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# ASSESSMENT OF THE POTENTIAL OF THE ARMENIAN PHARMACEUTICAL CLUSTER

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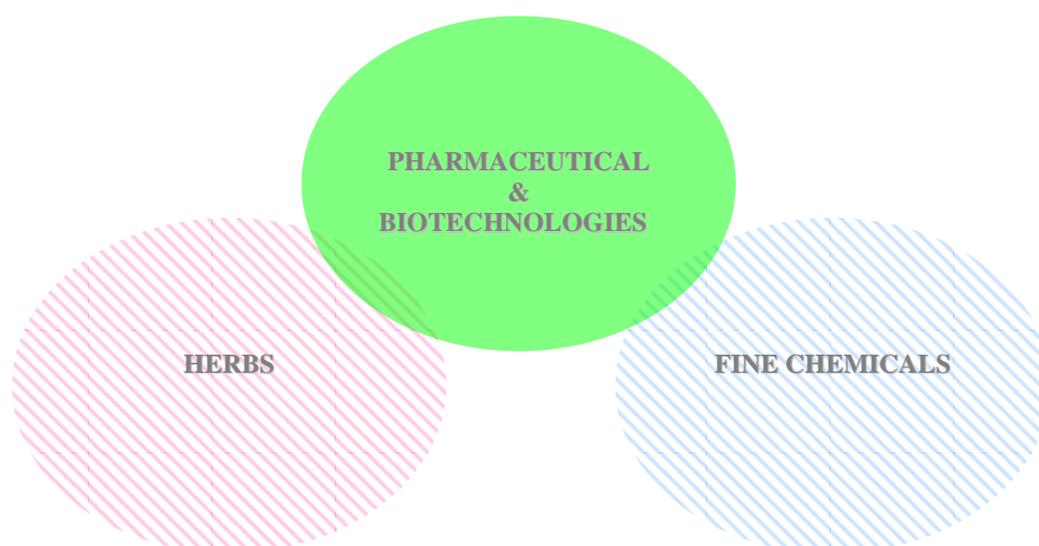
## TABLE OF CONTENTS

<b>1. INTRODUCTION .....</b>	<b>4</b>
<b>2. CLUSTER STRUCTURE .....</b>	<b>8</b>
<b>3. MARKET STRUCTURE, CONDUCT AND PERFORMANCE .....</b>	<b>16</b>
<b>4. COMPANIES AND STRATEGIES.....</b>	<b>21</b>
4.1 PharmaTech cjsc .....	21
4.2 Liqvor Pharmaceuticals cjsc.....	23
4.3 Arpimed cjsc .....	24
4.4 Esculap LLC.....	26
4.5 Yerevan Chemical Pharmaceutical Firm ojsc.....	27
4.6 Vitamax-E LLC .....	27
<b>5. SUPPORTING ORGANIZATIONS AND CLUSTER LINKAGES .....</b>	<b>30</b>
5.1 Government Agencies and Regulatory Framework .....	30
5.2 Quality Assurance Issues in Pharmaceuticals .....	33
5.3 Industry Related Associations.....	34
5.4 Educational Organizations .....	35
5.5 Supporting Infrastructure .....	36
<b>6. CLUSTER ANALYSIS TOOL-PACK.....</b>	<b>39</b>
6.1 SWOT Analysis.....	39
6.2 Value Chain of Pharmaceutical Industry .....	40
6.3 Diamond Model.....	41
<b>7. CONCLUSIONS .....</b>	<b>42</b>
<b>APPENDIX .....</b>	<b>43</b>

## 1. INTRODUCTION

The objective of this study is to provide guidance to CAPS in selecting additional industrial clusters for support and to rank the clusters in order of their attractiveness with respect to CAPS' objectives, i.e. growth in number of jobs, productivity, revenues and exports, and potential for increased competitiveness. The task will also provide guidance to CAPS and the industries in the content of their possible partnership. Within the framework of this report a detailed evaluation of **Pharmaceutical and Biotechnology Cluster** is provided.

When using the term “cluster” in our research, the consultant team does not assume the existence of a completely developed cluster with high inter-firm linkages and a critical mass of cluster players. The existence of cluster-related linkages and the stage of the cluster life-cycle within the cluster will be defined and evaluated based on the findings and results of the research. The purpose of using the “cluster” concept is to integrate the Pharmaceutical and Biotechnology companies and their supporting industries together with input and output markets within a single pool of study. In that, these supporting industries are mainly discussed in association with pharmaceuticals production and, the research does not cover those topics and issues of supporting industries which have no relationship with the pharmaceutical industry. In the discussion of the cluster we have mainly concentrated on pharmaceutical production, and wholesale and retail industries, while biotechnologies and fine chemicals are considered to be supporting industries and the main host of cluster innovation components.



The Armenian pharmaceuticals industry, which was mainly represented by one entity in Soviet times – the Yerevan Chemical Pharmaceutical Enterprise – in the past decade has

transformed into an independent industry with newly emerged domestic producers like Liqvor, PharmaTech, Arpimed, and Esculap. Simultaneously, the Armenian biotechnologies and fine chemicals industry has drastically deteriorated accompanied with undesirable and negative effects such as brain emigration, depreciation of fixed assets, lack of investments and new technologies. Fortunately, there were and are different international scientific organizations (ISTC, CRDF, etc), which act as donors and fund different scientific projects in fine chemicals and biotechnologies, therefore providing gradual development of these industries in Armenia.

Disorganization in the centralized system of drug supply has led not only to deficiency of medicines, but also to the appearance at the market of a number of drugs with unknown quality. After the fall of the Soviet Union, the market for pharmaceuticals was diversified and medicines began to be sold at the so-called street "little tables", posing challenges for proper control quality. However, there were some positive developments which made it possible to manage the quality of medicines at the pharmaceutical market by the end of the 1990s. These include the creation of a drug registration system in Armenia in 1992, and since 1997 identifying the requirements on the renewal of registration of all medicines, formerly registered in the USSR, and the introduction of licensing regimes for pharmaceutical enterprises and regulations on the import of drugs. According to data from the Agency on Drugs and Medical Technologies, the control of imported pharmaceuticals prevents the presence of poor-quality medicines (about 50 products per year) at the market. As a result, the percentage of unregistered medicines in the market was reduced from 28 % to 3-4 % for the period 1996–2001. Nevertheless, cases of selling medicines of unknown quality at community pharmacies are still observed. There are products that have bypassed the official import channels and others, produced in Armenia. Counterfeit medicines were also found among the products received through humanitarian assistance. The problem of counterfeit medicines exists all over the world, and during the last years counterfeit and poor-quality medicines were found out in many countries of the CIS.

The Certification system for pharmaceuticals, requiring the availability of a certificate of conformance for products at pharmacies, was introduced as a means of certifying quality through the channel of distribution. However it was cancelled very soon. This cancellation can be explained and is reasonable only by the fact that actually it has never operated at wholesaler and retail levels. As a result of the absence in the former USSR of the modern requirements on the organization of drug manufacturing, the industrial enterprises of that period did not meet the Good Manufacturing Practice (GMP) standards. Many manufactures continue to produce medicines under the same conditions, which do not assure an appropriate quality of products.

In the late of 1990s radical changes were held in pharmaceuticals and it started to expand slowly but with sustainable growth trends. New manufacturers appeared in the market, which were established partially or completely with foreign capital.

The industry is represented with companies either with 100% of foreign capital or 100% of domestic capital, or a mixed version of equity (40% foreign capital, 60% domestic capital). Besides, the representatives of this industry also attracted institutional investors such as EBRD (Equity financing in Liqvor Pharmaceuticals). The interesting thing within the Armenian pharmaceutical industry is the diversity of motivations for establishing pharmaceutical companies. None of the companies within the industry duplicates each other from the view of the motivation for establishment of a manufacturing unit in this industry. It means we may find, for example, a company which started manufacturing based on its extensive experience in drug wholesale and retail industry, and a company which started its operations as a green-field project with 100% foreign investments. At the same time, the industry is represented by relatively older firms, which were established in Soviet times (Yerevan Chemical Pharmaceutical Company) or were based on inter-hospital pharmacies (Liqvor Pharmaceuticals). The diversity of companies and their history provides evidence of a limited scope of entry barriers in the industry. Meanwhile, we should mention that the period of extensive growth of pharmaceutical companies is recognized by the manufacturers as a chaotic one and the low level of entry barriers was the result of inefficient regulation of this sector.

The experts agree that the pharmaceutical industry of Armenia has been developed and is continuing its development with a more rapid stride than biotechnologies and fine chemicals do. Indeed, we should mention that the pharmaceutical industry develops extensively rather than intensively. This is mainly due to different barriers for intensive development recognized by local manufacturers. The main impediments are the lack of R&D investments, obsolete scientific potential and limited scope of domestic market as well as strict regulation of the world pharmaceuticals market, which would obstruct further penetration of Armenian manufacturers into foreign markets. The potential for export promotion is feasible only in CIS countries given the current market situation and the competitiveness of local manufacturers.

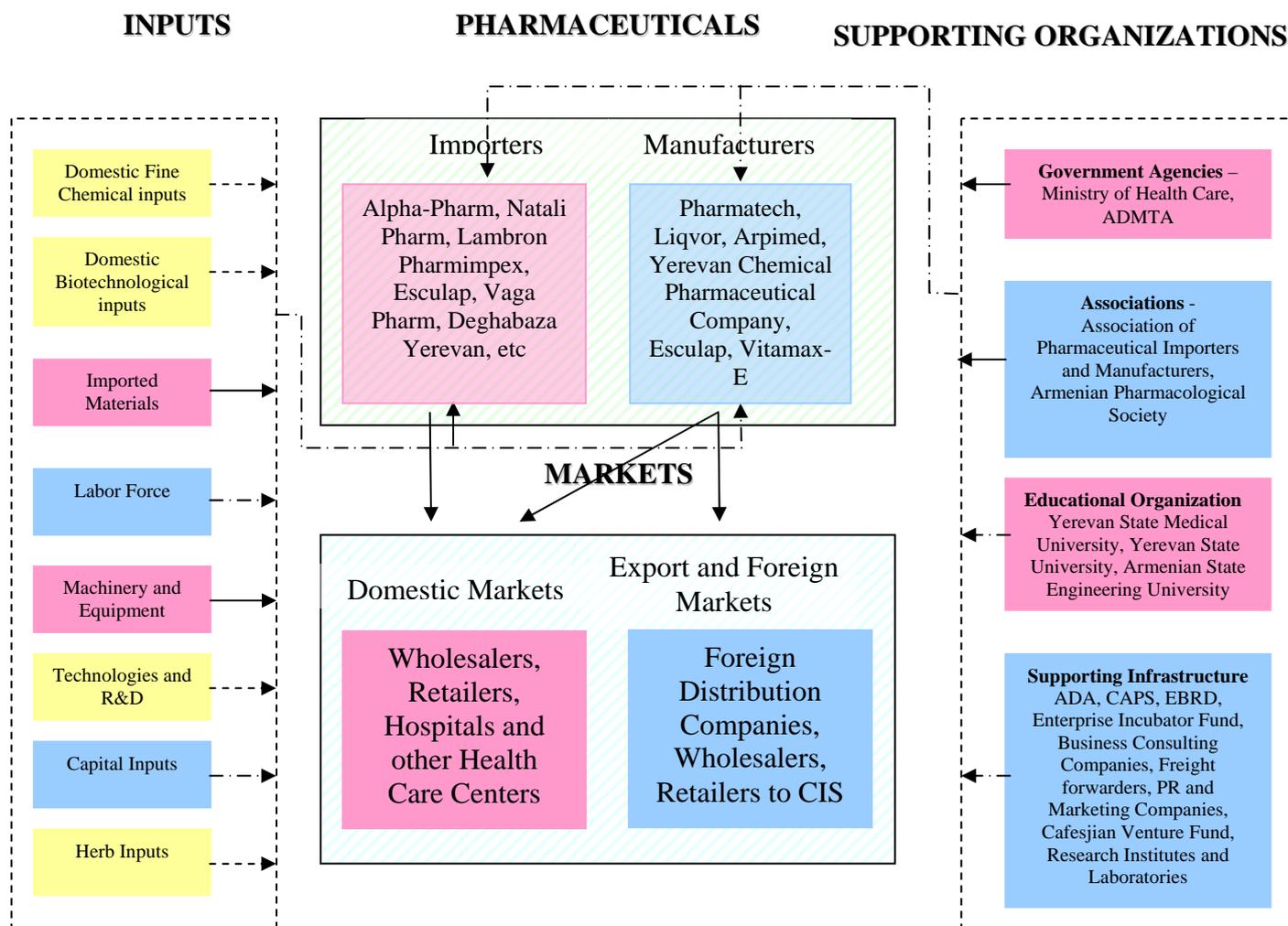
One of the most promising development directions, which may provide competitive advantages both in local and foreign markets, is phyto-pharmaceuticals. This direction will be mainly based on local inputs of herbs both cultivated and collected from different regions of Armenia. To date, 112 herbal medicinal products have been registered. Of all the nonprescription drugs in the Armenian pharmaceutical market, 23% consist of herbal medicinal products which represent \$100,000 to \$120,000 in annual sales volume. During the last decade, 13 local manufacturers of herbal medicinal products were licensed. The legislative basis for herbal medicinal products is the 1998 Law of the Republic of Armenia on Drugs. The basic authorization for herbal medicinal products in Armenia is the

Republic of Armenia's decision On the State Registration Procedure of Pharmaceutical Products and Payments for Their State Expertise of April 25, 2001. The experts of the Drug and Medical Technology Agency of the Ministry of Health of the Republic of Armenia published The Armenian National Formulary for Medicinal Plants and they are preparing to publish a list of essential medicinal plants.

In summary, the historical overview of the pharmaceutical cluster industries shows that it will be very difficult to clearly define the existence of an industrial cluster and relevant linkages between these sectors. However, we put a lot of efforts to quantify and assess the current situation as well as to evaluate current stage of cluster lifecycle based on the quantitative and qualitative assessment of interrelations and business linkages between pharmaceuticals, biotechnologies and fine chemicals in association with cluster supporting infrastructures.

## 2. CLUSTER STRUCTURE

Based on the research findings, a cluster map was elaborated for the pharmaceuticals cluster which illustrates in more detail the existing linkages and current status of each component.



- |           |                         |   |                             |
|-----------|-------------------------|---|-----------------------------|
| —————     | Strong Relationship     | <span style="display: inline-block; width: 20px; height: 10px; background-color: #f4a460; border: 1px solid black;"></span> | Well developed Components   |
| - - - - - | Developing Relationship | <span style="display: inline-block; width: 20px; height: 10px; background-color: #a4c4f4; border: 1px solid black;"></span> | Developing Components       |
| .....     | Weak Relationship       | <span style="display: inline-block; width: 20px; height: 10px; background-color: #ffffa4; border: 1px solid black;"></span> | Poorly developed Components |

The pharmaceuticals cluster is recognized as an interrelated aggregation of pharmaceutical, biotechnology and fine chemical industries in Armenia. The driver or

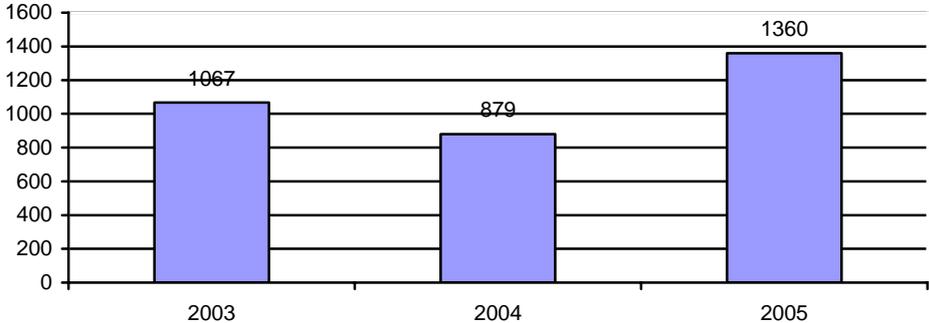
engine of the cluster is considered to be the pharmaceuticals. As described in the chart, the pharmaceutical industry is represented by two major groups of business entities – manufacturers and importers. In that, importers have been studied having their role of catalyst for the industry rivalry while the research is mainly focused on the pharmaceutical manufacturers.

The pharmaceutical industry is represented by 5 major manufacturers and 5-6 major importers. Domestic wholesale market of pharmaceuticals is estimated at \$40-45 million, while retail market is much bigger with more than \$55-60 million annual turnover. The major manufacturers of medicines are:

- PharmaTech cjsc
- Liqvor Pharmaceuticals cjsc
- Arpimed JV cjsc
- Esculap LLC
- Yerevan Chemical Pharmaceutical Firm ojsc
- Vitamax-E LLC

The list includes one representative of bio-additives and food supplement producers (e.g. narine) – Vitamax-E. There are also 4-5 minor producers of medicine, but the share of those entities is rather insignificant and we have not identified any developing trends for them. The majority of abovementioned companies are mainly specialized in the production of pharmaceutical products. But, for example, Esculap LLC diversifies its business activities with wholesale and retail trade, in that production comprises about 6-7% of revenues. Annual revenues of local manufacturers do not exceed \$6 million (or about 10-11% of domestic wholesale market of medicine) with 25-30% export share. These figures are also reported by the National Statistical Service of Armenia. If comparing dynamics of export during 2003-2005, we can find that the pharmaceutical industry provided 30% of growth for exports (2005 with 2003).

**Figure 1 Export of Armenian Pharmaceuticals ('000 USD)**



Source: National Statistical Service of RA

Foreign markets geography of Armenian pharmaceutical companies primarily covers CIS countries. Their finished products are marketed in Russia, Belarus, Ukraine, Central Asian countries, Georgia, etc. Export driver of Armenian pharmaceutical companies is the

existence of unsaturated market niches in target countries as well as the volume of demand in terms of absolute figures. There is no price-related incentive of exporting because local pharmaceutical companies export their products with lower prices in comparison with domestic ones. This situation is explained by managers of pharmaceutical companies with the economies of scale existing in export markets.

It is obvious that about 70% of local pharmaceutical products are marketed domestically. The following figure illustrates structure of annual turnover of local producers.

The largest manufacturer of pharmaceuticals is PharmaTech cjsc. Esculap LLC is a beginner in production and the major share of its revenues are generated from wholesale and retail trade of medicine. It is identified that only 25-30% of production capacities are currently used by local pharmaceutical companies.

Armenian pharmaceutical companies were established in different periods and different ways. The variety of motivations and the ways how these companies were established is explained with relatively low level of entry barriers in their establishment period. For example, Liqvor Pharmaceuticals, which is a coeval of the independence of Armenia, started its business on the basis of inter-hospital drugstore with completely private local investments. In contrast, PharmaTech, which was established in 1997, started its activities with 100% foreign investments. Another case of foreign investments is represented by Arpimed with 49% of foreign direct investments. The oldest pharmaceutical company is Yerevan Chemical Pharmaceutical Firm, which was established on the basis of former state-owned enterprise – the only pharmaceutical company in Armenia during soviet times. The company was privatized in 1990s and did not change its specialization given sufficient local demand for its pharmaceutical products as well as exporting opportunities in terms of barter with CIS countries.

Total investments of the abovementioned companies are estimated at about \$22.6 million. As a result of our studies the following figures were identified and presented in the report:

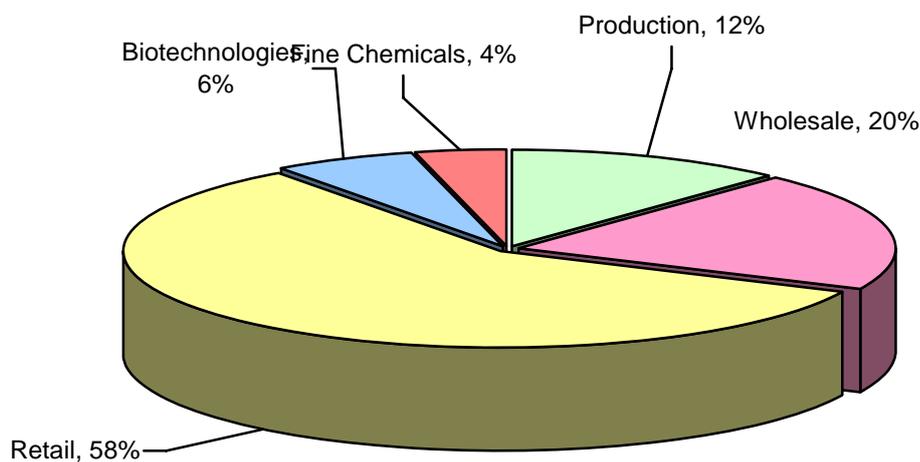
Although the main part of the investments was implemented during 1997-2002, we have identified that the pharmaceutical industry continues absorbing new investments by private and institutional investment organizations. Particularly, Liqvor Pharmaceuticals has been targeted by EBRD as an attractive investment project and during 2005. In fact, the industry is mainly financed by reinvestment of retained earnings of the companies as well as attracting short-term and mid-term loans from local commercial banks.

Current situation of pharmaceutical industry of Armenia can be described as a transition one to more improved production phase. This is obvious when discussing the structure of investments currently utilized by Armenian pharmaceutical companies. The vast majority of the investments are targeted to cover capital expenditures such as construction of plant

and workshops, acquisition of new equipment, introduction of internationally recognized standards, e.g. HACCP, ISO 9001-2000, GMP, etc. This tendency is identified in the development projects of Liqvor Pharmaceuticals and Esculap. Currently, these companies are implementing long-run investment projects aiming at construction of new production facilities according to the requirement of international standards for pharmaceutical industry.

Current employment level of pharmaceutical industry is rather insignificant. We found out that 550-600 employees are involved in the production of pharmaceuticals. However, when discussing the employment level of the cluster, which includes also wholesale and retail trade, biotechnologies and fine chemicals, it is estimated about 4,800-5,000. The structure of employment by cluster-related industries is as follows:

**Figure 2 Structure of Employment of Pharmaceutical Cluster in Related Industries and Spheres**



The main list of pharmaceutical inputs are imported from developed countries such as USA, Canada, Great Britain, Netherlands, Japan, Germany, etc. Given the share of material expenses in ex-works price is 40-45%, it is obvious that import volume of pharmaceutical substances and materials is estimated at about \$2.3 million. Local pharmaceutical companies import about 100 different substances and materials used in their production. Only some herbs (as inputs) are supplied by local companies, which mainly satisfy production needs of Esculap LLC (this company produces different kinds of medical extracts and liquid preparations based on local and imported herbs and herbal substances).

The next major component of inputs is working force or labor expenses, which makes up about 25-30% of ex-works prices of products manufactured by local pharmaceutical companies. It is estimated that annual remuneration fund of the industry amounts to \$1.6 million. Average monthly salary is estimated at \$220 per employee.

R&D expenses, technologies and equipment (in terms of amortization and depreciation), capital expenses (in terms of interests and dividends) as well as other indirect overheads make up about 8-10 % of ex-works prices. This figure shows low level of innovations, new product development efforts as well as absence of long-run strategic ambitions, which should be set for ensuring clear strategic vision of industry development. The situation of R&D in Vitamax-E case, which manufactures probiotics and other biotechnological substances, is rather different. The company spends about 20% of its revenues on R&D activities.

Wholesalers and importers of medicine are the next group within the core of the cluster. There are more than 100 wholesalers and importers in domestic market; however, the concentration ratio of the four largest companies is significantly high. The major market players among importers and wholesalers of medicine are:

- Natali Pharm
- AlphaPharm
- Lambron Pharmimpex
- Vaga Pharm
- Deghabaza Yerevan
- Esculap, etc.

It is estimated that the importers of medicine cover about 85-88% of domestic wholesale market of drugs. Some importers diversify their businesses establishing local retail trade chain, which serve both imported and locally produced pharmaceutical products. In recent years, there was no tendency of establishing pharmaceutical production by importers. This fact proves that entry barriers to this industry become stricter. It means that the local production of pharmaceuticals cannot be considered as a pure competitive industry. This argument is not true for retail trade of pharmaceuticals, because we identified more than 600 retail trade entities (drug stores). In case of probiotics and other bio-supplements, the imported goods cover only 60% of domestic market, which 40% of domestic demand is satisfied by local producers.

In fact, wholesalers and retailers are mainly specialized or concentrated on imported medicine given small share of local pharmaceutical production in the domestic market. Therefore, when talking about cluster linkages between pharmaceutical production and retail-wholesale trade, it is necessary to mention that this relationship is limited with the scope of local production. The same situation is identified between pharmaceutical industry, biotechnologies and fine chemicals. Practically there is no relationship between those industries. Even if we identified some potential linkages for cooperation, however, in practice, these cooperation opportunities are not realized. The main issues currently

hindering or limiting the cooperation between pharmaceuticals, biotechnologies and fine chemicals are as follows:

- Limited scope of supply needs by local pharmaceutical companies;
- Limited financial resources of local pharmaceutical companies necessary for Research and Development works;
- Inadequacy of requirements set by pharmaceutical companies for the input supply by local biotechnologies and fine chemicals (e.g. representatives of pharmaceutical industry acquired GMP certification, which requires that the supplier of the company should also have GMP standards)
- Obsolete technologies and laboratory equipment of biotechnologies and fine chemicals;
- Limited scope of strategic development goals in pharmaceuticals, which do not target long-term strategic goals of improvement of R&D activities in the industry;
- Due to abovementioned issues the inputs, which can be supplied by biotechnological and fine chemical industries, are more expensive in comparison with imported ones.

The potential growth of PBFC in terms of employment, production, sales and export is estimated based on the following assumptions and findings:

1. Currently Armenian pharmaceutical companies use only 30% of their production capacities.
2. Local wholesale and retail markets of drugs are becoming more saturated
3. There is no coherent industry development strategy and vision.
4. The inter-firm linkages between cluster stakeholders are in a low level. This assumption mainly relates to cooperation level of pharmaceuticals, biotechnologies and fine chemicals.
5. The industry is well regulated and the regulation environment is being periodically improved.
6. Pharmaceutical industry is represented by well functioning and gradually developing firms, and their interests are united in a well functioning association (Association of Pharmaceutical Importers and Manufacturers).
7. Local market is growing and there are potential domestic market niches for penetration by local producers.
8. The cluster is supported with relevant well-developed academies or educational institutions, and the relationship between pharmaceutical industry representatives and academies is considered to be in a developing stage.
9. Qualitative development of the cluster needs a lot of financial resources to be spent on R&D.
10. Currently foreign markets are limited with CIS countries.

11. Local pharmaceutical industry needs standardization and adoption of internationally recognized standards (GMP, ISO and HACCP), as well as meet quality requirements of foreign markets.
12. There is a necessity to establish national GMP standards for pharmaceutical industry.
13. There is a significant potential of establishing export-oriented production of herbal medicine.
14. Regulation of European markets for herbal medicine is in a transition period. This is a very good opportunity for development of local herbal medicine with export orientation to European markets.
15. There is a necessity to establish international certified herbal standardization laboratory to foster local production of herbal medicine.
16. In local market some venture funds are being established aiming at financing of pharmaceutical, biotechnological and fine chemical projects in Armenia, etc.

Given the abovementioned assumptions and findings, it is estimated that employment growth potential is not high if excluding herbal medicine development. Otherwise, the cluster will be expanded and the employment will be increased if well developed local chain of herb cultivation and collection will be established. Besides, the cluster will be expanded, and cluster-related linkages between pharmaceuticals, biotechnologies and fine chemicals will be intensified given export potential of herbal medicine.

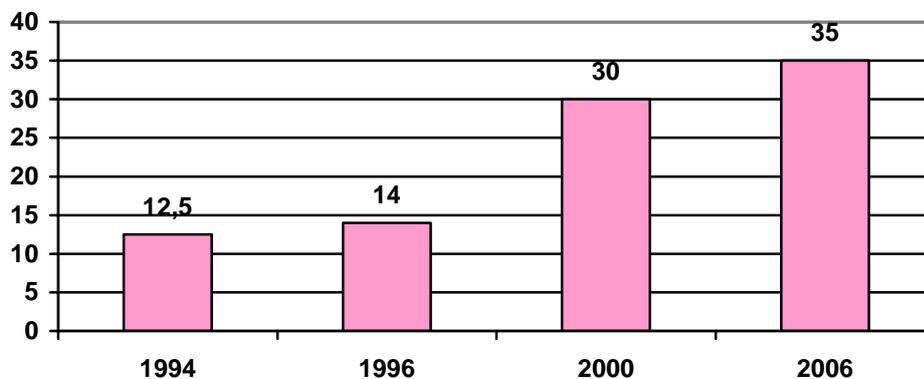
Growth potential in terms of production and sales will be realized (excluding herbal medicine) given current development strategy of pharmaceutical companies and ongoing capital expenditures of the industry. If fully realizing production capacities of local pharmaceutical industry, the production and sales will be increased by threefold with 45-50% of export share. It means that the potential of production and sales growth is estimated up to \$15.75 million (22-25% of domestic market), where export will reach up to \$7.5 million. Given current development trends, we assume that abovementioned targets are feasible during the next 4-5 years.

Given recent export growth of herbal medicine from Less Developed Countries to Developed countries, it should be noted that within the framework of the development of PBFC cluster, herbal medicine may play an important role. Sales of herbal medicine alone were estimated to have exceeded US\$ 12.5 billion in 1994 and US\$ 30 billion in 2000, with annual growth rates averaging between 5% and 15%, depending on the region. The herbal supplements market had an even higher annual average growth rate of 25% between 1990 and 1997.

According to international statistics (UN COMTRADE) the global herbal medicine market will surpass USD 35 billion in 2006. The use of natural and alternative medicines in the United States and Europe also continues to expand. World Health Organization figures

show that four billion people, nearly three-fourths of global population, have tried or currently use herbal medicine. Analysts see room for rapid growth in this market.

**Figure 3 Global Herbal Medicine Market, billions of USD**



Medicine in the U.S. is being profoundly affected by two contradictory trends. One is the increasing number of biotechnology products and processes, and the other is the growing use of herbal medicines.

Herbal medicines have a long history in Europe, where for over 100 years their quality control and good manufacturing practices have been comparable to those of conventional drugs. The global market for herbal medications in 2006 was estimated at about USD 35 Billion, distributed in the following manner: Europe; USD 17.5 Billion, Japan; USD 6 Billion; North America, USD 4 Billion; and the rest of the world, USD 7.5 Billion.

Economically and technologically, Germany has the most developed herbal medicine industry and the single largest market (\$3.5 Billion), followed by those of France (\$1.8 Billion) and Italy (\$0.7 Billion). The reason European consumers show such a strong preference for herbal remedies largely is due to an aging population afflicted with chronic diseases for which modern medicine has few satisfactory treatments. Consumers, who often reject conventional drugs with their potentially severe side effects, often prefer natural alternatives.

In Europe, consumer attitudes fit into a medical establishment that accepts the use of herbal medicines (i.e. phytopharmaceuticals). Courses in the use of herbal medicines are a regular component of medical and pharmacy curricula, and since 1993 this subject has been a regular component of medical and European medical examination. More than 70% of general practitioners prescribe herbal medicines, most of which are reimbursable by the public health insurance system.

The existence of a legal framework for herbal products has certain important consequences: they can be sold as drugs with both labels and inserts providing the

necessary information; they can be prescribed by physicians; they are reimbursable through medical insurance schemes.

In Europe, herbal medicines can be sold through apothekes (which also sell prescription drugs), pharmacies (which sell OTC products and cosmetics) and natural food stores. In the future, this system is likely to undergo major changes, since new EU regulations will require herbal medicines to be treated in the same way as chemical products or be sold only as a traditionally used drug.

The largest categories of herbal medicines sold in Europe are cardiovascular and respiratory treatments, tonics, and digestives.

### 3. MARKET STRUCTURE, CONDUCT AND PERFORMANCE

As mentioned earlier in the cluster map, the market of the cluster is a pool of finished pharmaceuticals or medicine, which is represented by imported and locally produced pharmaceutical products. The market for the pharmaceutical cluster is studied based on “*structure-conduct-performance*” paradigm.

**The market structure** is discussed with two dimensions – domestic market and foreign markets. As described in the previous chapter, the geography of export of pharmaceutical products mainly covers CIS countries. In that, it is noticeable that the vast majority (70-75%) of pharmaceutical exports target Belarus, Georgia and Russia. There are different motivations for targeting the abovementioned markets.

**Georgia** is a neighboring country, and transportation costs as well as market regulation standards allow organizing cost effective export of pharmaceutical products by Armenian manufacturers. **Russia and Belarus** provide attractive markets for Armenian pharmaceutical manufacturers given large volume of these markets. Below we describe the key trends and the structure of these markets in terms of production, sales and imports.

*The pharmaceutical market in Russia and Belarus includes the production and sales of medicines, biologically active food additives and preparations used for medical purposes. This is the fastest growing market in these countries. According to the data of the DSM Group research company, the total volume of this market amounted to USD 9.01 billion (about 2% of the world's market) in 2006, registering a 35% increase from the 2005 indicator.*

*The products circulating on this market and the respective cash flows are dealt with by the following groups of players: producers, distributors, retailers and the final consumers. Foreign companies play a key role on the Russian market of medicines. According to the DSM Group, their products account for 76% of the Russian market in value terms, with the two European companies - Sanofi-Aventis and Berlin-Chemie/Menarini Group being the market leaders. The Pharmstandart holding, which is the best of the Russian producers, is among the five leading companies, and Dr. Reddy's Laboratories Ltd., the Indian pharmaceutical company leading in the volume of sales, is among the 20 leading companies on the Russian market (in value terms).*

*In 2005, the Russian companies (like other companies on the world market) displayed a tendency towards mergers and takeovers. The Pharmstandart holding, for instance, changed hands recently: five pharmaceutical enterprises earlier owned by the US Company ICN, were purchased by a Russian investor. The new owner has added the new purchase to his old property - the UfaVita vitamin factory (based in Ufa). This has made it possible to establish Russia's largest pharmaceutical company uniting seven factories, i.e., Pharmstandart-Tomskkhimpharm, Pharmstandart-Leksredstva, Pharmstandart-Oktyabr, Pharmstandart-Marbiopharm, Pharmstandart-Polipharm, UfaVita and Fitopharm-NN.*

*The Otechestvennyye Lekarstva (National Medicines) holding formed several years ago is second largest among the Russian producers. It incorporates the Shchelkovo vitamin factory, Kraspharma and Novosibkhimpharm. All the above companies belong to Russian capital. Another major Russian pharmaceutical company - Nizhpharm - was purchased by Germany's Sttada Arzneimittel AG in 2004.*

*The most pressing issue for Russia today is the transition to international quality standards (Good Manufacturing Practice) in the production of medicines. At present, all the intellectual and investment efforts of the leading national producers are concentrated in this sphere. In the near future, GMP certification will be obligatory for Russian pharmaceutical factories. The range of products of Russian pharmaceutical enterprises consists mostly of generic medicines (generics, or non-patented medicines, are those medicines the active substances of which are no longer protected by patents, therefore they can be produced by any pharmaceutical company which has synthesized or bought this active substance on the chemicals market). Polysan, nearly the only Russian pharmaceutical company producing the original antivirus medication Cyclopheron, accounts for 11.5% of Russia's exports of medicines.*

*Despite the generic character of production, leading national producers, following the example of their foreign colleagues, have started producing their medicines under original brands putting sizeable funds and effort into the promotion of these brands. The forthcoming introduction of the obligatory GMP certification, the Russian producers' marketing strategies, and the tendency towards mergers and takeovers - all this shows that the Russian pharmaceutical companies are keeping abreast of the world trends.*

*Yet another conspicuous trend of the Russian pharmaceutical market is the localization of production by foreign pharmaceutical companies. Thus, Hungary's Gedeon Richter and Slovenia's KRKA have already built their factories in the Moscow Region and the construction of a factory of Yugoslavia's Hemopharm in Obninsk (Kaluga Region) is nearing completion.*

*Nearly all generics produced in Russia are made from imported raw materials, which is important for understanding the specifics of Russian pharmaceutical production. Pharmaceutical substances worth USD 97.7 million were brought into Russia in 2005 mostly from Germany, China, India, Switzerland and the Czech Republic.*

*Despite the localization tendency, a larger portion of medicines is imported now by both producers and pharmaceutical distributors, with producers accounting for 33% and pharmaceutical distributors for 53% of all pharmaceutical imports to Russia. Pharmaceutical distributors play the key role in ensuring the turnover of medicines all across the country. There are pharmaceutical distributors working on a nationwide scale, in all the constituent Federation members, and small local distributors operating on local and regional markets.*

*According to the latest rating of the Pharmexpert Marketing Research Center, the leading national distributors are TsB Protech, SIA International, ROSTA, the Shrea Corporation, Biotech, NPK Katren and Apteka-Holding. Most of these companies belong to Russian capital; Tamro, a Finnish pharmaceutical distributor, is the only foreign company having a*

stake in a Russian company - ROSTA. As for the Apteka-Holding company, the Carlyle investment group recently sold it to Alliance UniChem, a British pharmaceutical distributor. Like all markets closely connected with people's health, the pharmaceutical market is toughly regulated by the state. A certain set of state bodies' permits is necessary for work at any stage of the pharmaceutical market. Pharmaceutical producers need a license for the production of medicines and the obligatory certification of production (in the near future, the application of the internationally accepted GMP rules will also be obligatory). The trading organizations must have a license for wholesale or retail trade in medicines. Besides, the producer must receive a certificate of conformance for each batch of medicines and, if medicines are imported by a distributor, it is the distributor who must get such a certificate.

The state became more active on the Russian pharmaceutical market in 2006. It launched a program of Additional Provision of Medicines (APM) under which the categories of citizens enjoying state benefits (for instance, invalids, pensioners, etc.) receive medicines prescribed by doctors at state polyclinics free of charge, at the expense of the state. In future, the state is planning to pay even more attention to the provision of the population with free medicines. The government may allocate up to about USD 178 million for the APM program.

Despite the emergence of such a strong player as the state, all sectors of the pharmaceutical market registered growth, albeit not so fast. The segment of hospital medicines purchased by health care establishments grew by 9% (from USD 710 million in 2005 to USD 774 million in 2006), the retail pharmacy segment (drugstores) registered the same 9% increase (from USD 4,776 million to USD 5,215 million), and the parapharmacy sector demonstrated the most impressive 41% growth (from USD 1,170 million to USD 1,652 million)

Commercial sales of medicines to retail buyers through drugstores account for a larger share of the Russian pharmaceutical market. Like all other sectors, this sector obviously tends to unite drugstores into a single network. It is easier for network drugstores to work with pharmaceutical producers and distributors and attain better terms for them. In turn, the distributors and producers have to take various marketing measures to win network drugstores to their side. The attempts made by state and municipal bodies to restore their active role on the retail pharmaceutical market through uniting the drugstores that have not yet been privatized have become an important factor of late. Thus, the Moscow region's government has recently started creating a pharmacy chain uniting 502 municipal drugstores under the Mosoblpharmacia Company.

Private pharmacy chains also play a significant role on the retail pharmaceutical market. The largest of them (in turnover terms) are Apteka 36'6, Pharmakor, Implosia, 03, Doctor Stoletov, Vita, Rigla, Natur Produkt, Pervaya Pomoshch (First Aid) and Stary Lekar (Old Doctor). The 03 pharmacy chain, one of the leaders on the market, has been formed by merger of the two chains, i.e., ICN and Chudo Doktor (Wonder Doctor).

Despite the ongoing concentration of retail pharmaceutical turnover in drugstore networks, ten leaders account for merely 13.4% of this turnover. Most probably, the number of drugstores will not change greatly. At present, one drugstore services about 3,200 citizens. The concentration of drugstores in Russia is one of the highest among European countries: in Italy, for instance, one drugstore services 3,300 and in France 2,200 people. Thus, the Russian pharmaceutical market demonstrates a high degree of integration into the world market responding sensitively to the latter's trends. It is growing at an unprecedented pace. This gives a chance not only to the acting players to succeed on the market, but also to the newcomers who will manage to fit well into the stringent confines of state regulation, streamline the business process and find their bearing in today's highly competitive environment.

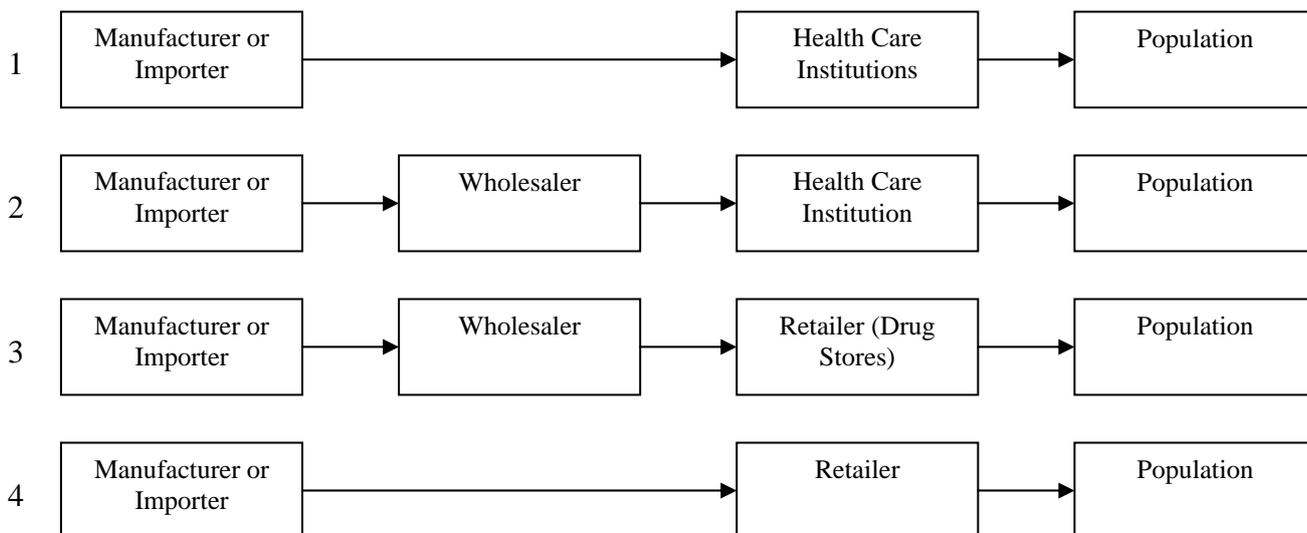
As the abovementioned analysis shows, Russian and Armenian pharmaceutical markets have similar and, at the same time, different characteristics. It is obvious that Russia also stands for the implementation of national GMP standards mandatory for all pharmaceutical manufacturers. The same issue characterizes Armenian market of pharmaceuticals. This means that the similarity of market environment is the next incentive for exporting of Armenian medicine to Russia.

On the other hand, given strict regulation of developed countries such as EU countries, US, Canada the market opportunities are rather insignificant, while CIS countries, which have merely the same regulating environment as Armenia, may be discussed as a core target markets for Armenian pharmaceutical products. From the other hand, in the future developed countries can be considered as target markets for specific biotechnological and fine chemical products.

Domestic pharmaceutical market is represented with 5 major manufacturers, about 10 large importers, more than 100 wholesalers and about 600 of retailers (drug stores). As mentioned earlier, domestic wholesale market of pharmaceuticals is estimated at \$40-45 million, while retail market is much bigger with more than \$55-60 million annual revenues. Annual revenues of local manufacturers do not exceed \$5.25 million (or about 10-11% of domestic wholesale market of medicine) with 30% export share. It means that the domestic market is dominated by imported medicine with more than 88% of market share. Local manufacturers are mainly specialized in the production of generic drugs (there are 4-5 brand drugs), which are marketed with the following forms:

- Tablets;
- Capsules;
- Ointments;
- Sterilized liquid preparations, including intravenous infusion liquids;
- Ophthalmologic medical preparations;
- Herbal extractions and liquid preparations (only produced by Esculap)
- Antiseptic preparations, etc.

The major part of these generic drugs is included in essential drug list adopted by Armenian government. Therefore, the major share of local pharmaceutical production is marketed directly through hospitals and other health care institutions. We have also identified other distributions channels, which are depicted as follows:



Generally, domestic market of pharmaceuticals is saturated. However, the share of imported and locally produced drugs is being changed on behalf of local manufacturers. This tendency will have continuing character if new law on drugs will be adopted. It will provide more transparent and will fill those gaps, which are reflected in current law.

Pricing policies of local manufacturers and importers are different. Pricing policies mainly depend on the selection of distribution channels, which are described above. However, we should mention that impressive pressure of foreign exchange fluctuations may harm the position of local manufacturers making them change their pricing policies and seek more efficient ways to realize their market opportunities both in domestic and foreign markets. The importance of this issue is stressed by the absence of foreign exchange hedging mechanisms. However, we also identified that 40-45% of ex-works prices are made of imported materials, which, to some extent, mitigate the foreign exchange pressure.

From the other hand, drug importers benefit from appreciation of Armenian dram against US dollar, thus it is expected that wholesale and retail prices of imported drugs either will be decreased or importers will earn high short-run profits. Having the abovementioned phenomenon in the market, one may expect that local drug manufacturers shall diversify their business activities and try to establish wholesale (import and domestic wholesale) or retail trade chains to control the pricing pressures by major importers.

Market promotion activities of local manufacturers are rather insignificant. However, we identified that currently more attention is given to promotion activities.

Market performance of Armenian pharmaceutical companies can be described with average profitability of 20-25%. In that, the major share of production costs belongs to imported materials and other inputs (40-45%). The profitability rate varies in domestic market and is rather lower in case of export. These variations occur mainly due to

changing market conditions and selected distribution channels as well as prices of purchased materials. It is obvious that, in case of export, companies should conform to lower prices and, therefore, with lower profitability rates. It is compensated with economy of scale as the export markets demand for larger volumes of products than domestic ones. The following figure shows estimated annual sales revenues and export amounts of abovementioned pharmaceutical companies:

Export share of 3 major pharmaceutical companies is about 25-30%. This figure is rather insignificant, when discussing the amount of imported materials for pharmaceutical industry. This unrealized export potential is a result of inadequate marketing strategy.

## 4. COMPANIES AND STRATEGIES

### 4.1 PharmaTech cjsc

Contact Person	Mr. Vahan Arushanyan – General Manager
Address	7 Baghramyan avenue, Yerevan, Armenia
Legal Status	Closed Joint Stock Company
Telephone	+ 37410 58 16 20
Major Product Line	Intravenous Infusion Solutions, Ophthalmologic Preparations (Eye drops)

PharmaTech cjsc is a wholly foreign owned pharmaceutical manufacturing company based in Yerevan. The Company was established in 1997. It is mainly specialized in the production of large volume intravenous solutions and eye drops. The scope of work also includes the development, manufacture and distribution of pharmaceutical products.

PharmaTech factory building is one of the most advanced of its kind in this region. The installation of the European Modular Equipment was carried out, in accordance with GMP standards by IPM of France. PharmaTech cjsc is managed in association with Cambridge Pharmaceuticals of London. Production started in June 1998. Today it produces 64 different Intravenous solutions of various types and volumes, as well as 5 different eye drops, the production of which started in March, 2005. The capacity of 3 million bags per year is well in excess of the requirements of Armenia and many products are already registered and distributed in Russia, Georgia and Turkmenistan.

PharmaTech has also clean room facilities for packaging of solid dosage forms. Packaging under license of branded products of Apotex (Canada) started in 2000. The factory also includes highly equipped, ambient and temperature controlled warehousing system occupying 7.500 sq. m.

GlaxoSmithKline, Schering Plough and Novartis are represented by PharmaTech in Armenia and the consignment stock of their products is kept at the plant warehouses. The stock is used to service the requirements in the Caucasus region in general. PharmaTech CJSC was the first pharmaceutical company in Armenia ISO 9001:1994 systems certified in November 23, 2000 by Quality Management Institute QMI. Starting from November 9, 2004 PharmaTech CJSC quality system is GMP and ISO system certified for the design and manufacture of intravenous solutions (certificate numbers GMP/LE2004/002 and EG04/040161QA). The certification has been carried out by Swiss certification company SGS.

Production process is fully automated and requires 9 specialists and operators to be engaged in this process. The Company covers about 70% of domestic market of intravenous solutions (based on their estimations). The rest of local market demand is satisfied by imported products and those produced by Liqvor Pharmaceuticals. The Company has its exclusive distributor in domestic market, which provides wholesale and retail trade of the Company's products. Currently, the Company mainly targets Georgian intravenous solutions market using business linkages with Georgian wholesalers and retailers.

This is the largest pharmaceutical project ever implemented in Armenia. The Company uses about 20 names of different substances and materials. 100% of its production materials and inputs are imported. According to the General Manager, they used to cooperate with domestic suppliers, but the trial had negative results due to higher prices, delivery delays, inadequate quality, etc. Currently, the Company manages to utilize only 30% of its production capacities. Share of R&D expenses does not exceed 10% of total production costs. However, the Company gradually increases its R&D activities ensuring new product development and commercialization through use of its own R&D resources (specialists, technologies, etc.).

The major issues of pharmaceutical industry, mentioned by the General Manager of the Company are as follows:

- Tax regulation
- Incomplete legislation
- Absence of domestically available quality inputs
- AMD appreciation against USD
- Limited scope of domestic market demand, etc.

PharmaTech has no experience with herbal medicine. However, the General Manager thinks that this specialization is highly demanded and can be based on domestic herbs. However, there are market-related and standardization problems, which hinder production and export of phyto-pharmaceuticals in Armenia.

## 4.2 Liqvor Pharmaceuticals cjsc

Contact Person	Mr. Sergey Matevosyan – General Director
Address	6 Margaryan street, Yerevan, Armenia
Legal Status	Closed Joint Stock Company
Telephone	+ 37410 318159; 318158
Major Product Line	Intravenous Infusion Solutions, Ophthalmologic Preparations, Injection Solutions, Local Haemostatic Preparations

Liqvor Company was founded in May 1991 and became the first non-governmental enterprise in Armenia producing finished drug preparations. In August 2005, Liqvor signed a major investment agreement with the European Bank of Reconstruction and Development (EBRD). The investments are implemented using loan and Direct Investment Facility mechanisms of EBRD.

Liqvor Pharmaceuticals is the member of the Chamber of Commerce and Industry of Yerevan and the Founder of the Association of Pharmaceutical Manufacturers and Importers of Armenia.

The main competitors of Liqvor Pharmaceuticals in the domestic market are PharmaTech (in terms of intravenous infusion solutions) and similar imported product of Bulgarian origin.

Within the framework of EBRD project, the Company manages to construct new production facilities and buildings to meet the requirements of international standards. Currently, the Company's production premises are located in the ground floor of one of the buildings of Republican Hospital. Current location of Company's production facilities hinders ISO and GMP certification of the Company.

However, Liqvor Pharmaceuticals tries to follow the requirements for the manufacturing process and the quality of medications set by the World Health Organization (WHO) and the rules of the Good Manufacturing Practice (GMP). Liqvor Pharmaceuticals quality management system includes Control and Quality Assurance Department. The Company controls all inputs and the quality of the finished products through well-equipped analytical and microbiological laboratories.

The Company's inputs are fully imported. The major suppliers of the Company are represented by developed countries such as USA, Japan, European countries, etc. It uses about 90 materials and substances in the production process.

The Company has no experience in herbal medicine and phyto-pharmaceuticals. General Director of the Company stressed export potential of herbal medicine and phyto-pharmaceuticals given the existence of high quality of local herbs. However, it will take great efforts to establish well functioning cultivation, collection, preparation and standardization of herbs for pharmaceutical use. The feasibility of establishment of herbal pharmaceutical production mainly depends on the organizational skills and it will take little financial resources, regardless establishment of certified herbal standardization laboratory.

### 4.3 Arpimed cjsc

Contact Person	Mr. Vachagan Ghazaryan – General Director
Address	19 2 <sup>nd</sup> microregion, town of Abovyan, Armenia
Legal Status	Closed Joint Stock Company
Telephone	+ 37422 2 17 03
Major Product Line	Different kinds of tablets, ointments, capsules, solutions, disinfectants <sup>1</sup> , Dietary Supplements, Veterinary preparations

Established in 2001 by the design of the European specialists, Arpimed pharmaceutical company is engaged in manufacturing of medicines, prophylactic and medicinal agents used in dentistry, antiseptic and disinfecting solutions, diagnostic preparations as well as medicines for veterinary use.

The geography of export mainly covers CIS. Currently the company is applying for registration of its medicine in Cyprus and Greece. The company produces the following forms of drugs:

- Tablets,
- Ointments,
- Capsules
- Solutions,

Arpimed product-line is a combination of essential drugs listed by Armenian Government. It has about 42 medical products registered in Armenia and in the following CIS countries: Ukraine, Belarus, Uzbekistan, Georgia. The Company intends to penetrate Russian pharmaceutical market and applies for registration of its product-line in Russia.

The production premises of Arpimed pharmaceutical company is as follows:

- Department of solid products
- Department of liquid products

<sup>1</sup> Full list of medicine produced by Arpimed is available in [www.arpimed.am](http://www.arpimed.am)

- Department of soft products
- Department of sterile products

Quality control on raw materials, intermediate and finished products is performed in the clinical, microbiological, and scientific laboratories equipped with up-to-date devices, reagents are provided by Merck Sharp. The company is certified according to GMP standards. It has also ISO 9001-2000 certificate audited by German accredited company - TUV.

Full list of its inputs are imported from Great Britain, Switzerland, Spain, Italy, China, India and Iran. The Main suppliers of the Company are:

- MEDEX (Great Britain)
- Select Chemia (Switzerland)
- ENDURA (Italy)
- GOMZOL (Spain)
- UFENC (China)
- UNZEN (India)
- EXIR (IRAN)

The company top management agrees with the fact that fully imported production inputs weakens their position in comparison with its rivals (importers, wholesalers). But the alternatives currently are not feasible. 50% of ex-works prices of the company consist of imported material costs, in which 10-15% makes up transportation costs. These import mark-ups are vulnerable sides of the company. In opinion of the General Director of the Company, there is no sound strategy for the development of pharmaceutical industry. For this purposes, the Association of Pharmaceutical Importers and Manufacturers can play the role of accelerant and can concentrate all efforts to elaborate and consistently implement an efficient strategy designed for pharmaceutical industry. It is also interesting to find out that General Director agrees that local biotechnologies and fine chemicals can realize their potential mainly concentrating on preparation of biological additives and auxiliary materials used in local pharmaceutical production. However, current financial and operational situation of these industries does not allow implementing such ambitious objectives. Rehabilitation of linkages between pharmaceuticals, biotechnologies and fine chemicals is feasible within cluster development.

Arpimed has experience with the production of herbal medicines. But the initiative had insufficient results given poor marketing skills of the company to promote and market new product by own means. However, the General Director of the company agrees that the potential of herbal medicine of Armenia should be realized joining efforts of pharmaceutical companies, R&D institutions as well as the efforts of cultivators and collectors (peasants and farmers) of herbs.

#### 4.4 Esculap LLC

Contact Person	Mr. Hrach Minasyan –Director
Address	58 Mamikonyants street, Yerevan, Armenia
Legal Status	Limited Liability Company
Telephone	+ 37410 23 31 46
Major Product Line	Different kinds of tablets, ointments, capsules, solutions, Herbal solutions, etc.

The Company was established in 1998. From the beginning of its activities, the Company was engaged in wholesale and retail trade of drugs. Esculap LLC is fully owned by Armenian citizens. Production activities were launched in 2001. Since its establishment the company increased employment level by threefold. Currently it employs 90 specialists. This figure includes both wholesale, retail and production activities of the company. Currently, production makes up about 6-7% of its business activities. About 93% of the Company's revenues are generated from wholesale and retail activities. The main sources of financing of company development were loans from commercial banks and retained earnings, which were efficiently reinvested, aiming at expansion of its business activities. Currently, the company is constructing new production building and facilities to ensure and meet the requirements of GMP and ISO standards. The current production territory of the company makes up about 460 sq. m, while the new one will consist of 1500 sq. m of production territory and supplementary areas for warehouses. Similar to Liquor Pharmaceuticals, the major barriers for certification are the location and conditions of production facilities.

Wholesale and retail activities provide about 12-15% of profitability. Given high level of wholesale and retail turnover in comparison with production, it is obvious that they ensure more efficient and short-term economic results than the indicators of pharmaceutical production. However, the company Director stressed the fact that organization of pharmaceutical production highly depends on long-term vision and strategic business approaches of Esculap owners and managers. That's why during the next 2-3 years the company will concentrate its efforts mainly on the development of pharmaceutical production. Chemical inputs of the company are fully imported.

Unlike other local manufacturers, ESCULAP is specialized in the production of herbal solutions and ointments. And it is interesting that about 95% of its inputs are provided by local suppliers such as Antaram cooperative production.

#### 4.5 Yerevan Chemical Pharmaceutical Firm ojsc

Contact Person	Mr. M. Matevosyan – Managing Director
Address	6 2 <sup>nd</sup> lane, Acharyan street, Yerevan, Armenia
Legal Status	Open Joint Stock Company
Telephone	+ 37410 62 74 10; +37410 62 96 37
Major Product Line	Injection preparations, solid and liquid medicine

Yerevan Chemical Pharmaceutical Firm ojsc is the oldest pharmaceutical company and was established on the basis of former state-owned enterprise – the only pharmaceutical company in Armenia during Soviet times. The company was privatized in 1990s and did not change its specialization given sufficient local demand for its pharmaceutical products as well as exporting opportunities in terms of barter with CIS countries.

More detailed information on strategies, specialization, production and scientific activities, performance indicators and major issues and problems of pharmaceuticals, biotechnologies and fine chemistry is presented in appendices.

#### 4.6 Vitamax-E LLC

Contact Person	Mr. Edward Dilanyan – Chairman and Director
Address	9/1 Leninakan highway, Yerevan, RA
Legal Status	Limited Liability Company
Telephone	+ 37410 392099
Major Product Line	Different kinds of probiotics (capsulated, tablets, powder, fruit, vegetable and meat powder, baby foods, etc)

The Vitamax-E LLC was founded in 1997, in Yerevan city. For more than five years the company has been developing, producing and realizing probiotic CDB “Narine”/“Narimax”, (culture of dry biomass in the form of powder and capsules) on the basis of the Lactobacillus acidophilus Er-2 317/402 strain. The company also produces natural fruit powders, which are used in different fields of food industry.

Currently “Vitamax-E” is among leading regional producers of dry probiotic complexes representing natural microbiological agents (Gram-positive bacteria), which in their turn

proved to be the source of anti-microbial compounds, vitamins, macro- and micro-elements.

The company's produce is the basis in manufacture of:

- highly efficient biocorrectors of gastro-enteric tract;
- dietary and health-improving nutritious products;
- cosmetic and hygiene means.

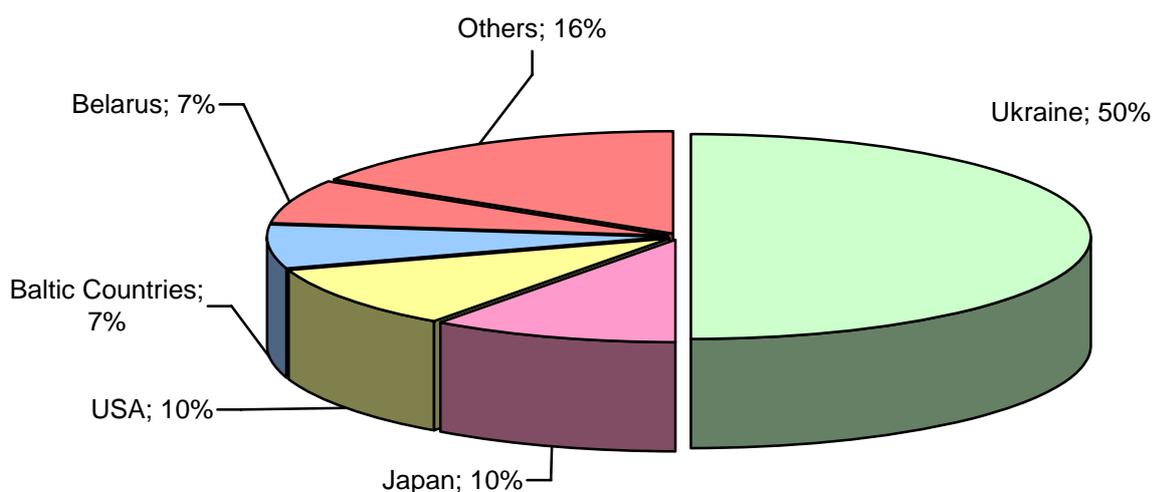
High effectiveness of the CDB “Narine” production has been proved by clinical trials and is intended to recover and strengthen human's health, provide prophylaxis of various diseases, and improve life quality of the population. The whole production of the company is manufactured according to exclusive home-made technologies, developed by its researchers.

The company carries out active scientific-research work in the field of biotechnologies, implements scientific-technical cooperation with the Research Institute of Biotechnology of NAS Armenia, as well as joint work with Japanese scientific institutions on developing novel production based on “Narine”. The company regularly participates in international exhibitions, symposia and conferences, organizes and carries out scientific-practical conferences and workshops on propaganda of healthy mode of life and rational nutrition with workers. In 2005, Vitamax-E acquired ISO 9001:2000 and GMP certificates from German accredited company TUV.

The major share of investments has been implemented during 2003-2006. The company possesses 6000 sq. m of production territory, which is equipped with European technologies. In the organizational structure of the company R&D department is included, which consists of 10 scientific researchers (biologists, chemists, microbiologists, etc). 70% of its products are exported to CIS countries and Japan. Only 30% of its products are marketed locally.

The geography of export markets of Vitamax-E is presented below. It mainly includes probiotics and other bio-supplements, which enjoy great demand in targeted foreign markets.

**Figure 4 Geographical Coverage of Vitamax-E Export Markets**



R&D department of the company has elaborated unique automated system of production management and computerized the main part of its production equipment with CNC systems.

In the process of new product development and R&D works, the company often cooperates with different local scientific research institutes such as Institute of Fine Organic Chemistry, Institute of Applied Biotechnologies, etc.

The company's material inputs are fully imported (Belgium, Netherlands, UAE and Iran). However, the research team identified that the share of material costs in the price structure of probiotics is rather small. That's why when discussing the issues of improvement of value chain and cost optimization, the substitution of imported material inputs with locally produced ones, is insignificant. The major share of costs belongs to labor expenses, which account for about 35-40% of ex-works prices. It means that value-added of probiotics is significantly higher than that of pharmaceuticals.

Given recent appreciation of Armenian dram exchange rate against foreign currencies, the Company seeks for more effective technologies to improve the productivity, ensure cost optimization and reduce export prices for improvement of competitiveness of its products.

When discussing, cost structure and value chain of Vitamax-E products, it becomes obvious that it is rather different in comparison with pharmaceutical products. It is estimated that in case of export, wholesale and retail markups of the company's products are five to tenfold higher than ex-works prices. The highest retail markup is observed in Japan and USA, correspondingly tenfold and 5 fold. Relatively lower retail markups are observed in Ukraine, Baltic Countries and Russia – twofold to threefold.

## 5. SUPPORTING ORGANIZATIONS AND CLUSTER LINKAGES

Supporting organizations of the Pharmaceutical Cluster are represented by the following institutions:

- Government Agencies and Regulatory Framework
- Industry Related Associations
- Educational Organizations
- Supporting Infrastructure

In addition to abovementioned institutions, the following organizations are also discussed within cluster linkages:

- Institute of Fine Organic Chemistry
- Institute of Molecular Biology
- Institute of Hydroponics
- Herb Manufacturers

### 5.1 Government Agencies and Regulatory Framework

The Pharmaceutical industry, which includes production, import, export, wholesale and retail trade, is regulated by the Ministry of Health Care of Armenia. The linkages between pharmaceuticals and government agencies are estimated as well-developed (according to the Cluster Map).

The main legislative document regulating this sphere is the Law on Medicine of Armenia. Currently, the National Assembly of Armenia discusses new draft law, which will improve the older one and will cover those gaps, which exist in current law.

The National Assembly passed the first Armenian Law “On medicines” in October 1998. It covers the following areas: terminology, pharmaceutical activity and its licensing, production, labelling, import and export, information, advertisement, destruction, registration, quality assurance, state guarantees of medicines ensuring to population and some others.

However, this document includes contradictions, unclear and doesn't cover all the necessary information. “A new draft of a law On Medicines” has been prepared by the ADMTA and presented to the National assembly about one year ago.

According to the “Law on medicines“, more than 10 regulation documents have to be developed and introduced by the Government and the Ministry of Health. The following normative acts are already enforced:

- Resolution of the Government N 396 of 8.01.1999 on “Social groups of population having the right to get medicines free or with privileges, and the list of diseases”.
- Resolution of the Government N 581 of 20.09.2000 on “Rules on import and export of medicines and pharmaceutical entities in Republic of Armenia”.
- Resolution of the Government N 347 of 25.04.2001 on “Rules on state registration of pharmaceuticals and fees for expert opinions of state registration of pharmaceuticals”.
- Resolution of the Government N 867 of 29.06.2002 on “Rules on Licensing Production of Medicines, Pharmacy Practice, Health Service, Implementation of Medical Professional Education Curricula, as well as on Approve of Licensing Forms for Implementation of Mentioned Activity”.
- Resolution of the Government N 63 of 24.01.2002 on “Rules on Implementation of Clinic Trials of New Medicines in the Republic of Armenia”.

In addition, Decrees of the Minister of Health approving the “List of OTC-drugs” and the first “Armenian State Register” have been enforced in November 2000 and December 2000, correspondingly. In 2001 the Decree of the Minister of Health on “Rules on medicines supply for persons from social groups of population having the right to get medicines free or with privileges, as well as suffering of selected diseases, at the policlinics” and in 2002 Decree N 100 of the Minister of Health of 26.02.2002 on “Rule on prescribing and dispensing medicines” were approved. The following important areas still not covered by the local norms and standards:

- Pharmacy practice,
- Manufacturing practice,
- Inspection,
- Advertising and drug promotion,
- Labelling, etc.

The abovementioned gaps will be fully covered by new legislation.

The drug regulatory authority (DRA) is the agency that develops and implements most of the legislation and regulations on pharmaceuticals. Its main task is to ensure the quality, safety and efficacy of drugs, and the accuracy of product information. This is done by making certain that the manufacture, procurement, import, export, distribution, supply and sale of drugs, product promotion and advertising, and clinical trials are carried out according to specified standards. Several of these functions also contribute to efforts to promote rational drug use.

A Drug Regulatory Authority in Armenia is the Drug and Medical Technology Agency (Drug Agency or ADMTA) or Scientific Center for Drug and Medical Technology Expertise. It was established in 1992. The Agency is responsible for pharmaceuticals and devices registration, professional studies of pharmaceutical organizations (in fact inspections), evaluating materials for issuing licenses for import and export of pharmaceutical products, quality control of medicines, adverse effects monitoring, drug information and some others.

The main departments of the Drug Agency are the following:

- Department of expertise and medicines evaluation
- Expert Department for licensing import and export of pharmaceutical products
- Expert Department on professional study of pharmaceutical institutions
- Department on rational drug use and adverse drug reaction monitoring
- Department on narcotics control
- Information – publishing Department
- Department on pharmaco-economic analysis.

The special Quality Control Laboratory set up in 1994 at the Agency is very well equipped according to the WHO Recommendations and intended for state quality control of pharmaceuticals. Established in 1997 the National Centre on adverse drug effects monitoring is also a structural element of the ADMTA.

The State Quality Control Laboratory is responsible for:

- Testing medicines at the process of registration (defining quality of products to specifications from dossier)
- Testing quality of imported medicines
- Testing quality of pharmaceuticals produced in Armenia
- Testing quality of products at the professional studies of pharmacies and wholesalers.

The following projects are being pursued by ADMTA within the framework of collaboration with WHO:

- Cost-effective drug management in a group of pilot hospitals, together with improved procurement methods, improved prescribing by better selection and use of guidelines, and a pro-active role of the hospital pharmacies;
- A regional drug reimbursement pilot in the Kotayk marz aimed at improving access to quality drugs for poor groups with relatively high drug costs;

- Improved quality of pharmaceutical services through enforcement of effective regulations;
- Better treatment outcomes through efficient use of various tools and mechanisms for appropriate drug prescribing and use;
- Development of an action plan for national drug policy implementation, needed for coordinated implementation and monitoring and for ensuring more active involvement of different stakeholders at various policy levels.

The tasks to be solved by the drug regulatory bodies are as follows: improving the control system for the quality of the herbal medicinal products of local manufacturers, which will make it possible to produce standardized and safe products; and improving legislation concerning the manufacturing and distribution of herbal medicinal products in Armenia. It is also necessary to improve post-marketing efforts on Adverse Drug Reactions monitoring, including for herbal medicinal products.

## **5.2 Quality Assurance Issues in Pharmaceuticals**

Quality assurance (QA) concerns both the quality of products themselves and all the activities and services that may affect quality. One of the main requirements of QA is adherence of Manufacturers to GMP. However, at present only 3 producers in Armenia are considered as complying with GMP. In addition, at present the majority of medicines from other NIS, registered in Armenia, are produced not under the GMP conditions. According to the ADMTA, 2103 of registered medicines were produced by manufacturers, which comply with GMP and 600 – by those, which don't comply. According to the results of interviewing local producers, the majority of them believe that manufacturers in Armenia have to comply with GMP. They suppose that there is an urgent need in developing an appropriate standard.

In 1997, Armenia entered a WHO project on the development and implementation of national GPP standards and quality assurance. A national pharmaceutical conference to introduce the GPP concept has been held in Armenia. GPP standards have been elaborated and adopted by ADMTA and implemented in 20 pilot pharmacies in Yerevan. Meanwhile, indicators for monitoring GPP standards have been developed and enforced, allowing for the measurement of pharmacy services effectiveness in relation to drug production, storage, delivery, and quality assurance, as well as for the evaluation of pharmacists interventions as they dispense drugs and respond to patient symptoms. However, Decree of the Minister of Health on pharmacy practice standards was not registered by the Ministry of Justice and, thus, did not become regulation document Requirements to pharmacy, approved by the Decision of Parliament this year as conditions for licensing, are too short and don't cover all the necessary standards. Thus, it can be said that pharmacy practice in fact is almost unregulated.

System of licensing of production and sale of pharmaceuticals was introduced still in 1991. This system is essential to ensure that all pharmacies and practices used to manufacture, store and distribute pharmaceutical products comply with requirements.

Inspection is a necessary tool to safeguard drug quality. Nevertheless, there is no officially approved inspection in Armenia to check pharmaceutical license-holders. Department of Professional Studies at the ADMTA conducts investigation of pharmacies, wholesalers and manufacturers but it is not based on national legislation documents. Furthermore, there is no legal provision for penal sanctions in place. Thus, no penalty action can be implemented in the event of failure to conform to any provision of the law. The single measure is license withdrawal.

Despite the fact that it is widely accepted by professionals that controlling the marketing, presentations and other drug promotion is very important in preventing irrational drug use, there were appropriate norms and standards. However, recently, this gap was covered by the government decree, which clearly defines the norms and ethics of drug marketing and promotion, including advertising tools.

### **5.3 Industry Related Associations**

We have identified two industry-related associations registered – Armenian Pharmacological Society and Association of Pharmaceutical Importers and Manufacturers (Director - Ashot Hakobyan). The latter joins interests of major producers, importers, retailers and wholesalers of drugs. Legal status of the Association is union of legal entities. Thus all members of the company are legal entities. The Association was established in 2003. It has 12 members – 5 manufacturers and 7 non-manufacturers, including wholesales, retailers and importers. The following is the list of the Association members:

- Liqvor Pharmaceuticals
- Arpimed
- Esculap
- Yerevan Chemical Pharmaceutical Firm
- Vitamax-E
- Lambron Pharmimpex
- Eliz Pharm
- Alpha Pharm
- UniPharm
- Tonus Les
- Pharm Gohar
- Pharm Trust

As seen from the abovementioned list, PharmaTech and Natali Pharm (one of the major importers and wholesalers) are not included in the list of Association members. Association performs with limited resources with 3 employees – Director, Assistant and Accountant. The major function of the Association is the advocacy and legislative initiatives on behalf of its members. The functions of Association also include marketing, promotion, HR development, etc. However, actually these functions are not realized given limited resources of the Association.

It is necessary to stress the role of the Association in the cluster development initiative. The Association can play a role of accelerant in the development of the cluster. To achieve this purpose, one needs to implement a strengthening component for improvement of the Association activities. The role of the Association is important when discussing the issues of implementing national GMP standards. Within the framework of PBFC cluster we identified that the linkages between manufacturers, importers and business-related associations is well developed, while the component of associations needs further development (see above cluster map).

#### **5.4 Educational Organizations**

There are developed educational traditions for pharmaceuticals, biotechnologies and fine chemicals in Armenia. The major institutions are the faculties of Chemistry and Biology (Pharmaceutical Chemistry) of the Yerevan State University, as well as the Pharmaceuticals Faculty of Yerevan State Medical University. The State Engineering University is also engaged in training of bio-medical engineers, environmental engineers in chemical industry, and specialists in biotechnologies, chemical technology of organic and synthetic bioactive substances. The scientific potential is also rather strong. In Armenia there is number of institutions engaged in the relevant scientific research, such as Engineering University (research in chemical technologies), Institute of Molecular Biology, Institute of Fine Organic Chemistry, etc.

Generally, the main function of educational organization within the cluster is to provide qualified specialists for cluster-related industries. In the pharmaceutical cluster, the following specializations should be provided for pharmaceutical industries:

- Pharmacologists – Synthesizers
- Pharmacologists – Technologists
- Pharmacologists for Pharmacy

The second and third categories of specialists are sufficiently educated and provided for pharmaceutical industry. The problem of this sphere is to ensure high qualified specialists for medicinal synthesis. These skills will be mainly utilized both by pharmaceutical manufacturers and R&D institutions, e.g. Institute of Fine Organic Chemistry. While the

component of “Educational organizations” (within cluster map) is identified as well developed one, we found out that the linkages between educational organizations and the core of the cluster should be improved and developed.

## 5.5 Supporting Infrastructure

Within cluster supporting infrastructure, the following organizations and institutions are discussed:

- Armenian Development Agency
- Enterprise Incubator Fund
- European Bank for Reconstruction and Development
- Business Consulting Companies
- Certification and Quality Assurance Companies
- Marketing and PR Consulting Companies
- Cafesjian Venture Fund
- R&D institutions and laboratories, etc.

Supporting infrastructure is identified as a developing component of the cluster with developing linkages to the core of the cluster.

Armenian Development Agency (ADA) has conducted several researches and recognized the pharmaceuticals, biotechnologies and fine chemicals as priority sectors. However, we identified that there is no tangible results from the support of ADA.

Enterprise Incubator Foundation (EIF) has ordered a study to Ameria cjsc to research and identify the issues and development barriers for pharmaceuticals; biotechnologies and fine chemicals (see appendices). Based on the results of the survey, EIF together with Cafesjian foundation established a venture fund, which aims at supporting high-tech and green-filed projects disbursing venture loans. Currently the Venture fund is conducting selection of potential clients and attractive as well as sound projects with high-tech components. The investment manager of the Fund – Mr. Magi Nargizyan told us that there were also some pharmaceutical, biotechnological and fine chemical projects in the list. At the first stage, the Venture fund will finance up to \$250,000 to each project. Total resources of the fund will not exceed \$1 million. However, as a result of the survey the venture fund identified more demand for equity funding by potential clients rather than demand for loan financing.

EBRD is interested in financing of cluster-related industries. The first step towards cooperation is loan and equity funding project of Liqvor Pharmaceuticals. EBRD has engaged in financing of Development project presented by Liqvor Pharmaceuticals. More detailed information on the project details is illustrated in previous chapters.

The representatives of the pharmaceutical cluster periodically cooperate with business consulting, marketing and PR companies. This relationship and the component of business consulting, PR and marketing companies are considered to be at the development stage.

As described above, some pharmaceutical companies have acquired ISO and GMP standards. The introduction and implementation of quality management systems have been conducted in support with Armenian quality assurance consulting firms (e.g. CSP Caucasus) and the certification was awarded by different European accredited organizations.

Among R&D and Research institutions the following organizations were identified and included in PBFC cluster. The criteria of their involvement are current and possible future cooperation and provision of R&D services to pharmaceutical companies. The list includes but not limited with the following organizations:

- Institute of Fine Organic Chemistry after Mnjoyan
- Institute of Molecular Biology
- Institute of Hydroponics

The Institute of Fine Organic Chemistry was the only organization in Soviet times which was specialized in drug synthesis and production of brand medicine. Currently the Institute uses only 5% of its scientific and production capacities. It is equipped with technologies and production facilities (1970s-1980s) for pharmaceuticals, laboratories for biological and chemical studies as well as herbal laboratory. According to the director of the Institute, it has 12 brand new drugs, which have already passed pre-clinic experiments. The institute lacks required financial resources to finish clinical experiments and commercialize its products.

Products capacities of the Institute allow manufacturing medicine in form of ampoules, tablets and capsules. However, experts argue with this fact stressing morally obsolete equipment and technologies existing in the institute.

In addition to its scientific research activities, the Institute produces two types of brand drugs (Gnagleron and Dicilin), which are marketed locally and in CIS countries, mainly in Belarus. Average annual turnover of the Institute from sales of the abovementioned drugs does not exceed \$50,000. It hardly covers 1/3 of its expenses (according to the Director of the Institute).

Given scientific potential and well equipped laboratories of the Institute, we believe that it may play an important role within PBFC cluster as a core R&D and research institute meeting R&D needs of pharmaceutical industry.

Institute of Molecular Biology is considered to be one of the most active and dynamically growing scientific research institutes in Armenia. Currently the Institute is engaged in different joint scientific project with European partners within the framework of Grant projects provided by European Community. The main asset of the Institute within the pharmaceutical cluster is considered to be its molecular diagnostic potential. It means that together with Institute of Fine Organic Chemistry, the Institute can provide full cycle of R&D and research services to the core of the cluster.

Institute of Hydroponics is included in the pharmaceutical cluster taking into consideration its R&D potential for herbal issues. As a result of current survey we identified that the Institute of Hydroponics may provide organic mass of herbs grown in their laboratories. It allows phyto-pharmaceuticals industry to reduce the costs of herb cultivation and collection as well as receive adequate quality, which is required to synthesize medicine from these herbs.

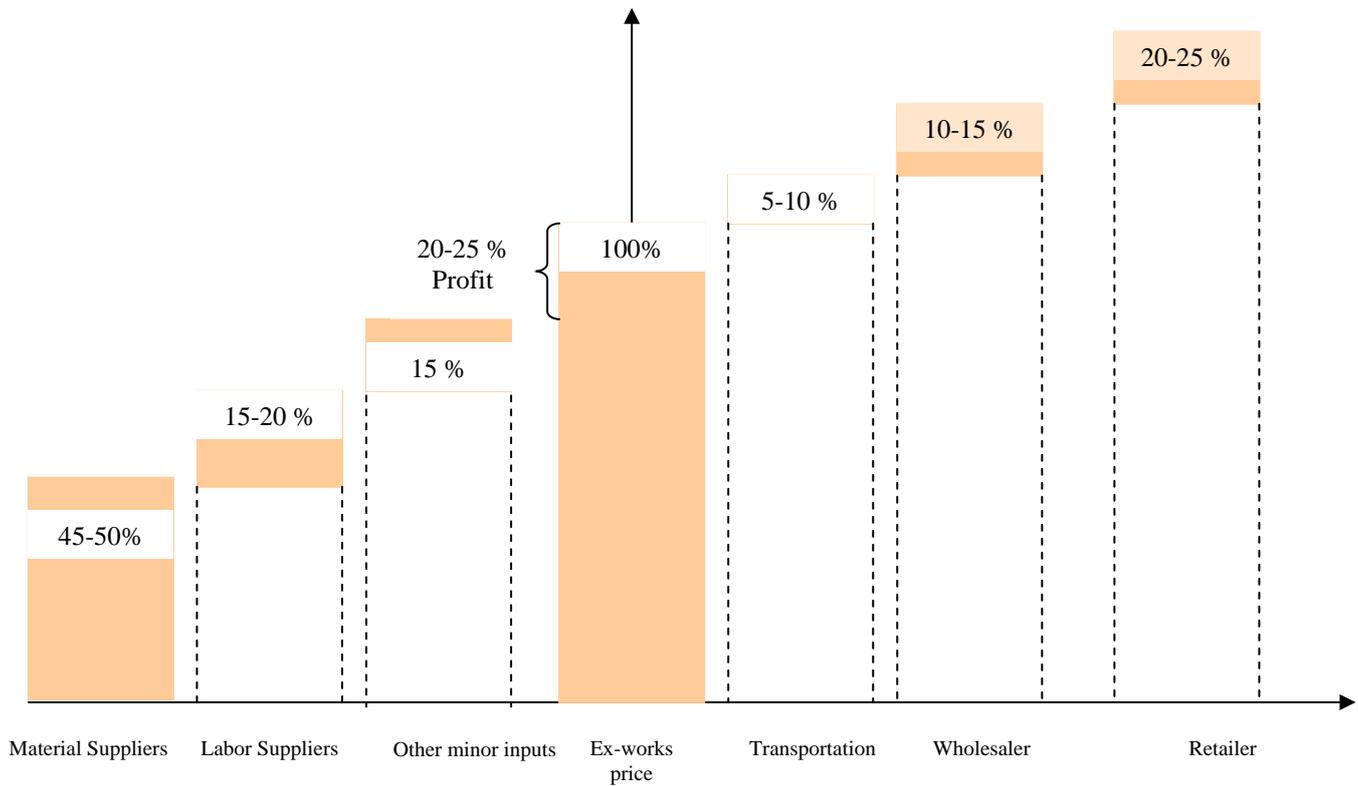
## 6. CLUSTER ANALYSIS TOOL-PACK

### 6.1 SWOT Analysis

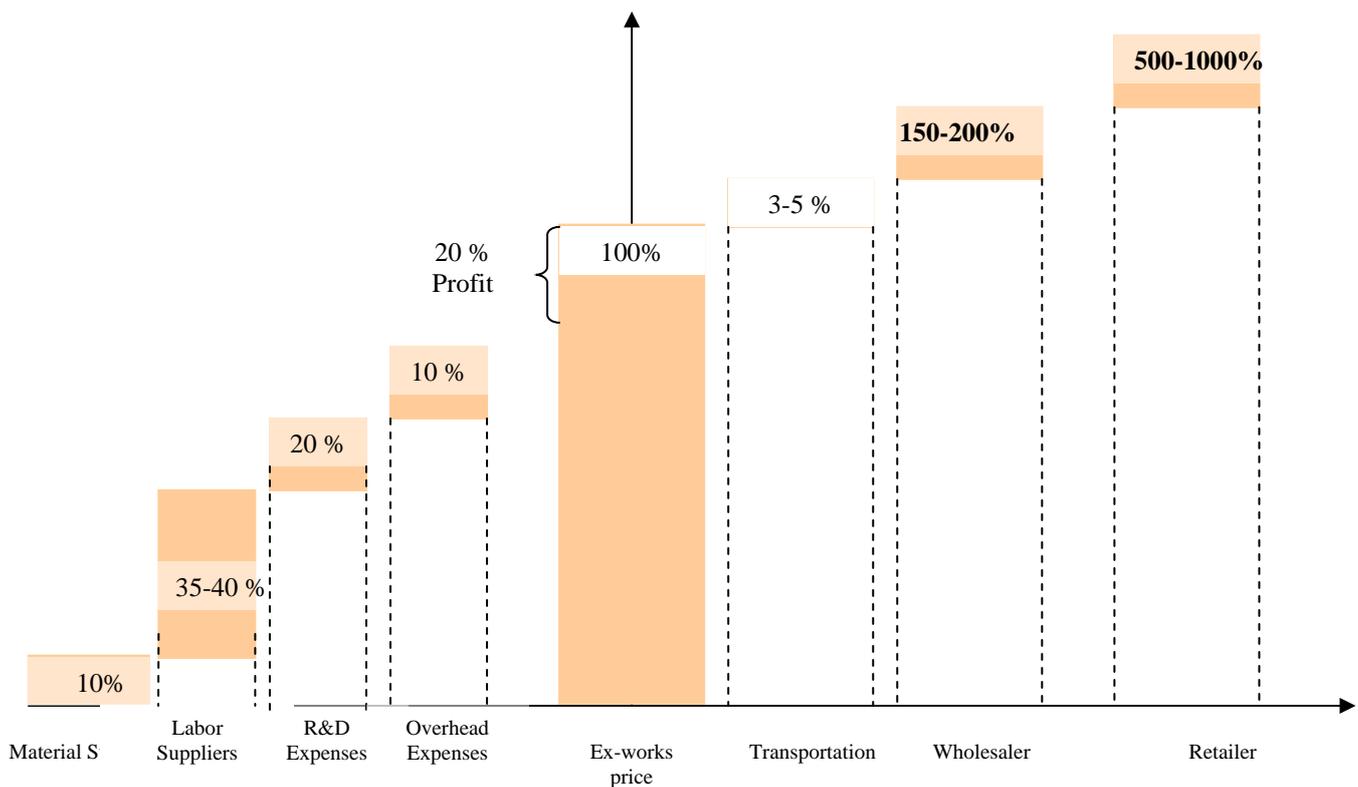
<p><b>S</b>trengths</p> <ul style="list-style-type: none"> <li>• Cluster already appears to have a lot of trust</li> <li>• Well-established and profitable firms and willing to cooperate together</li> <li>• Easy to gather information – firms are very open with information</li> <li>• Pharmaceuticals together with biotech, and including health/vitamin/herbal/additives, offers a high growth market</li> <li>• Technology based Industry</li> <li>• Big investment are currently undertaken (EBRD is invested in Liqvor company and interested to invest in other company too)</li> <li>• Armenia 2020 is considering Health care sector as one of promising and competitive sector</li> <li>• Probiotics enjoy with higher value-added potential in case of export</li> </ul>	<p><b>O</b>pportunities</p> <ul style="list-style-type: none"> <li>• Development of Phyto-pharmaceuticals and Mass production of herbal inputs for pharmaceutical industry</li> <li>• Further use of Venture Fund resources to finance R&amp;D projects of the cluster</li> <li>• Contract manufacturing</li> <li>• Further development of local market (85% of drugs currently imported)</li> <li>• Cooperation with European Association of Pharmaceutical Producers</li> <li>• Connections with academia</li> <li>• GMP certification</li> <li>• Organizing collective distribution</li> <li>• Improving quality assurance</li> <li>• Introducing marketing and commercialization skills to biotechnological and fine chemical institutions</li> <li>• Establishment of internationally recognized and certified herb standardization laboratory</li> </ul>
<p><b>W</b>eaknesses</p> <ul style="list-style-type: none"> <li>• Development of new drugs expensive, lack of technology and know how in research institute</li> <li>• Lack of market mentality in research area</li> <li>• Limited scope of supply needs by local pharmaceutical companies;</li> <li>• Limited financial resources of local pharmaceutical companies necessary for Research and Development works;</li> <li>• Only one biotech firm in Association</li> <li>• Little possibility for innovation</li> <li>• Problems with ‘Good Manufacturing Practices’ certification</li> <li>• Reliance on CIS market – only one or two firms are able to export to USA, Japan, Taiwan and UK</li> <li>• Many drugs not registered in Armenia</li> <li>• Fine Chemicals industry raises environmental issues</li> <li>• Inadequacy of requirements set by pharmaceutical companies for the input supply by local biotechnologies and fine chemicals (e.g. representatives of pharmaceutical industry acquired GMP certification, which requires that the supplier of the company should also have GMP standards)</li> <li>• Obsolete technologies and laboratory equipment of biotechnologies and fine chemicals;</li> <li>• Limited scope of strategic development goals in pharmaceuticals, which do not target long-term strategic goals of improvement of R&amp;D activities in the industry;</li> <li>• Due to abovementioned issues the inputs, which can be supplied by biotechnological and fine chemical industries, are more expensive in comparison with imported ones.</li> </ul>	<p><b>T</b>hreats</p> <ul style="list-style-type: none"> <li>• Further Appreciation of Armenian Dram against US dollar</li> <li>• Transportation problems, which will hinder export of pharmaceuticals;</li> <li>• In case of development of phyto-pharmaceuticals, occurrence of ecological problems concerning endemic herbs of Armenia;</li> <li>• Failure in CIS markets due to negative changes in drug regulation environment</li> </ul>

## 6.2 Value Chain of Pharmaceutical Industry

### Value Chain of Pharmaceutical Products



### Value Chain of Probiotics and Other Biotechnological Products (The Case of Vitamax-E)



## 6.3 Diamond Model

### Firm Strategy, Structure, and Rivalry (medium)

- Armenian pharmaceutical companies use only 30% of their production capacities.

- There is no coherent industry development strategy and vision

+ Local pharmaceutical companies understand the necessity of standardization and adoption of internationally recognized standards (GMP, ISO and HACCP), as well as meet quality requirements of foreign markets.

+ Some drug producers have developed production relationships and alliances with different wholesalers and retailers.

+ Pharmaceutical Manufacturers tends to increase export shares based on competitive advantages and economies of scale provided by foreign markets

+ Pharmaceutical industry is represented by well functioning and gradually developing firms, and their interests are united in a well functioning association (Association of Pharmaceutical Importers and Manufacturers).

+ Vitamax-E may provide significantly higher value-added based on the production of probiotics and other biotechnological products

### Factor Conditions (low/medium)

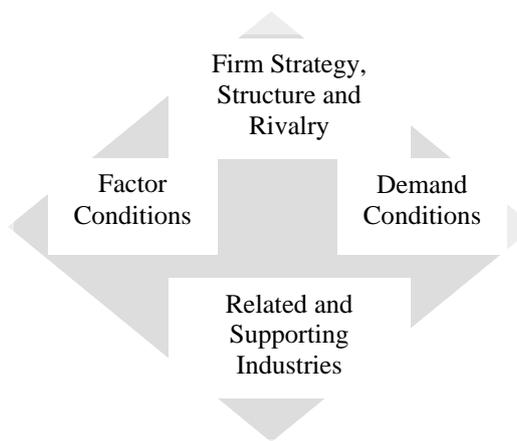
- The major inputs in terms of material and substances are imported

+ There is a sufficient level of investments and they are gradually increasing

-Transportation costs of imported materials is high

- Currently biotechnologies and fine chemicals are not capable to meet the requirements of pharmaceutical industry

+ There is a great development potential for herbal medicine and phytopharmaceuticals



### Demand Conditions (Medium/high)

- Local wholesale and retail markets of drugs are becoming more saturated

+ Local market is growing and there are potential domestic market niches for penetration by local producers.

- Currently foreign markets are limited with CIS countries.

+ There is a significant potential of establishing export-oriented production of herbal medicine.

+ Regulation of European markets for herbal medicine is in a transition period. This is a very good opportunity for development of local herbal medicine with export orientation to European markets.

### Related and Supporting Industries (Medium)

- The inter-firm linkages between cluster stakeholders are in a low level. This assumption mainly relates to cooperation level of pharmaceuticals, biotechnologies and fine chemicals (excluding the Case of Vitamax-E).

+ The industry is well regulated and the regulation environment is being periodically improved.

+ Developing potential of business related associations

+ The cluster is supported with relevant well-developed academies or educational institutions, and the relationship between pharmaceutical industry representatives and academies is considered to be in a developing stage.

- Qualitative development of the cluster needs a lot of financial resources to be spent on R&D.

- Yet Armenian government has not introduced National GMP standards for pharmaceutical industry.

+ There is a necessity to establish international certified herbal standardization laboratory to foster local production of herbal medicine.

+ In local market some venture funds are being established aiming at financing of pharmaceutical, biotechnological and fine chemical projects in Armenia.

### Role of Government (medium/high)

+ Government controls or regulations do not seem to be a part of any obvious problem  
+ Like all exporters, pharmaceutical sector is exempted from VAT.

## 7. CONCLUSIONS

### **CAPS Possible Involvement in and Support to the Development of the Pharmaceutical Cluster**

- Support for development of phyto-pharmaceuticals and extensive production of herbal inputs for pharmaceutical industry
- Joint technical support with Cafesjian Venture Fund to elaborate financing mechanisms for R&D projects of the cluster
- Technical support for organizing efficient herb cultivation and collection by farmers and peasants
- Support to capacity building of Union of Drug Importers and Manufacturers (Possibly in close cooperation with European Association of Pharmaceutical Producers)
- Support for Cooperation with Academia
- Support for establishment of National GMP standards
- Organizing seminars and on-job trainings for strengthening marketing capacities
- Support to pharmaceutical companies in marketing research conduct in foreign markets
- Within the framework of the cluster organize seminars and conferences to find the ways of cooperation of local biotechnological, fine chemical and pharmaceutical sectors
- Introducing marketing and commercialization skills to biotechnological and fine chemical institutions and organizations
- Support for establishment of internationally recognized and certified herb standardization laboratory
- Support for establishment of regulatory standards for herbal drugs and phyto-pharmaceuticals based on EU Directive (See Appendix to the report)
- Support to the UNION in elaboration of cluster development strategy

## APPENDIX

### ABBREVIATIONS

ADMTA	Armenian Drug and Medical Technologies Agency or Scientific Center for Drug and Medical Technology Expertise,
CAPS	Competitive Armenia Private Sector
CIS	Commonwealth of Independent States
CNC	Computer Numerical Control
CRDF	Civil Research and Development Foundation
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
HACCP	Hazard Analysis and Critical Control Point
ISO	International Standards Organization
ISTC	International Scientific Technical Center
PBFC	Pharmaceuticals, Biotechnologies and Fine Chemicals
WHO	World Health Organization