

PHARMACEUTICAL GUIDE ARMENIA 2014



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**THE MINISTRY OF ECONOMY
OF THE REPUBLIC OF ARMENIA**



**THE MINISTRY OF HEALTH
OF THE REPUBLIC OF ARMENIA**



USAID
FROM THE AMERICAN PEOPLE

EDMC
Enterprise Development &
Market Competitiveness Project

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WHY ARMENIAN PHARMACEUTICAL SECTOR?

**THE FASTEST
GROWING
PHARMACEUTICAL
SECTORS IN THE CIS**



**EU GMP STANDARDS
ADOPTED IN 2010
FULL IMPLEMENTATION
OF GMP AND OTHER
GXP STANDARDS BY THE
END OF 2015**



**TAX FREE
REGIMES FOR
RESIDENTS OF
THE FEZ**



**STRONG SCIENTIFIC
AND R&D POTENTIAL
HIGHLY SKILLED AND
WELL EDUCATED
WORKFORCE**

**LOW WAGES
AND ENERGY
COSTS IN THE
REGION**



**FAVORABLE
BUSINESS
ENVIRONMENT AND
EFFECTIVE SUPPORT
INSTITUTIONS**



**SIMPLE RECOGNITION
PROCEDURE
FOR MEDICINES
REGISTERED IN THE
EU, USA OR JAPAN**

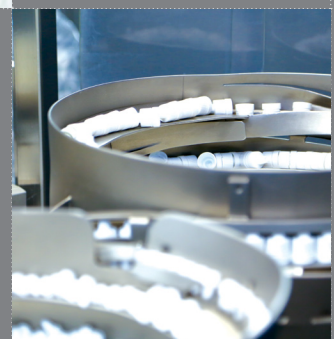


**OLD TRADITIONS
AND RICH
EXPERIENCE IN THE
FINE CHEMICAL
INDUSTRY**

**OPEN AND HIGH
COMPETITIVE
PHARMACEUTICAL
MARKET
EXPORT-ORIENTED
PHARMACEUTICAL
INDUSTRY**



**3,000 YEARS
OF HISTORY
IN HERBAL
MEDICINE**





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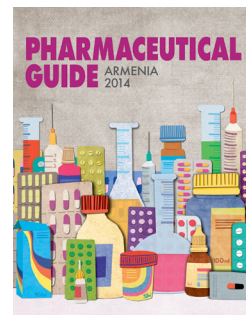


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**KAREN
CHSHMARITIAN
THE MINISTER
OF ECONOMY OF
THE REPUBLIC OF
ARMENIA**



DEAR COLLEAGUES,

Armenia's pharmaceutical sector is an important part of Armenia's economy, and has great growth potential. Ancient traditions that were precursors to Armenia's modern-day pharmaceutical industry were passed on from generation to generation, and have resulted in Armenia's predisposition and ability for scientific research. The ambition of private enterprises, support of the private sector by the Government of the Republic of Armenia, and donor organizations have been the most important factors contributing to the growth of Armenia's pharmaceutical sector and supporting the country's aspirations to continue to improve and grow the sector.

When the Government of RA adopted the Strategy of Export-Led Industrial Policy, representatives of the pharmaceutical sector were among the first to sign a memorandum committing to future cooperation between the industry and the government. The State has offered extensive support to pharmaceutical companies. The support of donor organizations, particularly USAID, is also very important to the sector's prosperity.

The progress of the Armenian pharmaceutical sector in recent years strengthens my belief that the development strategy was a good one, and that local pharmaceutical companies – particularly exporting companies – can achieve even greater success by investing in international standards and tapping Armenia's scientific potential, as well as taking ideas from the experience of other countries with advanced pharmaceutical industries.

With such importance being placed on Armenia's pharmaceutical sector, it is no doubt necessary to have an updated source of information about the sector's representatives and development. This Guide provides this information, and I am confident it will be of great value to pharmaceutical companies (importers, exporters, and producers), as well as to consumers.

YOURS SINCERELY,

KAREN CHSHMARITIAN

THE MINISTER OF ECONOMY OF THE REPUBLIC OF ARMENIA

**ARMEN
MURADYAN
THE MINISTER
OF HEALTH OF
THE REPUBLIC OF
ARMENIA**



DEAR INVESTOR,

The pharmaceutical sector is constantly in the public spotlight and, of course, is of great importance to the healthcare system. This sector has the attention of the President of the Republic of Armenia, and the Ministry of Health has undertaken to regulate the turnover of Armenia's pharmaceutical production. In regulating medicine production and the pharmaceutical market, the Ministry of Health and the Medicine Producers and Importers Union of Armenia have a successful record of cooperation.

With the latest developments in the pharmaceutical sector, the need to ensure correct drug prescriptions and the rational use of medicine has grown among healthcare professionals and the general population. The Ministry of Health is undertaking projects to achieve these objectives. Also important towards these goals is the provision of information by pharmaceutical companies.

I am certain that this Guide will provide useful information to doctors about Armenia's drug companies, partner organizations, and representatives who can be contacted.

Armenia's pharmaceutical companies continue to increase their assortments of drugs and to improve the quality of their products. Companies' continuing implementation of GMP compliance certification procedures and rules greatly contributes to their growth and success.

I know that future editions of this Guide will document the continuing development of Armenia's pharmaceutical sector as the Government of the Republic of Armenia continues to improve legislation that governs the sector, and as our country's pharmaceutical companies continue to grow in accordance with the best international standards.

YOURS SINCERELY,

ARMEN MURADYAN

THE MINISTER OF HEALTH OF THE REPUBLIC OF ARMENIA

INTRODUCTION



Armenia's pharmaceutical sector has been one of the country's most dynamic sectors over the last decade, becoming increasingly relevant to the Armenian economy. This fact is widely based upon the qualifications of its personnel and the driven innovation and research. The pharmaceutical sector has become a strategic sector for growing the Armenian economy due to both its export growing potential and investment attraction.

Over the past 10 years, the Armenian pharmaceutical sector's production volume has grown from about one million USD in 2004 to 12 million USD in 2014, with an annual growth rate of about 20% over the past five years.

More than half of the Armenian pharmaceutical sector's total production is exported. Exports of Armenian pharmaceuticals products have grown an average of 20% per year, and continued growth is expected due to rising incomes, state policy and the introduction of international standards.

Armenia's domestic market may be small, but Armenia offers easy access to surrounding and fast-growing CIS countries and other major emerging markets, including the Middle East.

Opportunities exist for manufacturing low-volume medicines that larger producers find uneconomical to produce, as well as herbal medicines. While investors need to carefully consider many factors, this guide should give the reader enough background information to assess the investment potential and enable them to move forward quickly.

This sector-specific guide supplements "Investment Guide • Armenia 2013", which provides general information about the attractive Armenian investment environment and business procedures. This guide provides a detailed review of the Armenian pharmaceutical industry's performance, regulatory environment and state policy. The aim of this guide is to highlight industry potential and recent performance, backed by quantitative and qualitative data. The guide also showcases investment competitive advantages and opportunities, and provides details on investment incentives.

At the end of the guide, the contact details of support institutions are provided to assist with gathering further information about the Armenian pharmaceutical industry. ■

MAIN MACROECONOMIC INDICATORS, 2009-2013

	2009	2010	2011	2012	2013
Gross Domestic Product (USD billion)	8.7	9.3	10.1	9.9	10.4
Gross Domestic Product per capita (USD)	2,666	2,844	3,102	3,290	3,447
Gross Domestic Product real growth, %	-14.1	2.1	4.7	7.2	3.5
Industry	-6.9	9.2	13.5	7.0	6.8
Agriculture	6.0	-16.0	13.7	9.5	7.6
Construction	-41.6	3.3	-12.5	3.3	-8.1
Services	-3.3	4.1	5.0	6.5	3.6
Inflation (year-end)	6.5	9.4	4.7	3.2	6.6
Budget balance (% of GDP)	-7.6	-5.0	-3.0	-1.6	-1.7
Investment (USD million)	935.5	702.6	816.3	751.8	567.4
incl. FDI (USD million)	732.1	483.0	631.4	567.4	271.2
Exports FOB (USD million)	710.2	1,041.1	1,329.5	1,380.2	1,480.0
Imports CIF (USD million)	3,321.1	3,749.0	4,151.4	4,261.2	4,476.8
USD/AMD exchange rate (average)	363.3	373.7	372.5	401.8	409.6

SOURCE: NSS, MINISTRY OF FINANCE OF RA

**PHARMACEUTICAL
SECTOR IS A
STRATEGIC SECTOR
FOR THE ARMENIAN
ECONOMY**

Historically, medicines were prepared by physicians and later by apothecaries, but today's medicines typically are the products of the collaboration between university research scientists and private corporations. The modern-era of medicines discovery and development began in the 19th century with scientists learning how to isolate and purify medicinal compounds and developing methods for mass-production.

Advances in science and technology are bringing the research-based pharmaceutical industry into an exciting new era for pharmaceutical product development. Research methods are evolving and improving, creating much promise for the advancement of medicine.

The current global pharmaceutical market shows constant growth in production, sales and profitability. The demand for medicines constantly grows despite the political and economic forces that have the opposite effect on other markets.

According to "IMS Health Consulting", an international analytical company, global pharmaceutical sales reached USD 959 billion in 2012 and are expected to reach USD 1 trillion in

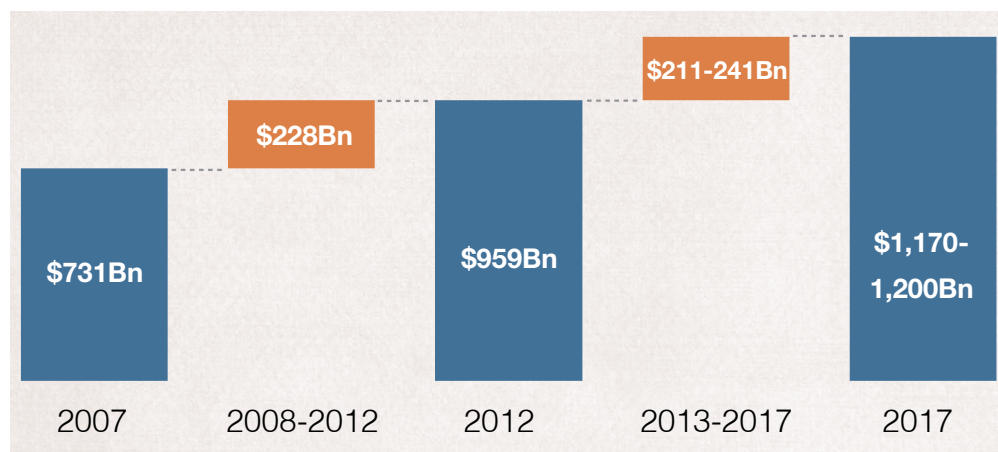
2014 and exceed USD 1.17 trillion by 2017. Absolute growth is expected to be USD 211-241 billion, compared to USD 228 billion over the prior five years (using variable exchange rates) (see Figure 1). Oncology is the leading therapeutic class; other focus areas include pain management, diabetes, hypertension, mental health, and respiratory.

Global pharmaceutical sales exemplify the international spread of medical technology resulting from highly intensive Research and Development (R&D) that is occurring in exporting countries. In general, the pharmaceutical industry is the sector with the highest ratio of R&D investment. According to the 2013 EU Industrial R&D Investment Scoreboard, the Pharmaceuticals & Biotechnology sector ranks number one with a share of 18.1% of total business R&D expenditure worldwide, with an annual growth rate of 4.1% since 2011. The largest number of companies involved in pharmaceutical R&D in 2012 - half of the world's activity - were concentrated in the U.S. where R&D costs are expected to reach about USD 83 billion in 2013. Twenty-six percent of companies involved in pharmaceutical R&D are in European countries (see Figure 2). ▶

GLOBAL PHARMACEUTICAL MARKET

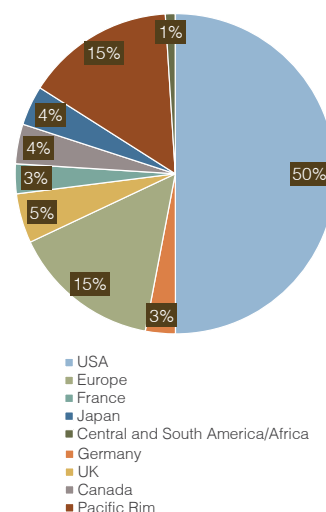


FIGURE 1. GLOBAL SPENDING AND GROWTH, 2008-2017



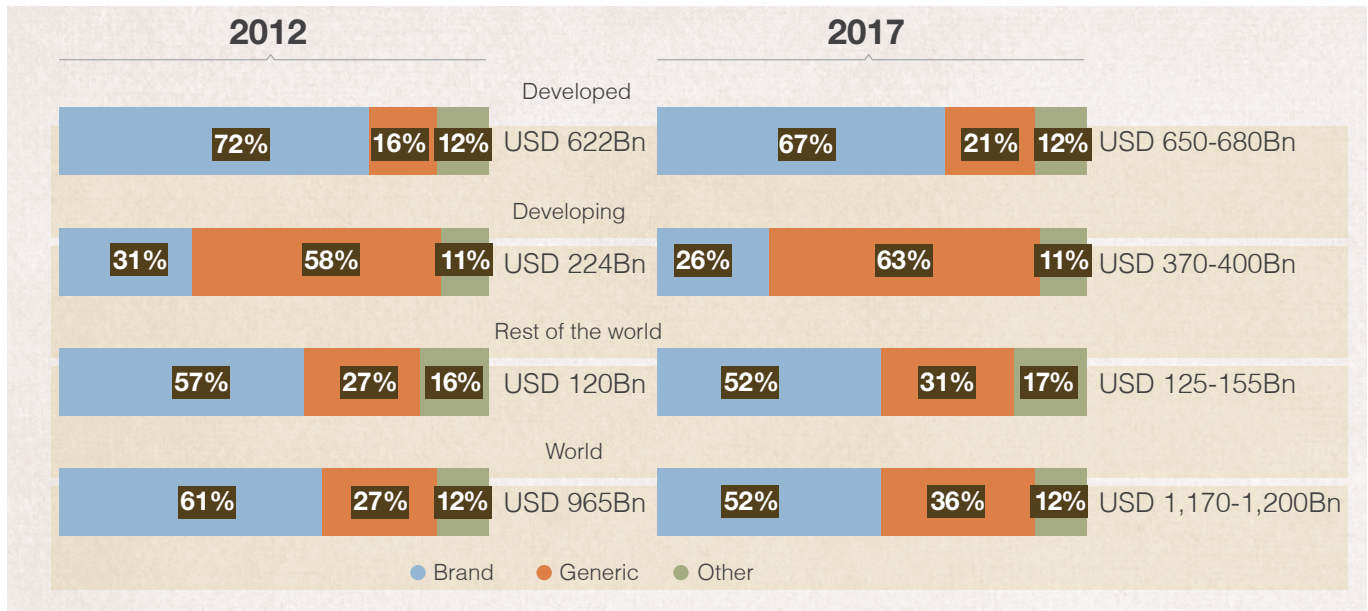
SOURCE: IMS MARKET PROGNOSIS, SEPTEMBER 2013

FIGURE 2. GEOGRAPHICAL STRUCTURE OF THE R&D SEGMENT OF THE GLOBAL PHARMACEUTICAL MARKET (BASED ON NUMBER OF COMPANIES INVOLVED IN PHARMACEUTICAL DRUG R&D)



SOURCE: MEDICINE PRODUCERS AND IMPORTERS UNION OF ARMENIA

FIGURE 3. GLOBAL SPENDING OF GERENICS, 2012-2017



SOURCE: IMS HEALTH THOUGHT LEADERSHIP, SEPTEMBER 2013

The research-based pharmaceutical industry greatly contributes to the world economy; having become a robust economic pillar of industrialized nations, and is increasingly becoming an important sector in the developing world. It creates employment (direct, indirect, and induced), increases imports and exports, generates spending on research and development, and builds technological capacity. It is also the foundation for the existence of the generics industry.

Though original brand-name pharmaceutical products (those with patents for approximately 20 years) accounted for nearly two-thirds of global spending in 2012, the generic market has increased significantly over the past decade. Generics are growing much faster than the protected sector and are a much larger slice of the pharmaceutical market than ever before. As some patents are set to expire this year in developed markets, that share is expected to rise. Generics will continue to grow and are expected

to account for 63% of the developing market by the end of 2017 (see Figure 3). Revenues from generics in 2016 are expected to reach USD 400–430 billion, approximately 70% of which will be outside of developed markets.

The biotechnology segment's total revenue reached USD 262 billion in 2013, representing an 11% increase over the previous five years*. The vast majority of revenue is generated in the European Union and the United States; however, the industry's major players have recently reported slower growth rates for US sales compared with other parts of the world. This trend is expected to continue over the next five years as standards of living and healthcare access improve in emerging nations, such as India, China and Brazil. Over the next five years, the industry is anticipated to continue to prosper; according to Deloitte "2014 Global Life Sciences Outlook" report, revenue is forecasted to reach USD 407.3 billion in 2018, with an average annual growth over the next five years at 9.2%. ■

* IBISWorld Global Biotechnology: Market Research Report, December 2013.

REGIONAL PHARMACEUTICAL MARKET



There are three leading geographic centers within the global pharmaceutical market: North America, Western Europe and Japan. In 2006 these markets collectively accounted for 73% of market volume. By 2012, that collective share of the market dropped to 71%. That year, North America accounted for 38% of world pharmaceutical sales, compared with 24% for Europe (European Union and non-EU countries). According to IMS data, the U.S. market accounted for 62% of sales of new medicines launched during from 2007 to 2011, compared with 18% in Europe.

According to research by the International Federation of Pharmaceutical Wholesalers, there are significant disparities between growth rates in developed and emerging markets, based on each groups' capacity to bounce back from the economic crisis.

Emerging economies such as Brazil, China and India show rapid growth in the pharmaceutical market and in research, leading to a gradual migration of activities from Europe to these fast-growing markets. In 2012, the Brazilian and Chinese markets grew by 16% and 21% respectively, compared to an average market growth of -0.8% for the European markets and -1% for the U.S. market.

CIS countries also have a large potential for the development of their pharmaceutical sectors. Global and regional economic integration along with the removal of trade barriers have created additional opportunities for manufacturers in the CIS, including Armenia which has one of the fastest growing pharmaceutical sectors in the CIS. The fine chemical industry, which encompasses medicine production, has been a prominent part of the Armenian economy for decades; in the 1980s, the chemical sector accounted for approximately 10% of Armenian manufacturing.

A new wave of pharmaceutical development began in the mid-1990s when Armenia's economy experienced an upturn as it gained macroeconomic stability and sustained economic growth. It was during this period that Armenia received its first foreign investments in its pharmaceutical industry.

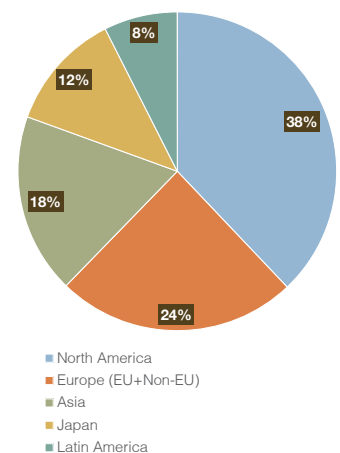
Over the last decade, Armenia's pharmaceutical industry has become one of its most dynamic economic sectors. Exports of medicinal products accounted for 52% of output in 2013, whereas the average annual export growth rate has been 24% since 2003. ■

TOP 10 GLOBAL PHARMACEUTICAL CORPORATIONS RANKING BASED ON SALES (2013)

Ranking	Company Name	Country	Sales (USD Million)
1	Novartis AG	Switzerland	50,576
2	Pfizer Inc.	United States	44,330
3	Sanofi	France	38,181
4	Merck & Co. Inc.	United States	36,359
5	Roche Holding Ltd.	Switzerland	36,146
6	GlaxoSmithKline PLC	United Kingdom	32,544
7	Johnson & Johnson	United States	30,784
8	AstraZeneca	United Kingdom	30,257
9	Teva	Israel	24,258
10	Eli Lilly & Co.	United States	23,045

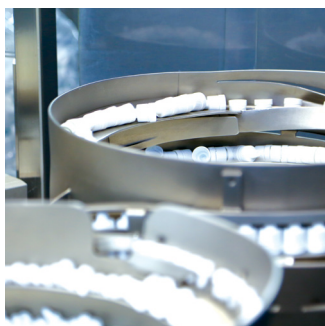
SOURCE: IMS HEALTH, 2014

GLOBAL PHARMACEUTICAL SALES BY REGION - 2012



SOURCE: IMS HEALTH

ARMENIA'S PHARMACEUTICAL SECTOR AT A GLANCE



Armenia's pharmaceutical market experiences the major development trends of the global pharmaceutical market. Although RA's pharmaceutical

market volume is considerably lower compared to those of more-developed countries, it has significant growth potential. ■

Industry Players <ul style="list-style-type: none"> • 18 licensed manufacturers • 25 pharmaceutical product importers/wholesalers and 1,278 retailers • 41 retail companies which have more than two drugstores • 47 representatives of foreign pharmaceutical companies (21 registered country offices) • 1702 pharmacies (2014) the turnover of which is more than USD 100 million (2013) 	Production Type <ul style="list-style-type: none"> • Tablets • Capsules • Ointments • Suppositories • Suspensions • Syrups • Solutions for injection including intravenous infusion solutions • Eye Drops • Herbal extracts and tinctures
Market Size <ul style="list-style-type: none"> • USD 12.9 million local pharmaceutical production (2013) • USD 127.8 million imports (2013), of which <ul style="list-style-type: none"> ◦ USD 10.2 million from CIS countries ◦ USD 80.0 million from EU ◦ USD 37.5 million from other countries • USD 7.8 million exports (2013) of which <ul style="list-style-type: none"> ◦ USD 4.5 million to CIS countries ◦ USD 3.3 million to other countries 	Workforce <ul style="list-style-type: none"> • 4700-4800 employees in the pharmaceutical sector <ul style="list-style-type: none"> ◦ 528 in production (2013) ◦ 3300 in retail (2012) ◦ 900 in wholesale (2012) • Average gross monthly salary (2012) <ul style="list-style-type: none"> ◦ 289 USD in production ◦ 205 USD in retail ◦ 321 USD in wholesale
Market Growth <ul style="list-style-type: none"> • 20% average annual growth rate in local pharmaceutical production (2009-2013), • 19.3% average annual growth rate in local production export (2009-2013) • 7% average annual growth rate in imports (2009-2013) 	R&D, Academia and Associations <ul style="list-style-type: none"> • ISO certified state-of-the-art laboratories • 8 R&D institutions • 8 universities and 4 colleges providing degree programs in pharmaceutical-related disciplines. • The Medicine Producers and Importers Union which contributes to the development of Armenia's pharmaceutical industry
Major Export Markets Russia, Georgia, Turkmenistan, Uzbekistan, Ukraine, Belarus.	Regulation & Standards <ul style="list-style-type: none"> • No pharmaceutical pricing regulations • Law on Medicine • Various related laws and regulations • Two GMP-certified companies (one will be certified soon) and several ISO-certified companies
Registered Drugs 4397 drugs were registered in Armenia (in 2013) of which: <ul style="list-style-type: none"> • 6.3% were locally produced • 31.13% were produced in countries of the EU • 18.53% were produced in countries of the CIS • 14.08% were produced in other countries 	Foreign Investment Liqvor, Yerevan Chemical-Pharmaceutical Firm, PharmaTech
Competitive advantages <ul style="list-style-type: none"> • High market growth in both domestic and major export markets • Old traditions and rich experience in the fine chemical industry • Highly educated workforce, increased every year with new graduates from Armenia's internationally-recognized universities • State-of-the-art research and testing laboratory facilities with cutting-edge equipment and highly skilled staff, • Commitment of producers to introduce the Good Manufacturing Practice (GMP) and other international standards • Government commitment to further develop a GMP certifying agency and support for the development of Armenian pharmaceutical sector • Favorable business environment and investment opportunities 	



INJECTIONS AND EYE DROPS
PREPARATION ROOM ACCORDING
TO EU GMP STANDARDS; LIQVOR
PHARMACEUTICAL COMPANY

INTRODUCTION OF THE GXP STANDARDS



Armenia adopted EU GMP standards on November 25, 2010 under the Decree of the Government of Armenia No. 1603-N "On the Approval of Rules of Good Manufacturing Practice", thereby laying the foundation for the production of medicines in compliance with the highest international standards. To make the process go smoothly, for the first time in the history of Armenia a memorandum of cooperation was signed between the Government of the RA and medicine producers, which approved the Action Plan for Pharmaceutical/Biotechnology Sector Development 2012-2015.

The Government granted the request of producers to be given a few years to conform their production to GMP requirements. All Armenian pharmaceutical companies are currently working on the implementation of the GMP standards, which is scheduled to be completed no later than 2015. The companies have step-by-step guidance and follow-up Corrective and Preventive Action (CAPA) plans for GMP compliance. Several local producers received tailored mentoring from international consultants on the implementation of their CAPA plans.

**ALL ARMENIAN
PHARMACEUTICAL
COMPANIES WILL
ACHIEVE GMP
CERTIFICATION BY
THE END OF 2015**

All producers made the necessary technological investments. As a result one local producer, Liqvor, obtained GMP certification in 2013, issued by the Ministry of Health of Armenia based on the inspection report of the Scientific Center of Drug and Medical Technology Expertise (SCDMTE). Arpimed is the second company that obtained GMP certification (2014), issued by the Ministry of Health of Armenia. Another producer, Pharmatech, will achieve GMP certification by the end of 2014. Other producers continue investing in equipment, infrastructure and personnel in order to achieve compliance and obtain GMP certification by the end of 2015.

In parallel with the introduction of the GMP standards, a GMP inspectorate was established within the SCDMTE. Now the SCDMTE not only reviews, tests and registers individual pharmaceutical products, but also issues GMP certification for the manufacturing process itself. To that end, with the assistance of international organizations and particularly USAID EDMC project, the inspectors received trainings by leading international specialists and participated in joint inspections in Europe.

In 2012 the SCDMTE applied for the pre-accession for the membership to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S scheme) in order to achieve automatic recognition by the PIC/S scheme countries (the EU, the U.S., Japan, Singapore, and others). This will make it possible to export locally produced Armenian medicines not only to developing countries such as in the CIS and Africa - where at least some government GMP certification is required - but also to developed countries.

The Government of Armenia continues to introduce GxP standards in the country's pharmaceutical sector. According to the action plan, the Government will announce the adoption of Good Distribution Practice (GDP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Storage Practice (GSP), Good Pharmacy Practice (GPP) and other GxP standards by the end of 2015. ■



PHARMACEUTICAL
MANUFACTURING
15-32

**GROWTH
PERFORMANCE**



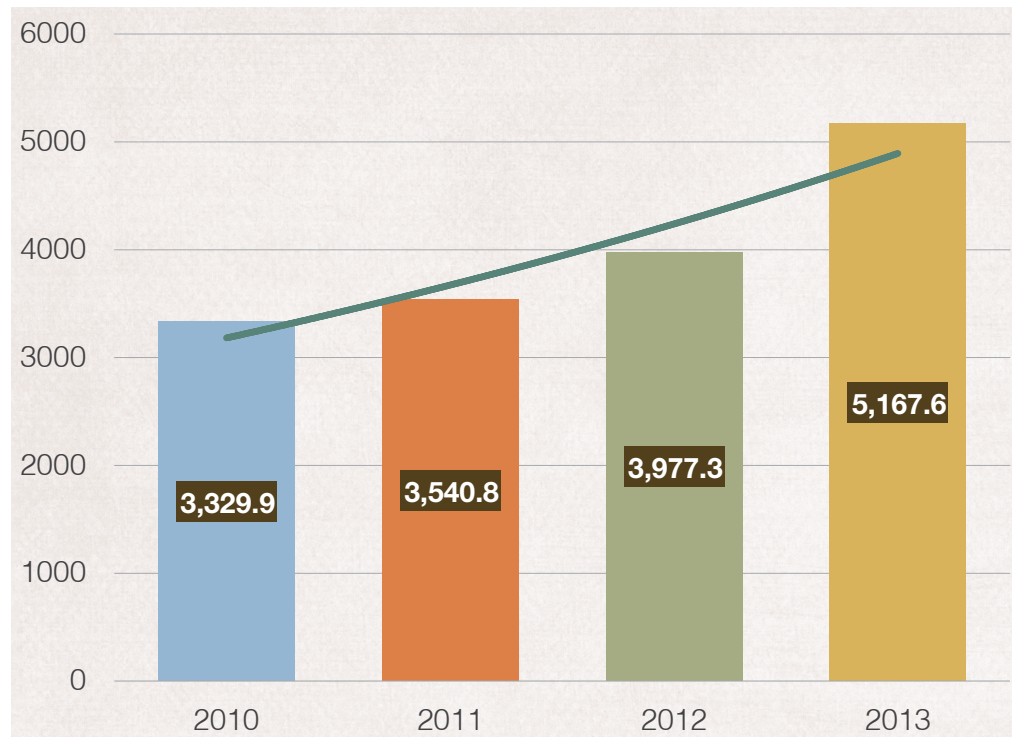
The Armenian pharmaceutical industry has presented a remarkable growth in the past five years, boosted by sales in the domestic and external markets, with a significant growth of investment in the sector. It is one of the fastest growing economic sectors of Armenia, the average growth of which has exceeded growth in the manufacturing industry as a whole and the overall national economy. In particular, the pharmaceutical industry has grown from AMD 3.3 billion (USD 8.9 million) in 2010 to AMD 5.2 billion (USD 12.6 million) in 2013, with an average annual growth rate of 20% (see Figure 4).

According to the RA's National Statistical Service (NSS), pharmaceutical production (in comparable prices) was approximately AMD 5.2 billion in 2013, 29.9% higher than 2012's numbers (see Figure 5). Finished product realization totaled AMD 5 billion (out of which 2.7 billion, about

52%, was exported), an increase of 22.2% over 2012. Like production, the export of pharmaceutical products from Armenia has grown at a brisk pace over the past five years, with an average annual growth rate of 20%.

Armenia's pharmaceutical sector has great growth potential. According to the "Export-Led Industrial Policy" strategy of Armenia, the Government named the pharmaceutical industry as one of the strategic sectors to be boosted in the period between 2010 and 2020. The long-term goal of this strategy is to form new "export driver" sectors by expanding not only current export potential, but also those with major export potential. Through this strategy the Government intends to increase the production of medicine from USD 8 million in 2010 to USD 30-35 million in 2015. During the same span, exports are expected to expand from USD 5 million in 2010 to USD 20-25 million by 2015 (see Table 1). ■

FIGURE 4. LOCAL PRODUCTION OF MEDICINE (AMD MILLION)



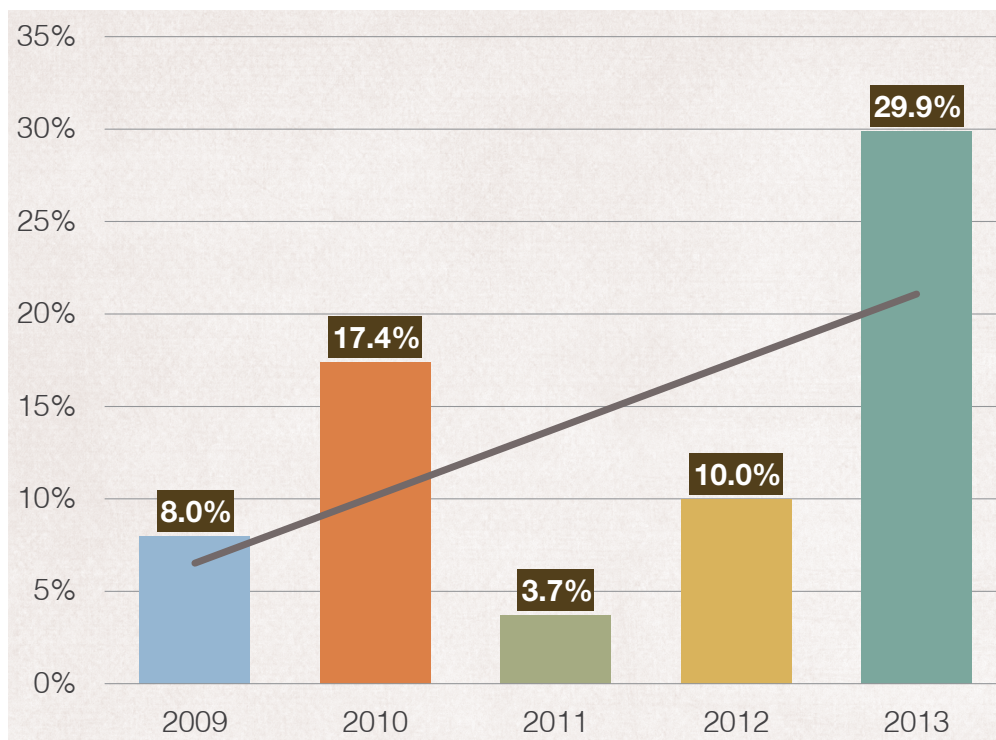
SOURCE: NSS OF THE RA; 2014

TABLE 1. MEDIUM-TERM TARGETS FOR PRODUCTION GROWTH

	2010	2015	2020
Production	USD 8 mil.	USD 30-35 mil.	USD 95-135 mil.
Exports	USD 5 mil.	USD 20-25 mil.	USD 75-115 mil.
No. of employees	550	900-950	1,600-1,800
How to achieve the targets?	2011-2015 <ul style="list-style-type: none"> • GMP certification of Armenian producers • Investing in the development of industrial capacities • Establishing new financing tools for export • Expand packaging process • Attracting orders from TNCs to Armenia 		2016-2020 <ul style="list-style-type: none"> • International recognition of Armenian GMP certificates • Transform packaging process to medicine production • Negotiate with TNCs to establish or outsource production • If necessary, establish a new free economic zone
Capacity building	<ul style="list-style-type: none"> • Strengthen cooperation between manufacturers and educational institutions • Support the GXP Centre of Excellence in developing and conducting training courses 		n.a.

SOURCE: MINISTRY OF ECONOMY, PHARMACEUTICALS AND BIOTECHNOLOGIES SECTOR STRATEGY 2011-2020

FIGURE 5. MANUFACTURING GROWTH PER YEAR (%)



SOURCE: NSS OF THE RA; 2014

THE ARMENIAN PHARMACEUTICAL INDUSTRY HAS EXPERIENCED REMARKABLE GROWTH OVER THE PAST FIVE YEARS

PHARMACEUTICAL PRODUCTION WAS APPROXIMATELY AMD 5.2 BILLION IN 2013, WITH GROWTH OF 29.9% OVER 2012

INDUSTRY SNAPSHOT



There are 18 licensed pharmaceutical companies in Armenia (See Table 2), three of which produce significant volumes. In 2013, these three companies provided 70% (8.8 million USD) of the total turnover of all local producers and 6.5% of the total turnover of Armenia's pharmaceutical market as a whole (USD 134 million). The pharmaceutical industry is one of only a few export-oriented industries in Armenia. Considering there are so few GMP-certified producers, that the sector exports 52% of its production is a clear indicator of its export capacity. The key foreign markets for Armenian pharmaceutical companies are in the CIS, and predominantly Central Asian countries (Uzbekistan, Kazakhstan, Turkmenistan, and Tajikistan). Armenian companies also compete successfully in the Georgian, Belarusian, Russian and Ukrainian markets.

Local manufacturers mainly specialize in production of generics, although a few produce branded products. Most of these generic medicines are included in the list of essential medicines of the Republic of Armenia. Locally produced generic products cost 10-30% less than imported alternatives. Contract

manufacturing also exists to a limited extent.

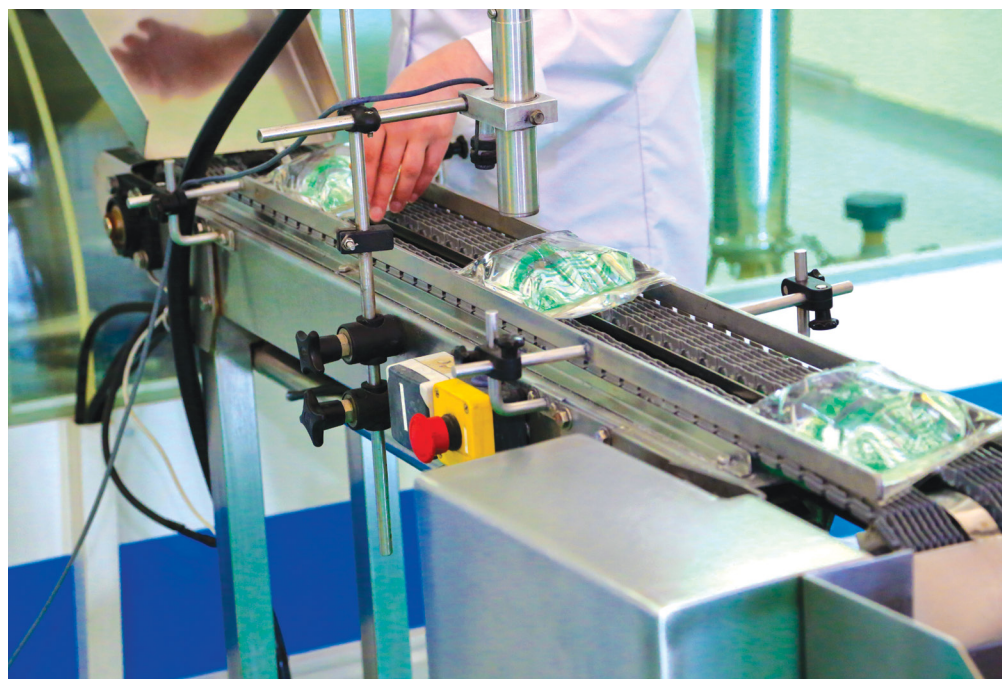
The main dosage forms produced by Armenian pharmaceutical companies are:

- Tablets
- Capsules
- Ointments
- Suppositories
- Suspensions
- Syrups
- Solutions for injection including intravenous infusion solutions
- Eye Drops
- Herbal extracts and tinctures

Product quality is a high priority of Armenian manufacturers. Therefore, most raw materials and chemical compounds used in production are bought from EU and US suppliers.

The industry is in the process of introducing and implementing international quality standards (GxP standards). Two Armenian pharmaceutical producers have already been successfully audited and have been awarded a GMP certificate by the Ministry of Health of the Republic of Armenia. All Armenian pharmaceutical companies are planning to achieve GMP certification before 2016, and ►

**EXPORTS OF
MEDICINAL PRODUCTS
FROM ARMENIA
ACCOUNTED FOR 52%
OF THE ARMENIAN
PHARMACEUTICAL
SECTOR'S OUTPUT
IN 2013**





**"PHARMA-ARMENIA 2013";
THE 5TH INTERNATIONAL
PHARMACEUTICAL COMPETITIVENESS
CONFERENCE**

**PRODUCT QUALITY
IS A HIGH PRIORITY
FOR ARMENIAN
PHARMACEUTICAL
MANUFACTURERS**

are investing in technology in order to improve product quality and meet GMP requirements.

To ensure fair competition and promote ethical practices in the marketing of pharmaceutical products, Armenia's pharmaceutical manufacturers have developed "The Code of Marketing Practice for the Pharmaceutical Industry in Armenia". The Code takes into account the: realities of marketing practices; the need for a complete set of rules regulating marketing practices; contemporary means of promotion and communication, including advertisements and the internet; cooperation with healthcare professionals; and, general trends in ethical regulation found in Europe and globally, particularly the "Code of Practice" developed by the International Federation of Pharmaceutical Manufacturers and Associations.

To promote the development of the knowledge-based economy in Armenia the first Free Economic Zone (FEZ) was opened on August 1, 2013. The FEZ is in the territory where RAO Mars CJSC and the Yerevan Scientific Research Institute of Mathematical Machines are located, and specializes in the production and export of innovative technology and R&D, including pharmaceuticals and biotechnology (For more information about FEZ, please visit www.fez.am or "Investment Guide • Armenia 2013".) The FEZ provides ample of incentives to residents of the zone. In particular, residents of the FEZ are exempt from all taxes except the payroll taxes:

- profit tax - 0%
- VAT - 0%
- import customs duties - 0%
- export customs duties - 0%
- dividend taxes - 0%
- real estate and property taxes - 0%. ■

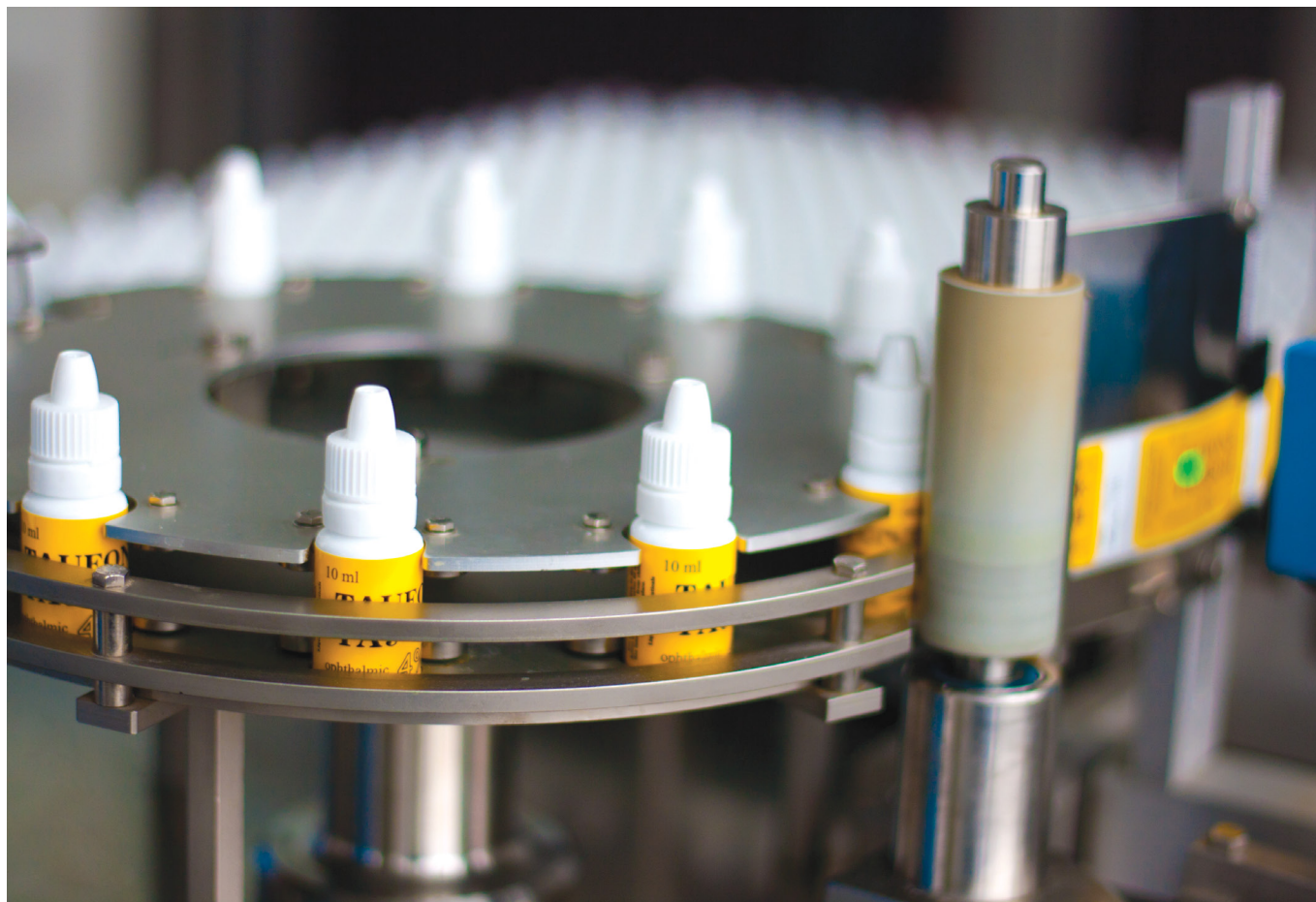


TABLE 2. LIST OF PHARMACEUTICAL PRODUCERS OF ARMENIA

#	Name of the Company	Address	Phone number and e-mail
1	Alex Grig	127/21 Arshakunyats Avenue, 0007, Yerevan	Phone: (+374 10) 490606
2	Alfa Pharm	62 Tbilisyan Highway, 3109, Gyumri	Phone: (+374 10) 465092 E-mail: alfapharm@alfapharm.am
3	Armenicum+	26 Azatutyan Avenue, 0037, Yerevan	Phone: (+374 10) 548001 E-mail: armenicum@arminco.com
4	Arpimed	Building 19, 2-nd microdistrict, 2204, Abovyan, Kotayq Marz	Phone: (+374 222) 21703 E-mail: info@arpimed.com management@arpimed.am
5	Arsanit	Town Masis, Ararat Marz	Phone: (+374 10) 522673 E-mail: info@arsanit.am
6	Bio-Chem	1/1, 33 Manandyan Street, 0046, Yerevan	Phone: (+374 10) 425679 E-mail: info@biochem.am
7	Esco-Pharm	24 apt., 10 Hrachya Nersisyan Street, 0014 Yerevan	Phone: (+374 10) 673929 (+374 10) 673903 E-mail: farm-esco@mail.ru
8	Esculap	1 st block, Davidashen, 0054, Yerevan,	Phone: (+374 55) 405603 E-mail: g.grigoryan@esculap.am
9	Hagenas	1 Gortsarneri Street, Artashat, Ararat Marz	Phone: (+374 10) 466466 E-mail: hagenas@arminco.com
10	Leykoalex	27 Fuchiki Street, 0048, Yerevan	Phone: (+374 10) 350303
11	Liqvor	7/9 Kochinyan Street, 0089, Yerevan	Phone: (+374 60) 378800 E-mail: info@liqvor.com
12	Lizin	1 Gortsaranain Street, Charentsavan, Kotayk Marz	Phone: (+374 94) 496939
13	Medical Horizon	22 Gorcaranayin, Masis station, Masis, 0802, Ararat Region	Phone: (+374 93) 080880 E-mail: info@medicalhorizon.am marketing@medicalhorizon.am
14	NOKI	Nor Kharberd, Ararat Marz, 0817,	Phone: (+374 10) 285153
15	PharmaTech	111 Raffi Street, 0064, Yerevan	Phone: (+374 10) 741410 E-mail: info@pharmatech.am
16	Shirinyan Brothers	Nor Geghi, Nairi, Kotayq Marz, 2411	
17	The Institute of Fine Organic Chemistry after L. Mnjoyan	26, Azatutian Avenue, 0014, Yerevan	Phone: (+374 10) 288334 E-mail: vtop@web.am
18	Yerevan Chemical-Pharmaceutical Firm	6 Acharyan Street, 2 nd lane, Yerevan, 0040	Phone: (+374 10) 627410 (+374 10) 613470 E-mail: yeximfarm@mail.ru chiffseyraz@mail.ru

**RESIDENTS OF THE
FEZ SPECIALIZING
IN PHARMACEUTICAL
AND BIOTECHNOLOGY
R&D ARE EXEMPT
FROM ALL TAXES**



ARPIMED LTD

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Website:

www.arpimed.am

Number of employees:

90

Arpimed, which was established in 2001 by European specialists, manufactures solid, semisolid and liquid medicines, prophylactic and medicinal preparations used in dentistry, antiseptic and disinfecting solutions, diagnostic preparations and cosmetics. The company produces over 150 types of medicines in the form of tablets, capsules, oral and topical solutions, injectable solutions and ointments, which are used in different branches of medicine (Cardiology, Neurology and Psychiatry, Endocrinology, Gastroenterology, Stomatology, and others). Sixty five percent of Arpimed's products are included in the list of Essential Medicines of the Republic of Armenia.

The quality of Arpimed's imported raw materials, intermediate and finished products is controlled in the Quality Control Laboratory, using state-of-the-art devices.

Arpimed exports approximately 30-35% of its product. The company's main export markets are:

- Belarus
- Ukraine
- Georgia
- Uzbekistan
- Kyrgyzstan

Many of Arpimed's products are currently in the registration stages in several countries:

- Russia
- Kazakhstan
- Kyrgyzstan
- Georgia
- Egypt
- Jordan

Arpimed follows international standards for quality management system ISO 9001:2008, and Good Manufacturing Practice standards. The company was certified by Germany's TÜV Rheinland and France's AB Certification companies in 2013. In 2014, the company has been awarded a GMP certificate by one of PIC/S scheme country. Arpimed was also officially certified in accordance with the Good Manufacturing Practice standards by the Ministry of Health of the Republic of Armenia (July 2014). Arpimed's equipment is imported from world-renowned companies like ROTA (Germany), Telstar (India), Millipore (France), PamPac ACG (India), Liotechnic (Italy), and others.

Arpimed's advantages include diversified production and the existence of current assets. ■





EU GMP COMPLIANT INJECTION
PRODUCTION LINE; ARPIMED
PHARMACEUTICAL COMPANY



LIQVOR CJSC

CONTACTS

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Number of employees:

106

Liqvor Pharmaceuticals, which was founded in May 1991, was the first private company in Armenia producing finished medicines. In its 23 years of existence, Liqvor has demonstrated stable and dynamic growth. In 2005 the EBRD became a shareholder of the company and together with the Government of the RA has implemented an investment project.

Liqvor produces a wide range of intravenous and intramuscular injection solutions for various therapeutic purposes. Liqvor's main focus is on the production of contemporary ophthalmic medicines, which currently include 14 pharmacological groups.

The main export markets of the company are:

- Russia
- Belarus
- Moldova
- Georgia
- Uzbekistan
- Kazakhstan
- Tajikistan
- Kyrgyzstan.

The company plans to continue expanding its exports to offer a wide range of modern and effective

pharmaceutical products to meet the unique demands of the region's consumers.

The company was officially certified in December 2013 in accordance with Good Manufacturing Practice standards, guaranteeing that its production meets international quality standards.

Liqvor's quality management system includes the Control and Quality Assurance Department, which uses modern analytical and microbiological laboratories to control all incoming materials and ensure the quality of all finished products.

The company is a member of the Chamber of Commerce of the Republic of Armenia. It is one of founders of the Medicine Producers and Importers Union of Armenia.

Liqvor's new plant meets EU GMP international standards for sterile pharmaceutical production and guarantees long-term innovations. With its new plant, the company will be able to increase production of modern and competitive medicines to fill its product portfolio. ■





**MULTI-STAGE WATER DISTILLER,
LIQVOR PHARMACEUTICAL COMPANY**

PharmaTech

PHARMATECH CJSC

CONTACTS

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Vahan Arushanyan, Director

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0064, Armenia

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info@pharmatech.am

Website:

www.pharmatech.am

Number of employees:

50

PharmaTech CJSC is a UK-owned pharmaceutical manufacturing company based in Yerevan. The company specializes in the production of intravenous solutions, producing 70 different solutions. PharmaTech's production capacity far exceeds Armenia's requirements, and many products are already registered and distributed in Georgia and CIS countries. About 35% of the company's production is exported, which is expected to increase to 55% within the next three years.

PharmaTech CJSC also imports and distributes pharmaceutical products of leading companies GlaxoSmithKline, MSD, Octapharma, and Eurodrug.

PharmaTech was certified on November 23, 2000 by the Quality Management Institute for quality management system ISO 9002:1994. On November 9, 2004, the Swiss certification company SGS certified the quality system for the design and manufacturing of their intravenous solutions as meeting both GMP and ISO 9001:2000 standards.

PharmaTech continuously upgrades its production facilities in order to meet the increasing demand for its products in Armenia and export markets. The installation of European Modular Equipment was carried out by IPM (France) in accordance with GMP standards, in one of the region's most advanced building complexes managed by Cambridge Pharmaceuticals of London. PharmaTech is in the process of installing two new facilities, one for aseptic filling, which will be completed in 2014, and one for packaging of solid doses. Installation of small-volume parenterals is planned for 2016. PharmaTech also has a highly-equipped, ambient and temperature-controlled warehousing system.

The company plans to increase the range of its IV products, launch production of eye-drops and solid form medicines, organize contract manufacturing and packaging for third parties, and provide services for the design, installation and organization of production. ■

BIOHEM

BIO-CHEM LTD

CONTACTS

Contact Person:

Ashot Avetisyan, Director

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Website: www.biochem.am

Number of employees:

30

Bio-Chem LTD was established in 1991. It is the first and only national scientific-industrial enterprise in Armenia that produces more than 30 types of skin and hair care cosmetics, dental materials, antiseptic and disinfecting solutions. Bio-Chem LTD is one of leading companies in the region that is involved in the development of cosmetic products formulas and the manufacturing of cosmetic goods. The company produces cosmetics for both professional and personal use, and for both men and women.

The company currently exports its products to Georgia under the brand name Nica. Other possible markets are USA, Russia, Iran, Uzbekistan and other

Middle East and Central Asian countries.

Raw materials are imported from world-renowned suppliers such as German companies Cognis, Clariant, and Drom; Belgian companies Goodrich and Dow Corning; French company General Aromatics; English company Croda; and others.

The company is in the process of introducing EU GMP requirements for the production of dental materials and dentistry medicines, and modernizing its production facilities.

The company's priority is to attract consumers with high-quality products and affordable prices. ■



ESCO-PHARM LLC

CONTACTS

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Website:

www.escopharm.am

Number of employees:

32

Esco-Pharm LLC is the successor of the manufacturing line of Esculap LLC, founded in 1998. In 2011 Esculap LLC was divided into two separate companies: one for manufacturing, and the other for retail/wholesale trade.

Esco-Pharm currently produces almost 60 types of non-sterile products, including ointments and creams, liquids, tinctures, oils, powders, skin care products, and others.

Esco-Pharm's products are in high demand in the Armenian pharmaceutical market. Several products are also in the process of being registered in the Russian Federation, Georgia and Uzbekistan.

The company is in the process of conforming its production to EU GMP standards and is preparing for GMP certification. A quality assurance system is in place, including production and quality control practices. The quality of active and adjuvant ingredients, packaging materials, and intermediate and final products is controlled for each batch and is in compliance with international pharmacopeia requirements.

Esco-Pharm's production is compatible with other local and imported production, and is known for its high quality. The company offers lower prices for the same quality as imported products. The company continuously upgrades its production facilities in order to maintain the high quality of its production and to be in line with market development trends. ■





VITAMAX-E

VITAMAX-E LLC

CONTACTS

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Eduard Dilanyan, President

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info_vitamaxe@mail.ru

Website:

www.vitamaxe.com

www.narine.am

www.myfruitsmax.com

Number of employees:

55

Vitamax-E, an applied biotechnology plant founded in 1997, is the only company in the region specializing in the production of dry probiotic complexes with natural microbiological agents (Gram-positive bacteria). The company started its business with the production of "CDB" (culture of dry biomass) in powder and capsule form, based on the *Lactobacillus acidophilus* Er-2 317/402 strain, also known as "Narine"/"Narimax". The company also produces natural fruit powders, which are used in the food industry.

Vitamax-E currently produces 160 forms of products for both local and international markets, including bacterial powders, probiotics in capsule and tablet form, dietary supplements in capsule and tablet form, yogurt starters, freeze-dried fruit powders, vegetable powders, meat powders, baby food, pet supplements. Vitamax-E is in the process of presenting a new product: bio-ices and yogurts that are free of fat, sugar, artificial coloring and preservatives.

Vitamax-E exports approximately 50% of its products. The company's main export markets are:

- USA

- Japan
- Australia
- South Korea
- Russia
- Ukraine
- Lithuania
- Kazakhstan
- Moldova
- Georgia

The company follows international quality management standards prescribed in ISO 9001:2000, and GMP standards. The company is also creating an ISO 14001 environmental management system.

One of the company's new directions is in the production of natural fruit, vegetable and meat powders, which are used in pharmaceutical and nutritional productions. The company derives powders from fresh fruit, vegetables, herbs, meat, egg white and yolk. One innovation of the company is nutritious instant bio-breakfasts with vibrant bacteria.

Vitamax-E is active in biotechnology research, cooperating with Armenian universities and research institutes and foreign scientific institutions located in Germany and Japan. ■



Medical Horizon was established in 2006, and its first product was released to the market in January 2008. During this period, the plant was designed and constructed in accordance with GMP standards. As Armenia's most recently established pharmaceutical company, Medical Horizon has gained a stable, continuously growing share of the Armenian pharmaceutical market.

Medical Horizon is the only Armenian pharmaceutical company that produces suppositories. The company also produces oral drops, syrups and suspensions, liquids, and personal hygiene products. Currently the company produces 15 names of products in 34 different dosage forms and strengths.

The main export markets of Medical Horizon are:

- Uzbekistan
- Ukraine

- Georgia
- Kazakhstan

One of Medical Horizon's basic strategies is to establish a representation in Uzbekistan. The company is conducting marketing research for the purposes of registering in and exporting to Central Asia and CIS countries.

Medical Horizon is constantly improving its production skills and technical equipment to meet GMP standards, and is working to obtain a GMP certificate of conformity in 2014. The company's quality control conforms to United States Pharmacopoeia (USP) and British Pharmacopoeia (BP) standards.

Medical Horizon's competitive advantages are its quality, price policy, compliance of its marketing strategy which ethical norms, and constant development. ■



**MEDICAL
HORIZON LTD**

CONTACTS

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E-mail: info@medicalhorizon.am

Website: www.medicalhorizon.am

Number of employees:

28

Yerevan Chemical-Pharmaceutical Firm OJSC, the successor to Yerevan Chemical-Pharmaceutical Plant, was founded in 1967. Its first products, including 10 different pharmaceutical products, were released in 1968. In 1969 the company began producing non-sterile bandages of various sizes, as well as tablets. In the late 1970s, the company released 56 pharmaceutical products in different dosage forms: injections, tablets, and bandages.

Yerevan Chemical-Pharmaceutical Firm OJSC is the largest pharmaceutical company producing injectable medicines. In 2013 the company produced 107 different medicines, 34 of which were for injection. Every year the company expands its range of products, including introducing new generic medicinal products.

The company has a number of cooperation offers from companies from Belarus, Kazakhstan, Tajikistan and Kyrgyzstan. However, its ability to take advantage of these offers is being postponed due to limited production capacity. The company is currently expanding its ties with the Russian Federation and Republic of Uzbekistan.

The company began the construction of a new plant meeting GMP standards in 2012 to expand the production capacity.

Yerevan Chemical-Pharmaceutical Firm OJSC's main area of focus is on the production of generics, which are in high demand in the former Soviet Union republics due to the company's affordable prices and good reputation. ■



YERCHDF OJSC

CONTACTS

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Number of employees:

182

COMPETITIVE NICHE SUB-SECTORS



Armenia's competitive strength in the pharmaceutical sector comes from 3,000 years of history, evidenced by a high level of medical arts development in ancient Armenia. Armenian folk medicine included flora, fauna and inorganic materials.

Armenian historians Movses Khorenatsi, Pavstos Buzand, Lazar Parpetsi and Thovma Ardsruni have compiled important information on the practice of medicine in ancient Armenia. Armenian physicians of the Middle Ages studied ancient medicine and scrutinized the achievements of folk medicine. Davit Anhaght, a famous Armenian philosopher of the Middle Ages who lived at the end of the 5th century A.D. and beginning of the 6th century A.D., in his work "Definitions of Philosophy", discussed questions of anatomy, biology and pharmacology. Anania Shirakatsi, an eminent Armenian astronomer who lived in the 7th century A.D., was greatly interested in theoretical and practical problems of medicine. Mekhitar Heratsi, a famous Armenian physician from the 12th century A.D., was the founder of medieval Armenian medicine and played the same role in the history of Armenian medicine as Hippocrates did for Greek, Galen for Roman, and Ibn Sina for Arabic medicine.

One of the most brilliant figures of Armenian medical science in the Middle Ages was Amirdovlat Amasiatsi (Amirdovlat of Amasia, 15th century A.D.). In his books "Usumn bzhshkutyan" (The Study of Medicine, 1459), "Ogut bzhshkutyan" (The Benefits of Medicine), "Girk ramkakan" (Popular Handbook, 1474) and other works he dealt with human anatomy, hygiene, diagnosis and pharmacology. In the 25 chapters of "Akhrapatin" (Pharmacology, 1459) Amasiatsi described various medicines and their therapeutic properties. His most important and best known book is "Angitats Anpet" (Useless to the Ignorant, 1478-1482), which is an

unusually extensive encyclopedic pharmacopeia providing details of more than 3,700 medicines, arranged in alphabetical order in Armenian and five other languages.

Ancient authors including Herodotus, Strabo, Xenophon, Tacitus and Ibn Sina mentioned curative plants of the Armenian flora in their descriptions of Armenia.

Three pharmaceutical niches in which Armenia has competitive advantages and strong development potential are (1) herbal medicine production and (2) research and development (R&D) and (3) development and production of active pharmaceutical ingredients.

HERBAL MEDICINE PRODUCTION

One of Armenia's most promising development directions providing competitive advantages both in local and foreign markets is phyto-pharmaceuticals. This is mainly based on local herbs cultivated and collected from different regions of Armenia. Armenian medicine, with its 3,000-year history, has created a rich treasury of natural medicaments. Medicine is an inseparable part of ancient Armenian culture; its roots are embedded deep in the past. Over the years, its practitioners continuously collected and recorded an expanding body of information on therapeutics for use in the daily medical care of ordinary people.

In ancient times, medicinal herbs of the Armenian highland were well-reputed, and were exported to the East and to several countries in the West. Ancient and Arabian writers such as Herodotus, Strabo, Xenophanes, Tacitus, Pliny the Elder, Dioscorides, Galen, Ibn Sina and al-Biruni, when discussing Armenia, mentioned its natural medicinal plants.

Currently a number of Armenian manufacturers (mainly small and medium-size enterprises) specialize ►

**ARMENIAN MEDICINE,
WITH ITS 3,000-
YEAR HISTORY, HAS
A RICH TREASURY
OF NATURAL
MEDICAMENTS**

in the production of natural and herbal medicines and dietary substances from medicinal, spicy and aromatic herbs. These include Khazaros, Antaram Phytotherapeutic Cooperative, Zara Akunts-Natural Products, A. Ashotyan, and Fito-pharm, among more than 15 registered legal entities specializing in cultivation/harvesting of medicinal herbs and/or production of herbal medicine. These companies mainly produce herbal substance, teas, extracts, lotions, gels, topical creams and oils, ointments, powder-derived medicines and dietary substances. They are engaged in primary and secondary production and sell not only in the domestic market, but also export their products all over the world.

Global demand for medicinal herbs and plants is currently growing and, according to Global Industry Analysts, Inc, it is expected to reach close to USD 115 billion by 2015. With over 2500 varieties of medicinal herbs and berries growing wild in its high mountainous regions, Armenia has a competitive advantage in the area of herbal medicine production.

Through investment in R&D, cultivation, processing and marketing, there are opportunities to increase sales (both quantities and varieties) of raw medicinal herbs and herbal medicines, and to expand export markets.

RESEARCH AND DEVELOPMENT IN ARMENIA

Product innovation in pharmaceuticals involves a uniquely long and costly R&D process, typically divided into discovery and development. Discovery of a pharmaceutical product includes basic science and research on disease physiology, identification and validation of disease targets in a body, identification and optimization of drug candidates, and pre-clinical testing.

R&D was one of Armenia's core economic sectors before the collapse of the USSR. For 15 years Armenia

was the USSR's leading center of pharmaceutical development and production. The first Armenian pharmaceutical company, Yerevan Chemical Pharmaceutical Plant, had started production of ten different medical preparations a year after its founding in 1967.

After becoming independent, Armenia inherited a quite ramified and developed network of research and education institutions distributed among academic, university and branch/enterprise sectors.

The development of a knowledge-based economy that promotes R&D and innovation is core long-term strategic objective of the Government of Armenia. On February 17, 2011 the Government approved the "Concept Paper on the Initial Strategy of the Formation of Innovation Economy." Rich research and educational traditions, along with skilled human resources, played an important role in attracting numerous global technology firms to establish their branches and R&D centers in Armenia over recent years.

The National Center of Innovation and Entrepreneurship, operating under the Ministry of Economy, plays an important role in the implementation of Armenia's innovation policy. The Center implements innovative and entrepreneurship processes, and supports the realization of innovative ideas and projects. It also provides scientific-technical information and library services.

Armenia's pharmaceutical industry has strong scientific and R&D potential, which can be developed with the improvement of inter-cluster relations among R&D, production and educational institutions. There are 8 scientific research institutes undertaking research in the pharmaceutical and related areas (a full list is available in pages 68-72 of this guide). ►

**THERE ARE OVER
2,500 VARIETIES
OF MEDICINAL
HERBS AND BERRIES
GROWING IN
ARMENIA**

**ARMENIA'S
PHARMACEUTICAL
INDUSTRY HAS
STRONG SCIENTIFIC
AND R&D POTENTIAL**

DEVELOPMENT AND PRODUCTION OF ACTIVE PHARMACEUTICAL INGREDIENTS

Armenia has a rich tradition in science and technology, with qualified personnel and wage rates that are very competitive in the region. In pharmaceutical R&D and production Armenia has a special niche in the area of development of active pharmaceutical ingredients (APIs). In Soviet times, six R&D institutes and all R&D facilities within the state universities, with more than 5,000 specialists, were actively involved in the development of APIs, which were used in production of medicines throughout the entire Soviet Union. These institutes continue to operate today, though with limited capacity. They have developed and patented new APIs and have implemented groundbreaking research in various areas:

- APIs for treatment of cardiovascular, neuropsychic, and infectious diseases and malignant tumors;
- New amino acid technologies: microbiological synthesis,

biotransformation, enzymatic hydrolysis;

- Clinical results (cellular level) for novel cardioactive hormones, and new metal-containing proteins and enzymes for treatment of neurodegenerative diseases.

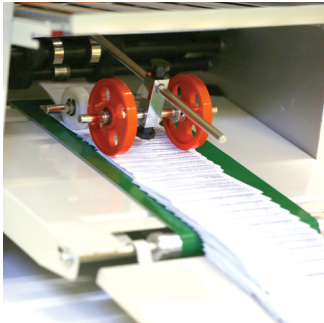
Armenia's strong scientific and R&D potential and research experience in API development have served to attract investments in this sector. In particular, Swiss-based AZAD Pharmaceutical Ingredients, a leading developer of non-infringing APIs with a presence in the Armenian market since 2005, in cooperation with the Institute of Organic Chemistry and with the support of the Armenian Government, is setting up a laboratory for the reproduction of API formulas.

With further investment in R&D and marketing, there is strong potential for increasing the development and establishing the production of APIs in Armenia. ■



**PHARMACEUTICAL
WHOLESALE AND
RETAIL
33-44**

GROWTH PERFORMANCE



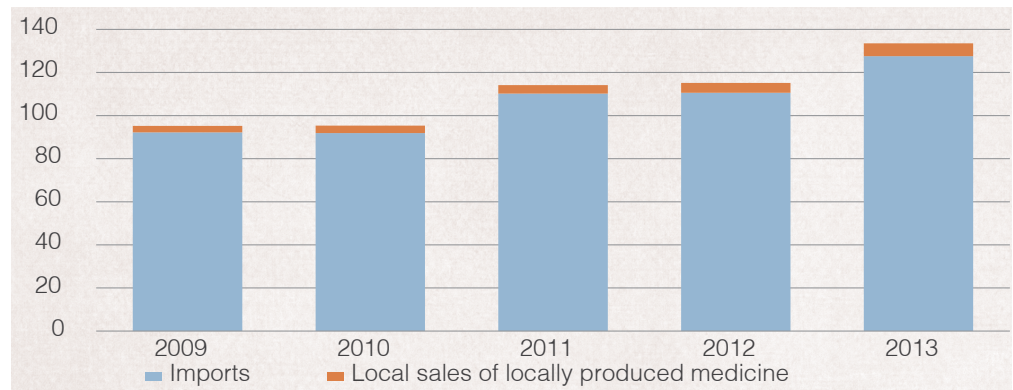
The pharmaceutical industry is one of the most profitable industries in the world, and has large development potential in Armenia. Though the Armenian pharmaceutical market is highly dominated by imports, it has grown dramatically, from approximately USD 93.5 million in 2009 to USD 128 million in 2013, with an average annual growth of 10%. These statistics are based on the value of pharmaceutical imports plus the value of locally produced medicines sold in Armenia (see Figure 6).

The pharmaceutical market is a complex market, given the great variety of stakeholders, significant involvement of the government and high degree of regulation aimed at achieving different objectives. The Armenian pharmaceutical

market is characterized by its openness and high competitiveness. The number of pharmaceutical wholesale-retail structures in Armenia has significantly increased over the past 10 years. According to data from the Ministry of Health, over 1,600 licenses for the right to engage in the pharmaceutical retail industry have been issued since 2002, with an annual average growth rate of 30%.

Pharmaceutical wholesalers supply products to both the public and private sectors. The vast majority of the market is made up of commercial private purchases (pharmacies and pharmacy kiosks). A small portion of medicine consumption in 2013 consisted of public procurements (1%). ■

FIGURE 6. ARMENIA'S PHARMACEUTICAL MARKET (USD MILLION)



SOURCE: NSS OF THE RA, MINISTRY OF FINANCE OF THE RA; 2014

MARKET STRUCTURE



Armenia's pharmaceutical industry is represented by three major groups of business entities: manufacturers, importers/distributors and pharmacies. There are 18 local manufacturing companies (2013), as well as 47 foreign firm representatives and more than 1700 pharmacies.

Pharmaceutical imports are greater than exports, creating a negative trade balance. The total value of imports of pharmaceutical products was USD 127.8 million in 2013, with 15% growth over 2012. In general, imports of pharmaceuticals to Armenia have grown over the past

four years, with an average annual growth rate of 7% from 2009 to 2013. Imports accounted for about 90% of local pharmaceutical sales in Armenia in 2013.

The main imported product of the pharmaceutical sector is medicine, representing by 85.8% (USD 109.6 million) of the total import of the sector in 2013. Other relevant imported products are human and animal blood, wadding, gauze, bandages and similar articles and other pharmaceutical products, which are 10.0%, 1.2% and 3%, respectively, of pharmaceutical imports. ►

TABLE 3. TOP 10 PHARMACEUTICAL RETAIL CHAINS IN ARMENIA (BASED ON NUMBER OF PHARMACIES)

1	Alfa Pharm	6	Armfarm
2	Natali Pharm	7	Pharmdom
3	Esculap	8	New-International Business Farm
4	Gedeon Richter pharmacy JV	9	Agata Farm
5	Ritm Farm	10	Amikus

SOURCE: MINISTRY OF HEALTH OF THE RA; 2014

TABLE 4. TOP 10 IMPORTERS OF PHARMACEUTICALS IN ARMENIA (BASED ON USD IMPORTS IN 2013)

1	Natali Pharm	6	Alfa pharm import
2	Alfa Pharm	7	Esculap
3	Vaga Pharm	8	Deghabaza Yerevan
4	Richter Lambron	9	Argo Pharm
5	PharmaTech	10	Amicus

SOURCE: MINISTRY OF HEALTH OF THE RA; 2014

As shown in Figure 7, imports are coming from a diverse range of countries, although the majority (74%) is from European countries. In 2013 Armenia imported pharmaceutical products from 68 countries. Germany leads in import numbers, accounting for 15.6%, followed by Switzerland (10.6%), France (9.6%), the US and Russia (5% each).

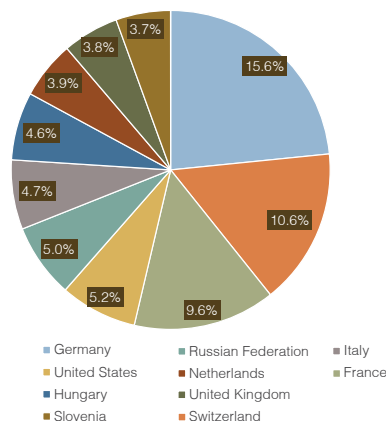
The Armenian pharmaceutical wholesale and retail market is very competitive. As of February 2014, there were 25 pharmaceutical importers, and more than 1,700 pharmacies.

The Armenian pharmaceutical market is based on developed retail pharmacy chains. There are around 1,700 pharmacies and pharmacy kiosks in Armenia, which are prevalent in almost all cities and even rural areas of Armenia (approximately one drugstore for every 1,900 people). These pharmacies are owned by 1,278 companies, but only 41 of them have more than two drugstores. The largest pharmacy chains are Alfa Pharm, Natali Pharm and Esculap, with a combined total of 212 shops. The other seven companies among the top ten retail chains (in terms of number of shops) own and operate fewer than 20 retail outlets (see Table 3).

In recent years pharmacies have been faced with increasing competition. Pharmacies try to compete not only by reducing prices of medicines and expanding their assortment, but also by increasing business hours (the majority up to 24 hours), and offering free consultations.

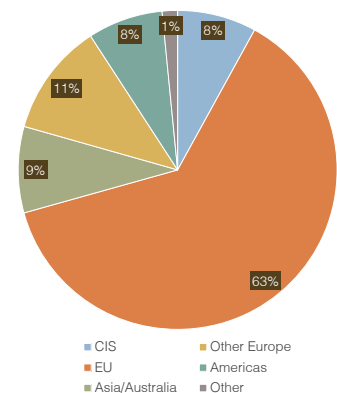
In 2013, there were 25 companies in Armenia that imported pharmaceuticals on a commercial basis. 52% of all commercial imports in 2013 were imported by largest three companies: Natali Pharm; Alfa Pharm; and, Vaga Pharm. (see Table 4 for the list of top 10 importers.) ■

TOP 10 COUNTRIES IMPORTING PHARMACEUTICALS TO ARMENIA (BASED ON USD IMPORTS IN 2013)



SOURCE: MINISTRY OF FINANCE OF THE RA; 2014

FIGURE 7. IMPORT OF PHARMACEUTICAL PRODUCTION BY REGION (2013, USD THOUSAND)



SOURCE: NSS OF THE RA; MINISTRY OF FINANCE OF THE RA; 2014

THE ARMENIAN PHARMACEUTICAL MARKET IS CHARACTERIZED BY ITS OPENNESS AND HIGH COMPETITIVENESS



NATALI PHARM LLC

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Number of employees:

450

Natali Pharm was founded in 1998 and is one of the largest importers of medicines and medical supplies in Armenia. The company constantly expands its range of imported drugs to satisfy market demands and keep up with market developments. The organization follows GDP standards. Natali Pharm has a fully re-equipped pharmaceutical warehouse, which provides faster and more accurate deliveries.

Natali Pharm cooperates with more than 60 leading pharmaceutical companies, such as Roche, Les Laboratoires Servier, Novartis Consumer, Novartis Pharma, Teva, Abbott, Sandoz, Polpharma, Bayer Consumer, Bayer Pharma, Nizhpharm, B. Braun, Nipro and others.

The company imports about 8000 pharmaceutical products of the following types:

- Anti-infective medicines;

- Cardiovascular medicines;
- Gastrointestinal medicines;
- Anti-allergics;
- Analgesics and antipyretics, non-steroidal anti-inflammatory medicines.

Natali Pharm's development strategy for the coming year is to expand its range of imported medicines and medical supplies.

Main advantages of the company are following:

- **Up-to-date distribution center**

In 2011 Natali Pharm fully re-equipped its drug warehouse with a conveyor from Austrian-company Shafer, enabling it to provide faster and more accurate delivery of customer orders.

- **Large network and reach**

The company operates more than 60 pharmacies in Yerevan and other regions of Armenia, which provide high-quality customer service. ■





DRUG WAREHOUSE FULLY
RE-EQUIPPED ACCORDING TO GDP
STANDARDS; NATALI PHARM



ALFA PHARM CJSC

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Number of employees:

600+

Since its establishment in 1996, Alfa-Pharm has been successfully engaged in the import, wholesale and retail of medicines in Armenia, occupying a leading position in Armenia's pharmaceutical market.

The company's shareholders are the European Bank for Reconstruction and Development (EBRD) and founders with many years of experience in the Armenian pharmaceutical market.

The company has direct delivery from 100 leading European, Russian, U.S., Indian and CIS manufacturers, such as Les Laboratoires Servier, Sanofi-Aventis, Abbott, Berlin-Chemie AG, Novartis Consumer, Bayer Consumer, Hoffman-La Roche, Astellas Pharma Europe, AstraZeneca and others.

The company imports about 4500 pharmaceutical products of the following types:

- Analgesics and antipyretics, non-steroidal anti-inflammatory medicines;
- Anti-allergics;
- Antidotes and other substances used in poisoning;
- Antiepileptic medicines;
- Anti-infective medicines;
- Immunosuppressives and medicines used in palliative care;
- Antiparkinsonism medicines;
- Oncology medicines;
- Medicines affecting the blood;
- Cardiovascular medicines;
- Dermatological medicines;
- Antiseptics;
- Diuretics;
- Gastrointestinal medicines;
- Hormones, other endocrine medicines and contraceptives;
- Ophthalmological medicines;
- Medicines for mental and behavioural disorders;
- Uterine stimulants and relaxants;
- Children's otolaryngology

medicines;

- Medicines for newborns;
- Medicines affecting the respiratory system;
- Multivitamins and minerals;
- Diagnostic tools.

Alfa Pharm's central distribution area is equipped with a state-of-the-art, computer-controlled conveying storage system, which meets all applicable quality control requirements for storage, handling and release of medicines. The storage capacity allows timely and accurate delivery of products to over 600 pharmacies and 150 medical institutions.

Company's development strategy for the coming years is to expand its pharmacy chain in the territory of Armenia.

Main advantages of the company are following:

- **High-quality medicine from top manufacturers**
The company has direct delivery from more than 100 leading international manufactures.
- **Qualified personnel**
Employees undergo continuous education and training to provide high quality customer service.
- **Up-to-date distribution center**
The company's distribution center has been developed by the Austrian company Shafer and meets the Good Storage Practice (GSP) standards. An automated system allows fast and accurate service to 600 pharmacies and medical institutions.
- **The largest pharmacy chain**
Alfa Pharm is one of the largest pharmaceutical retail chains in Armenia, operating 120 pharmacy outlets in almost all of the regions in Armenia. ■



ALFA PHARM PHARMACY IN YEREVAN



**RICHTER-
LAMBRON
JV LTD**

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Number of employees:

73

The Armenian-Hungarian joint-venture Richter-Lambron LTD was founded in 1998 by the Hungarian pharmaceutical plant Gedeon Richter and Armenian company Lambron-Pharmimpex LTD. The latter has been engaged in the Armenian pharmaceutical market since 1994 and is ranked among the ten best and largest importing companies in Armenia. The company also owns and operates 22 pharmacies located in Yerevan and regions.

Richter-Lambron's partners are well-known producers such as Gedeon Richter, Krka, Sanofi-Aventis, Egis, Janssen Pharmaceuticals, Boehringer Ingelheim, Sopharma, GM Pharmaceuticals, LMP, Piere Fabre, Biopharm, Biosola, MPI Pharmaceuticals, Sebapharma, Arabia Diamond Tex, Waritex, Abbott Products Operation AG, Berlin Chemie, and others.

The company meets European product standards, ensuring all necessary conditions are met for the storage of pharmaceuticals, cosmetics and hygiene items. There are special cold rooms for storage of product groups with different temperature requirements, and a special bunker for the storage of psychotropic and narcotic drugs. The company's warehouse is equipped with high technology.

Richter-Lambron imports about 1,500 pharmaceutical products of the following types:

- Cardiovascular medicines;
- Anti-seizure, anti-epileptic medicines;
- Non opioid analgesics, non-steroidal anti-inflammatory medicines;
- Gastrointestinal medicines;
- Anti-allergics and medicines used in anaphylaxis;
- Contraceptives;
- Anti-infective medicines;
- Medicines affecting the respiratory system;
- Hormones, other endocrine medicines including diabetes medications.

Main advantages of the company are existence of:

- **Streamlined purchasing system**
They use direct sales agreements with leading European medicine producers.
- **State-of-the-art equipment**
They use high-quality logistics for medicine storage.
- **Streamlined delivery service**
Good conditions (specialists, transportation, and high-quality paperwork) for fast delivery of medicinal products to customers ■





RICHTER LAMBROŃ JV PHARMACY IN
GYUMRI


ESCULAP LTD
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Number of employees:

125

Esculap was established in 1996 and today is considered as one of the leading wholesale and retail pharmaceutical companies in Armenia, cooperating with many famous European pharmaceutical companies. It owns and operates 25 pharmacies.

Esculap has direct distribution with many leading international pharmaceutical companies, such as Sanofi-Aventis (France), Astellas Europe, Pfizer (USA), UCB Pharma (Belgium), Novartis Group (Switzerland), Media Pharm (Switzerland), Zentiva (Slovakia), Alkaloid AD (Macedonia), Medial (Switzerland), and others. The company has exclusive distribution with Alkaloid AD (Macedonia), ReplekFarm (Macedonia), Intas Pharmaceuticals, Plethico, and the Himalaya Drug Co. (India). In addition to distributing of pharmaceutical products in Armenia, the company also organizes their

registration, marketing and promotion.

Esculap imports about 680 pharmaceutical products of the following types:

- Cardiovascular medicines;
- Anti-infective medicines;
- Analgesics and antipyretics;
- Oncology medicines;
- Medicines used to affect the nervous system;
- Gastrointestinal medicines;
- Dermatological medicines.

Esculap's development strategy for the coming years is to increase direct imports by starting new partnerships, and to expand its pharmacy chain as much as possible.

Competitive advantages of the company are its sustainable development, highly professional services, and management autonomy. ■



Amikus LTD was founded in 1997 as a medicine retail seller and now is one of Armenia's major pharmaceutical importers. The company has established strong links with drug manufacturers from Switzerland, France, Germany, Finland, Hungary, and Slovenia. Amikus also is the exclusive importer of Wockhardt (India), KIN (Spain) and Medgamal (Russia). The company also produces patient care products.

Together with the pharmaceutical wholesale and retail, the company produces also preparations for patient care (such as sterile bandages, cupping glasses, accessories for processing vaginal cavities, syringes etc.)

Recently the company began the construction of a new production facility, meeting GMP standards.

The company plans also to expand the number of partner organisations and its pharmacy chain.

Amikus imports more than 140 medicinal products of the following types:

- Gastrointestinal medicines;
- Medicines affecting the blood;
- Cardiovascular medicines;
- Anti-allergics;
- Anti-infective medicines;
- Medicines affecting the respiratory system;
- Antiparkinsonizm medicines;
- Hormones;
- Medications for skin conditions;
- Diuretics;
- Anti-diabetes medicines;
- Analgetics and non-steroidal anti-inflammatory medicines;
- Ophthalmic medicines;
- Oncology medicines;
- Vitamins. ■



AMIKUS LTD

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Number of employees:

85-120

Argo-Pharm LTD was founded in 1997 and is one of the largest medicine importers in Armenia. In 2011 it founded the 36.6 Pharmacies chain. The company's main goal is to maintain and expand its position in the market. It continuously expands its list of imported medicines to meet demand and stay in line with market developments.

Argo-Pharm LTD follows Good Distribution Practices (GDP) standards and cooperates with leading pharmaceutical companies such as Pharmstandart, Biosintez, Master Lek, RBHC, Help, and others.

Currently the company imports 25 types of medicinal products, cosmetics, dietary supplements, and medical devices.

It specializes in the import of the following types of products:

- Analgesics and antipyretics, non-steroidal anti-inflammatory medicines;
- Medicines affecting the respiratory system;
- Gastrointestinal medicines;
- Cardiovascular medicines;
- Anti-infective medicines;
- Psychotropic medicines;
- Immunomodulatory medicines. ■



ARGO-PHARM LTD

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Website:

www.argo.am

Number of employees:

More than 20



AMIKUS PHARMACY IN YEREVAN

EXPORT MARKETS

45-48

**EXPORT
GROWTH
PERFORMANCE**



Armenia's pharmaceutical industry has blossomed over the past decade into an export-oriented economic sector. This shows the growth of the sector and quality of the production.

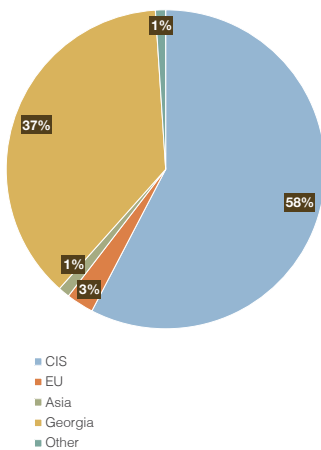
According to the National Statistical Service of the Republic of Armenia, exports of locally produced pharmaceuticals amounted to USD 7.8 million in 2013, 13% above 2012 (See Figure 8). The pharmaceutical industry is still a very small export industry, comprising only 0.5% of Armenia's total export volume. But it is one of the fastest growing export industries, increasing by an average of 20% annually between 2009 and 2013, reflecting the strengthening of the industry.

Today, exports account for 52% of Armenia's pharmaceutical output. This export growth shows the importance of external markets to place the production of the Armenian pharmaceutical industry. The importance of boosting

pharmaceutical export has been reflected in the Pharmaceutical/ Biotechnology sector action plan adopted by the Government. Moreover, a large number of highly profitable original brand medicines produced by top manufacturers are due to lose patent protection, providing opportunities for generic manufacturers to begin production of these off-patent medicinal products. It is therefore expected that by 2015, Armenia's pharmaceutical exports will increase by USD 20-25 million, and by 2020, USD 75-115 million.

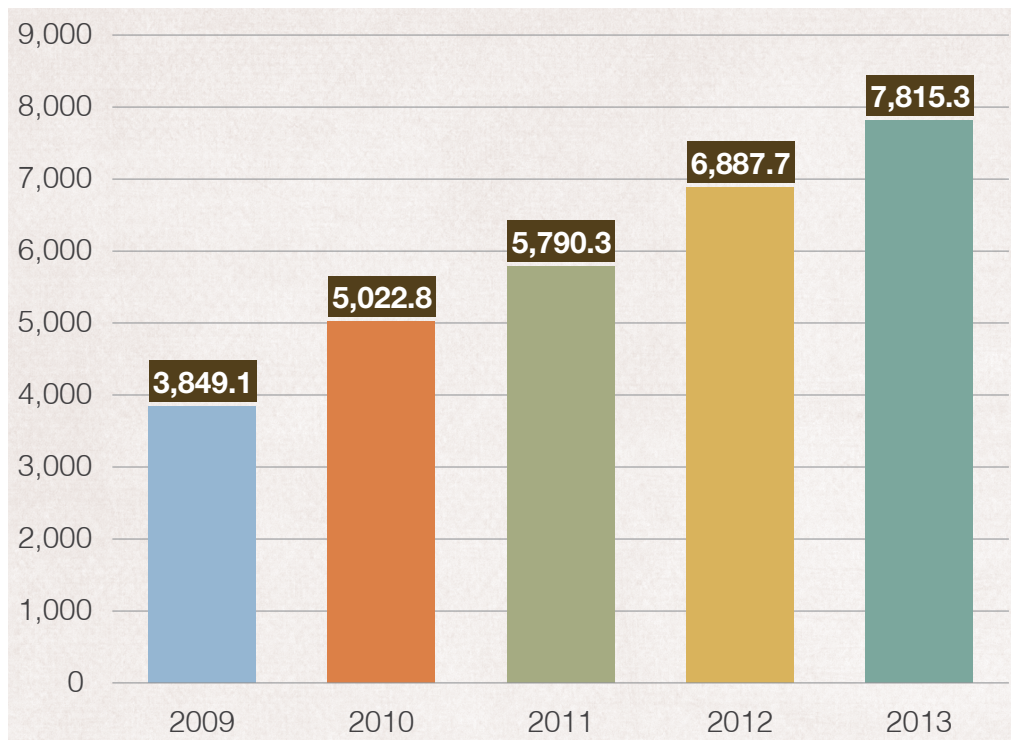
The main product exported from the pharmaceutical sector is medicine, representing by 83.8% of the total export of the sector in 2013, with a 10.6% growth over 2012. Other relevant exported products are human and animal blood, and wadding, gauze, bandages and similar articles, which are 12.0% and 3.8%, respectively, of pharmaceutical exports. ■

FIGURE 9. EXPORT OF ARMENIAN PHARMACEUTICAL PRODUCT BY REGION, 2012



SOURCE: MINISTRY OF FINANCE OF THE RA; 2014

FIGURE 8. TOTAL EXPORTS OF PHARMACEUTICAL PRODUCTION 2009-2013 (USD THOUSAND)



SOURCE: NATIONAL STATISTICAL SERVICE OF THE RA; 2014

MARKET STRUCTURE AND VOLUMES



In 2013, Armenia exported locally produced medicine to 24 countries. As shown in Figure 12, 58% of Armenian exports go to CIS countries, 37% to Georgia, 3% to EU countries and 2% to other countries, mainly USA, Japan and Korea (See Figure 9).

In 2013 exports to the CIS countries equaled USD 4,505.3 thousand, representing an annual growth rate of 22%. Export to other countries in 2013 equaled USD 3,310.0 thousand, representing an annual growth rate of 4%. The last figure shows that the volume of exports into CIS countries has risen. This is due to:

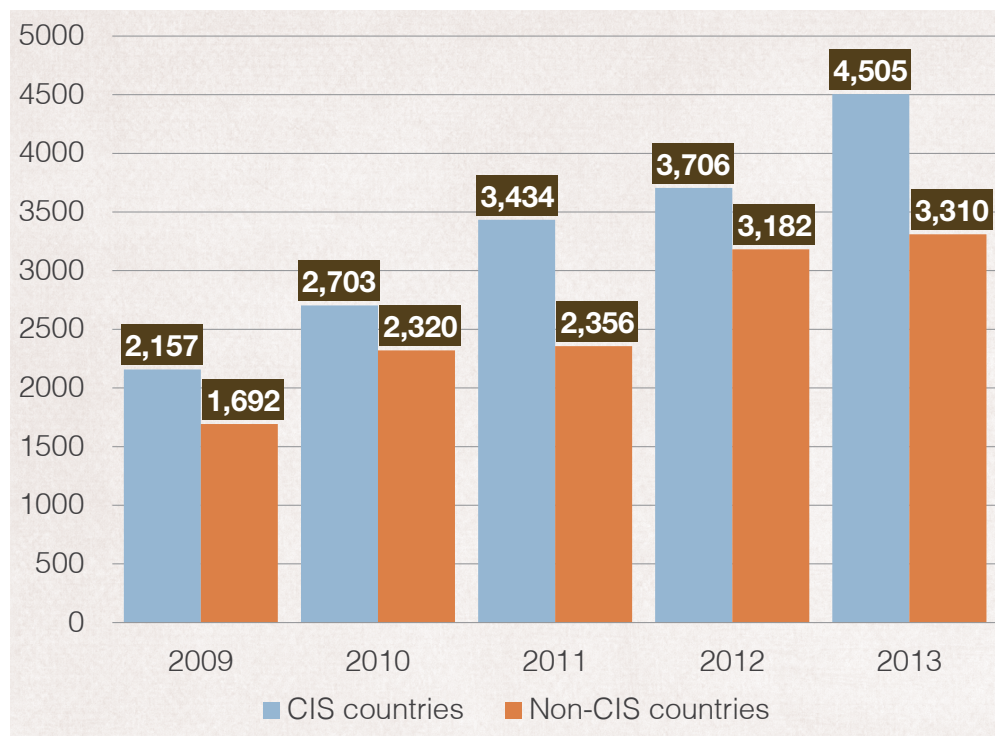
- Common use of Russian language and free trade agreements with CIS countries;
- Historical links with these countries, resulting in local producers establishing good relations and partnerships with these countries' distributors; and,

- Consumers in CIS countries have a general awareness of Armenian products and thus it is easier to compete in these countries, even with well-known international producers.

The biggest exporters are Liqvor, Yerevan Chemical-Pharmaceutical Firm, and Arpimed. These three companies together accounted for approximately 70% of Armenian's total pharmaceutical exports in 2013 (see Figure 10).

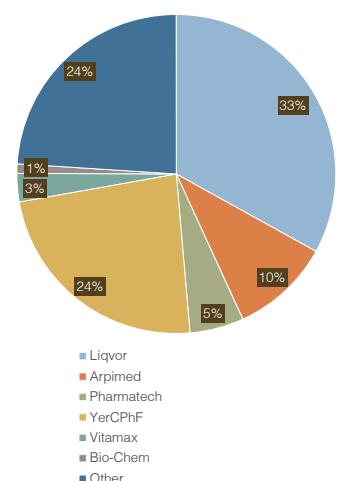
Almost all Armenian producers plan to expand their export markets. Primary target markets are CIS countries, particularly those whose markets are not yet penetrated. However, as Armenian pharmaceutical companies have implemented GMP standards in their production, attractive markets for Armenian pharmaceutical producers will also include the EU, Middle East/ North Africa, and Asia. ■

EXPORT TREND OF ARMENIAN PHARMACEUTICAL PRODUCTION TO CIS AND NON-CIS COUNTRIES (USD THOUSAND)



SOURCE: NSS OF THE RA, MINISTRY OF FINANCE OF THE RA; 2014

FIGURE 10. EXPORT OF PHARMACEUTICAL PRODUCTS BY COMPANY (2013)



SOURCE: MEDICINE PRODUCERS AND IMPORTERS UNION OF ARMENIA; 2014



"PHARMA-ARMENIA EXPO 2013";
THE ANNUAL SPECIALIZED
EXHIBITION OF PHARMACEUTICS

HUMAN
RESOURCES
49-66

LABOR COSTS



The Government of Armenia envisions Armenia becoming a producer of high-value and knowledge-intensive goods and services with creative human capital at its core. The highly educated workforce, increasing every year with new graduates from Armenia's internationally recognized universities that have close educational cooperation with well-known Western universities, is one of the key advantages of the Armenian pharmaceutical sector.

Armenia's pharmaceutical industry employs a high percentage of professionals and technicians. In 2012, about 24% of employees in the pharmaceutical industry belonged to a technical-professional class. Due to recent significant technological investments in the sector and specialized training, it is expected that the percentage of technicians and professionals employed in the Armenian pharmaceutical industry will grow in coming years.

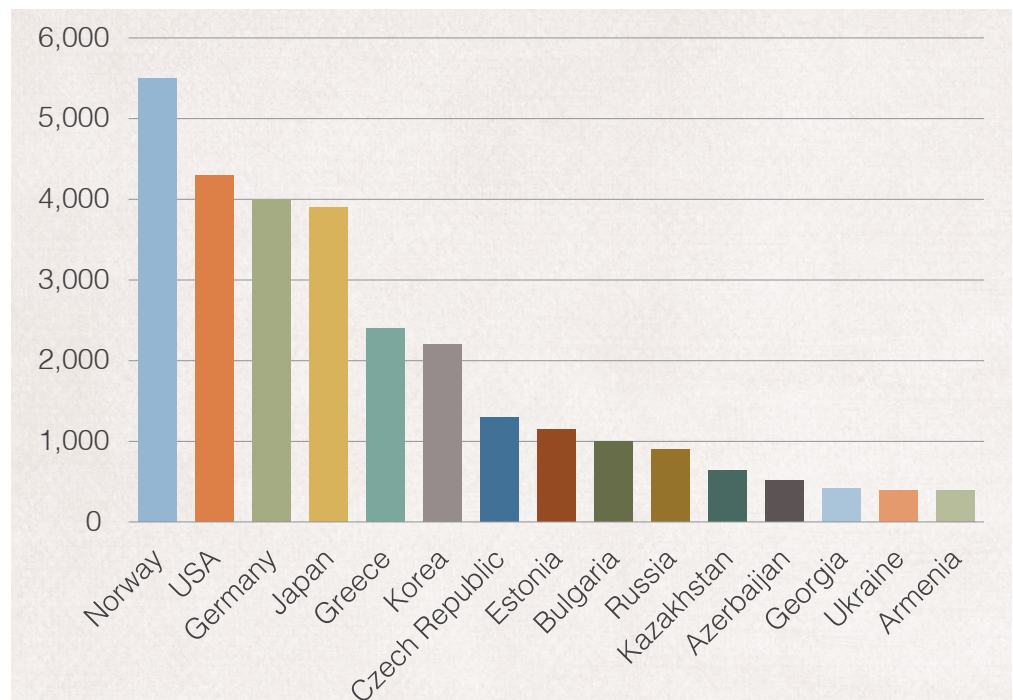
According to data published on January 1, 2013, the total number of people employed in Armenia's pharmaceutical sector is around 4,700 – 4,800. The vast majority (~3,300) are employed on the retail side of the sector.

Wages in Armenia are comparatively lower than wages in other countries of the region and Western and Eastern Europe, with an average monthly wage of USD 388 in 2013 (See Figure 11).

Average monthly wages (as of 1 January 2013) in Armenia's pharmaceutical sector (USD 241) are in line with the overall national average monthly wages (USD 282). In 2012, the average monthly salary for pharmaceutical production jobs was USD 289; for retail jobs, USD 205; and for wholesale jobs, USD 321. The average annual remuneration received by the pharmaceutical industry employees has grown rapidly, with growth rate estimated at 34% from 2009 to 2012. ■

**ARMENIA'S
HIGHLY EDUCATED
WORKFORCE IS
ONE OF THE KEY
ADVANTAGES OF ITS
PHARMACEUTICAL
SECTOR**

FIGURE 11. AVERAGE MONTHLY SALARY IN ARMENIA AND SEVERAL COUNTRIES, 2013 (USD)



SOURCE: MEDICINE PRODUCERS AND IMPORTERS UNION OF ARMENIA



THE ANNUAL PHARMA CAREER FAIR,
SEPTEMBER 2013

EDUCATION, SKILLS AND RESEARCH INSTITUTES



Armenia's long history of educational excellence has resulted in a skilled and qualified workforce. Literacy is almost 100% and Armenia has one of the highest percentages of graduates in the former Soviet Union. Human capital development is an essential part of the country's industrial growth policy, with education seen as an incentive for progress. There are currently 26 public and 41 private universities in Armenia. The Armenian education system participates in the Bologna process and complies with international standards. There is a continuing trend of rising standards in Armenia's higher education institutions.

Eight public and private universities (higher education institutions) in Armenia offer degrees in pharmaceutical disciplines. The leading universities in terms of reputation,

infrastructure and standards are the Yerevan State Medical University after M. Heratsi, Yerevan State University, Russian-Armenian (Slavonic) University and State Engineering University of Armenia.

Twelve state and private universities and colleges in Armenia offer an education in pharmacy, some of which confer master's degrees and Ph.D's. The Faculty of Chemistry of the Yerevan State University offers bachelor's programs and master's programs in pharmaceutical chemistry and pharmacy. The Faculty of Pharmacy of the Yerevan State Medical University (YSMU) offers bachelor and master degrees in general pharmacy. Specializations, i.e., clinical studies, are provided at the post-master's stage. The Department of Chemical Technologies and Environmental ►

**TEN PUBLIC AND
PRIVATE HIGHER
EDUCATION
INSTITUTIONS IN
ARMENIA OFFER
DEGREES IN
PHARMACEUTICAL
DISCIPLINES**



Engineering of the State Engineering University of Armenia offers bachelor and master degree programs in chemical technology of medicinal substances. The Institute for Mathematics and High Technology of the Russian-Armenian (Slavonic) University offers majors in medical biochemistry and pharmacy.

Students in their final years of study undertake internships in pharmaceutical companies. The majority of graduates who study pharmaceutical-related specializations in higher education institutions find jobs in pharmaceutical companies and pharmacies, and a small number find jobs in hospitals or clinics.

The quality of pharmaceutical skills among the workforce is solid in terms of education. All pharmaceutical companies attach great importance to employees undergoing specific professional or pharmacy-related trainings. The Medicines Producers and Importers Union has founded a special training center for the pharmaceutical industry: the GXP Centre of Excellence. Pharmaceutical manufacturers and big retail companies also provide in-house trainings for newly hired specialists.

UNIVERSITIES:

- Yerevan State Medical University after M. Heratsi
- Yerevan State University
- State Engineering University of Armenia
- Russian-Armenian (Slavonic) University
- Yerevan Medical Institute after Mehrabyan
- University after Saint Teresa
- Yerevan Haybusak University
- University of Traditional Medicine

COLLEGES:

- Yerevan State Basic Medical College
- Yerevan State Medical College Erebuni
- Grigoris Medical-Humanities College
- L. Orbeli Medical College

THE GXP CENTRE OF EXCELLENCE

The GXP Centre of Excellence was established in 2009 by the Medicines Producers and Importers Union of Armenia, with the aim of training Armenian pharmaceutical manufacturers and distributors in international best practice standards.

The Centre also provides consultancy services that assist companies achieve compliance with international production and distribution standards. It is the only center in the region offering well-organized training courses developed by experienced international experts in appropriate fields that is approved by the RA Ministries of Health and Economy.

The courses and seminars cover various professional topics and are open to both foreign and Armenian citizens. Upon completion, trainees are granted a state certificate.

1. General GxP Training Courses:
 - EU Guide for Good Manufacturing Practice (GMP)
 - GMP principles
 - SOP Development and Documentation
 - Good Distribution Practice (GDP)
 - Good Laboratory Practice (GLP)
 - Good Clinical Practice (GCP)
 - Qualified Person
2. Special Topic Training Courses:
 - Sterile Production
 - Validation & Qualification
 - Factory Design & HVAC
 - Effective Audits
 - Regulatory Affairs
 - Critical Cleaning & Validation
3. General Management Training Courses:
 - Middle Management
 - Pharmaceutical Marketing
 - Medical Representative
 - HR Systems & Appraisal
 - Export Marketing ■

THE GXP CENTRE OF EXCELLENCE IS THE ONLY CENTER IN THE REGION OFFERING WELL-ORGANIZED TRAINING COURSES APPROVED BY THE RA MINISTRY OF HEALTH AND MINISTRY OF ECONOMY



YEREVAN STATE UNIVERSITY (YSU)

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Number of employees:

1,588

The Yerevan State University was founded in 1919 and has more than 100,000 graduates. Currently, more than 18,000 students study in 19 faculties of YSU and four faculties in the regional campus, with more than 100 general and professional departments.

Since 1995, the university has introduced a two-level qualification system, with bachelor and master degrees. In 2007, the European Credit Transfer and Accumulation System was introduced in all master programs, and a year later in bachelor programs.

According to data available as of January 1, 2013, YSU runs 60 bachelor, 130 master and 70 doctoral programs that involve nearly 18,000 students. The educational process is conducted

by more than 1,580 highly qualified specialists and experts (206 professors, 557 associate professors, 378 assistants and 447 lecturers). 39 academicians of the National Academy of Sciences of Armenia and 26 associate members of the National Academy of Science (NAS) of Armenia are also involved in YSU's educational process.

Pharmaceutical-related education is provided in the Department of Pharmaceutical Chemistry of the Faculty of Chemistry, which was founded in 1998.

The Department conducts laboratory and practical trainings at the Departments of Pharmaceutical Chemistry, Ecological Chemistry and Magistracy Chemistry. ►

NUMBER OF ADMITTED AND GRADUATED STUDENTS

	Admitted			Graduated		
	2011	2012	2013	2011	2012	2013
Total	13,836	11,403	12,296	3,937	3,863	4,168
Department of Pharmaceutical Chemistry of the Faculty of Chemistry	14	73	62	57 (5 year education)	68 (5 year education) 47 (bachelor)	48

NUMBER OF ADMITTED AND GRADUATED STUDENTS OF DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

Year	Admitted			Graduated		
	Bachelor	Master	PhD	Bachelor	Master	PhD
2011	14	-	-	-	-	-
2012	73	36	-	47	-	-
2013	62	39	-	48	-	-

NUMBER OF ADMITTED AND GRADUATED ARMENIAN AND FOREIGN STUDENTS IN PHARMACEUTICAL-RELATED SPECIALIZATIONS

Year	Admitted		Graduated	
	Armenian citizens	Foreigners	Armenian citizens	Foreigners
2011	10	4	55	2
2012	66	7	62 (5 year education) 47 (bachelor)	6 (5 year education)
2013	58	4	48	-

The Department teaches the following major specialties: fundamentals of pharmacology, clinical pharmacology, molecular biology, clinical biochemistry, chemistry of natural compounds, biotechnology, pharmacogenetics, pharmacokinetics, engineering enzymology, pharmacopeia analysis, technology of medical preparation production (pharmaceutical and industrial), pharma-chemistry, pharmacognosy, toxicological chemistry, organization and economy of pharmaceuticals, and others.

Since 2010, the European Credit Transfer System in harmony with

the Bologna Process has been fully introduced in the department. In 2011, two-year programs for master degrees were developed, which comply with international standards and are licensed by the Ministry of Health of Armenia.

The Department of Pharmaceutical Chemistry cooperates closely with well-known research institutes and companies abroad, including the A. Nesmeyanov Institute of Organoelement Compounds RAS (Russia), Institute of Human Brain RAS (Russia), Karolinska University Hospital (Sweden), Acros Organics Company (Belgium), Paris-Sud University (France), among others. ■





YEREVAN STATE MEDICAL UNIVERSITY (YSMU)

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Number of employees:

3,079

The Yerevan State Medical University was founded in 1930, an independent extension of the medical department of the Yerevan State University, which was established in 1919. Approximately six thousand students study under seven faculties (General Medicine, Public Health, Stomatology, Pharmacy, Military Medicine, Postgraduate and Continuing Education). YSMU has more than 100 academic departments. More than 1,200 foreign students are enrolled.

In the 2005-06 academic year, the University introduced a two-level education system in order to meet international education standards.

The educational process is conducted by more than 1,100 highly qualified specialists, including 171 professors

and 504 associate professors. Seven academicians of the NAS RA are also involved in YSMU's educational process.

The Faculty of Pharmacy conducts the following educational programs:

- Bachelor of Pharmacy – four-year undergraduate course
- Master of Pharmacy – two-year course
- Diploma Specialist Program (for foreigners) - pharmacist.

Education in the Faculty of Pharmacy is conducted in Armenian, Russian, and English. Students specialize in medicines technology, pharmaceutical management, pharmaceutical chemistry, or clinical pharmacology. ►



Pharmaceutical-related departments are:

- Department of Drug Technology** (one professor, two associate professors, four assistants including one PhD): The Department of Drug Technology's main research involves the development of technological processes and study of pharmacological activity of biologically active ingredients from herbal materials.
- Department of Pharmaceutical Management** (three associate professors, 11 assistants): The Department of Pharmaceutical Management's main research is related to regulations in the sphere of pharmaceuticals and increasing economic accessibility of medicines.
- Department of Pharmacy** (four associate professors, four assistants): The Department of Pharmacy's main research topic is "Research on natural and synthetic origin compounds' anti-inflammatory and analgesic activity."
- Department of Pharmacognosy** (three associate professors, three assistants): The Department of Pharmacognosy's research is "Pharmacognostic research of the RA flora."
- Department of Clinical Pharmacology** (one professor, two associate professors, six assistants): The Department of Clinical Pharmacology's research is "Pharmacological correction of cardiac-cerebral-vascular diseases."
- Department of Organic Chemistry** (one professor, five associate professors, two assistants including one PhD): The Department of Organic Chemistry's research is "Biological activity of natural and synthetic origin porphyrins." ►

NUMBER OF ADMITTED AND GRADUATED STUDENTS

	Admitted			Graduated		
	2011	2012	2013	2011	2012	2013
Total	1,710	1,035	1,713	778	822	1,119
Faculty of Pharmacy (Bachelor)	10	118	104	47	37	47
Faculty of Pharmacy (Master)	38	31	43	5 (5 year education)	32	33
Faculty of Pharmacy (Foreigners)	8	10	13	1	1	3

NUMBER OF ADMITTED AND GRADUATED STUDENTS OF PHARMACEUTICAL-RELATED FACULTIES

Year	Admitted			Graduated		
	Bachelor	Master	PhD	Bachelor	Master	PhD
2011	10	38	2	47	- 5 (degreed specialist)	2
2012	118	31	2	37	32	1
2013	104	41	1	47	33	1

**YSMU'S
PHARMACEUTICAL-
RELATED
EDUCATIONAL
PROGRAMS ARE
PROVIDED IN
ARMENIAN, ENGLISH
AND RUSSIAN**

- Department of Pharmacology**
 (two professors, five associate professors, eight assistants including one PhD): The Department of Pharmacology's research is "Pharmacological correction of ischemic brain injury."

YSMU has established close relations

in the areas of medical education and healthcare with medical universities of different countries and international development organizations. Foreign exchange programs with universities and health organizations enable YSMU students and postgraduates to have a short clinical practice in top foreign clinics and medical institutions. ■

NUMBER OF ADMITTED AND GRADUATED ARMENIAN AND FOREIGN STUDENTS

Year	Admitted		Graduated	
	Armenian citizens	Foreigners	Armenian citizens	Foreigners
2011	1,333	377	534	244
2012	712	323	704	118
2013	1,460	253	1,002	117



The State Engineering University of Armenia (SEUA) is the successor to the Yerevan Polytechnic Institute that was founded in 1933. From its 78 years of existence, the University has nearly 115,000 graduates.

Presently, SEUA has over 10,000 students under 19 faculties, with four training programs of vocational, higher and post-higher professional education, conferring junior specialist, bachelor, master and researcher degrees. The regular academic staff of the University exceeds 1,000, most of whom have earned Candidate or Doctor of Science degrees.

The University's specializations include all main areas of engineering and technologies, with 44 bachelor and 39 master specializations in Engineering, Industrial Economics, Engineering Management, Applied Mathematics and Sociology.

The Faculty of Chemical Technologies and Environmental Engineering is the main department providing education in pharmaceutical-related fields. The faculty has three departments:

1. General Chemistry and Chemical Processes
2. Chemical Technologies
3. Environmental Protection and Biotechnology

Education is provided in several specialties, such as Chemical Technology of Pharmaceuticals and Biotechnology, among others. The faculty has a modern, fully-equipped laboratory for biological synthesis of active substances.

Competitive advantages of the University are:

- All academic programs of SEUA are periodically reviewed to keep up with changes in labor demand and economic priorities;
- The University has developed quality assurance principles based on the standards of the European Association for Quality Assurance in Higher Education; and,
- The University has a leading role in the reformation of Armenia's higher education system. SEUA was the first higher education institution in Armenia to introduce two-level and three-level higher education systems. ►



**STATE
ENGINEERING
UNIVERSITY OF
ARMENIA (SEUA)**

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Number of employees:

1,000+

NUMBER OF ADMITTED AND GRADUATED STUDENTS

	Admitted			Graduated		
	2011	2012	2013	2011	2012	2013
Total	473	1,917	1,618	2,389	2,537	2,326
Faculty of Chemical Technologies and Environmental Engineering	16	32	30	95	99	79

NUMBER OF ADMITTED AND GRADUATED STUDENTS OF PHARMACEUTICAL-RELATED FACULTIES

Year	Admitted			Graduated		
	Bachelor	Master	PhD	Bachelor	Master	PhD
2011	10	8	1	36	9	-
2012	16	10	-	28	10	1
2013	16	11	2	33	7	-

It implemented the European Credit Transfer System in harmony with the Bologna Process.

SEAU has also developed an extended network of cooperation that includes

many of the world's leading universities and research centers. The University is a member of European University Association, Mediterranean Universities Network, and Black Sea Universities Network. ■

NUMBER OF ADMITTED AND GRADUATED ARMENIAN AND FOREIGN STUDENTS

Year	Admitted		Graduated	
	Armenian citizens	Foreigners	Armenian citizens	Foreigners
2011	435	38	2,337	52
2012	1,871	46	2,493	44
2013	1,559	59	2,305	21

**THE FACULTY
OF CHEMICAL
TECHNOLOGIES AND
ENVIRONMENTAL
ENGINEERING
HAS A MODERN,
FULLY-EQUIPPED
LABORATORY
FOR BIOLOGICAL
SYNTHESIS OF ACTIVE
SUBSTANCES**



The Russian-Armenian (Slavonic) University is a unique institution in the region and a brilliant example of integration in the field of education. RAU was established through an agreement between the Governments of the Republic of Armenia and Russian Federation (RF) on August 29, 1997. Despite its short existence, RAU has already become the leading educational and scientific center in Armenia.

Education at the University is conducted in the Russian language with programs developed in accordance with Russian educational standards. The University has five institutes: Mathematics and High Technology; Economics and Business; Law and Politics; Human Sciences; and Media, Advertising and Film. Students are trained in 32 chairs by highly qualified specialists. Training is offered in almost all branches of modern science and humanities, at both bachelor and master levels.

Pharmaceutical education is provided in the following chairs of the Institute of Mathematics and High Technology:

- Medical Biochemistry and Biotechnology
- General and Pharmaceutical Chemistry
- Bioengineering and Bioinformatics

Students are trained in the following specialties:

- Medical Biochemistry (6 years)
- Bioengineering and Bioinformatics (5 years)
- Pharmaceutical (5 years)

The following majors in the field of medical biology are offered for PhDs:

- Organic Chemistry (RF)
- Biochemistry (RF)
- Organic Chemistry
- Bioorganic Chemistry
- Zoology
- Biophysics ►



**RUSSIAN-
ARMENIAN
(SLAVONIC)
UNIVERSITY (RAU)**

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Website:

www.rau.am

Number of employees:

646

NUMBER OF ADMITTED AND GRADUATED STUDENTS

	Admitted			Graduated		
	2011	2012	2013	2011	2012	2013
Total	442	698	757	635	641	638
1. Pharmaceutical	4	4	6	–	–	–
2. Medical Biochemistry	4	18	9	15	16	16
3. Bioengineering and Bioinformatics	5	7	4	7	6	6
Number of post-graduates (pharmaceutical-related specializations)						
1. Organic Chemistry	–	2	1	1	1	1
2. Biochemistry	2	1	2	–	–	1

NUMBER OF ADMITTED AND GRADUATED ARMENIAN AND FOREIGN STUDENTS IN THREE PHARMACEUTICAL-RELATED SPECIALIZATIONS

Year	Admitted		Graduated	
	Armenian citizens	Foreigners	Armenian citizens	Foreigners
2011	6	7	20	2
2012	18	11	17	5
2013	15	4	16	6

- Molecular and Cellular Biochemistry
- Biochemistry

The above-mentioned majors have appropriate technical base and laboratories:

- Laboratory of General Chemistry
- Laboratory of General Biology, Zoology and Botany
- Laboratory of Biochemistry
- Laboratory of Cellular Engineering
- Laboratory of Chromatography and Spectroscopy
- Laboratory of Nature Protection

In the field of medical biology, RAU cooperates with a number of leading foreign universities and institutions, including:

- Moscow State University after Lomonosov
- Zoology Institute of the Academy of Science of Poland
- Institut für Informatik Humboldt-

Universität zu Berlin

- Institute for Pharmaceutical Biology, Philipps-Universität Marburg
- Institute of Biology, Leiden University
- Technische Universität Braunschweig,
- Universität Erlangen, Lehrstuhl für Pharmazeutische Biologie
- USA, CA, Institute for Molecular Medicine
- USA Ann Arbor, University of Michigan
- Czech Republic, Masaryk University
- Poland, Bureau of Chemical Substances Management

RAU also cooperates with leading research centers in Armenia (NAS Institute of Molecular Biology, Institute of Fine Organic Chemistry of Scientific-Technological Center of Organic and Pharmaceutical Chemistry, Virusology and Epidemiology Institute, Institute of Medical Genetics Center), enabling ►





THE MAIN BUILDING OF THE RUSSIAN-
ARMENIAN (SLAVONIC) UNIVERSITY



**THE CHAIRS OF
MEDICAL BIOCHEMISTRY
AND BIOTECHNOLOGY,
AND BIOENGINEERING
AND BIOINFORMATICS
OF THE RUSSIAN-
ARMENIAN UNIVERSITY
ARE THE ONLY ONES
OF THEIR KIND IN
ARMENIA**

students to gain practical knowledge and skills with the help of qualified professionals.

Students specializing in medical biology regularly travel to Russia, Poland, USA, Germany and Czech Republic through exchange programs, where they receive training at the above-listed universities and conduct joint scientific research in scientific research centers.

The university has the following advantages:

- With its scientific schools, strong reputation, and history of achievements, RAU attracts the youth of the region with the promise of a high-quality higher education;
- Education is based on Russian

educational standards and is conducted in Russian, which enables students from Russian-speaking countries to study at RAU on an equal basis;

- RAU students are awarded with Russian Federation and Armenian diplomas;
- Postgraduate studies at RAU are accredited and licensed by the Russian Federation and the Republic of Armenia;
- RAU's future graduates have an opportunity to continue their education in higher education institutions in Russia and other countries;
- One of the priorities of the University is the integration of the Armenian Diaspora. The RAU has become the alma mater for students from CIS and other countries. ■

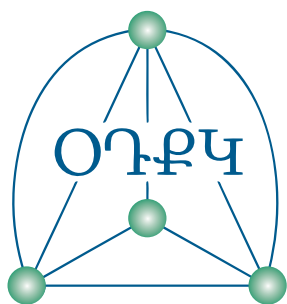
LIST OF OTHER HIGHER EDUCATION INSTITUTIONS PROVIDING EDUCATION IN THE PHARMACEUTICAL AND BIOTECHNOLOGY FIELDS

University	Pharmaceutical-related departments	Key courses/pharmaceutical-related programs
<p>Yerevan Medical Institute after Mehrabyan (www.armmed.am)</p> <p>Established in 1996, it provides higher and secondary education in the fields of the dentistry, pharmacy, midwifery science, nursing care, dental mechanic science, cosmetics.</p>	Pharmacy	History of Pharmacy Biochemistry Organic Chemistry Pharmaceutical Chemistry Pharmacognosy Drug technology
<p>Medical University after Saint Teresa (www.sterezameduni.com)</p> <p>Founded in 1992, it teaches not only the principles of medical education, but practical skills and psychological-pedagogical capacities.</p>	Pharmaceutical	
<p>Yerevan Haybusak University (www.haybusak.org)</p> <p>Established in 1991, it offers both full-time and part-time instruction, master courses, trainings, PhD courses and post-graduate courses in Medicine.</p>	Pharmacy	Pharmaceutical Chemistry Pharmacology Pharmaceutical technologies Biotechnology Pharmacognosy Clinical pharmacology
<p>University of Traditional Medicine (www.unifradmed.com)</p> <p>Founded in 1991, it is unique in the region and aims to restore traditional medicine in parallel with contemporary medicine, taking into consideration centuries-old practices of Armenian and eastern folk medicine.</p>	Traditional Medicine Complementary and Alternative Medicine	Medical-Biology Traditional Medicine Prophylactic Medicine



MEDICAL LIBRARY OF THE RAU

PHARMACEUTICAL
AND
BIOTECHNOLOGY
R&D INSTITUTES
67-76



INSTITUTE OF FINE ORGANIC CHEMISTRY AFTER L. MNJOYAN

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Number of employees:

295

Armenia historically has strong scientific research institutes that still operate today. Two of these are the Institute of Fine Organic Chemistry and the Institute of Molecular Biology, which operate under the National Academy of Sciences of the Republic of Armenia and play a key role in the development of Armenia's pharmaceutical sector.

The Institute of Fine Organic Chemistry after L. Mnjoyan was founded in 1955. It specializes in the development of efficient drugs for the treatment of cardio-vascular, neuro-psyche and infectious diseases, malignant tumors, and for use in surgical practice.

It is equipped with technology and production facilities for pharmaceuticals, laboratories for biological and chemical studies, and an herbal laboratory. The Institute has 22 laboratories, eight groups and three establishments.

Production capacity allows the Institute to manufacture medicine in the form

of ampoules, tablets and capsules. In addition to its scientific research activities, the Institute produces two types of own original medicines, Gangleron and Ditolin, which are marketed locally and in CIS countries.

Other pharmaceutical products developed at the Institute are: Subecholine (respiratory stimulant), Arpenal (bronchial asthma, gastro-duodenal ulcers and Parkinsonism), Quateron (stenocardia, gastro-duodenal ulcers and hypertension), Mesphena (hyperhidrosis, gastro-duodenal, bronchial asthma), Fubromegan (peptic and duodenal ulcers, bronchial asthma), Nalecin (typhoid fever, dysentery), Espenal (stenocardia, bronchial asthma), Puphemid (epilepsy of various etiology), and Tiodine (radiculitis, neuritis, polyneuritis).

With its scientific potential and well-equipped laboratories, the Institute plays a core role in meeting the R&D needs of Armenia's pharmaceutical industry. ■



The Institute of Molecular Biology is one of the most active and dynamically growing scientific research institutes in Armenia. It was founded in 1966 to encourage the development of molecular biology in Armenia. The research conducted at IMB in the twentieth century was significant in elucidating the structural and functional organization of nucleic acids, proteins, cells, and organelles.

Research at IMB focuses on the investigation of regulatory mechanisms of cell activity and its alterations in a number of pathologic conditions including auto-immune, auto-inflammatory, cerebrovascular, infectious, oncological, and psychiatric disorders. Special attention is paid to mediators of the immune and signal transduction systems. The research is conducted using experimental animal models, cell cultures, computer modeling and clinical samples.

Today IMB has 14 scientific-research units (one scientific department, eight laboratories, three independent research groups, two interdisciplinary laboratories), and two educational units.

IMB has 132 employees, including 15 with DrSc degrees and 52 with PhDs. Forty-four percent of IMB employees are young researchers aged 35 and younger. In 2007-2013, 71 bachelor's and master's students and 26 PhD students studied/trained under the supervision of IMB scientists and received degrees.

In the last three years, IMB has conducted the following pharmaceutical-related research activities:

1. Computer 3D models for μ -, δ - and κ morphine receptors have been created. These models can be used for investigating morphine and morphine-like compounds interactions, as well as in drug design.
2. A new interferon-stimulating polyoxometalate compound with antiviral activity has been developed and tested.
3. A test system for early diagnosis of overtraining syndrome (OTS) has been developed. It is reliable, non-invasive,

and has high sensitivity and specificity. Athletes, pilots, military officers and truck drivers are potential customer groups for this product.

4. New cyclic amino acid derivatives possessing immunomodulatory and antioxidant activities have been synthesized and tested. These compounds reduce mortality and enhance recovery after ionizing radiation and can be considered as potential radioprotective agents.
5. Standardized cell culture screening systems have been established for in vitro assessment of cyto- and genotoxic effects of physiologically active compounds and potential drugs in different cell populations.

Currently, IMB is implementing pilot production technology for immune stimulating antiviral preparation, aimed at the development of production technology and testing of new biologically active preparation for prevention of infectious disease in cattle and poultry (foot-and-mouth disease, Newcastle disease).

IMB's laboratories are equipped with modern instruments such as PCR machines, a real-time PCR machine, DNA sequencer, patch clamp, microplate reader, and fluorescent microscope.

IMB maintains a collection of DNA samples of healthy subjects and patients with various diseases, as well as a cell culture collection and animal house. IMB is also connected to the ArmGrd and EuroGrid high-throughput computing systems.

IMB has a strategy for 2010-2020 to develop further in the following directions:

- Genomics and "Armenian genome" project;
- Cell Biology, pathological processes modeling;
- Molecular, cellular immunology, immune response mechanisms of disorders;
- Investigation of irregularities in signaling, effector system, biochemical cascades; and,
- Information biology, bioinformatics, biological statistics, molecular modeling. ■



INSTITUTE OF MOLECULAR BIOLOGY (IMB)

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Number of employees:

132

INSTITUTE OF BIOCHEMISTRY AFTER H. BUNIANIAN

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The Institute of Biochemistry was founded in 1961. The main scientific focus of the institute is biochemistry of brain – neurochemistry. The institute has 9 laboratories serving the scientific research of the Academy of Sciences system and universities, with modern equipment and highly qualified specialists.

The main fields of research activity in the institute are:

- Biochemistry of novel cardioactive hormones and specific proteins of hypothalamus and atrium;
- Immunomodulators of the brain;
- Neurohormonal regulation of cyclic nucleotides and neurotransmitters biosynthesis;
- Biochemistry of new metal-containing proteins and enzymes in the brain and other organs; and,
- Cardioactive hormones' influence on diseases of cardioactive system.

The institute has established close scientific connections with the Institute for Neurochemistry and Drug Addiction in New York (also known as the Center for Neurochemistry), UK Royal Society; Institute of Physiological Chemistry of Tubingen University; Free University in Berlin; Max Plank Institute of Neurobiology (Germany); and, A. N. Bach Institute of Biochemistry, among others.

SCIENTIFIC AND PRODUCTION CENTER "ARMBIO- TECHNOLOGY"

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The Scientific and Production Center "Armbiotechnology", which was established in 2010, specializes in biotechnology and bio-organic chemistry. It has three institutes: Institute of Biotechnology, Institute of Microbiology and Center of Microbial Depository. The center has 14 laboratories where research activities are conducted in the following fields:

- Development of methods and technologies for production of biologically active substances, study of basic problems of modern microbiology and deposition of new prospective microorganisms of research and production significance;
- Solutions for urgent biotechnological problems in the fields of medicine, pharmacology, agriculture and food industry, geology and nature protection;
- Fulfillment of applied scientific researches in the field of biotechnology directed at the development of production technologies for biologically active substances; and,
- Development of new highly effective methods and techniques for:
 - Simultaneous measurement and prediction of nanoparameters of numerous processes occurring in cells (microorganisms, cells of plants, mammals and insects) in suspension cultures
 - Control of processes occurring in single cells of suspension culture to increase the productivity of biotechnological processes, as well as processes using strain-producers with low productivity.

INSTITUTE OF ORGANIC CHEMISTRY

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The Institute of Organic Chemistry of Scientific-Technological Center of Organic and Pharmaceutical Chemistry was established in 1935. It is specialized in the organic synthesis and polymer chemistry. Main research areas of the institute are the:

- Investigation of methods of functionalization of unsaturated molecules for the construction of low-molecular bioregulators;
- Construction of low-molecular natural bioregulators, aromatic and organoleptic materials, aromatizators and other molecules;
- Synthesis and study of oxygen, phosphorus and nitrogen containing unsaturated compounds and polymers with a complex of properties;
- Elaboration of scientific principles for synthesis and application of polymeric materials, composites and their application; and,
- Development of modern methods for synthesis of chemicals necessary for scientific research and organization of its production.

MOLECULAR STRUCTURE RESEARCH CENTER

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Established in 1994, the Molecular Structure Research Center of Scientific - Technological Center of Organic and Pharmaceutical Chemistry specializes in the research of molecular structure by physical chemistry methods (X-Ray Structural Analysis, NMR-, IR-, UV-, Mass-Spectroscopy, Chromatography). The Center has four laboratories, two groups and 34 employees, including one with DrSc degree and 11 with PhD's.

The Center conducts research in the following fields:

- Structure determination of organic compounds by various physicochemical methods;
- Structural investigations of pyrrolidine derivatives possessing antiviral properties;
- The study of interaction of biologically important gas molecules with sublimed layers of metalloporphyrins and the creation of stable layers with selective coordination ability; and,
- 3D structure determination of biological and organic molecules by NMR spectroscopy in liquid crystals and weakly-oriented environments.

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The Armenian Institute of Applied Chemistry (ARIAC) is a successor to the Soviet Institute of Specialty Chemicals and High-Purity Reagents that was established in 1975. ARIAC provides a large number of services from contract manufacturing to syntheses route development and manufacturing facility design. It combines chemical synthesis experience with scientific know-how to create one-stop manufacturing on-demand solutions.

ARIAC is one of leading manufacturers of various fine chemicals, intermediates and reagents.

Currently, the major classes of organic compounds available on both laboratory and commercial scales include:

- Heteroatom-containing organic compounds of various functionality, such as alcohols, carbonyl compounds, carboxylic acids, nitro compounds, amines, alkyl halides;
- Sulfur- and phosphorus-containing chemicals;
- Metal-organic compounds;
- Heterocyclic compounds;
- Composition materials; and,
- Biologically active compounds and means, such as diagnostic kits, solutions for dialysis and antiseptic formulations.

ARIAC also produces raw materials for the pharmaceutical industry.

The Institute has customers in chemical manufacturing, biochemical research, pharmaceutical and scientific research in Europe, the Americas, Japan and other countries.

INSTITUTE OF HYDROPONICS PROBLEMS AFTER G.S. DAVTYAN

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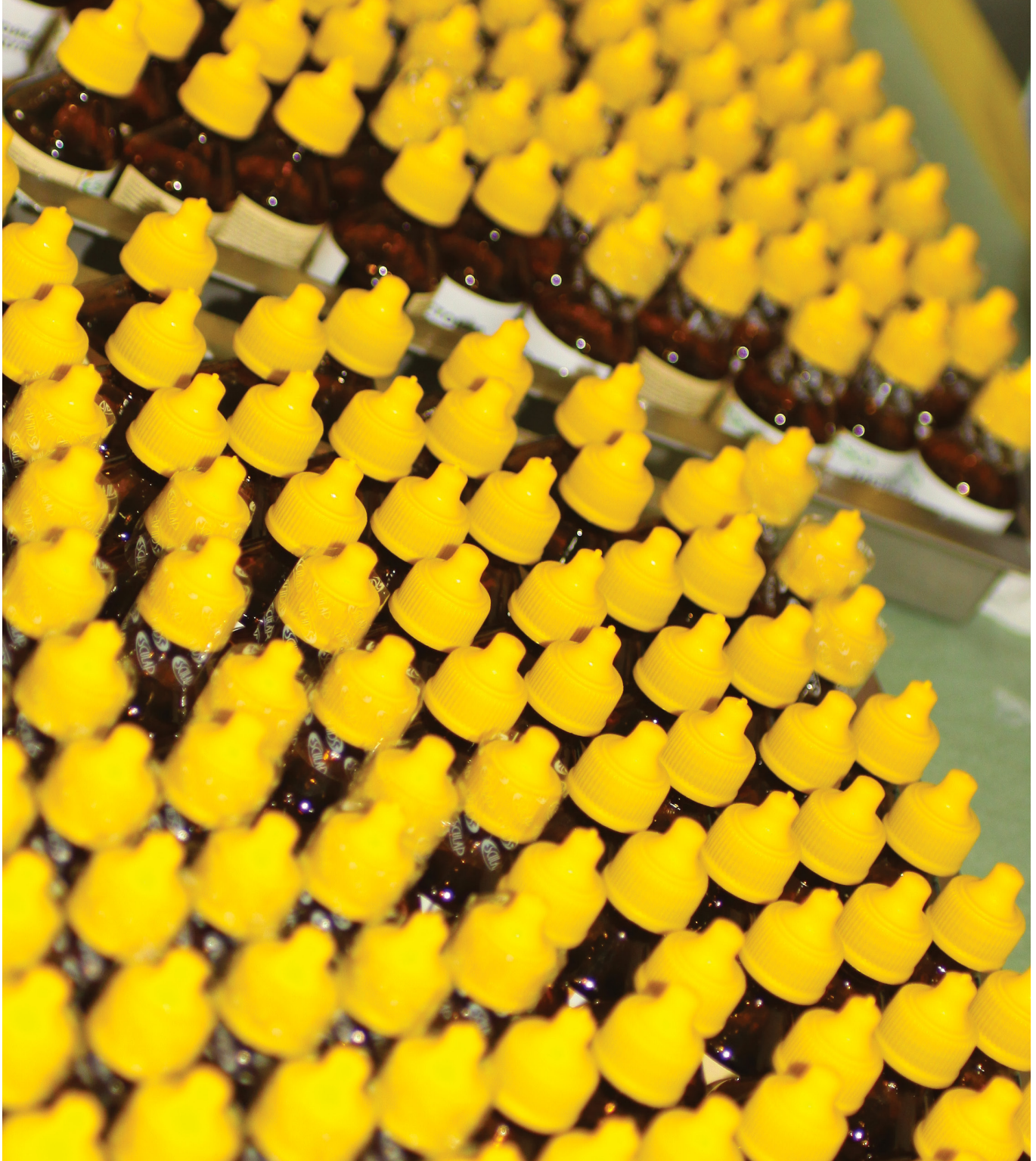
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Institute of Hydroponics Problems After G. S. Davtyan was founded in 1947 and is specialized in the soilless production of plants using industrial methods. The main research topics of the institute are the:

- Development of biotechnology for a number of valuable little-tonnage, rare and endangered medicinal, aromatic, dye-bearing and tree-shrub plant soilless production
- Studies of physiological; biochemical, pharmacochemical and radiochemical and other peculiarities of crops grown under soilless conditions;
- Development of biotechnologies for some agricultural and other crop planting material production by combination of in vitro method and hydroponics; and,
- Introduction of rare and endangered plants with valuable adaptogen properties to Armenia and investigation of their soilless cultivation feasibility.

The Institute is able to provide organic mass of herbs grown in their laboratories, which allows the phyto-pharmaceuticals industry to reduce the costs of herb cultivation and collection as well as receive adequate quality as required to synthesize medicine from these herbs.



TINCTURE PRODUCTION LINE, ESCO-
PHARM PHARMACEUTICAL COMPANY

DarmanTest



DARMA TEST
LABORATORIES
LLC

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Number of employees:

20, plus additional,
temporary contractors

Darmantest Laboratories (DTL) is a contract research organization (CRO) specializing in Bio-Equivalence, Bio-Availability and Bio-Similar studies for the pharmaceutical industry.

DTL was established in 2009 and is managed by American and Armenian professionals whose goal is to offer a high quality of service at a reasonable cost.

With its primary client being an American generic pharmaceutical manufacturer, at present DTL conducts pilot and pivotal studies for single or multi-dose pharmaceutical products in full compliance with ICH GCP, GLP and GDP, and especially U.S. FDA (U.S. Food and Drug Administration) and EMA (European Medicines Agency) regulatory guidance. To date, DTL is the only laboratory within the region that is entirely GLP, GCP and GDP compliant.

DTL has three divisions: Analytical Laboratory, Clinical Research Center, and Quality Assurance and Statistical Departments.

Quality control is conducted by the independent Quality Assurance Department with both regularly scheduled and impromptu audits, and document control.

DTL's Clinical Research Center can house up to 65 study subjects, has a self-contained intensive care unit, and a large community and dining room with all the amenities for a comfortable stay for both male and female study subjects.

The mainstay of the Analytical Laboratory is the AB Sciex API 4100 LC/MS/MS. Additional state-of-the-art equipment includes the Agilent 1290 UHPLC, as well as other Waters HPLC's.

Protocols are submitted to a fully independent Institutional Review

Board of the company, which is in full compliance with US FDA and EMA regulatory guidelines, to approve and monitor all aspects of DTL's studies.

DTL's research and provided services list includes:

- Pilot or Pivotal Studies;
- Beginning-to-end study management;
- Study design;
- Protocol preparation;
- Method development and validation;
- IRB Submissions;
- Subject recruitment and screening;
- Clinical study;
- Study monitoring;
- Analytical, statistical & data management;
- Pharmacokinetics and bio-statistical services using WinNonlin and SAS;
- Final study report;
- Strict adherence to quality assurance; and,
- Nutritionist preparation of special diets.

Quality assurance oversight includes:

- Ongoing and impromptu internal audits;
- Strict adherence to standard operating procedures (SOP's);
- Ensuring compliance with regulatory guidelines;
- Review & audit of clinical activities and data;
- Document control; and,
- Responsibility for corrective action and preventive action.

DTL is in the process of adding another ~450 square meters to its facility in anticipation of expected growth over the next few years. The projected growth for the next five years, which is already in process, is to double the size of the laboratory and staff and add additional equipment in order to increase productivity and the number of annual studies. The company has prepared a business development plan that ►

**DTL IS THE ONLY
LABORATORY IN
THE REGION THAT IS
ENTIRELY GLP, GCP
AND GDP COMPLIANT**

includes developing additional business with generic pharmaceutical manufacturers from the U.S., Europe, Middle East and CIS region.

In order to achieve and maintain its competitive edge, DTL is:

- Continually upgrading techniques and procedures;
- Ensuring the scientific validity of work; and,
- Creating benchmarks to shape the future of the company.

The company has assembled a young, energetic and motivated team which is not afraid to develop new and different approaches. DTL's staff is fluent in English, Armenian, Russian, Farsi, Arabic and French, and can prepare reports and/or documentation in any of these languages.

DTL is also as competitive as possible in the cost of studies and completing studies in a timely manner. ■





FDA LAB ANALYTICAL LABORATORY

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Number of employees:

11

The FDA Lab is equipped with state-of-the-art facilities operated by highly qualified specialists. The laboratory is certified in ISO 17025. "FDA Lab" consists of four laboratories:

- Food Safety Analysis Laboratory;
- Drug Quality and Bioequivalence Analysis Laboratory;
- Microbiological Analysis Laboratory; and,
- Tobacco Analysis Laboratory.

The company's laboratories provide a wide range of services. The Food Safety Laboratory has the ability to analyze antibiotics, hormones, heavy metals, dyes, toxins and other materials in meat and meat products, fish, eggs, dairy products, diet and baby food, alcoholic and non-alcoholic beverages, and natural honey.

The Drug Quality and Bioequivalence Laboratory conducts in vivo/in vitro analysis of bioequivalence, quality control of medicines and pharmaceutical raw materials, and processing and validation of analytical methods for quality control. In order to perform proper analysis of bioequivalence there is a 32-bed clinic

near the laboratory, which is in line with all requirements of Good Clinical Practice.

The Tobacco Quality Laboratory has the ability to determine the nicotine content, carbon monoxide content (CO) in dry smoke, water and tar content, content of residual chloro-organic and dithiocarbamate compounds in tar.

The Microbiological Laboratory performs the following types of analysis:

- Pharmaceutical microbiology; and,
- Sanitary microbiology: food safety analyses in compliance with microbiological parameters, sanitary and microbiological monitoring of bottled, mineral, spring and tap water

FDA Lab is unique in that it has four different laboratories under one roof, the only such facility in the region. FDA Lab is already accredited within its 32 fields (Certificate ISO 17025 No. 001/T-001).

In the future, a research center for bioequivalence study will be established. All the analyses carried out in FDA Lab are in accordance with current reference standards, sanitary rules and industry norms. ■

**FDA LAB IS THE
FIRST LABORATORY
COMPLYING WITH
ISO/IEC 17025
REQUIREMENTS
AND IS ACCREDITED
WITHIN ITS 32 FIELDS**



**INVESTMENT
ENVIRONMENT
77-82**

INVESTMENT ENVIRONMENT



The promotion of investment is one of the key focuses of Armenian economic policy. Armenia has declared an “open door” policy, which is defined in the law “On Foreign Investments” and has one of the most open investment regimes among emerging market countries. According to this law, foreign investors can benefit from the following incentives:

1. 100% Ownership;
2. No screening and no specific authorization required to make an investment;
3. Land ownership: Companies registered by a foreigner in Armenia have the right to buy land. Foreign citizens may have only long-term lease contracts;
4. VAT is deferred for three years on the import of goods destined for use in investment projects that exceed the value of AMD 200 million;
5. No export restrictions and duties;
6. Zero rating for goods and services exported under “Free Turnover” and “Re-exportation” customs regimes;
7. Five-year grandfather clause, national treatment and non-discrimination for foreign investors are guaranteed;

8. No tax and custom restrictions in Free Economic Zones;
9. Free exchange of foreign currencies;
10. No restrictions on remittances;
11. No restrictions on repatriation of profit, capital, dividends, interest, royalties, management or technical service fees;
12. No restrictions on staff recruitment; and,
13. No sector-specific or geographic restrictions on investments.

In addition to the specific investment incentives described above, the following factors make Armenia attractive for foreign direct investment:

- a. Stable macroeconomic situation;
- b. Sustainable banking system in line with international standards;
- c. Highly experienced, creative, cost efficient, and well-educated workforce;
- d. Strong Armenian diaspora; and,
- e. High levels of hospitality and safety.

Armenia is a signatory to the 1958 Convention on the Recognition and Enforcement of Foreign Arbitral Awards, and is also a signatory to the International Convention on Investment Disputes. ■

FOREIGN INVESTMENTS



As mentioned above, the Armenian pharmaceutical industry has experienced sustained growth in recent years, driven by the increase of sales to the domestic market and exports, together with a significant increase in investments.

A number of multinational corporations (Astellas Pharma Europe B.V., Eli Lilly, Gedeon Richter, GlaxoSmithKline, Hoffmann-La Roche, Les Laboratoires Servier, Novartis, Pfizer, Sanofi and Takeda Pharmaceutical Company Limited) have representation in Armenia to handle imports and/or to conduct brand marketing and monitoring.

Several pharmaceutical manufacturing companies have managed to attract foreign direct investment from both private and institutional investors.

Foreign investors are also interested in conducting Bioequivalence and Analytical Studies in Armenia. An example is Darmantest Laboratories founded and managed by American-Armenian partners. The first of its kind in Armenia and the CIS region, it is a state-of-the-art Bio-Equivalence and Analytical laboratory that maintains the highest standards required by U.S. and European regulatory agencies. ■

Armenia, which largely depends on foreign trade, is making significant efforts to attract foreign direct investment. The Government of Armenia has adopted an “open door” policy, with Most Favored Nation and National Treatment regimes in place, and legal protection to promote foreign investment.

Foreign investors are entitled to implement investments through:

- Establishing a fully foreign-owned company (including representatives, affiliates and branches), or purchasing an existing company;
- Establishing a new joint venture company with the participation of Armenian companies or citizens, or purchasing of shares in an existing company;
- Purchasing different types of securities;
- Procuring permits to use the land, or creating a concession agreement for the use of Armenian natural resources with the participation of Armenian companies or citizens; and/or
- Procuring other property rights.

The areas that are attractive for investment in Armenia’s pharmaceutical sector are discussed below.

PHARMACEUTICAL PRODUCTION AND CONTRACT MANUFACTURING ORGANIZATIONS

Armenia already has a strong base of pharmaceutical producers, some GMP-certified and some in the process of attaining GMP certification. Pharmaceutical production has been growing at a fast pace, averaging at 20% annually for the past five years, with production totaling USD 12.9 million in 2013. Exports have also been increasing, accounting for 52% of Armenia’s pharmaceutical output. With rising incomes, still relatively low expenditures on pharmaceuticals in Armenia, a favorable business environment and effective support institutions, it is believed that the growth in Armenia’s pharmaceutical sector is just beginning.

In order to seize expansion opportunities, many of Armenia’s main pharmaceutical producers are open to investment. Investment opportunities range from a few hundred thousand USD, to several million USD for the construction of new facilities. Some key players that can serve as local partners, both for new ventures and for investing into existing businesses, are discussed on pages 22-29 of this guide.

Investment opportunities exist in pharmaceutical product packaging, either through establishing a stand-alone pharmaceutical packaging facility or partnering with existing companies. Armenia has a developed printing industry that provides packaging, and the Government of Armenia has established a favorable business environment for development of the industry. The FEZ in the territory of “RAO MARS” CJSC and the Yerevan Scientific Research Institute of Mathematical Machines provides a number of incentives for companies interested in pharmaceutical packaging:

- No VAT for delivering services and supplying goods to the territory;
- Tax-free profit to legal entities and no income tax for sole proprietors;
- No property taxes on public and industrial buildings and structures owned or leased within the FEZ;
- No customs charges and non-tariff regulation measures applied to the export of goods; and,
- Freely convertible currency allowed as a medium of exchange while trading within FEZ.

HERBAL MEDICINE PRODUCTION

The global demand for medicinal herbs and plants is currently growing at approximately 11% annually (according to International Trade Centre, ITC), and Armenia offers a number of competitive advantages in this sub-sector. Armenia has over 2,500 varieties of medicinal herbs and berries growing wild in its mountains, and Armenia’s knowledge of herbal medicines has been developed over 3,000 years. Today, some of the larger Armenian pharmaceutical ►

INVESTMENT OPPORTUNITIES AND COMPETITIVE ADVANTAGES



ARMENIA HAS A FAVORABLE BUSINESS ENVIRONMENT AND EFFECTIVE SUPPORT INSTITUTIONS

producers are manufacturing herb-based pharmaceuticals and dietary supplements, and a number of smaller players are involved in the cultivation and production of teas, extracts, lotions, gels, topical creams and oils made from medicinal spices and aromatic herbs. These companies, mainly SME's, use solar dryers and sell their production not only in the domestic market, but also export them all over the world. There is opportunity to increase the export volume of herbal medicines and to penetrate new markets and achieve greater value added within Armenia. There is ample opportunity to invest in the manufacturing of herb-based pharmaceuticals and dietary supplements, as well as in cultivation, packaging, and expanding export through start-up ventures, establishing partnerships with existing Armenian players, or consolidating some of the many players of the herbal medicine segment of the pharmaceutical industry.

R&D AND CONTRACT RESEARCH ORGANIZATIONS (CRO'S)

R&D is one of the core sectors of Armenia's economy. Due to its rich history in research, educational traditions and skilled human resources, Armenia has attracted numerous global technology firms over the past few years who have established branches and R&D centers in Armenia.

The Armenian pharmaceutical industry has strong scientific and R&D potential, which can be developed through the improvement of inter-cluster relations among R&D, production, and education. There are eight scientific research institutes undertaking research in pharmaceutical and biotechnology related areas.

However, R&D levels in Armenia are still lower than in most developing countries such as India, China, Brazil and others. Furthermore, more than 80% of investment in R&D is by public entities or public financing. One of the primary

objectives of the pharmaceutical/ biotechnology sector is to promote the attraction of foreign direct investment in intensive knowledge through the development and promotion of research centers established in Armenia. For its part, the Government of Armenia is ready to provide the necessary assistance for R&D promotion.

Investors and pharmaceutical companies can establish their own CRO's in Armenia, or can invest in or collaborate with existing CRO's, research institutions or pharmaceutical producers with CRO capabilities. There are already CRO's established by Armenian and/or foreign professionals that are in full compliance with standards of the U.S. Food and Drug Administration, European Medicines Agency, International Conference on Harmonization Good Clinical Practice, Good Laboratory Practice and Good Distribution Practice. There are also a number of hospitals that conduct clinical trials. Armenia is a unique region for clinical trials due to a number of factors:

- Armenia has highly professional doctors with extensive medical practices in various areas;
- Doctors are highly motivated, both professionally and financially, to be actively involved in clinical studies; and,
- Patients are motivated to volunteer for clinical trials in order to receive high quality treatment, which they cannot otherwise afford.

In addition to clinical trial capabilities, there are a number of research institutes and local production companies with the skills to handle contract work.

COMPETITIVE ADVANTAGES

Pharmaceuticals is one of the fastest growing sectors of Armenia's economy. In addition to a favorable business environment, Armenia offers certain competitive advantages that make investment in the pharmaceutical sector attractive:

**THE GOVERNMENT
OF ARMENIA HAS
ESTABLISHED A
FAVORABLE BUSINESS
ENVIRONMENT
FOR DEVELOPMENT
OF THE
PHARMACEUTICAL
INDUSTRY**



PRODUCTION OF OINTMENTS
ACCORDING TO EU GMP STANDARDS;
ARPIMED PHARMACEUTICAL COMPANY

Favorable business environment with no pharmaceutical price control

Armenia is a relatively easy country for doing business. According to the World Bank study, Doing Business 2014, Armenia is the 37th easiest country in which to do business out of 189 countries, the best ranking among CIS countries. There are absolutely no price controls on pharmaceuticals in Armenia, and Armenia is updating its pharmaceutical-related legislation to enhance free competition and competitiveness.

R&D institutions involved in the development of medicines, chemistry, genetics, and availability of professional, highly educated research staff

Armenia historically had strong scientific research institutions that still operate today. There are 72 research institutions in Armenia, ten of which are involved in pharmaceutical and biotechnology related research activities.

Highly educated workforce, complemented every year by new graduates from Armenia's internationally recognized universities

There are 12 state and private universities and institutions in Armenia that offer education in pharmaceuticals. Some of them offer master and doctoral level degrees in pharmacy.

Low labor and energy costs

The average wage in Armenia is less than that in Western and Eastern Europe and the South Caucasus region, and in China and nearby Turkey. Human capital is regarded as the most valuable resource of the country; the literacy rate is 99.6%.

Energy tariffs are competitive throughout the region. Armenia has significant domestic electricity generating resources: a nuclear power plant, gas-fired thermal power stations, hydroelectric, cogeneration and wind power stations.

State-of-the-art testing and laboratory facilities

These facilities have cutting-edge equipment and highly skilled staffs conducting all types of laboratory testing and research. Moreover there are several private-owned laboratories which provide Bioequivalence, Bioavailability and Biosimilar studies for the pharmaceutical industry.

Open and collaborative cluster with enthusiastic entrepreneurs

Open and willing to adopt international standards, these industry leaders are ready to invest and be certified by local and international accreditation bodies. Armenia announced the adoption of EU GMP standards in 2010, and all Armenian pharmaceutical companies are currently working on the implementation of the GMP standards, a process contemplated to be completed in 2015. Two producers (Liqvor and Arpimed) are already GMP certified (in December 2013 and July 2014 respectively), one (Pharmatech) is close, and the others plan to be by the end of 2015.

The Government of Armenia has already established the GMP certification body within the SCDMTE, which applied for the pre-accession for the membership to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation in 2012. It is expected that Armenia will apply for the membership in 2014.

Competitive advantage in herbal medicines and medicinal herbs

The mountainous nature and tremendously diverse climate of Armenia creates favorable conditions for herbal plants. There are over 2,500 varieties of medicinal herbs and berries growing in the high mountains of Armenia. A number of manufacturers specialize in the production of natural and herbal medicines and dietary substances from medicinal spices and aromatic herbs, with growing exports to CIS and other countries. ■

**ARMENIA'S
KNOWLEDGE OF
HERBAL MEDICINES
HAS BEEN
DEVELOPED OVER
3,000 YEARS**

**REGULATORY
ENVIRONMENT
AND QUALITY
CONTROL
83-94**

PHARMACEUTICAL POLICY AND LEGISLATION



The pharmaceutical sector of the Republic of Armenia has undergone fundamental changes in recent years, aimed at providing high quality pharmaceuticals and related services.

Development of the pharmaceutical sector is a priority of the Government of the Republic of Armenia, as reflected in the “Export-Led Industrial Policy of the RA” strategy adopted in 2011. The strategy is principally focused on 11 sectors and the corresponding action plan for the pharmaceutical sector, which has already been developed and is being implemented now.

The main strategic directions of the action plan are:

1. Set-up of the quality control system;
2. Establishment of the base for local raw materials;
3. Capacity building;
4. Financial support;
5. Involvement of Trans National Corporations; and,
6. Sales promotion.

Results of the policy are already being seen. GMP standards have been legally introduced in Armenia. Companies have developed schedules for meeting GMP standards. Legislation for other GxP standards is being devised. Local pharmaceutical producers are receiving support by several donor organizations (particularly by the USAID EDMC project) for entering international markets and expanding exports.

As a result, exports of pharmaceutical production reached 52% in 2013.

LEGISLATION

The Pharmaceutical sector in Armenia is regulated by a number of legal acts intended to ensure safe, quality and effective medicines.

The fundamental legal act regulating Armenia’s pharmaceutical sector is the Law “On Medicines”, adopted in 1998. It regulates the manufacture,

registration, quality control, export, import and sale of pharmaceutical products.

Other major legal acts regulating Armenia’s pharmaceutical sector are:

- **Decree No. 581 of the Government of RA on “The Approval of Rules on Import and Export of Medicines and Pharmaceutical Substances in the RA,” adopted on September 20, 2000.**

Ensures that medicines can only be imported to Armenia with a certificate issued by the Ministry of Health.

Only medicines registered in Armenia can be imported.

Imported medicines should have a manufacturer’s quality certificate.

The Decree has separate sections on rules for the import and export of medicines (e.g. application for getting the certificate, terms of the expertise, types of laboratory and documental expertise, legal and technical bases for rejection of imports or exports, etc.).

- **Decree No. 347 of the Government of RA on “The Approval of Rules on State Registration of Medicines and Fees for Expertise of State Registration of Medicines,” adopted on April 25, 2001.**

This decree is based on the requirements of the Law “On Medicines” and has two sections. Section 1 establishes the registration procedure, the basis for rejecting a registration, and the rules for withdrawing a registration. Section 2 is devoted to the types of registration and relevant fees (see Table 5). (A detailed description of the registration procedure is provided in section 10.3 of this guide.)

- **Decree No. 867 of the Government of RA of June 29, 2002 on “The Approval of Rules on Licensing Medicine Production, Pharmacy Practice, Health Service, Implementation of Medical Professional Education Curricula, and on ►**

Approval of Licensing Forms for Implementation of Mentioned Activities”

Establishes general requirements for licensing, specifying detailed procedures for licensing several types of activities, including pharmaceutical production. (A detailed description of the licensing procedure for medicine production is provided in section 10.4 of this guide).

Other important regulations affecting the pharmaceutical sector include:

- Law “On Narcotics and Psychotropic Substances”, adopted on December 26, 2002;
- Law “On Licensing”, adopted on May 30, 2001;
- Law “On Advertising”, adopted on April 30, 1996;
- Law “On State Duty”, adopted on December 27, 1997;
- Law “On Value-added Tax”, adopted on May 14 1997;
- Law “On Medical Aid and Population Services”, adopted on March 4, 1996;
- Decree No. 1608-N of the Government of RA “On the Approval of Rules of Granting Permission to Advertise Medicines, Medical Equipment and Methods of Treatment and Requirements for these Advertisements”, adopted on November 2, 2006;
- 8. Decree No. 63 of the Government of RA “On the Approval of Rules for Implementation of Clinical Trials of New Medicines”, adopted on January 24, 2002;
- Decree No. 281-N of the Government of RA “On the Approval of the Licensing Procedures during Production, Export or Import and Wholesale Trade of Narcotic Drugs, Psychotropic Substances and their Precursors, Defined by the RA Government”, adopted on March 18, 2011;
- Decree No. 1129-N of the Government of RA “On the Approval of the List of Narcotic Drugs, Psychotropic Substances and their Precursors, Subject to Control in the RA”, adopted on August 23, 2003;
- Decree No. 1603-N of the Government of RA “On the Approval of the Rules of Good Manufacturing Practice”, adopted on November 25, 2010; and,
- Decree No. 1089-N of the Government of RA “On the Approval of Rules for Implementation of GMP Compliance Inspection and Issuing GMP Certification for Medicines and Pharmaceutical Substances Produced in the RA”, adopted on September 26, 2013. ■



**ARMENIA ADOPTED
EU GMP STANDARDS
IN 2010**

STATE ADMINISTRATION



The Ministry of Health of the Republic of Armenia (MoH, www.moh.am) is the main regulatory body of the pharmaceutical sector. The MoH is responsible for initiating laws, supervising and regulating, developing public policy for the healthcare sector, develop and monitor the implementation of health education programs, among other responsibilities. The MoH is solely authorized to license certain activities, including the production of medicines, pharmacy practice, and health services. The MoH also issues and rejects medicine registrations and medicine import certificates.

The medicine regulatory authority in Armenia is the Scientific Center of Drug and Medical Technology Expertise (SCDMTE, www.pharm.am), which was established in 1992. The Center is involved with numerous aspects of pharmaceutical regulation:

- **Registration** – Expert assessment of medicines (including veterinary medicines), herbal medicines, medical cosmetics, for the purpose of state registration;
- **Import and export expertise** – Expert assessment of medicines for the purpose of certification for import and export;
- **Specialized expertise of pharmaceutical organizations** – Assuring the quality of medicines and other pharmaceutical products available in Armenia, as well as detecting counterfeit medicines;
- **Control over Narcotics and Psychotropics** – Calculating an annual demand for narcotics and psychotropics in Armenia, certification for import and export of narcotics and psychotropics, and submission of reports to the U.N. International Narcotics Control Board;
- **Monitoring adverse effects of medicines** – Registration of adverse drug reactions in Armenia and provision of relevant information to the World Health Organization International Program on Monitoring Adverse Drug Reactions;

- **Implementation of the concept of rational use of medicines** – Reviews and updates the National Essential Medicines List, develops optimal pharmacotherapy schemes, studies medicine prescription practice, carries out pharmaco-epidemiological research;
- **Control of clinical trials** – Expert assessment of protocols and other required documents for granting permission of clinical trials in RA, and monitoring of current clinical trials; and,
- **Research activity** – Conducts studies in the medical and pharmacy fields, conducts surveys of the pharmaceutical market, and conducts pharmaco-economic analysis.

Based on recommendations by the World Health Organization and with substantial support by donor organizations, the Center has created modern laboratory facilities (Laboratory of Quality Control of Medicines). The Laboratory received quality management ISO 9001-2008 in December 2010.

The main functions of the Laboratory are:

- Providing expertise in medicine quality and meeting specifications, for the purposes of state registration;
- Quality analysis of imported and exported medicines;
- Quality control of medicines and other pharmaceutical products sampled during inspections of pharmacies and wholesalers;
- Laboratory analysis of medicines and substances by the request of the state bodies;
- Examination of quality and safety of food; and,
- Bioequivalence studies.

State control and supervision over the implementation of pharmaceutical related legislation and other normative legal acts and imposition of disciplinary sanctions are carried out by the State Health ►

**“DOING BUSINESS
2014” RANKED
ARMENIA AS THE
37TH EASIEST
COUNTRY TO DO
BUSINESS OUT OF
189 COUNTRIES
SURVEYED**

Inspectorate of the Ministry of Health. One of main tasks of the inspectorate is conducting inspections of pharmacies, pharmaceutical export and import companies.

SUPPORTING INSTITUTIONS

The Medicine Producers and Importers Union of Armenia (MPI Union, www.pharmunion.am) was founded in 2003 and unites 23 leading pharmaceutical companies. Along with Armenia's leading pharmaceutical manufacturing, wholesale, and retail companies, the MPI Union also has representatives from well-known foreign companies. The aims of the MPI Union are to integrate Armenian companies into the international pharmaceutical market, implement constant improvements, and provide fair and equal competition in the industry.

To achieve its aims, the MPI Union's activities include:

- Continuous monitoring of legislation related to pharmaceutical, economic and other areas;
- Presenting legislative proposals to RA Government;
- Protecting interests of the pharmaceutical industry in the Parliament of RA;
- Implementing programs to introduce international standards and advanced technologies in pharmaceutical companies;
- Assisting in the technological modernization of domestic medicine-producing companies, including involvement in RA Government supportive measures;
- Presenting projects and realizing their goals;
- Implementing and conducting educational and international ►

A PPP BETWEEN THE GOVERNMENT OF RA AND MPI UNION WAS CREATED TO FURTHER DEVELOP THE SECTOR, ENHANCE PRODUCT QUALITY AND BOOST EXPORTS





exchange training programs for pharmacy sector specialists; and,

- Raising awareness of Armenian pharmaceutical products within domestic and international markets via campaigns, exhibitions, establishment of business relations, business forums and conferences.

In 2009, the MPI Union founded the “GXP Centre of Excellence” (www.gxp.am) with the mission to develop professional knowledge and ensure reliable information in the RA pharmaceutical and biotechnological sectors. Unique in the region, the GXP Centre of Excellence organizes professional and internationally standardized training courses on GxP standards, inviting professionals from EU member states and other developed countries.

The MPI Union and GXP Centre attach importance to the development of pharma-biotechnology science in Armenia. In furtherance of this goal, they created “Pharma”, a scientific and business pharmaceutical magazine (www.pharma-mag.am). The

magazine covers the development of the pharmaceutical industry and publicizes the industry and the medicine market. While its goals are to reflect the priorities of the Armenian pharmaceutical industry and to represent Armenian pharmacists and pharmacologists to medical society, “Pharma” also focuses on global pharmaceutical and pharmacological trends.

Every year the MPI Union organizes the annual “International Pharmaceutical Competitiveness Conference” (www.pharma-armenia.am) with the support of the RA Ministries of Health and Economy. It unites all representatives of pharmaceuticals: legislative and executive authorities, heads of domestic and international medicine-producing and importing companies, doctors, pharmacists and other specialists. In conjunction with the conference, the Union holds an annual “Pharma-EXPO”, a specialized exhibition of pharmaceuticals (www.pharma-expo.am). Local and foreign pharmaceutical companies and/or their representatives in Armenia take part in this exhibition. ■

**“PHARMA” IS
A SCIENTIFIC
PHARMACEUTICAL
MAGAZINE THAT
COVERS THE
DEVELOPMENT OF
THE ARMENIAN
PHARMACEUTICAL
INDUSTRY**

STATE REGISTRATION OF MEDICINAL PRODUCTS



Medicinal products can be produced, imported, stored, distributed, sold and used in Armenia only after being state registered. Registration, registration renewal and withdrawal of registration are controlled by the Ministry of Health. The registration of medicinal products is based on scientific criteria and analysis of safety, efficacy and quality conducted by the SCDMTE.

The following are subject to registration:

- New original and generic medicinal products (including immunological, veterinary and homeopathic);
- Additional dosage strengths, pharmaceutical forms and new indication of registered medicinal products; and,
- New combinations of medicinal products.

Registration of medicinal products in Armenia expires after five years, after which they can be renewed (please visit http://pharm.cals.am/pharm/drug_images for the list of registered medicines in Armenia).

MEDICINE REGISTRATION PROCEDURE

1. Medicines registered in EU countries, the US or Japan are subjected to a simple recognition procedure. Assessments of products registered in these countries are completed within 30 days, without any laboratory examination. The decision to grant a registration certificate is made by the Ministry of Health within 10 days on the basis of the analysis, after payment of the state duty.

2. For medicines not eligible for the simple recognition procedure noted above, the importer or manufacturer (the applicant) must submit a set of registration documents, samples of medicinal products, and the standards followed to the SCDMTE. The SCDMTE conducts a preliminary examination of submitted

documentation and samples within 10 days, after which the applicant is notified in writing and charged an advance fee for expert analysis of the product. The expert analysis is begun after payment of the fee. The maximum duration of the assessment is 180 days.

3. For renewal of previously registered medicinal products, there is a simplified procedure that is completed in a maximum of 23 working days after submission of all required documents: (a) the application; (b) a letter confirming the desire for renewal of the previously registered product and the absence of changes or additions in the previous registration documents; (c) Periodic Safety Update Report (PSUR); and (d) documentation of payment of the state duty.

4. Registration applications for medicinal products should be submitted to the SCDMTE in CTD (Common Technical Document) format.

The procedures for registration and analysis of medicinal products are detailed by the Decree of the Government of the RA No. 347 adopted on April 25, 2001, "On Adopting the Rule of Registration of Medicinal Products and Expertise Fees for Registration of Medicinal Products in the Republic of Armenia"; and Order No. 123-N of the Ministry of Health of the RA, dated February 7, 2006, entitled "On Approval of the Procedure of Expertise for Registration of Medicinal Products in the Republic of Armenia, Form and Description of the Registration Certificate and the List of Variations of Medicinal Products Registered in the Republic of Armenia that Do Not Require New Registration."

During the process of registration of medicines packages and labels, the SCDMTE is guided not only by the RA law "On Medicines," but also by the EU Directive 2001/83/EC. ►

**MEDICINES
REGISTERED IN THE
EU, USA OR JAPAN
ARE SUBJECTED TO A
SIMPLE RECOGNITION
PROCEDURE**

TABLE 5. FEES FOR MEDICINAL PRODUCT REGISTRATION ANALYSIS

No.	Type of application for registration	Expertise Fee (including VAT) (AMD)
1.	The first dosage form and dosage strength of generic medicinal products	900,000 (USD 2,197)
	• for each additional pharmaceutical form	450,000 (USD 1,099)
	• for each additional dosage strength	240,000 (USD 586)
	• for each new indication	450,000 (USD 1,099)
2.	New combination of known medicinal products	1,200,000 (USD 2,930)
3.	The first pharmaceutical form and dosage strength of medicinal products containing new active substances	2,250,000 (USD 5,493)
	• for each additional pharmaceutical form and dosage strength	1,200,000 (USD 2,930)
4.	The first pharmaceutical form and dosage strength of homeopathic medicinal products	240,000 (USD 586)
	• for each additional pharmaceutical form, dosage strength and new indication	60,000 (USD 147)
5.	Herbal preparations and other preparations of natural substances and dietary supplements	240,000 (USD 586)
6.	Re-formulating of the registration certificates, in cases of changes of product name and/or manufacturing company, changes of packaging, and other minor changes which do not affect the approved quality, safety and efficacy of the product	24,000 (USD 59)

STATE DUTIES FOR THE REGISTRATION OF MEDICINAL PRODUCTS IN ARMENIA

No.	Type of application for registration	Rate of the State Duty (AMD)
1	For the first dosage form or dosage strength of medicines with new active substances, new dosage form or dosage strength of a new medicines	70,000 (USD 171)
2	New combination of known medicinal products	40,000 (USD 98)
3	For the first dosage form or dosage strength of generic medicines and for each following dosage form or dosage strength	40,000 (USD 98)
4	New indications	10,000 (USD 24)
5	For state registration of pharmaceutical substances	30,000 (USD 73)
6	Herbal preparations and other preparations of natural substances	10,000 (USD 24)
7	Homeopathic medicinal products	2,000 (USD 5)
8	Dietary supplements	20,000 (USD 49)
9	For updates in the registration certificate related to pharmaceutical production, the name of the producing company, packaging and product safety, efficacy and other alterations and changes that do not affect quality	5,000 (USD 12)

**A SIMPLIFIED
PROCEDURE IS
APPLIED FOR
RENEWING
PREVIOUSLY
REGISTERED
MEDICINAL
PRODUCTS
(MAXIMUM 23
WORKING DAYS)**

PHARMACEUTICAL MANUFACTURING



LICENSING

The law “On Medicines” requires businesses that manufacture pharmaceutical products in Armenia to be licensed. The licensing procedure is detailed in Decree No. 867 of the Government of the RA, “The Approval of Rules on Licensing Medicine Production, Pharmacy Practice, Health Service, Implementation of Medical Professional Education Curricula, as well as on Approval of Licensing Forms for Implementation of Mentioned Activities”, adopted on June 29, 2002.

Licenses for medicine production are issued by the Ministry of Health. In order to obtain a license the applicant must include in the application the expert opinion given by the SCDMTE on the availability of material and technical resources necessary for medicinal production.

Applicants for the pharmaceutical manufacturing license submit required documents by either visiting the Ministry of Health, or through the online licensing system (www.e-gov.am/licenses).

Assuming there is no reason to reject an application for a license, the Ministry of Health issues the medicine production license within 23 working days of receipt of the application. The license is for an unlimited term. State duty for obtaining the license is 200,000 AMD (488 USD) per year. Payments can be made electronically through the e-payment system of the Government of RA (www.e-payments.am/en).

GMP CERTIFICATION

In 2013 Armenia introduced a process of certification of medicine production compliance with GMP. Certification is currently voluntary, however all Armenian pharmaceutical companies are realigning their production processes, readjusting infrastructure, and training their workers in preparation for applying for GMP certification.

GMP certification is issued by the Ministry of Health. The procedure for GMP certification is detailed by the Decree of

the Government of RA No. 1089-N, “On the Approval of Rules for Implementation of GMP Compliance Inspection and Issuing GMP Certification for Medicines and Pharmaceutical Substances Produced in the RA,” adopted on September 26, 2013.

A GMP certificate is initially issued for three one-year periods. After three years of continuous GMP conformity, the certificate is issued on a two-year period basis.

QUALITY CONTROL & ASSURANCE

Quality control is crucial in the pharmaceutical sector, to ensure that pharmaceutical substances and other raw materials are suitable for use in medicine and that manufactured medicinal products meet the highest quality standards.

Product quality is a high priority for Armenian medicine producers. Therefore, most raw materials and chemical compounds used in production are purchased from EU and US suppliers. As stated above, Armenia officially introduced GMP requirements for medicine manufacturing in 2013. Two Armenian medicine producers have already achieved GMP certification; others are working towards certification.

According to the legislation, the quality of medicinal products registered in the RA shall comply with the requirements of currently used Pharmacopoeias in Armenia: former Soviet Union State Pharmacopea XI, European Pharmacopea (Ph. Eur.), International Pharmacopea (Ph. Int.), United State Pharmacopea, British Pharmacopea, German Pharmacopea (DAB), German Homeopathic Pharmacopea (HAB), French Pharmacopea (PhF).

The Quality Control Laboratory of SCDMTE is responsible for:

- Testing medicines at the process of registration;
- Testing the quality of imported medicines;
- Testing the quality of pharmaceuticals produced in Armenia; and,
- Testing the quality of products sampled during inspection of pharmacies and wholesalers. ■

**APPLICATIONS FOR
A PHARMACEUTICAL
MANUFACTURING
LICENSE CAN
BE SUBMITTED
THROUGH THE
ONLINE LICENSING
SYSTEM ([WWW.E-GOV.
AM/LICENSES](http://WWW.E-GOV.AM/LICENSES))**

PHARMACEUTICAL SALES



IMPORT OF MEDICINE

The procedures for importing medicinal products into Armenia are set forth in the Decree of the Government of the RA No. 581 “On the Approval of Rules on Import and Export of Medicines and pharmaceutical substances in the RA,” adopted on September 20, 2000.

Only entities registered in Armenia can import medicine. Importing medicinal products and/or pharmaceutical substances into Armenia requires an import certificate, which is provided by the Ministry of Health of the RA based on documentation and laboratory expertise.

Only medicines registered in Armenia can be imported. Importers must submit a manufacturer quality certificate and/or batch certificate or their verified copies. According to legislation, parallel imports are also allowed. Unregistered medicines can be imported for:

- Pre-clinical and clinical trials;
- Registration of medicinal products in Armenia;
- Exhibits at exhibitions, conferences etc. without the right to sell;
- Humanitarian aid or during disasters, epidemics and other emergencies; and,
- Packaging purposes (if the medicines underwent all stages of production, except packaging and marking).

The import certificate for medicinal products and/or pharmaceutical substances is issued by the Ministry of Health based on the expertise of the SCDMTE. The Ministry issues the import certificate within ten working days of receiving the application and all necessary documents. The import of medicines and pharmaceutical substances with a remaining expiry date less than one year (or 2/3 if the shelf life is less than one year) is not allowed.

All medicinal products imported to the territory of Armenia are subject to state quality control, which is performed by the SCDMTE.

RETAIL (PHARMACIES AND PHARMACY KIOSKS)

Retail sale of medicinal products in Armenia is permitted only through pharmacies and pharmacy kiosks, which are subject to requirements as to type, area, sanitary conditions and other standards. Pursuant to the law of RA “On Medicinal product” and “On Licensing,” medicinal products can be sold at retail by legal entities and sole proprietors having a relevant license. The procedure and conditions for obtaining a retail medicine license are detailed in Decree No. 867 of the Government of RA “On the Approval of Rules on Licensing Medicine Production, Pharmacy Practice, Health Service, Implementation of Medical Professional Education Curricula, and on Approval of Licensing Forms for Implementation of Mentioned Activities,” adopted on June 29, 2002. Retailers must have the necessary personnel that meet specific qualifications and must adhere to medicine storage requirements.

According to the Law “On Licensing,” the license for selling pharmaceuticals is issued by the Ministry of Health. Applicants should submit required documents either by visiting the Ministry of Health, or via the online licensing system (www.e-gov.am/licenses).

If there are no grounds for denial of a license application, the Ministry of Health issues a license within 23 working days of receipt of the application. The license is given for an unlimited term. State duty for obtaining the license is 50 thousand AMD (USD 122) per year. Payment of the duty can be made electronically through the e-payment system of the Government of Armenia (www.e-payments.am/en).

Medicines prepared in pharmacies are not subject to state registration and their sale to other medicinal product sellers is prohibited. Pharmacies making medicinal products are required to have the necessary equipment. ►

**THERE ARE 25
PHARMACEUTICAL
IMPORTERS AND
MORE THAN 1,700
RETAIL OUTLETS AND
PHARMACIES IN
ARMENIA**

“Good Pharmacy Practice” is a set of standards promoted by the Minister of Health and are to be introduced in pharmacies.

STORAGE AND TRANSPORTATION

The storage and transportation of medicinal products is governed by the Order of the Minister of Health No. 17-N “On the Approval of Rules on Transportation, Storage and Maintenance of Medicinal Products”, adopted on September 9, 2010.

At each storage site (manufacturer, distributor, wholesaler, pharmacy) there should be an adequate number of qualified personnel who receive proper training on GSP, regulations, procedures and safety.

There are also detailed requirements for storage areas, cleaning procedures,

maintenance conditions, and drug containers. Pharmaceutical products and materials should be stored in accordance with GSP standards.

Medicinal products should be transported according to storage conditions indicated on the packaging.

It is the responsibility of the distributor to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable. This includes ensuring appropriate equipment to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind. Delivery drivers (including contract drivers) should be trained in the relevant areas of GDP. ■



INTELLECTUAL PROPERTY



Armenian legislation protects intellectual property rights, patents, know-how, trade secrets, trademarks, and service marks, which is in compliance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

The “Law on Copyright and Related Rights” provides for the legal protection of literary works, musical works, paintings, films, software, and other intellectual property rights, as well as the legal protection of the rights of performers, producers of sound recordings and broadcasting organizations. Armenia has ratified a number of international conventions for the protection of copyright and related rights: the Berne Convention for the Protection of Literary and Artistic Works; the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations; the WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty; and others.

The registration and protection of trademarks, service marks and geographical indications is governed by the laws “On Trademarks” and “On Geographical Indications”. A trademark or service mark is subject to legal protection in the Republic of Armenia by virtue of international treaties, acknowledgement of its renown, or after its state registration. Designations of origin are also subject to legal protection by virtue of

international treaties or after their state registration. Armenia is a signatory to such international treaties as the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods; the Madrid Agreement Concerning the International Registration of Marks; the Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks; and, the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks.

The rules for registration and legal protection of inventions, industrial designs and utility models are set by the law “On Inventions, Utility Models and Industrial Designs,” which provides patent protection for inventions (20 years), industrial designs (5 years with extension possibility) and utility models (10 years). Armenia has also ratified several international conventions in this area, such as the: Patent Cooperation Treaty; Paris Convention for the Protection of Industrial Property; Strasbourg Agreement Concerning the International Patent Classification; Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, and, others.

The Intellectual Property Agency of the Ministry of Economy (www.aipa.am) is responsible for granting patents and for overseeing other IPR related matters. ■

**ARMENIA IS A
MEMBER OF THE
WORLD INTELLECTUAL
PROPERTY
ORGANIZATION
AND HAS SIGNED
A NUMBER OF
INTERNATIONAL
AGREEMENTS ON
INTELLECTUAL
PROPERTY RIGHTS**



USEFUL CONTACTS

95-99

MINISTRY OF HEALTH

CONTACTS

Drug Policy and Medical Technology Department

Head of

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Arayik Baghryan

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The Ministry of Health of the Republic of Armenia is an executive body that elaborates and implements the policies of the Government of Armenia in the healthcare sector. The Ministry's mission is: the development and implementation of healthcare policy; ensuring RA population's sanitary and epidemic safety; organizing the provision of first and specialized medical care and services to RA's population; implementation of maternal and child health policy; state control of locally produced and imported medicines; registration of pharmaceutical products among others.

The Drug Policy and Medical Technology Department is a subdivision of the Ministry of Health and is responsible for elaborating, introducing and monitoring the implementation of Armenia's drug policy.

SCIENTIFIC CENTER OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE (SCDMTE)

CONTACTS

Scientific Center of Drug and Medical Technology Expertise

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The Scientific Center of Drug and Medical Technology Expertise was established in 1992 to implement the national drug policy in order to ensure the safety, efficacy and quality of medicinal products in Armenia.

The main tasks of the Center are:

- Expert assessment of medicines for the purpose of state registration, including veterinary drugs, herbal drugs, medical cosmetics, dietary supplements and medical devices;
- Expert assessment of medicines for the purpose of certification for import and export;
- Assuring the quality of medicines and other pharmaceutical products available in Armenia, including detecting counterfeit drugs;
- Calculating an annual demand for narcotics and psychotropics in Armenia, certification for import and export of narcotics and psychotropics, and submission of reports to the U.N. International Narcotics Control Board;
- Registration of adverse drug reactions in Armenia and provision of relevant information to the World Health Organization International Program on Monitoring Adverse Drug Reactions;
- Reviews and updates the National Essential Medicines List, develops optimal pharmacotherapy schemes, studies drug prescription practice, and carries out pharmaco-epidemiological research;
- Expert assessment of protocols and other required documents for granting permission for clinical trials in RA, and monitoring of current clinical trials; and,
- Conducts studies in the medical and pharmacy fields, surveys of the pharmaceutical market, and pharmaco-economic analysis.

MINISTRY OF ECONOMY

CONTACTS

Investment Policy Department

Head of

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Website:

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The Ministry of Economy of the RA is an executive body that elaborates the economic development policies of the Government of RA. The main goals of the Ministry are to increase competitiveness and promote sustainable economic development, as well as ensure security of the RA's economy through the development, implementation, coordination and evaluation of economic policies. To achieve these goals, the Ministry; develops economic policy and strategy; ensures balanced regional economic development; promotes investments, a knowledge-based economy, entrepreneurship and innovation; ensures access to efficient markets; and, improves the business environment of the country.

The Investment Policy Department, is a subdivision of the Ministry of Economy and is responsible for developing investment policy and regulating investment activities.

INDUSTRIAL DEVELOPMENT FOUNDATION

CONTACTS

Industrial Development Foundation

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The Industrial Development Foundation was established in 2012 and implements the activities prescribed in Armenia's "Export-Led Industrial Policy" strategy. The chairman of the board of directors of the Foundation is the Minister of Economy of Armenia.

The main goals of the Foundation are:

- The implementation, financing, coordination and monitoring of innovation programs and programs aimed at industry development;
- Providing public assistance in order to increase the competitiveness of industrial organizations; and,
- Supporting public and private partnership.

The main tasks of the Foundation are:

- Implementing activities to attract and provide access to multinational corporations and their research centers in the industrial sector, in particular the FEZ and technological centers;
- Providing co-financing for acquisition of international certifications and subsidies for loans for production purposes (including registration of medicines abroad);
- Providing market information, activities to promote Armenian products in target markets and presentations of Armenian products (including public relations about Armenian products abroad, assistance for participation in international exhibitions, and facilitating visits of representatives of foreign distributors to Armenia);
- Financing the development, organization and implementation of training courses;
- Conducting research for identifying solutions to issues raised by the industrial sector development strategy; and,
- Coordinating and managing of industry development state support programs.

NATIONAL COMPETI- TIVENESS FOUNDATION OF THE REPUBLIC OF ARMENIA

CONTACTS

National

Competitiveness Foundation of the Republic of Armenia

Chief Executive

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The National Competitiveness Foundation (the Foundation) is a public-private partnership established in 2008 by the Government of Armenia and a group of global business leaders of Armenian descent from the United States, Russia, the EU and the Middle East. The purpose of the Foundation is to develop, implement and monitor projects in sectors - mainly education, health care and tourism - where there is a significant unrealized potential for development and a clear competitive advantage within a regional and global context.

In addition to operating in the sectors mentioned above, the Foundation develops cross-cutting programs to promote competitiveness through increased access to information and know-how.

The National Competitiveness Foundation of Armenia carries out its activities with the vision of building a knowledge-based economy through bringing together the national capacity of Armenia and Diaspora. The projects implemented by the Foundation are based upon the principle of public-private partnership.

The governing body of the Foundation is its Board of Trustees, which is composed of government representatives, distinguished international business executives, and representative of the international donor community in Armenia. The Chairman of the Board is the Prime Minister of the Republic of Armenia.

SMALL AND MEDIUM ENTREPRENEURSHIP DEVELOPMENT NATIONAL CENTER OF ARMENIA (SME DNC)

CONTACTS

“Small and Medium Entrepreneurship Development National Center” Fund of Armenia

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SME DNC provides state support to small and medium entrepreneurship in the country. SME DNC carries out its activities through a network of regional branches and representative offices covering all marzes (regions) of Armenia. SME DNC's duties are to:

- Ensure effective dialogue between SMEs and the government
- Increase efficiency and competitiveness of SMEs
- Ensure availability of business development services for SMEs
- Expand access to finance for SMEs
- Promote innovations and R&D activities of SMEs
- Assist establishment of new SMEs
- Support internationalization of SME activities.

SME DNC is also a member of the Enterprise Europe Network. The Enterprise Europe network serves as a “one-stop shop” for SMEs, providing free information and practical advice on market opportunities and on EU-relevant legislative and regulatory requirements for export purposes. The Enterprise Europe Network helps SMEs to find suitable business partners using its business and technology cooperation database, provides information on tender opportunities and supports international networking.

SME DNC is governed by a Board of Trustees headed by the Minister of Economy. Members of the Board of Trustees include the Deputy Ministers of Economy, Finance and Agriculture, President of Union of Entrepreneurs of Armenia, the Head of Expertise and Analysis Department of the Government, the Head of the “Armenian Entrepreneurship Small and Medium Entrepreneurship Association”, the Executive Director of the Union of Business Support Organizations, the Deputy President of Union of Manufactures and Businessmen (Employers) of Armenia, the Executive Director of the Union of Banks, and the Executive Director of the Union of Information Technology.

ARMENIAN DEVELOPMENT AGENCY (ADA)

CONTACTS

Armenian Development Agency

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The Armenian Development Agency was established in 1998 to facilitate foreign direct investments and promote exports. ADA acts as a “one-stop shop” agency for investors, assisting them in setting up their business in Armenia, helping implement projects, coordinating with the RA Government, providing information on local investment opportunities, and advising on the investment-related legal and regulatory framework. ADA is also responsible for export promotion, and assists companies in finding markets for products. In addition, it undertakes market studies and seeks out partners for joint ventures aimed at increasing the volume of exports and development of Armenian enterprises. ADA organizes international conferences, business forums, trade fairs and exhibitions. ADA is governed by its board, the chairman of which is the Prime Minister of Armenia. ADA's board includes the Chief Economic Adviser to the President; the Ministers of Finance, Economy and Foreign Affairs; the General Director of ADA; and Presidents/Directors of several private companies.

ADA provides the following services –

- Providing comprehensive information: Preparation of tailored information packages corresponding to the needs of foreign investors;
- Organizing site visits – Planning, preparing for and managing site visits by foreign investors, arranging appointments with both private and public organizations;
- Brokering business partnerships – Helping find appropriate business partners in Armenia;
- Follow-up support – Managing post-visit support, preparation of additional information and documentation;
- Investment project implementation – Assisting with company registration and staff recruitment (including job announcements and interviews); and,
- Liaising with government institutions.



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ABBREVIATIONS**100****ADA**

Armenian Development Agency

ADB

Asian Development Bank

AMD

Armenian Dram

BP

British Pharmacopoeia

CAPA

Corrective and Preventive Action

CDB

Culture of Dry Biomass

CIS

Commonwealth of Independent States

CJSC

Close Joint Stock Company

CRO

Contract Research Organization

CTD

Common Technical Document

DTL

Darmantest Laboratories

EBRD

European Bank for Reconstruction and Development

EMA

European Medicines Agency

EU

European Union

FEZ

Free Economic Zone

GDP

Good Distribution Practice

GMP

Good Manufacturing Practice

GLP

Good Laboratory Practice

GCP

Good Clinical Practice

GPP

Good Pharmacy Practice

GSP

Good Storage Practice

GXP

Good (Varies, ie Manufacturing, Distribution, Storage, etc.) Practice

HPLC

High Performance Liquid Chromatography

ICH

International Conference on Harmonization

IMB

Institute of Molecular Biology of Armenia

IPR

Intellectual Property Rights

ISO

International Organization for Standardization

JICA

Japan International Cooperation Agency

JV

Joint Venture

LLC

Limited Liability Company

LTD

Limited Company

MPI UNION

Medicine Producers and Importers Union of Armenia

MOH

Ministry of Health of the Republic of Armenia

NAS

National Academy of Science of the Republic of Armenia

NSS

National Statistical Service of the Republic of Armenia

OJSC

Open Joint Stock Company

PPP

Public-private Partnership

RA

Republic of Armenia

RAU

Russian-Armenian (Slavonic) University

RF

Russian Federation

R&D

Research and Development

SCDMTE

Scientific Center of Drug and Medical Technology Expertise

SEUA

State Engineering University of Armenia

SOP

Standard Operating Procedures

TNC

Transnational Corporation

UHPLC

Ultra High Performance Liquid Chromatography

UK

United Kingdom

U.N.

United Nations

U.S. (USA)

United States (United States of America)

USD

United States Dollar

U.S. FDA

U.S. Food and Drug Administration

USP

United States Pharmacopoeia

USSR

Union of Soviet Socialist Republics

VAT

Value Added Tax

WIPO

World Intellectual Property Organization

WTO

World Trade Organization

YSMU

Yerevan State Medical University after M. Heratsi

YSU

Yerevan State University



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