Pharmaceutical industry in Ukraine
Dear Reader,

It is my great pleasure to introduce you to our new publication about attractive sectors of Ukraine, made in partnership with Deloitte.

We developed these brochures to make information about sectors of Ukraine accessible and easy to understand. The booklets provide analysis of economic attractiveness, as well as comparative characteristics and undiscovered opportunities.

Ukraine enjoys a long industrial tradition, robust transportation and technical infrastructure, rich natural resources, strong secondary and tertiary education, a broad network of research and development institutes, and a large pool of technically skilled labor. As a WTO member since 2008 and having signed International Agreements for the Avoidance of Double Taxation with 63 countries, Ukraine is a fair player in the business world, a transparent and predictable partner.

InvestUkraine offers individual support to investors and is here to assist potential investors with setting up production in Ukraine. We offer professional support in obtaining information and analysis, legal advice, site visits, site selection services, assistance in communication with local authorities, and an aftercare program.

I encourage you to consider Ukraine as a place for your future business and discover all the benefits of locating your company’s operations in our country.

I look forward to welcoming you in Ukraine.

Sergiy Yevtushenko,
Head
InvestUkraine
State Agency for Investment and National Projects of Ukraine

A favorable geographic position, vast consumer market, ample resources and high level of education – all these factors ensure great investment potential for the economy of Ukraine.

At present, Ukrainian market is at the development stage. There are many niches and opportunities for introducing new players and strengthening the positions of existing ones. However, most of Ukraine’s industries lack investments, though international investors are highly interested in them. We believe that foreign investments will be very successful and promote economic growth if a favorable investment climate is created in Ukraine.

To assist you in determining the most promising areas to invest in and get an insight into Ukrainian market, Deloitte experts in cooperation with InvestUkraine have conducted this research.

We hope that this overview will be useful and interesting for all companies interested in investing in various industries of our country.

Vladimir Vakht,
Managing Partner
Deloitte

Deloitte.
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Executive summary

Pharmaceutical industry is traditionally one of the main industry sectors in the economy of Ukraine. It covers production of pharmaceuticals and medical purpose articles, wholesale and retail trade, specialized storage and distribution through developed sales network. It is one of the most dynamic and profitable industries.

During 2009-2011 Ukrainian pharmaceutical market showed strong growth reaching pre-crisis level in volume terms. Total Ukrainian market was estimated to be USD 3 bn in 2011 and is the second biggest market in the CIS.

Today Ukraine, despite the fact that its retail market of medicines amounts to billions of dollars has low per capita consumption of medicines.

The pharmaceutical market has significant potential for further growth due to currently low total healthcare spending as compared to other countries in Central and Eastern Europe and expected increase of real income in the long run.

Imported medicines account for c.70% of Ukrainian pharmaceutical market. However, local producers have been steadily increasing their share from 24% in 2008 to 29% in 2011. It was mainly due to higher demand for cheaper substitutes produced by local manufacturers.

Distribution sector is highly concentrated with TOP-5 players controlling 88% of the market (up from 79% in 2009).

Hospital segment of drug distribution share decreased from 18% in 2008 to 14% in 2011 due to restricted state financing of the industry and slow pace of healthcare reforms.

Retail segment includes 13 thsd pharmacies and 7 thsd smaller selling points. Retail segment is very fragmented with TOP-10 retail chains controlling 15% of the market. In addition, leading players are mainly locally owned.
Industry overview

Market dynamics

The total value of Ukrainian pharmaceutical market, including retail and hospital segments in 2011 reached USD 3 bn exceeding the figure for the same period the previous year by 16%. Market has finally exceeded pre crisis value in USD terms. Total volume reached 990 m packages showing 1% growth in real terms.

For the first 9 months of 2011 imports of finished pharmaceutical products in Ukraine amounted to USD 2.8 bn for 376 m packages, exceeding the figure for the same period the previous year by 21% in cash and 14% in real terms.

In 2011 pharmaceutical market of Ukraine has fulfilled optimistic expectations of the operators as it grew by 15% in USD equivalent. In volume terms the market barely reached pre-crisis level.
Export of pharmaceutical products from Ukraine, USD m

- 2006: 92
- 2007: 130
- 2008: 151
- 2009: 150
- 2010: 199
- 2011: 195

Source: State Statistic Service of Ukraine

Export of pharmaceutical products by countries, %

- Uzbekistan: 17%
- Russia: 20%
- Kazakhstan: 4%
- Belarus: 8%
- Azerbaijan: 9%
- Moldova: 11%
- Georgia: 12%
- Other: 19%

Source: State Statistic Service of Ukraine
In 2011 Ukrainian pharmaceutical manufacturers exported products on the amount of USD 0.2 bn, 90% of which were supplied to CIS (Uzbekistan USD 40 m, Russia USD 36 m, Kazakhstan USD 23 m, Belarus USD 21 m and other countries).

The industry produces some 1400 medicines of approximately 3000 sold in the country. In the 2011 the share of local production of drugs on the market of pharmaceutical sales reached 27.5% in monetary and 65.1% in real terms, for a segment of the foreign producers, the figure was 72.5 and 34.9% respectively. Prescription drugs are estimated to constitute 52% of sold medicines, while other 47% are OTC.

The value of biotech products in the pharmaceutical market of Ukraine is approximately USD 5.5 m, but Ukraine’s share is only about USD 1.6 m (20 to 30%). It should be noted, however, that these are rough estimates as the Ukrainian biotech market is poorly structured and official statistics do not exist. The largest segments of the pharmaceutical biotechnology market in Ukraine are probiotic drugs, vaccines and seraums, closely followed by blood proteins, antibiotics, enzymes and genetically engineered drugs.

In the hospital segment marked by the processes of import substitution – is prevails products of Ukrainian origin, accumulating 87% of the volume of hospital purchases in bulk and 50% in cash terms. Hospital segment share decreased from 18% in 2008 to 14% in 2011 due to restricted state financing of the industry and slow pace of healthcare reforms.

Fragmented nature of the Ukrainian pharmaceutical market allows a relatively easy entry. There is a lot of room for consolidation. During the crisis cost of market entry has lowered considerably as land, construction and wage prices decreased. Desired prices for already existing manufacturers declined as well.

**Spending on medicines per capita in Ukraine in comparison with other countries**

**Healthcare spending in Ukraine and comparable countries, USD per capita**

![Healthcare spending chart]

Source: World Healthcare Organization, Economist Intelligence Unit
Five-year forecast

It is expected that the government’s budget position will be more restricted as compared to pre-crisis period. This will limit growth in healthcare spending in Ukraine over the forecast period, despite the country’s significant healthcare challenges.

Total healthcare spending is expected to grow at an average rate of 13.9% per annum in value terms until 2015 (nearly doubling 2010 level). Despite such strong increase healthcare spending in Ukraine will still remain considerably lower than in other CEE countries. Spending per capita in Ukraine is forecast at USD 407 in 2015 (USD 1,055 in Russia and USD 1,366 in Poland).

This gap between amounts of healthcare spending in Ukraine and comparable countries will likely persist due to lower income per capita in Ukraine as well as slower pace of reforms in the healthcare industry. The Ukrainian pharmaceutical market is the least saturated in the region in per capita terms, but growth is expected to be strong over the next few years.

Main market players

Production

Main market players in retail segment in 2011 in value terms

<table>
<thead>
<tr>
<th>#</th>
<th>Company</th>
<th>Local/ Foreign</th>
<th>2011 market share, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Farmak</td>
<td>Local</td>
<td>4.63%</td>
</tr>
<tr>
<td>2</td>
<td>Berlin-Chemie/ Menarini Group</td>
<td>Foreign</td>
<td>4.31%</td>
</tr>
<tr>
<td>3</td>
<td>Sanofi-Aventis</td>
<td>Foreign</td>
<td>3.59%</td>
</tr>
<tr>
<td>4</td>
<td>Nycomed</td>
<td>Foreign</td>
<td>3.37%</td>
</tr>
<tr>
<td>5</td>
<td>Teva</td>
<td>Foreign</td>
<td>3.07%</td>
</tr>
<tr>
<td>6</td>
<td>Darnitsa</td>
<td>Local</td>
<td>2.98%</td>
</tr>
<tr>
<td>7</td>
<td>Arterium</td>
<td>Local</td>
<td>2.78%</td>
</tr>
<tr>
<td>8</td>
<td>Zdoroviye</td>
<td>Local</td>
<td>2.38%</td>
</tr>
<tr>
<td>9</td>
<td>Servier</td>
<td>Foreign</td>
<td>2.37%</td>
</tr>
<tr>
<td>10</td>
<td>KRKA</td>
<td>Foreign</td>
<td>2.36%</td>
</tr>
</tbody>
</table>

Source: Proxima Research
The main trend is fast development of local pharmaceutical production segment. Before the 2008 crisis share of imported medicines was steadily growing reflecting increased real personal incomes. However, during the financial and economic crisis customers switched to cheaper medicines produced by local companies.

Already there is a trend of foreign pharmaceutical companies deepening their presence in Ukraine beyond just commercializing their products. This is clear from the wave of representative offices being turned into limited liability companies, the handful of marketing and manufacturing collaborations that have emerged between local producers and foreign companies, as well as the interest in M&A of the local players. Perhaps the most known example of such collaboration is of Ukrainian manufacturer Farmak with its end-stage production of Lilly’s recombinant insulin product.

### Retail sales dynamics of top pharmaceutical companies during 2009-2011, m UAH

![Retail sales dynamics of top pharmaceutical companies during 2009-2011, m UAH](chart.png)

Source: Proxima Research

The group of domestic leaders in pharmaceutical production includes Darnitsa, Arterium Corporation, Zdorovyie Group, Borschagovskiy Chemical and Pharmaceutical Plant, as well as Farmak. Each of these companies holds no more than 10% of the market. These are followed by the group of more than thirty companies, each occupying around 1% of the market. The group includes Indar, Kiev Vitamin Plant, StirolBioPharm and others. The third group includes over a hundred enterprises manufacturing only one or two drugs, that are simple and cheap in production: iodine, Solutio Virdis nitentic spirituosa, peroxide hydrogen etc.
Import vs domestic production in value terms, %

Source: Proxima Research

Import vs domestic production in volume terms, %

Source: Proxima Research
Farmak (№ 1 in 2011)

Farmak’s range of products covers different maladies in the sphere of: endocrinology, ophthalmology, otolaryngology, X-ray contrast media and others. The company produces more than 200 pharmaceutical drugs and exports over 18% of manufactured products to CIS (Russia, Belarus, Kazakhstan, Uzbekistan and others), EU (Germany, Austria, Poland, Bulgaria, Latvia, Lithuania, Estonia) as well as others. Production lines of Farmak are GMP certified.

Darnitsa (№ 6 in 2011)

Kyiv-based pharmaceutical company offers products for hormonal treatments, vitamins and muscle pain relieving gels as well as other products. It produces over 250 medical preparations. Production capacities of Darnitsa are GMP certified.

Arterium Corporation (№ 7 in 2011)

The Arterium Corporation was created in 2005 by two leading pharmaceutical enterprises – Kievmedpreparat (Kyiv), the national leader in antibiotics manufacturing and Halychpharm (Lviv), the largest producer of herbal medications. Currently Arterium Corporation manufactures over 140 generic and several original drugs. Company’s products top the list in several segments of the pharmaceutical market including anti-infectives for systematic use, antineoplastic and immunomodulating agents, medicines for genitourinary system, nervous system, cardiovascular system, respiratory system and hormonal treatments.

Zdorovye (№ 8 in 2011)

Pharmaceutical company Zdorovye (Kharkiv) is among the top three largest producers of ampouled medicines in Ukraine (about 12% of total output of ampoules by domestic manufacturers). The company uses modern high-tech production equipment which meets all international requirements. Zdorovye has in it’s assortment all pharmacotherapeutical groups from the international ATC-classification. Also, Zdorovye owns a chain of medical stores which offer pharmaceutical and hygiene products.

As examples of investment in pharmaceutical industry could serve Gedeon Richter (packaging facility for drugs), Bioton (29% stake in domestic insulin producer Indar), Sopharma (acquisition of Vitaminy), Kusum Pharm (Indian company that invested in construction of a production plant) and Sperko (Spanish–Ukrainian joint venture).

Many foreign medicine manufacturers import their products to Ukraine as for example Abbot Laboratories, Actavis Group, AstraZeneca, Bayer, GlaxoSmithKline, etc.

Distribution

Distributors segment in Ukraine is characterized by a high level of consolidation compared to other segments. Thus, the five leading companies – BaDM, Optima-Pharm, Alba Ukraine, Fra-M and Venta – held 88% of the total pharmaceutical market in 2011.

<table>
<thead>
<tr>
<th>#</th>
<th>Company</th>
<th>Market share, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BaDM</td>
<td>28%</td>
</tr>
<tr>
<td>2</td>
<td>Optima-Pharm</td>
<td>26%</td>
</tr>
<tr>
<td>3</td>
<td>Alba Ukraine</td>
<td>20%</td>
</tr>
<tr>
<td>4</td>
<td>Fra-M</td>
<td>7%</td>
</tr>
<tr>
<td>5</td>
<td>Venta</td>
<td>7%</td>
</tr>
</tbody>
</table>

Source: Proxima Research
Main pharmacy chains

Retail segment included 13 thsd pharmacies and 7 thsd smaller selling points at the end of 2011.

Pharmacy segment of Ukrainian pharmaceutical market is highly fragmented; market share of the leading players in total retail sales does not exceed 3%. TOP-10 retailers control approximately 15% of the total retail pharmaceutical market.

Pharmacy chains rating in terms of retail sales in value terms

<table>
<thead>
<tr>
<th>#</th>
<th>Company</th>
<th>Market share,%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Med-Service Group</td>
<td>2.95%</td>
</tr>
<tr>
<td>2</td>
<td>Farmaciya (Lugansk)</td>
<td>2.26%</td>
</tr>
<tr>
<td>3</td>
<td>Ukrainian Pharmacy Holding</td>
<td>1.89%</td>
</tr>
<tr>
<td>4</td>
<td>Arnika</td>
<td>1.88%</td>
</tr>
<tr>
<td>5</td>
<td>Farmastor</td>
<td>1.75%</td>
</tr>
<tr>
<td>6</td>
<td>Farmaciya (Kyiv)</td>
<td>1.55%</td>
</tr>
<tr>
<td>7</td>
<td>Bazhayemo Zdorovya</td>
<td>1.53%</td>
</tr>
<tr>
<td>8</td>
<td>Apteka Nyzkyh Tsin</td>
<td>1.5%</td>
</tr>
<tr>
<td>9</td>
<td>Falbi</td>
<td>1.46%</td>
</tr>
<tr>
<td>10</td>
<td>Titan</td>
<td>1.42%</td>
</tr>
</tbody>
</table>

Legislation

Ukrainian legislation mandates licensing for the following types of activities:

- medicinal products (hereinafter referred to as the “MP”) manufacturing, wholesale and retail trade,
- production of veterinary medicines and drugs, veterinary practice.

MPs are subject to obligatory state registration, except for drugs prepared in pharmacies by prescription or ordered by medical preventive institutions with permitted for use active substances and excipients.

Leading players are mainly locally owned. Retail sales in 2011 have increased by 15.9% as compared to 2010 in value and by almost 0.1% in volume and reached USD 3.4 bn /1.9 bn packs.

For state registration of the MPs they should pass pre-clinical research and clinical trials. Pre-clinical research is usually conducted by research organizations. Conducting clinical trials is more formalized. It may be held in the preventive and treatment facilities defined by the Ministry of Healthcare of Ukraine (hereinafter referred to as the “MHC”) or it’s authorized body after obligatory evaluation of the ethical, moral and legal aspects of the clinical trial program (by special ethical committees) and approval of such program by MHC or it’s authorized body. Application for clinical trial with all needed documents is to be submitted to the MHC or it’s authorized body.
Manufacturing of MPs is subject to requirement of compliance with GMP standards.

MPs can be sold only if the seller has certificate issued by manufacturer. Recent changes in the field of pharmaceutical legislation introduced also the procedure of declaration of changes in wholesale prices for MPs and medical devices to be purchased by state and local budget funds. The regulation which introduces the declaration procedure is effective from the 1 September 2012. The declaration has replaced the previous procedure of state registration.

Moreover, there are specific limitations regarding trade markup. For MPs and medical devices included in the National list of the essential MPs and medical devices the markups are: 12% of the wholesale price – for supply, 25% of supply price – for sales prices. For MPs and medical devices to be purchased by state and local budget funds – 10% for both supply and sales.

There are also some specific requirements and restrictions, namely for labeling of MPs (set of information that must be stated on the label) or advertisement of MPs (i.e. the advertisements of MPs to be prescribed by doctor is forbidden). Additionally MHC on 17 August 2012 has introduced the List of the OTC MPs which may not be advertised.

MPs may be imported into Ukraine in case they are registered in Ukraine and providing that there is quality certificate issued by manufacturer. There are several exceptions from this rule - unregistered MPs can be imported for: conducting pre-clinical research, pharmaceutical development, clinical trials, registration in Ukraine, exhibiting, medical provision of legally present foreign armed forces divisions in Ukraine, individual use by citizens. Moreover starting from the 1 March 2013 import of the MPs will be subject to licensing.

There is industry-specific Law of Ukraine “On Medicinal Products” dated 4 April 1996. Beyond there is a big amount of substitutory legislative acts, including regulations of Cabinet of Ministers of Ukraine, MHC’s orders etc.

The central executive body in the field of pharmaceutics, health care and biotechnologies is MHC. Other authorities involved in management of this field are: the State Service of Ukraine on Medicinal Products and the State Drug Inspectorate of Ukraine. Scientific and organizational support for objectivation of permit for use of MPs is performed by State enterprise State Expert Centre of the MHC of Ukraine.

With regards to corporate income tax (hereinafter referred to as the “CIT”) there is no special treatment of the activities connected with pharmaceutics, health care and biotechnologies field. CIT is currently calculated at a flat rate of 19% until 31 December 2013 and will be 16% from 1 January 2014 onwards.

Value added tax (hereinafter referred to as the “VAT”) currently levied at a rate of 20% of the taxable value of domestic supplies, imported goods and auxiliary services. The VAT rate will be reduced to 17% from 1 January 2014.

In respect of pharmaceutical market in Ukraine there are several exemptions from VAT: supply of technical and other devices for rehabilitation, their repair and delivery; supply of the devices of intended use including medical devices for individual use, for invalids and other welfare beneficiaries according to the list enshrined in the law; provision of healthcare services and rehabilitation services for invalids and children-invalids by licensed institutions; supply of MPs listed in the State register of MPs which are permitted for manufacturing and use in Ukraine as well as medical devices according to the list set by the Cabinet of Ministers of Ukraine.

For trade activities at points of sales entities also need to receive trade patents and are obliged to pay special fee for conducting certain types of activities. The rate of such fee is defined locally.
## Organizations and associations of the industry

<table>
<thead>
<tr>
<th>Association</th>
<th>Description</th>
<th>Web-site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Producers of Ukraine</td>
<td>The main goal is protection of interests of Ukrainian pharmaceutical industry.</td>
<td><a href="http://www.afvu.org.ua">http://www.afvu.org.ua</a></td>
</tr>
<tr>
<td>Pharmaceutical Association PharmUkraine</td>
<td>The Association consists of five corporate members - labor collectives of the leading distribution companies:</td>
<td><a href="http://www.pharmukraine.org/ua/">http://www.pharmukraine.org/ua/</a></td>
</tr>
</tbody>
</table>
|                                      | 1. Alba Ukraine,  
|                                      | 2. BaDM,  
|                                      | 3. Biocon,  
|                                      | 4. Optima-Pharm,  
|                                      | 5. Fra-M.  
|                                      | The main goal is to represent and protect legal interests of its members in economic and social spheres.                                                                                           |                                               |
List of references:

1. Consumption of medicines in Ukraine // PharmXplorer
3. Ukraine’s pharmaceutical market in 2010. Variations on vertical races. (available only in Ukrainian/Russian) // Proxima Research, 2010
5. Country statistics // World Healthcare Organization, - apps.who.int/ghodata/?vid=20400&theme=country