Market Access Pricing in Central and Eastern Europe: Practical Guide to Successful Reimbursement in Bosnia and Herzegovina

Tarik Čatić, MScPharm, PhD(s), Researcher and Past President, ISPOR Bosnia and Herzegovina Chapter, Sarajevo, Bosnia

Bosnia and Herzegovina as a former country of Yugoslavia since 1995 when Dayton peace agreement has been signed is highly a decentralized country. Administrative organization is based on few levels: state/national level, two entities: 1. Federation of Bosnia and Herzegovina consisted of 10 cantons as sub-administrative units and 2. Republic of Srpska and 3. Brcko district as special administrative unit. The Ministry of Civil Affairs on a state level deals with health sector in terms of coordination between entities and international relationships. It is also responsible for establishing the Agency for Medicines and Medical Devices of Bosnia and Herzegovina (ALIMS). This institution has unified pharmaceutical market in terms of marketing authorization. Also, the intention of ALIMS is to introduce medicines price control mechanism through referral pricing system (referral countries Serbia, Slovenia, Croatia, and additionally Austria and Italy in case referent product is not available in primary referral countries).

Reimbursement policy and decision making process is performed on the entity and cantonal level, based on different policy approaches. Officially, there is no health technology assessment (HTA) in place, even though some activities on incorporating this process have been performed, and some postulates in this field have been set up in the recent legislation.

The Federation of Bosnia and Herzegovina has 11 ministries of health; one at the Federation level and one in each of the ten cantons. Federal Ministry of Health (FMoH) is responsible for setting up the list of essential medicines, which is actually the reimbursement list. In order to unify access to medicines at the whole territory level the Federation of Bosnia and Herzegovina, FMoH, from 2011 onwards has annually revised and established this list which consists of List A (100% reimbursed medicines) and List B (with different copayment levels upon decision at cantonal level depending on available cantonal HIFs budgets). Beside these lists, the List of drugs used in hospitals is also set up by FMoH, while also, hospitals can expand and define the list of medicines on a micro-level. All medicines used in hospitals are purchased through tenders. FMoH set up price for each INN included into the list. List A must be adopted at cantonal level and fully implemented, while the List B can be modified by the cantonal Health Insurance Funds depending on the budget. The Federal Health Insurance Fund is mandated to control and supervise 11 compulsory insurance funds.

At a federal level, the Federal Health Insurance fund established Federal Solidarity Fund, in order to reduce the duplication of services and enable movement of patients from one location to another in order to receive the needed services where available. This reduced the fragmentation of services between cantons and along the ethnic lines. In practical terms, it means that lower income cantons can now equally benefit from expensive interventions that before solidarity could not be afforded. This fund mainly covers costs for expensive therapeutics (oncology, biologicals, HI) and procedures (hemodialysis, transplantation etc.). All drugs financed by the solidarity fund are purchased through annual tenders.

The Republic of Srpska is another administrative unit in Bosnia and Herzegovina and has a centralized government and health care financing. Health Insurance Fund of RS (HIFRS) is the only and the main payer, buying health services, medicines and medical materials for all insured population. There are several lists of medicines. Lists A and B cover all of medicines prescribed directly by the primary care physicians and most medicines recommended by the specialist in a secondary and tertiary health care institution that are then prescribed by primary health care physicians. Medicines are then bought in pharmacies. For medicines on an A list HIFRS reimburses 90% of drug prices and for medicines on B list that amount is 50%. Prices on those two lists are formed through internal reference system by the generic name...
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of medicine. Fund accepts the lowest proposed price for one generic medicine name (one INN). The list for ambulatory health care medicines covers medicines that are used in urgency departments on primary health care level. They are bought by public procurement and delivered to primary health care facilities. Hospital list includes medicines that are used in hospitals. Medicines on this list are also bought by public procurement and via distributors delivered to secondary and tertiary level health care facilities. There is also a List for cytotoxic and biologic drugs with oncology indications. Medicines on this list are proposed by the specialists in hospitals and mainly also used in hospitals as well. Public procurement is the way of buying medicines for this list too but it is announced every two years. There is a new list, List of drugs with a special way of financing.

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<th>Institution</th>
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<th>Federation of B&amp;H</th>
<th>Republic of Srpska, B&amp;H</th>
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<tr>
<td>Ministry of Civil Affairs</td>
<td>Federal Ministry of Health / Cantonal Ministries of Health</td>
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<td>Marketing approval for medicines Pricing control (IRP)</td>
<td>Coordinative role among entities and International organizations</td>
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Table 1. Overview of key stakeholders in Bosnia and Herzegovina and their jurisdictions

Decision Making Process and Reimbursement

In the last five years, reimbursement decisions are set up through legislation and different rulebooks. In general, manufacturers or marketing authorization holders submit reimbursement file. Beside the general documentation about drug that is a subject of decision, pharmacoeconomics criteria are also requested such as: the price and cost-effectiveness/utility analysis with local data. Unfortunately, the decision criteria have not been publicized which actually makes the decision process less transparent. Specific drug committees are set up by MoH or HIFs who make selection and send proposals for reimbursement list to the Ministry of Health for final approval.

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For the innovative and new expensive drugs, there are several options of negotiation process. Mainly, access to these drugs is delayed and restricted. Sometimes, these medicines are financed through different programs and agreements between the manufacturer and the payer. This is the case in both entities. These programs include price negotiation, discounts or different compensation (e.g. reimbursement of new drugs and financing some other program or project in health care – device donations etc.). There are no clearly defined options for market access such as risk sharing schemes, previous experiences showing that such projects are highly valuable for patients to get novel therapies. Figure 1 shows that firstly the reimbursement through projects helps to gain full market access.

Conclusion

As health care budgets are restricted, and price pressure measurements are recently more evident, the reimbursement decision making process should be more transparent and clearly defined. Introduction and full implementation of PE criteria would be preferable. In order to ensure access to novel therapies, introduction of different models like risk sharing schemes, budget/patient caps etc. would be preferable in future. In order to fulfill this it is important to invest in capacity building, since Bosnia and Herzegovina lacks health economics and PE experts, education is a key factor. In order to contribute to further development of HEOR in the country, the ISPOR Bosnia and Herzegovina Chapter has organized several activities such as: conferences, courses, translations of ISPOR publications and IDLP modules into Bosnian.

Market Access Pricing in Central and Eastern Europe: Practical Guide to Successful Reimbursement in Ukraine

Olha Zalis’ka, PhD, DSci, President, ISPOR Ukraine Chapter, Professor & Head of Department of Management and Economy of Pharmacy and Pharmacoeconomics, Postgraduate Faculty, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine

The legal requirements for the introduction of medicines into the market and their inclusion in the insurance and reimbursement lists in Central and Eastern Europe are very different.
Market Access used in Pharmacoeconomics refers to the process by which a company gets a medicine to market so that it becomes available for patients. Access is defined as a patient's ability to obtain medical care. Ease of access is determined by such factors as the availability of medical services and their acceptability to the patient, location of health care facilities, and cost of medical care. The reimbursement of new pharmaceuticals traditionally was based on the registration data such as efficacy, safety and quality parameters. Every government is eager to control the increase of expenses by the implementation of central cost containment policies particularly in relation to pharmaceuticals.

In the U.S., there are specific AMCP guidelines describing the requirements of the submission dossier. In Europe, there are central guidelines for health economic evaluation and the requirements of a reimbursement dossier. The requirements by the decentral decision makers in each country may vary and they may inhibit the opportunities and incentives for pharmaceutical companies to invest in innovation.

There is growing evidence that especially the impact of the cost-effectiveness data in the decision-making process is increasing. Considerable consequences for all the different stakeholders involved, which include pharmaceutical industry, payers, patients, patient associations. An unfavorable cost-effectiveness outcome, may lead to a negative reimbursement decision. During the CEE Network Forum the topic of “Market Access Pricing in CEE,” was presented by speakers from Bosnia-Herzegovina, Turkey, Russia, and Romania. Each presentation discussed the experience of regulation of market for innovative, orphan medicines in a country and controversial aspects of increasing access to medicines for population.

The Application of the HTA Process and a Reflection on the Reimbursement in Croatia

Pero Draganić, MD, PhD, President, ISPOR Croatia Chapter, Assistant Professor, HALMED - Agency for Medicinal Products and Medical Devices of Croatia, Zagreb, Croatia

Introduction

Health technology has, among other things, a potential to improve population’s health outcomes, helps to treat the disease better and explains the need for the reform of the health system. The program of the ISPOR 18th Annual European Congress in Milan introduced a forum on: “Health Technologies Pricing and Decision Making in the Central South Europe”. CEE countries belong to the group of the middle-income countries with a limited budget, which covers a large public health care system. In these circumstances reimbursement from the public budget imposes the need for the developed health technology assessment (HTA) processes and issues of pricing of innovative health technologies. The health care system in Croatia has the commitment to promote the quality of life and make conditions for the improvement of health of each individual and the entire population. The Ministry of Health of the Republic of Croatia has the task to ensure optimal conditions in developing the health care system, grounded on the scientifically-based knowledge.

The Reimbursement Policy

Most of its activities by the Ministry are carried out through the Croatian Health Insurance Fund (CHIF, HZZO) as well as the agreement and the payment of the national mandatory health insurance. In that way the CHIF establishes performance standards and price settings for services covered by the Fund and, it is responsible for pricing and the reimbursement decisions on drugs and medical devices. The drugs (and medical devices) are included on the CHIF List of drugs through the expert council of the CHIF body. The essential list of medicines contains medically and economically most appropriate medication for the treatment of diseases. The referenced drug prices (the prices one pays CHIF through the compulsory health insurance) are at the lowest price. The CHIF is conducted in the public bidding