The pharmaceutical sector in the Republic of Srpska, Bosnia and Herzegovina

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Summary: Medicines are one key component in the maintenance and restoration of the health of communities and individuals, which is why they are placed amongst the top priorities in the health system of the Republic of Srpska, one of the two entities that make up Bosnia and Herzegovina. This is being achieved through the development of a national medicines policy. A central objective in the area of pharmaceutical activity to ensure that citizens have access to safe, good quality and effective medications that are made available at reasonable price and used in a rational manner.

Keywords: pharmaceutical policy, drug regulatory agency, Republika Srpska, Bosnia and Herzegovina

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The Pharmaceutical Chamber and the Pharmaceutical Association.

Developments in the pharmaceutical sector

Pharmaceutical supply during the war and postwar period was mostly channelled through humanitarian aid programmes, which thus heavily influenced pharmacotherapy, with medicines delivery based upon humanitarian donors own estimation and stocks. Since the 1990s the pharmaceutical sector has undergone much reform, both through EU CARDS programme (Community Assistance for Reconstruction, Development and Stabilisation) and various World Health Organization (WHO) projects which have supported health care reforms in Bosnia and Herzegovina.

Marketing authorisation, quality control and inspection improved considerably in 1997 when the List of Essential Medicines was introduced, based on the WHO’s Essential List Model. Further improvements came with the creation of a pharmaceutical department within the Ministry of Health and Social Welfare and the appointment of a junior minister with responsibility for pharmaceutical issues. There has been a strong orientation...
towards the EU, aligning pharmaceutical legislation with EU directives. Legislation harmonised according to European standards provides the basis for maintaining standards for the quality assurance of medicines. The current applicable Law on Medicines, approved by the Parliament in 2001, was developed by local experts through the EU CARDS Programme, and was fully compliant at that time with European pharmaceutical legislation. This law was subsequently revised and updated in March 2008. Other specific aspects of pharmaceutical policy are covered through a number of bylaws.

An official national medicines policy document, linked to overall health policy, was adopted by the government in 2006. Its overall objective is to ensure access to effective, safe and quality medicines, made available in a rational and cost-effective manner to the whole population. This objective will be fulfilled through strategic action plans.

The Drugs Regulatory Agency
One of the main outcomes of the WHO and EU CARD projects was the adoption of the Law on Medicines and the establishment of the Drug Regulatory Agency (DRA) of the Republic of Srpska. The role of the DRA is clearly reflected in the Law on Medicines, by which it was established in 2002 as an independent professional body responsible to the minister of health. All core pharmaceutical quality assurance functions fall under the auspices of the DRA, i.e. marketing authorisation, classification of medicines, licensing, quality control, medicines information, pharmacovigilance and clinical trials. It has a staff of forty employees, the majority of whom are pharmacists. Since the DRA was established, an upward trend in the number of medicines that receive marketing authorisation, in accordance with the system of international non-proprietary names (INN), has been observed. This increased from 104 INNs in 2005 to 260 in 2007.

The increased number of medicines on the market can be directly linked with improved access to medicines by the population. A department of pharmacovigilance is responsible for collecting data on adverse drug reactions (ADR) and for promotion of the importance of monitoring and reporting of ADR. Through organised workshops the DRA provides pharmacists and physicians with the most relevant data on ADR, as well as demonstrating practical skills on how to report them (both spontaneous reporting and within clinical trials). A brochure entitled Guidelines for Detecting and Reporting the Adverse Effects of Medicines has also been published and reports can be submitted online or by post. The DRA is also responsible for monitoring clinical trials according to related bylaws and guidelines on good clinical practice. The case for each proposed clinical trial, including harmonisation with clinical practice guidelines, is evaluated by the RS Ethical Committee.

Pharmaceutical inspection is regulated by the Law on Inspection, with an Inspectorate established as the competent authority. Inspectors have the authority and obligation to take appropriate measures where non-compliance with legislation is identified. One problem however is a shortage of pharmaceutical inspectors, with only two currently in operation. Moreover, neither has a Good Manufacturing Practice (GMP) qualification.

Distribution, supply and quality control
The majority of medicines are imported, with the majority coming from manufacturers elsewhere in the former Yugoslavia, as well as from multinational pharmaceutical companies. There is only one local pharmaceutical manufacturer, Hemofarm, now a subsidiary of the German pharmaceutical company Stada.

Pharmaceuticals are supplied by wholesalers to pharmacies. There are twenty-five licensed wholesalers, all privately owned. Four wholesalers dominate, having around 80% of the market. Prescription and over the counter medicines can only be obtained through the 274 pharmacies in RS, the majority of which are privately owned. Pharmacies may be owned by non-pharmacists, but can only be operated by one or more of the 523 licensed pharmacists in RS, usually working in partnership with a team of pharmaceutical technicians. One recent change has been

### Table 1: Overview of demographic indicators, Republic of Srpska

<table>
<thead>
<tr>
<th>Indicators</th>
<th>1998</th>
<th>1999</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (millions)</td>
<td>1.43</td>
<td>1.45</td>
<td>1.49</td>
</tr>
<tr>
<td>% population 65+</td>
<td>11.0</td>
<td>16.0</td>
<td>17.6</td>
</tr>
<tr>
<td>Birth rate (per 1,000 population)</td>
<td>9.4</td>
<td>10.0</td>
<td>7.7</td>
</tr>
<tr>
<td>Death rate (per 1,000 population)</td>
<td>8.7</td>
<td>8.5</td>
<td>9.3</td>
</tr>
<tr>
<td>Life expectancy at birth (female)</td>
<td>74</td>
<td>74</td>
<td>82</td>
</tr>
<tr>
<td>Life expectancy at birth (male)</td>
<td>71</td>
<td>71</td>
<td>75</td>
</tr>
<tr>
<td>Infant mortality (per 1,000 live births)</td>
<td>8.3</td>
<td>8.2</td>
<td>4.3</td>
</tr>
</tbody>
</table>

Sources: Republika Srpska Institute of Statistics, 2007; Cain J et al, 2002; US Central Intelligence Agency

### Table 2: Medicines consumption in Bosnia and Herzegovina, and relative share of consumption by the two entities

<table>
<thead>
<tr>
<th>Year</th>
<th>Total medicine consumption in Bosnia &amp; Herzegovina (million €)</th>
<th>Republic of Srpska (%)</th>
<th>Federation of Bosnia and Herzegovina (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>115</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>2004</td>
<td>123</td>
<td>27</td>
<td>73</td>
</tr>
<tr>
<td>2005</td>
<td>132</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>2006</td>
<td>148</td>
<td>35</td>
<td>65</td>
</tr>
<tr>
<td>2007</td>
<td>174</td>
<td>40</td>
<td>60</td>
</tr>
</tbody>
</table>
the creation of specialist stores operated by pharmaceutical technicians in which herbal medicines, foodstuffs, other complementary medical products, cosmetics, hygiene products and specified medical devices may be sold.

There are 35 pharmacists per 100,000 inhabitants compared with 72 per 100,000 in the EU.8 There is one pharmacy per 5,430 inhabitants. Density in urban areas is much higher than in rural areas; these largely remain underserved, with pharmacists having little incentive to work in such areas. Hospital pharmacies serve only inpatients, again being run by licensed pharmacists. There remains a persistent shortage of hospital pharmacists while self-dispensing by doctors is not allowed.

As noted earlier the Essential Medicines List (EML) is based upon the WHO EML model. The EML provides a base from which other outpatient and inpatient medicine lists reimbursed by the HIF have been developed. These include the Hospital List of Medicines (for inpatients), the List of Medicines used in Dom zdravljas (similar to polyclinics) by general practitioners (for ambulatory acute situations) and the Positive List of Medicines (for prescription only medicines). These lists are broader than those of the EML, reflecting therapeutic needs, but adjusted to take account of the financial considerations faced by the HIF. The WHO ATC (Anatomical Therapeutic Chemical) classification system is fully applied to all medication on these lists, while the Hospital and Dom zdravlja lists are also used for the central tender on the procurement of medicines, according to the Law on Public Procurement in Bosnia and Herzegovina.

Reimbursement and drug price regulation
Outpatient medicines reimbursed under the Positive List are dispensed through a network of pharmacies contracted by HIF. Criteria for reimbursement are defined by the HIF. The evidence on the therapeutic benefits and economic impacts of medicines are assessed by the Medicines Committee. Marketing authorisations are mandatory for all medicines but exceptions can be made in the case of medications of great clinical significance.

Since May 2008 the list has comprised two categories of medicine. Those on the A List are fully reimbursed up to a reference price level, while those on the B List are reimbursed at a 50% rate. A medicine can appear on either list depending on clinical indication. The A List covers medications for major chronic diseases including diabetes, epilepsy, cardiovascular disease and chronic psychiatric problems. Medications for a number of severe and/or chronic diseases including cancers, HIV/AIDS, multiple sclerosis, haemophilia and hepatitis C and B are fully reimbursed and dispensed separately through the hospital pharmacy system.

The reference price is set up to be equivalent to the cheapest generic medicine in a cluster, with medicines clustered on the fifth ATC level; thus medicines with the same active ingredient (INN), dosage form and administration route have the same price. A flat fee-for-service of €0.56 per prescription is paid by HIF to contracted pharmacies to supply and deliver reimbursable medicines to patients.

Pharmacists are allowed to substitute any prescribed medicine with another that has the same INN, but pharmacists are obliged to provide the lowest priced equivalent without any requirement for an out of pocket payment. If there remains a demand for a specific brand, either by the patient or physician then the patient must pay out-of-pocket any difference in price.

Free pricing applies to non-reimbursable and OTC medicines with patients having to pay the full retail price. A wholesale mark-up of 8% is applied to the ex-factory medicine price plus a further CIF (Cost, Insurance and Freight) levy of approximately 2%. Since 2006, Bosnia and Herzegovina has levied value added tax at a flat rate of 17% on all imported goods, including medicines. The retail mark-up is 20% of the wholesale price. According to Bosnia and Herzegovina legislation the customs tariff for pharmaceuticals ranges between 0% and 10%.

Better use of medications and strengthening human resources
A number of efforts have been undertaken to encourage the more efficient and rational use of medications. Detailed information on medicines are available on the DRA website. Information tailored to health care professionals can also be found in the annual Medicines Formulary. Since 2006, the DRA has also begun to collect data on medicine consumption, using the ATC/DDD (Defined Daily Dosage) methodology. Eighteen standard therapeutic guidelines relating to the most common health problems seen in primary health care have been published; others are in preparation.

Hospital Medicine Committees can also play an important role in encouraging more rational use of medicines. All hospitals have now established such bodies.

One key challenge is the limited capacity in pharmacy. The Department of Pharmacy within the medical faculty at the University of Banja Luka, is the only teaching centre for pharmacy students. This is funded by the government. With undergraduate training lasting five years, 120 qualified pharmacists have been trained in the past decade. However the lack of teaching staff for both undergraduate and postgraduate pharmacy education has meant that there has been a reliance on attracting teaching staff from outside RS. In future, much effort needs to be invested in expanding and training indigenous university staff in order to help address the challenges created by the insufficient number of pharmacists having professional specialisation and academic titles, as well as the lack of hospital-based pharmacists.

Conclusions
Health systems should be designed so as to provide equitable access. The main challenge is to continue to make progress towards achieving key health system objectives, namely improving the health of the population and providing protection against the financial costs of illness, while ensuring financial sustainability in the health sector. The pharmaceutical sector, despite all its complexity, is well aware of the role and the impact that it can have in meeting these objectives.

Considerable efforts have already made in RS to both improve access to medicines...
and make them more affordable. We have noted that access to medications has recently been significantly improved through the development of extended hospital and outpatient positive medication reimbursement lists. In the field of legislation considerable progress has been achieved in moving towards a regulatory framework compliant with EU standards. Effective and transparent functions within the DRA have made a notable contribution to the implementation of this legislation. Much more, however, remains to be done to strengthen capacity within the pharmaceutical sector.

REFERENCES


