The Role of Health Technology Assessment in Reimbursement Policy – Experiences from the Republic of Serbia

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This manuscript reviews past and current approaches to Health Technology Assessment (HTA) in Serbia. It presents an overview of the product pricing and reimbursement processes for pharmaceuticals protected by patents. It reviews the approaches that Serbian National Insurance Fund (RZZO) utilized to regulate reimbursement policies. The manuscript attempts to forecast the further development of HTA in Serbia and its relationship and to product pricing and reimbursement. It also raises points learned from most recent HTA deployment in neighbouring countries.

Jelen összefoglaló Szerbia múltbeli és a jelen egészségügyi technológiaértékelési gyakorlatát mutatja be. Bemutatja az árazási és gyógyszerár támogatási folyamatokat a szabadalmi védettséget élvező termékek körében. Ismerteti a Szerb Nemzeti Egészségbiztosítási Pénztár (RZZO) támogatásszabályozási szemléletét. Cél az is, hogy ismertessük a szerb egészségügyi technológiaértékelés lehetséges fejlődési irányait, azok kapcsolatát az ártámogatással és az árképzéssel, illetve mit is tanultunk e tárgyban a szomszédos országoktól.

AN OVERVIEW OF THE SERBIAN HEALTHCARE REIMBURSEMENT SYSTEM

After the split of former Yugoslavia, Republic of Serbia, as well as other ex-Yugoslav countries, inherited Bismarck healthcare system model. Bismarck healthcare system model reflects publicly provided healthcare system financed through social healthcare insurance. National Health Insurance Fund (RZZO [1] of Serbia covers recurrent expenditure through input based provider payments. In 2010, majority of RZZO funding (income) [2] originated from two major sources: 69.48% came from the employment contributions and 29.01% from the pension plan contributions (see figure 1).

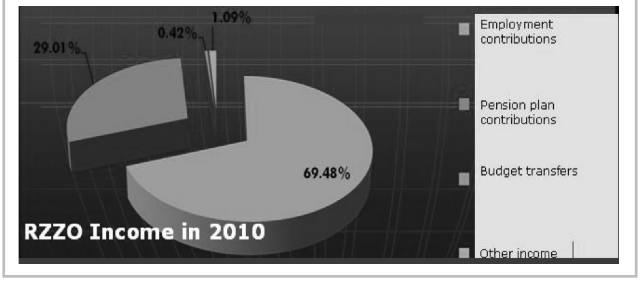

Figure 1
RZZO Income in 2010

In 2010, RZZO expenditure [2] on prescription drugs was third in-line at 12.85% (see figure 2), following RZZO employees' salaries at 44.54% and Health Protection expenses: hospitals, medical equipment, and utilities at 36.22%.

RZZO funding for 2010 dropped by €100 million from the previous year's funding and came down to €1.75 billion [2]. Based on this information, total RZZO national expenditure on prescription drugs was €225 million.

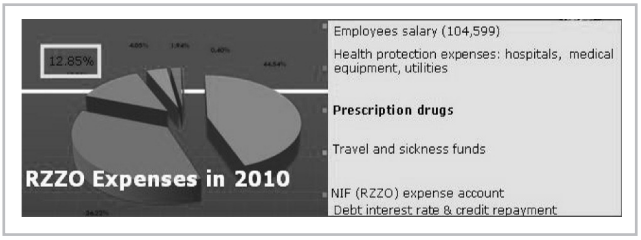

Figure 2
RZZO Expenditures in 2010

According to Miomir Nikolic [3] (the head of the Serbian Chamber of Commerce's group of drug wholesalers, which covers 85% of the market), Serbian drug market is expected to grow by 15% in 2011 and reach €1.1 billion in retail prices. The difference between the RZZO national expenditure on prescription drugs (positive list) and the total drug market cost indicates that majority of the expense for prescription medicines is carried by the patient. HTA implementation and effective HTA communication with the prescribers may lead to greater efficiency and direct savings to patients for out-of-pocket expenditures.

DRUG / MEDICAL DEVICE APPROVAL, PRICING AND REIMBURSEMENT PROCEDURES

A new drug or a medical device application is submitted to Medicines and Medical Devices Agency of Serbia (ALIMS) [4] . ALIMS turnaround time is up to 210 days from the date of application. Upon ALIMS approval to enter the market, manufacturer is to address pricing and reimbursement with RZZO in order to gain access to a positive list. Positive list contains different categories for different products and also a varying level of reimbursement.

As of May 2011, a new set of regulations was introduced. According to the Regulations on the Criteria, Methods and Procedures for Placing or Removing Drugs From the List of Drugs that are Prescribed and Dispensed at the Expense of Health Insurance, under article 20, paragraph 14, it is required that the RZZO be provided with the pharmaco-economic analysis by the manufacturer of the innovative medicine. This is the first step forward to HTA

(Health Technology Assessment) implementation. However, the old regulations pertaining to product pricing remained stipulating that the brand product price is not to be more than 20% higher than the price of the generic products in the same product category. Under such regulation, introduction of required pharmacoeconomic analysis may be seen as an unnecessary stipulation. At the same time, it may be viewed as the first step forward towards HTA implementation and potential phasing out of old regulations over the next period.

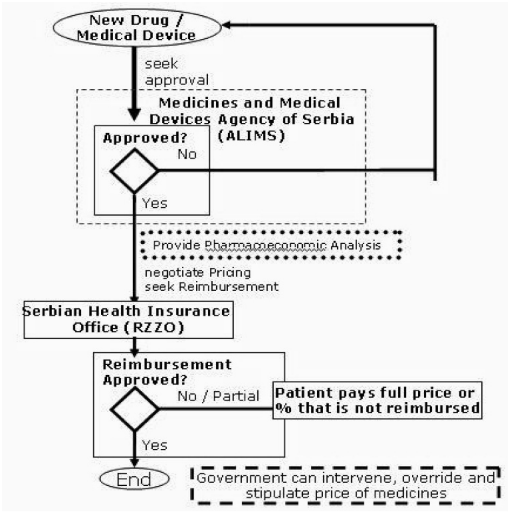

Figure 3
Drug / medical device approval, pricing and reimbursement procedures

At any point in time, government reserves the right to intervene, override and stipulate price of medicines. This is another potential threat in the supply of innovative medicines, which until this year have been sparingly present on the positive list. Sudden price cuts or adjustments based on exchange rate favourable to RZZO caused delays and steady supply of such medicines.

International reference pricing used to play a key role in pricing in the Republic of Serbia. According to the Regulations [5] published in 2009, mean value of the same product price from Slovenia, Croatia and Italy is multiplied by factor 0.685 to derive maximum allowable price in the Republic of Serbia. Although, pharmaco-economic study indicators were stipulated as one of the key criteria for forming the price, it was not truly considered.

PHARMACO-ECONOMIC ANALYSIS REQUIRED IN SERBIA

The new Regulations [6] published in May 2011 do take into account necessity for the new therapy, for the pharmaco-economic indicators of justification for the new therapy application, as well as for the wholesale price of the new therapy.

A closer look at the pharmaco-economic analysis now required by the Regulations, pursuant to article 20, paragraph 14, shows a fairly wide-spectrum of analyses from which a manufacturer can choose the most appropriate one. It stipulates that pharmaco-economic parameters that confirm economic justification of usage of a specific medicine, expenses – benefits (effectiveness) should be submitted in Serbian language and should contain at least:

- The wholesale price of the medicine – daily drug dose (DDD),
- Therapy expenditure per insured person, for the appropriate length of treatment (number of days), by therapy cycle or monthly,
- Annual expenditure on therapy (for chronic diseases),
- Comparator relation of expenses and effects between innovative or original medicine for which you are submitting the Request & medicines for the same indication, in case that there are medicines on the existing (positive) list. Comparative ratio should be implemented using a suitable modeling technique (decision tree, Markov model and other similar models) adjusted to the current situation in the Republic of Serbia in terms of expenditure and/or effects of therapy,
- Estimated number of insured persons that would be receiving the medicine, with calculated financial effect on total expenditure on medicines of the National Insurance Fund (RZZO), at an annual level,
- Tabular representation of the medicine presence on positive lists in EU countries and other countries.

OTHER FACTORS

Being financed predominantly by salaried workers and the respective level of salaries, RZZO directly depends on the economic up/down turn. According to the Statistical Office of the Republic of Serbia [7] , in April 2011, the unemployment rate was 22.2% (3% higher than six months before), not including 19.9% comprised of not formally employed population. With global recession underway, this may further complicate and diminish RZZO funding.

Total employed population is 36.2% [6], out of which 1.4% are employed by RZZO.

If a product is not on a positive (reimbursement) list, it becomes more difficult for a prescriber to provide it to the outpatient and almost impossible to inpatient.

One of the key budgetary factors for many innovative medicines is the fact that they may reduce hospital stay, avoid complex surgeries or visits to the doctor, this could potentially mean that if the RZZO was to introduce more innovative medicines at the expense of such strategies, RZZO would have to let go some of its own employees / facilities, which may not be a favourable political option.

NEIGHBOURING COUNTRIES – CROATIA

Croatia introduced HTA in January 2010 [8] . HTA is evaluated by the Department for Development, Research and HTA, Agency for Quality and Accreditation in Health. On a broader scope, Agency receives external suggestions for

HTA topic and takes it through selection process. Prioritization of HTA topic depends on: a) burden of the disease, b) resource impact, c) policy importance and d) inappropriate variations in practice across the country.

Agency then develops a final scope that describes the boundaries of the assessment and the issues that will be investigated; namely, objectives and research questions. They have four main types of HTA report: 1) Full HTA report in English language, 2) Summary of the full English HTA report translated to Croatian language, 3) Short advice to the Minister of Health and 4) Short advice to HZZO (Croatian Institute for Health Insurance). HZZO in Croatia has the same healthcare system role as Serbian RZZO.

Since January 2010, HZZO requires Budget Impact Model with each submission. Budget impact Model is to be designed based on ISPOR (International Society for Pharmacoeconomics and Outcomes Research) Principles of Good Practice for Budget Impact Analysis. In the near future, CEA (Cost Effectiveness Analysis) will be undertaken by the Croatian Agency for Quality and Accreditation in Health.

CONCLUSION

HTA is slowly gaining momentum in Serbia. The key cause for its slow implementation is the lack of health economic experts in the country. However, RZZO already has a growing HTA department that supports reimbursement decisions. This may also be viewed as part of the cost containment strategy, whereby pharmaco-economic analysis is not evaluated by an independent third party, but by the RZZO itself. HTA implementation and effective HTA communication with the prescribers may lead to greater efficiency and direct savings both to healthcare system and as well to patients per out-of-pocket expenditures.

DISCLAIMER

LITERATURE

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BIOGRAPHY

Vladimir Zah, PhD(c), Health Economics Consultant, graduated from Marketing Management in 1995. 2007-2011 President of ISPOR Serbia Chapter. He has worked at Dymaxium Inc. in 2000-2002. From 2003 till now he works at ZRx Outcomes Research Inc. as CEO. **School and trade qualifications:** 1992-1995 BSc. Marketing Management,1998 CPIAPD (Programmer Analyst), 2009-2012 PhD(c) Health Economics **Work experience:** ZRx Outcomes Research Inc., Health Economics, Consultant, with over 150 decision models, evaluations and economic opinions provided across different disease / therapy areas. "Early vs. Late HIV Detection", Budget Impact Model accepted by UK HPA agency and welcomed by UK BMA and UK parliament 2010 / 2011.

ISPOR Serbia, Health Economics / HTA, President and one of the founders of the local ISPOR Chapter. Provided education on approaches to decision modelling.

Dymaxium Inc, HEOR Decision Modelling, Project management of over 50 decision models across different disease / therapy areas.

ISPOR Society – HTA related Special Interest Groups member, judge on posters, issue panels and presentations over the last 10 years.