

**Development of Studies for Sectors with Potential  
Pharmaceutical Sector Study, Bosnia and Herzegovina**

Draft

## The pharmaceutical sector

The definition of the pharmaceutical sector in this analysis differs from the standards used in western Europe. We concentrated on the following companies or product groups:

- Medicinal products (medicaments)
- Medical devices (incl. medical dressings)
- Homeopathic products
- Cosmetic products

The pharmaceutical sector comprises the production, the trade in and the development of the product groups listed above. The product groups of the pharmaceutical sector are connected with other sectors, particularly with the chemical industry, the textile industry and agriculture.

The international trend in the pharmaceutical sector is presently heading towards research and development of drugs, medical devices and homeopathic medicines for the treatment of widespread modern-day illnesses, immune system diseases and cardiovascular disorders. One field of research subject to controversy is genetic engineering.

## Companies and competition

In the former Yugoslavia, 80 % of the demand for medicinal products was covered by local production in 16 specialist companies, four of which were in Bosnia and Herzegovina. Problems that the entire Bosnian industry had to contend with after the war also affected the pharmaceutical industry. Company managements had to deal with unregulated and unclear ownership conditions caused by the partial privatisation under Markovic's economic programme just before the war broke out.

During the war, the companies either ceased manufacture or manufactured with a drastically reduced utilisation of capacity. The war damage to the industrial plants is enormous. The more modern parts of the plants were especially targeted, making complete reconstruction necessary after the war. However, no funds were available for investment. Owing to unregulated ownership conditions, the interest in investing was also very much reduced. The plan for renewal and development of Bosnia and Herzegovina was initially restricted to infrastructure and administration. Only 8.2 % of the volume of the donor credit lines went to industrial investment - and at high rates of interest.

Both the political and the economic upheavals have completely changed the picture of the pharmaceutical industry in Bosnia and Herzegovina. Four large pharmaceutical companies were successful on the market in 1991, Bosnalijek and Sanofarm in Sarajevo, Medic in Cazin and Saniteks in Velika Kladuša. They employed over 2,000 staff and served local and international markets. All four companies are in federation territory, two in Sarajevo canton and two in Una-Sana canton. They are still present on the market today, with varying degrees of success. Some were able to overcome the consequences of the war to a very large extent, to modernise production, to ensure quality and to sell their products on the domestic market despite being faced with strong competition from large foreign pharmaceutical companies. The overwhelming majority of the companies, however, face bankruptcy.

So far, Sanofarm is the only company to have been privatised, while the others are still in the process of privatisation by public sale of shares.

The number of private companies on the pharmaceutical market is growing. Their strict market economy orientation can already boast its first successes. Although they are still relatively small, all the private companies are making a profit. These are companies with smaller capacity and with smaller staff numbers. They have more flexible production programmes and can adapt more easily to the market situation at any given moment. The trend in the service sector is heading towards a growing number of private pharmacies and to wholesaling of medicinal products.

**Table 1: Overview of the local companies in the Federation of Bosnia and Herzegovina**

	Company	Place	Activity	Ownership structure (%)	
				State	Private
1	Bosnalijek AG	Sarajevo	Pharmaceutical production	48.71	51.29
2	Saniteks AG	Velika Kladusa	Manufacture of medical dressings	62.93	37.07
3	Medic AG	Cazin	Medicinal products	33.00	67.00
4	Astro AG	Sarajevo	Soap and cosmetic production	45.09	55.91
5	Sanofarm AG	Sarajevo	Pharmaceutical production	50.13	49.87
				Private	Investor
6	DKS Loversan GmbH	Cazin	Medicinal products	1.00	99.00
7	Semikem GmbH	Sarajevo	Medical devices	100.00	-
8	Pharmamed GmbH	Travnik	Medicinal products	100.00	-

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The pharmaceutical and cosmetic products are for the most part manufactured by two companies; among other things, Bosnalijek in Sarajevo manufactures preparations:

- for the treatment of high blood pressure
- for blood formation
- for the cardiovascular system
- for urology
- for skin treatment
- for the treatment of infections
- for diseases of the nervous system

In addition, it manufactures and sells preparations from the non-pharmaceutical sector.

Saniteks in Velita Kladusa manufactures hygiene and cosmetic care products for adults and children.

There is obviously strong competition on the pharmaceuticals market in Bosnia and Herzegovina. In addition to the largest manufacturer of medicinal products, Bosnalijek, almost all the major international players are represented there. So far, 32 representations of foreign pharmaceutical companies with over 500 authorised preparations have been registered. In the Republic of Srpska, there are more than 60 pharmaceutical representations – with over 1,000 authorised preparations. Bosnalijek has 92 authorised preparations on the market.

### **Estimate of the market size**

Currently no accurate data exists on the size of the total pharmaceutical market in Bosnia and Herzegovina. A rough estimate of the industry based on 1997 comprised the entire official market for medicinal products (including the private market) and the medical devices market (including humanitarian organisations and the black market) and arrived at a figure of approx. US\$ 147 million. Pharmaceutical costs accounted for 60 % of this. In the Federation of Bosnia and Herzegovina, the per capita costs were given as US\$ 35 in 1998, while no comparable data were available for the Republic of Srpska. Let us compare this with the data for two neighbouring states: Croatia US\$ 80-85 (World Bank Estimates, 1998), Romania US\$ 18 (Australian Health Insurance Commission, 1998). The current pharmaceutical costs (not including humanitarian organisations) are no doubt considerably lower. Despite its importance, the market volume of medicinal products in free circulation which are available without prescription is not shown.

### **Quality assurance**

The quality assurance system monitors the safety, efficacy and good quality of the medications. The medications in the Federation of Bosnia and Herzegovina are included in a general control system beginning with the control of the starting substances, continuing with the production process control and going on to the control of the finished product. The quality assurance system also comprises the assessment of the standard of the medication in the marketing authorisation process, the work of the national quality control laboratory, the issue of authorisations to manufacturers, wholesale drug sellers and pharmacies, and the

pharmaceutical inspection and the withdrawal of non-compliant medications. All these activities are based on internationally recognised standards.

### **Procedure for marketing authorisation**

There are currently two different procedures for marketing authorisation in Bosnia and Herzegovina. For the Federation of Bosnia and Herzegovina, the procedure for marketing authorisation is conducted at the Institute for the Quality Control of Medicinal Products. The institute's capacities are not being fully utilised. In the Republic of Srpska, there is no such institute. Here, a "shortened" procedure is employed, requiring a minimum of documents for the registration of drugs in the Republic of Srpska. One of the more recent initiatives is that a laboratory for the analysis of immunobiological medicinal products is being established and equipped in Banja Luka. There is no such laboratory in Sarajevo. This institute could perform the marketing authorisation procedure for the whole of Bosnia and Herzegovina under the supervision of the Medicinal Products Agency of Bosnia and Herzegovina. In view of a better utilisation of the capacities of the Institute for the Quality Control of Medicinal Products of the Federation of Bosnia and Herzegovina, this would be both desirable and technically feasible.

In parallel to the legal market, there is a grey market in both entities. Some of the medicinal products come to the Republic of Srpska from Yugoslavia. The exchange takes place in the special zone of Brcko and is not monitored. It is via this route that these medicaments enter the market of the Federation of Bosnia and Herzegovina, where they have no marketing authorisation. This unregulated cross-border market for medicinal products circumvents market control and has far-reaching consequences for the pharmaceutical sectors of both entities. The situation is aggravated by the fact that some of the medicaments are imported by wholesalers owing to the large demand.

In the Republic of Srpska, the Medicinal Products Act has already been passed. In the Federation of Bosnia and Herzegovina, however, reading of the bill before parliament has not yet been completed. The enactment is expected on 1 August 2001. The laws have been very largely adapted to the EU directives within the framework of an EU Phare Programme. An improvement of the situation in the pharmaceuticals sector is expected as a result of the application of these laws. However, the situation in the Brcko district remains unsolved, and this district will remain a stronghold of incomplete control of pharmaceutical marketing in the future too.

### **Homeopathic remedies and herbal preparations**

Homeopathy is relatively unknown in Bosnia and Herzegovina and not recognised as a treatment method according to the laws to date. The aforementioned law from the Republic of Srpska also regulates the use of homeopathic and herbal preparations. The special production conditions and the conditions for registration are regulated by statutory provisions (regulations), which are in preparation and which are due to be ratified by the Minister of Health by the end of 2001.

The greatest problems facing non-medical practitioners are of an administrative nature, particularly as regards registration in the Federation. Owing to unfavourable statutory regulations, it is easier to import these products than to manufacture them locally. This is highly regrettable, since most of the raw materials for production can be found on the domestic market and are of a high quality. There is also sufficiently trained personnel with

the requisite knowledge, and the technological investments are relatively small. Local production would provide employment opportunities for inhabitants of rural areas. There are real chances for the placement of homeopathic preparations on the domestic market and for the export of these products. The more appropriate utilisation of natural resources for the production of medicinal and homeopathic preparations is not, however, possible without better co-operation with government agencies and the ministries of health. This concerns the registration of the preparations and the opening of new pharmacies selling homeopathic and herbal remedies. One of the insufficiently utilised potentials of Bosnia and Herzegovina is the collection of wild medicinal plants, which is currently still insufficiently organised. In Bosnia and Herzegovina, the conditions for planting medicinal plants are excellent. There is already a market for these plants in Bosnia and Herzegovina, and export opportunities also exist. The following can be planted, in particular: Salvia officinalis, Menta piperita, Juniperus communis, Inula helenium, Taraxacum officinalis, Melissa officinalis, Capsela bursa pastoris, Achillea millefolium and Hypericum perforatum.

In order to fulfil export ambitions and to take over the domestic market, it is absolutely necessary to pay attention to quality, not only when planting, but also when processing the medicinal plants. There is sufficient qualified personnel for the entire production process. All that is needed is good organisation and legal conditions conducive to production and export.

### **Government measures**

The pharmaceutical industry in Bosnia and Herzegovina is in the sphere of responsibility of the Ministry for Energy, Mining and Industry of the Federation of Bosnia and Herzegovina and of the Ministry for Industry and Technology of the Republic of Srpska. The pharmaceutical industry is closely connected with the public health system, and the responsible departments for drug policy, production, import, export, wholesaling and distribution are to be found in the institutions of the public health system. Pharmacies, etc. are assigned to the respective ministries for public health of the Federation and of the Republic of Srpska.

The Pharmaceuticals Committee was established at the end of 1996 as a supervisory organ of the Ministry for Public Health of the Republic of Srpska for the purpose of defining and supervising the implementation of pharmaceutical policy and the reform of the pharmaceutical sector. The strategic plan for the reform of the pharmaceutical sector was drawn up by this committee and approved by the Ministry for Public Health and the Ministry for Social Affairs. One year later, the draft of the implementation plan was elaborated in co-operation with WHO within the framework of an EU Phare Programme. The main features of this implementation plan for the development of the pharmaceutical sector are:

1. Law and regulation
2. Quality assurance
3. Supply with and distribution of medicines
4. Pharmaceutical prices, financing and charges
5. Rational use of medicines
6. Training

The reorganisation of the Ministry for Public Health resulted in the creation of the pharmaceuticals department at the beginning of the year 2000. The deputy minister is also the head of this new department. The general policy on pharmaceuticals, the regulation of medicinal products, marketing authorisation, licensing, regulation of opiates and quality assurance are the responsibilities of this department.

### **Development perspectives**

With its some 3.6 million inhabitants, the country of Bosnia and Herzegovina is a market which does not offer sufficient potential for the majority of national manufacturers and distributors. Niche providers exist, but their growth potential is also restricted. All economic activities are therefore to be viewed from the point of view of internationalisation:

#### **Manufacturers**

- Local manufacturers such as the Bosnalijek and Saniteks companies need the international market for their products.
- Small- and medium-sized enterprises must be offered assistance so that they too can outgrow the local or regional market.

#### **Distributors**

- State-owned and privately owned pharmacies can only survive on the local and regional market if they include other products in their assortments.

#### **Products**

- The purely medicinal products are limited in their growth by the large international players.
- In the case of herbal products, e.g. local herbs for natural teas, ointments, etc., there are good opportunities for micro- and small enterprises on the local and regional market and for niche suppliers with international co-operation partners on the international market.

All local/regional suppliers in the pharmaceutical industry need foreign support in the form of foreign investments, partnerships or joint ventures. This also applies in particular to the transfer of pharmaceutical, technical and commercial know-how.