): Can FDI improve the resilience of health systems? Policy note for discussion at the second session of the 2020 Roundtable on Investment and Sustainable Development; retrieved at **www.oecd.org/investment/Can-FDI-improve-the-resilience-of-health-systems.pdf**

Attempting to stimulate FDI in healthcare infrastructure and services in Armenia by using traditional policies to promote FDI in healthcare goods and technologies (for example, investor targeting, sector-specific investment incentives, targeted economic zones) will not be enough. Various analytical papers point out, that for Armenia to attract more private investment in healthcare infrastructure, the country needs to undertake health insurance reform first to reduce out-of-pocket payments and improve healthcare access.[65] Therefore, in the short term, FDI is unlikely to improve the resilience of Armenia's healthcare.

6.3. Institutional Arrangements and the Role of IPA

If the Government decides to pursue the two niche subsectors for investment promotion, this sector-scan results can be used by Enterprise Armenia as an input for policy advocacy and for investor targeting, that is, proactively reach out to investors identified as being desirable and likely to invest and present them with tailored business cases for selecting Armenia as their future investment destination.

Each target sector needs a tailored investment promotion strategy. There is enough strong empirical evidence to support a sector-based organizational set-up for IPA.[66] It is recommended that a healthcare sector specialist be appointed to lead the investment promotion effort in the identified pharma segments on the basis of an agreed business plan.[67] FDI promotion in the healthcare sector is always a long-term investment. However, the pay-offs even in the medium to long term can be significant. There may be some easier wins, for example by targeting the diaspora (those already involved and those not yet involved), possibly through niche projects and by winning smaller CRO contracts. The investment propositions for both subsectors will be based on:

- preferential market access to EAEU (customs and import fee-free access to EAEU, mutual recognition of GMP and drug registration, preferential access to public procurement)
- existing investment track record, including NEMs (both domestic and FDI showcases)
- cost efficiencies (labour costs, transport costs, regulatory costs)
- skills availability (current labour market and educational system data).

65 See, for instance: IFC Country Strategy (2019); Armenia: Expansion of the Benefits Package (World Bank Group, 2018) or FinHealth Armenia (World Bank, 2020)

66 World Bank (2020), Strengthening Service Delivery of Investment Promotion Agencies, retrieved at **https://openknowledge.worldbank.org/bitstream/handle/10986/33498/Strengthening-Service-Delivery-of-Investment-Promotion-Agencies-The-Comprehensive-Investor-Services-Framework.pdf**

67 Additional recommendations may come up from an institutional assessment of IPA which recently underwent organizational overhaul.

At the operational level, the IPA should identify firms meeting the following company profiles:

	CMOs	CROs	Generic pharmaceuticals
What is the type of operation that should be promoted?	Outsourcing production of generic pharmaceuticals for the EAEU market to Armenia	Selected CRO activities where Armenia has sufficient skill base; growth and expansion of existing FDI in Armenia	*Initial probe with MNCs with sales in the EAEU market*
What size of investment should Armenia target?	Small to medium size operations to meet the capacities of existing Armenian domestic producers	Small to medium-sized operations depending on the skills base	*Medium to large-sized operations to reach economies-of-scale benefits*
What would be the motivation for a company to locate its operation in Armenia?	Production costs and Armenia's pool and export performance of existing domestic producers; barrier-free access to EAEU market	Operational costs and, possibly, access to a pool of highly qualified professionals	*Production costs and barrier-free access to EAEU market*
What are the main source markets?	Russia, EU, USA	USA, India	*India*
What kind of organizations would invest in such an operation?	Companies with existing presence in the EAEU market, for whom production outsourcing would lead to cost advantages	Any CRO looking for additional cost advantage or EAEU market access	*Companies that need to localize their production within the EAEU internal market to benefit from preferential market access to retail and public procurement*
Leading players (global and/or EAEU-based)	Sanofi-Aventis, Bayer Healthcare, Johnson & Johnson, Pfizer, Merck Sharp & Dohme	IQVIA, Laboratory Corp. of America Holdings, Syneos Health, PPD, Charles Rives Laboratories, Covance, GCT, ICON	*Sun Pharmaceutical, Aurobindo Pharma, Cadila Pharmaceuticals, ZEE Laboratories, Dr. Reddy's Laboratories, Cipla, Lupin, Advanced Pharmaceuticals*

Services provided by the sector specialist to potential foreign investors typically cover four distinct categories: marketing, information, assistance, and advocacy (figure 54).

Figure 54: : Illustrative example of investment promotion services provided by IPA's sector specialist

Marketing	• Build or reinforce a positive image of Armenia and its advantages via targeted international media outlets in target markets • Promote CMO/CRO by proactively participating in business events and investment-related trade shows for the pharmaceutical/health sector domestically or abroad • Proactively promote priority sectors through a network of intermediaries, including the Armenian diaspora • Reach out to targeted investors in the priority sectors; seek face-to-face meetings to communicate Armenia's value proposition • Reach out to established investors; seek meetings to communicate the Armenia's value proposition for CMO/CRO; and discuss ways the IPA can help to identify potential CMO/CRO clients and support business links with domestic firms.
Information	• Update Armenia's investment guide for the pharmaceutical/healthcare sector using data/statistics used by investors during investment site selection process • Gather and adapt data and information supporting the investment proposition for CMO/CRO sectors—this will often require international benchmarking data and understanding sector trends • Produce detailed sector profiles based on market intelligence and relevant to investors in CMO/CRO sectors • Produce detailed project opportunity profiles based on specific information on concrete projects of interest to relevant investors • Issue a guide to regulatory procedures in CMO/CRO sectors • Provide tailored responses to investors' unique questions and inquiries and follow up on satisfaction with the services provided to determine next steps (IPA needs to use a good CRM system to be able to build a relationship with potential investors and properly structure its promotional effort).

Assistance	• Support the first-time and follow-up site visits with agenda suggestions, planning, and meeting confirmations • Accompany investors on site visits; outside of site visits, respond to specific requests to introduce investors to other foreign companies, domestic companies, potential suppliers, and institutions (public, private, educational, or government) • Follow up proactively with investors after site visits to assess other needs • Provide guidance on government structure and on (non)regulatory aspects for the healthcare sector and business start-ups through advice and introductions • Provide comprehensive support through project management intervention for business start-ups, including A-to-Z follow-up; tactical problem solving for individual investors; compliance with licensing, permitting, and regulatory procedures; and support for linking with service providers • Facilitate and coordinate investor participation in initiatives and events that provide networking opportunities in the local market • Proactively coordinate periodic visits and meetings with individual investors to monitor well-being and explore new investment opportunities • Reach out to investors to gather information on grievances related to government • Conduct and direct investor grievances to relevant parties looking for a solution. • Organize and invite market players (buyers and suppliers) to relevant events to provide matchmaking and networking opportunities.
Advocacy	• Coordinate and interact with investors and private sector representatives to identify issues and challenges limiting FDI in pharmaceutical/ healthcare sector; define strategies and actions to address challenges • Analyze and report on the state of the investment ecosystem for pharmaceutical/ healthcare sectors; formulate and submit proposals to improve the investment climate based on feedback from prospective investors in priority sectors • Advocate and follow up on government actions to improve the investment ecosystem for investors in pharmaceutical/healthcare sectors.

6.4. Developing a Short to Medium-term Promotion Strategy

Enterprise Armenia's initial pharmaceutical sector investment promotion action plan, in seeking to build these essential services for the longer term, could step up its activities as its capacity to undertake promotion develops and as the government tackles the more fundamental constraints. These activities could, for instance, include:

- Ensure good quality promotional information on EA's website (including case studies and testimonials, etc.)
- Produce a pharma promotional brochure, perhaps even a short sector video
- Recruit a pharma specialist to lead promotion efforts in this sector
- Organize industry training for its sector team (including company visits, etc.)
- Attend leading pharma fairs or expos (for example, to gain experience and to get Armenia seen by prospective investors)[68]
- Set up meetings/interviews with the diaspora currently involved in the pharma sector in Armenia (figure 51) and domestic companies involved in the sector (figure 45 and others) to gather more intelligence, identify potential allies and "champions", and to search for possible leads and quick-win projects
- Undertake targeted promotion around identified niche project opportunities (even small ones) to build track record, rather than go immediately for full segment promotion
- Organize online sessions to present Armenia's experience and value proposition and build momentum around the pharma sector
- Engage policy makers to discuss necessary reforms; EA's advocacy role could be instrumental in designing the right set of policy measures that will boost the sector's competitiveness.

6.5. Policy Options to Promote FDI in the Healthcare Sector

Although this report has not identified many sector-linked investment impediments that can be rectified by short-term government policy tools, in the future the government may want to explore some policies used to promote FDI in healthcare sectors elsewhere. A recent UNCTAD survey monitoring policy measures, taken by governments in the health sector in response to pandemic, identified three different types of policy instruments to encourage FDI in the healthcare sector.[69] These include: (i) proactive investment promotion and enhanced facilitation measures, such as actions by IPAs or other government institutions to attract or facilitate foreign investment, specifically in the health sector; (ii) SEZs and clusters dedicated to investment in the health sector; and (iii) financial, fiscal and regulatory incentives for investors in the health sector.

68 https://tradefest.io/en/tag/pharmaceuticals

69 UNCTAD, World Investment Report 2021 (Section C /Investment in the Health Sector, pp. 134 -155)

The key principles of **investment targeting** by the IPA have been described in chapter 4 of this report. The UNCTAD survey also identified similar measures by IPAs targeting the healthcare industry and life sciences as priorities to attract FDI: organizing campaigns to promote medical tourism and export of medical services, medical fairs and sector-targeted events; facilitating partnerships with local companies; and offering dedicated permitting and support to help establish specific projects in the sector. IPA activities involve reaching out to a wide spectrum of investors, including private companies, followed by institutional investors, impact investors,[70] and diaspora.

Sector-specific investment incentives typically include fiscal incentives (corporate tax exemption, cost-based tax deductions and credits, exemptions from indirect and administrative taxes, including duty-free imports of machinery or materials needed in the sector for both R&D and manufacturing), and financial incentives (for example, grants for costs such as training, infrastructure, land/building, utilities, or equipment). Some incentive programs aim to facilitate positive spill over of foreign investment to strengthen local healthcare systems and economies through skill development, technology transfer, and cooperation with local partners (figure 55).

Figure 55: Examples of targeted investment incentives schemes

Australia	Offers R&D grants to companies in the health sector, consisting of 30 cents per dollar spent on eligible R&D activities, above a base level.
USA	Provides incentives at both federal and state levels. Federal government programs include R&D support for small businesses in the health sector and grants to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology.
France	Has several public funds dedicated to supporting medical technology and research. *Biothérapies Innovantes* et *Maladies Rares* is a public fund for companies working on innovative therapies targeting rare diseases. *Accélération Biotech Santé* is a fund that supports companies, mainly at the seed stage, that develop therapeutic products and medical devices in the field of human health, as well as small and medium-size enterprises, technology platforms, and scientific or technological service providers. The fund *InnoBio* helps companies, technology platforms, and scientific or technological service providers that are directly or indirectly involved in developing innovative life science and health products in the pre-clinical or clinical phase.
Kazakhstan	Government can conclude an investment priority contract with companies constructing, Running, and/or investing in a sanatorium or hospital, offering tax preferences, custom duties exemptions, government grants (up to 30 percent of all costs) and investment subsidies.

70 Impact investing is about deploying capital with the intent of bringing about some socially desirable outcome with expectations of a financial return. Affordable healthcare, equitable education, sustainable agriculture, affordable housing, or clean technologies are examples of sectors that create opportunities for impact investing.

Nigeria	Offers free capital repatriation and income tax exemptions to local and foreign companies with "pioneer status" involved in the manufacturing of pharmaceuticals and personal protective equipment, as well as medical and dental equipment.
Philippines	Offers a range of incentives to investors in healthcare and wellness services, including both fiscal incentives (for example, a four-year income tax holiday on income from serving foreign patients and tax and duty-free importation of medical equipment), and non-fiscal incentives (for example, on the recruitment of foreign nationals and special residency visas for investors).
Italy	Has allocated special funds within its Development Contract programme to support investment in biomedical and telemedicine activities, particularly those connected to the production of medical equipment and devices, and technologies and services to prevent health emergencies.
Thailand	Has announced new incentives to accelerate investment in the medical industry, including a 50 percent reduction in corporate income tax for another three years (existing law already provides a tax holiday of three to eight years for qualified investors). Moreover, starting in 2020, manufacturers of medical parts or devices could be exempted from import duties on machinery. Additional tax benefits are also offered to companies producing non-woven fabric used to manufacture medical masks or medical devices.
Russia*	Offers special investment contracts under which the investor is granted certain benefits. These benefits may include tax incentives or the security of set tax and legal frameworks for the investor for the entire duration of the special investment contract.

Source: World Investment Report 2021, * data on Russia are based on independent research.

Targeted investment incentives may, in some cases, correct for market failures or advance development goals. Russia, for instance, launched an investment incentive scheme in 2015 introducing the concept of special investment contracts that also covers the pharmaceutical industry.71 A special investment contract is an investment agreement between the Russian government and the investor under which the investor is granted certain benefits. These benefits may include tax incentives or the security of set tax and legal frameworks for the investors for the entire duration of the special investment contract. However, as noted by legal advisors, from the investor's perspective, the most important benefit arising from the special investment contract is the "Made in Russia" certificate, which is issued for the products manufactured by the investors in Russia, provided that the products are covered by the special investment contract. The "Made in Russia" certificate is important due to the government's recent policy of import substitution and enables the investors to participate in state procurements.72

71 Resolution No. 708 of the Government of Russian Federation dated July 6, 2015 "On Special Investment Contracts for Certain Industrial Sectors".

72 See, for instance, Special investment contracts in How to Invest in Russia (retrieved at **www.beiten-burkhardt.com/sites/default/files/downloads/how-to-invest-in-russia_2017_Bilgeis%20Mamedova.pdf)**

This report's findings do not indicate that Armenia's international competitiveness in the targeted subsectors depends on the immediate introduction of fiscal and/or financial investment incentives, although some selected non-fiscal incentives (for example, a smart work-visa program for high-skilled experts, investors, and employees in the sectors or some of its subsectors) may help enlarge the pool of qualified labour needed, for instance, by CROs.

Should the GoA consider introducing an investment incentive programme, it first needs to put in place a general development strategy for the healthcare sector to quantify expected future outcomes of the policy measures. Secondly, it should conduct a cost-benefit analysis to assess the extent to which, and at what cost, incentives meet their intended objectives in the sector and how they will contribute to a country's economic welfare, with the program's benefits exceeding the costs. It is also worth mentioning that incentive schemes used elsewhere may not deliver the same intended benefits in Armenia. Introducing "special investment contracts" inspired by the Russian incentive scheme, for instance, may not improve Armenia's international competitiveness, if the contracts cannot guarantee free access to the Russian market under identical Made in Russia (Made in EAEU) rules.

Finally, targeted economic zones under special regulatory regimes are a policy tool used by governments to promote investment in particular sectors. Three types of designated special economic zones (SEZs) are used commonly to promote FDI in the healthcare sector. The first type of SEZs are essentially medical tourism parks found, for instance, in ASEAN countries offering high quality medical services and facilities to foreigners. Medical tourism has not been included in this report as it was covered by another FDI sector scan on tourism.

The second type of SEZs are industrial or export processing zones developed in support of manufacturing for domestic and/or export markets (for example, the Eastern Economic Corridor in Thailand, which prioritizes the manufacturing of medical devices and pharmaceuticals, or the Russian Dubna SEZ, which focuses on technology and innovation activities). Providing dedicated infrastructure and a mix of fiscal, financial, and regulatory incentives, these zones are supported as a part of a wider government economic development policy. While there seems to be an appetite among GoA policy makers for developing a dedicated SEZ for the healthcare sector in Armenia, none of the interviewed private firms indicated that a SEZ should be established to alleviate their operational or trade constraints.

The third type of zone is a science (technology) park that accommodates and fosters the growth of tenant firms with affiliated universities so that knowledge can be shared, innovation promoted, and research outcomes progressed to viable commercial products. Examples in the healthcare sector include Biopolis in Singapore and the Skolkovo Innovation Centre in Russia.

73 For a detailed description of the Russian pharmaceutical market trends and regulations, see, for example: DSM Group (2020): Фармацевтический рынок России 2019, retrieved at www.dsm.ru/docs/analytics/2019_Report_rus_2019.pdf.

SEZs in the form of medical tourism parks or export processing zones are mainly located in Asia, while science parks (healthcare clusters) are most common in Europe and North America.

While this report lists various policy options to promote investment in the healthcare sector, it does not give any prescriptive recommendations as to whether and what investment incentives or economic zones under special regulatory regimes the GoA should introduce. These measures should be designed as part of a (currently missing) wider healthcare sector development policy and not seen only as a tool for FDI attraction.

6.6. Summary of Recommendations

The primary objective of the FDI sector-scan report was to provide the Government of Armenia with an assessment of potential FDI opportunities in the healthcare (pharmaceutical) sector and to suggest how this information can serve for the purposes of sector-specific investment promotion and investment climate reform.

More broadly, the report also finds that there is scope for significant upgrading of Armenia's investment promotion efforts from the more traditional reactive approaches, based on large and unfocused investor conferences, to a significantly more targeted and more proactive approach focusing on outreach to those sectors with the most competitive potential for Armenia.

In summary, the following reform steps can assist the government to strengthen effectiveness of its investment promotion efforts with respect to targeting promising FDI sectors and upgrading investment-promotion capacity:

a. GoA (Ministry of Economy and Enterprise Armenia) should decide whether the two identified pharmaceutical subsectors should be pursued as priority targets for FDI attraction; if yes, the IPA needs to accordingly commence a targeted investment promotion effort to obtain the expected FDI results.

b. GoA (Ministry of Economy and Ministry of Health) needs to revisit the national healthcare (pharmaceutical) sector development strategy, engaging the private sector; the Ministry of Education should assist in upgrading the degree and talent pool with supporting university education programs geared towards private sector needs. Strengthening the operation of existing domestic firms and increasing sector output and export volumes will help promote the country to greenfield FDI in pharmaceutical manufacturing.

c. GoA (Ministry of Economy and Ministry of Health) should closely follow pharmaceutical sector policy development in Russia, the largest regional market. A key policy document of the Russian government for the pharmaceutical sector (Pharma 2020) is soon to be replaced by a new policy

framework (Pharma 2030). GoA needs to maximize the benefits of Armenia's EAEU membership and make sure that Armenia-based firms enjoy the same treatment as Russian domestic companies.

d. Enterprise Armenia should design and implement a targeted international promotion strategy in the two recommended subsectors in selected markets (for example, Russia and India). The Ministry of Foreign Affairs and its network of commercial counsellors at Armenian foreign missions can potentially play an important role in foreign investor outreach. Similarly, Armenian sector association (ArPharMa) could be instrumental in identifying high-caliber domestic companies for international joint ventures/M&As and assessing contacts at the global level through their membership in international sector associations.

e. As part of the preparation of an investor outreach program, Enterprise Armenia needs to collect additional information related to the CRO sector to gain better insight into the sector, in particular on labour skills and costs, CROs' activities undertaken in Armenia, domestic growth trends, CRO export destinations, and operational bottlenecks.

f. GoA (Ministry of Economy and Enterprise Armenia) should engage senior pharmaceutical/healthcare professionals in the Armenian diaspora to get expert opinion and direct industry insight into the sector from and seek recommendations on how best Armenia can extend its R&D capability and small generics industry into larger-scale manufacturing.

g. Enterprise Armenia should prioritize development of key internal processes and guidelines and introduction of a CRM system and sector market intelligence.

h. Enterprise Armenia should initiate establishment of a platform for a public-private dialogue (for example, in the form of a joint Task Force). As a key first step in operationalizing the findings of the sector scan, EA will initiate a sector Task Force in the Armenian pharmaceutical sector, comprising representatives from the Armenian Ministry of Healthcare, the Ministry of Economy, the Scientific Centre for Drug and Medical Technology Expertise, sector associations, and other stakeholders. The Task force will be asked to help coordinate investment promotion efforts under the sector.

i. Enterprise Armenia should define detailed sectoral value propositions for the targeted pharmaceuticals sectors, creating tailored information and marketing materials (brochures and presentations) that are targeted at the identified priority sectors, providing a sufficient level of detail on cost/quality of critical operational factors.

7. Annexes

7.1 Annex 1: FDI Terminology and Principles

Investment typically refers to private, productive investment. This is a private company establishing facilities and hiring people to produce goods or services that are sold in the marketplace. An individual investment may take the form of a manufacturing plant, service centre, sales office, distribution centre, research and development facility, or headquarters, among others. It does not refer to liquid portfolio investment in which an investor merely purchases equities of foreign-based companies but does not exercise any effective control or influence over the decision making of a foreign business. The term investment does not refer to public investment or international donor funds, although both public and private financial institutions, such as banks, governments, and IFC, may provide financing to the private companies that make these investments.

The source of investment may be domestic or foreign **investors**, a term that is often used interchangeably with "companies." The global pool of foreign investors is, of course, very much larger than the pool of investors based in Armenia, and they collectively possess all the value chain activities, investment capital, skills, technology, and market knowledge that Armenia might aspire to. For this reason, **foreign direct investment, or FDI**, is often seen as an indispensable means of catalyzing sector growth and diversification.

Investment policy, if well-crafted, can enhance the attractiveness of a location by providing a transparent and predictable legal and regulatory framework (such as specifying where FDI is permitted and under what conditions), improving investor protections (for example, against expropriation, as minority shareholders), reducing operating costs through improved infrastructure, and streamlining government procedures (such as customs clearance, obtaining permits) to reduce associated costs and risks, and facilitating the full range of company operations. More loosely, investment policy can refer to any Armenian government policy that affects the relative competitiveness of particular sectors. For example, education and immigration policies may increase the numbers and skills of available workers. Together, all these factors affecting a location's attractiveness to investors comprise the **investment climate.**

However, simply having a good investment climate does not guarantee that a location will capture the attention of potential investors, that investors will not have trouble identifying and realizing investment opportunities, or that the investment climate cannot be

improved further. **Investment promotion** is an umbrella term for all activities designed to make sure that these things happen. Most of these activities fall under the heading of one of five typical investment promotion functions: investor targeting, investment facilitation, investor servicing, investor aftercare, and policy advocacy.

Investor targeting (a.k.a., **investor outreach or proactive promotion**) involves proactively reaching out to investors identified as being desirable and likely to invest, in order to present them with tailored business cases for selecting a given location. **Investment facilitation** attempts to convert investor interest into a decision to invest, through the provision of information and assistance during the site selection process. **Investor servicing** then helps convert that decision into an operational project.

Even after a company becomes operational, it remains a potential source for new investment, often called "reinvestment" when it comes from an existing investor. Identifying potential for reinvestment and facilitating its realization is a dimension of **investor aftercare.**

In any given location, there will be many institutions, both public and private, that undertake one or more of these various investment promotion functions. For example, a sector-specific ministry, such as a Ministry of Health, may conduct investor targeting, and a pharma producers' association might conduct investment facilitation and investor servicing. Any such institution might be described as an **investment promotion intermediary (IPI)**. Wanting to ensure that all essential functions are performed in a coherent and strategic manner, most governments have designated one body to be its lead investment promotion body. This is sometimes an investment regulatory body or a subunit of a ministry, such as commerce, but it is frequently a standalone investment promotion agency (IPA), which itself is a subcategory of IPI. In Armenia, the mandate of investment promotion agency rests with Enterprise Armenia.

As IPIs are not generally policymakers, their investment climate reform efforts fall into the category of **policy advocacy**, whereby they identify obstacles to competitiveness and support relevant decision-makers and stakeholders with the formulation and implementation of solutions.

Based on A Guide to Investor Targeting in Agribusiness, World Bank, 2014.

7.2. Annex 2: List of Consultations

From October 2020 to March 2021, the Consultant interviewed over 25 representatives from both public and private sectors.

The public sector organizations included the Ministry of Economy, Ministry of Health, Scientific Centre of Drug and Medical Technologies Expertise, IFC, Enterprise Armenia, Scientific Research Institute of Physical Therapy and Spa Treatment, and Yerevan State Medical University.

Within the private sector, the Consultant met with 15 private firms from the pharma/ healthcare sector.

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