

The value of innovation in decision-making in health care in Central Eastern Europe

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Abstract

The Pharmacoeconomics Section of the Pharmaceutical Association of Serbia organised a one day international conference on the value of innovation in decision-making in health care in Central and Eastern Europe. The focus of the conference was on reimbursement decisions for medicines using health technology assessment and the use of managed entry agreements (MEAs). The objectives of this conference were firstly to discuss the challenges and

opportunities with the use of MEAs in Central and Eastern European countries; secondly the role of patient registries especially with outcome based schemes, and finally new approaches to improve accessibility to new medicines including better managing their entry.

Background

Central and Eastern European (CEE) health care systems are faced with a number of challenges through ageing populations, rising patient expectations and constrained resources (1). Improving access to new and valued innovative technologies within increasingly constrained budgets is becoming very difficult. For example, there are concerns regarding the impact of delays in evaluating new technologies on patients' health as well as concerns that current high patient co-payments for medicines, including biological medicines, restricts their use (2, 3). The lack of transparency in some countries can also make interpreting decision making challenging (4).

Tanja Novakovic (Pharmaceutical Association of Serbia) introduced the key concept of value in evaluating health innovations and challenges for decision-making. This is not helped by a lack of an agreed definition of innovation (5, 6). She presented data from IMS Health International Comparison of the Serbian Market showing that since 2010, 139 new medicines were registered in the EU. Out of these, Bulgaria reimbursed 44, Croatia 27 and Serbia only 1. After a 5 year wait in Serbia, the Managing Board of the National Health Insurance Fund approved 23 innovative drugs for inclusion onto the Positive Drug List (7). 18 drugs were subsequently also included on the list of medicines with Managed Entry Agreements (MEAs) and the remaining five drugs intended for the treatment of children were reimbursed without restrictions on their use.

Managed Entry Agreements

Alessandra Ferrario (Harvard University) discussed the use of MEAs as instruments which may be implemented to address issues of uncertainty around effectiveness, cost-effectiveness and uptake in real-life and/or high prices affecting decision-making processes. Different MEAs, both financial and health-outcome based, can be used to modulate effectiveness, e.g. coverage with evidence development, price such as discounts and free doses, payment by result, and the use, e.g. registries, of medicines which in turn influence two key decision-making criteria, cost-effectiveness and budget impact (8, 9).

Studies have found that MEAs are widely implemented among Western countries and more recently in a number of CEE countries. Ferrario presented the results of a 2017 survey on the implementation of MEAs in sixteen CEE countries. All countries with MEAs in place (10) implemented different types of financial agreements. Eight countries (Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Poland and Romania) allowed for the implementation of health-outcome based MEAs. Ferrario highlighted issues related to the administrative burden of their implementation, price transparency and raised the need for a monitoring framework to evaluate their impact. According to Ferrario, MEAs should be seen as a stepping stone that could contribute to improving access to new medicines while working towards sustainable solutions to ensure equitable access to affordable medicines for all eligible patients throughout CEE countries.

Bojan Trkulja (The Association of the manufacturers of innovative drugs in Serbia) presented examples of the Serbian experience with implementation of MEAs. Trkulja highlighted that for MEAs to be truly successful, several principles must be met. This includes simplicity to avoid substantial monitoring and implementation costs. Moreover, Trkulja highlighted the

need for clarity, whether this relates to providing more evidence relating to clinical outcomes, estimating population sizes, offsetting costs, assessing the budget impact or the cost-effectiveness of the new medicine at the list price. In addition, MEAs should be tailored to the particular setting, therapeutic area and product requirements. MEA schemes should also enable payers to optimise recommendations regarding new and existing technologies in a consistent and rational manner aided by transparency and trust between parties to ensure more efficient decision-making (11).

Managed Entry Agreements and Health Technology Assessment

Krzysztof Landa (National Center of Research & Development, Poland) introduced an alternative reimbursement mode for development (RMD) whereby a country not only purchases goods or medicines but also attracts companies to invest in production and R&D. Industry investments within the country may provide additional employment opportunities and have a positive multiplier effect for other parts of the host economy. RMD uses the incremental cost-utility ratio (ICUR) as a tool to enhance industrial investments in the host country. The concept is that a pharmaceutical company may improve its chances of success in gaining a positive reimbursement decision if the company already provides significant contributions to the host economy. It is feasible to multiply the effective cost of a new technology by the RMD factor while assessing its cost-utility against a comparator. This aims to persuade pharmaceutical companies to provide greater investment into the host country and in return the company receives more favourable reimbursement conditions.

Dávid Dankó (Corvinus University of Budapest) discussed links between MEAs and health technology assessment (HTA), raising the point that MEAs help mitigate clinical and economic uncertainties regarding new health technologies. However, without HTA they may be suboptimal health outcomes if the uncertainty and risks surrounding the use of new technologies is not fully evaluated (12). The pricing and reimbursement process must be constructed in a way that HTA fully captures relevant uncertainties so that MEA negotiations can be seamlessly connected to, or even integrated into, the technology assessment and appraisal phase. This enhances the role of a deliberative element in the decision process and is likely to introduce a negotiating element into it.

Real world evidence and accessibility to new medicines

Jaroslav Duba (OAKS Consulting) discussed the role of patient registries in facilitating access to medicines. For originator products, or in case of a new indication, it is mandatory to submit data from clinical trials as well as cost-effectiveness and budget impact analyses in the Czech Republic. Real-World Evidence (RWE) data is an important component for successful reimbursement. The Czech Republic is a leader in providing RWE as there is free access to anonymised public information and there has been a significant rise in the number of registries in recent years. Some of these have become part of the 'National Healthcare Information System' (13). In the Czech Republic, currently four sources of data can be used for RWE. These include specific disease area registries, health care providers, payers (Data providing based on "*Freedom of information law 106/1999 Col.*") and public administration. Consequently, there is great potential for combining clinical data and RWE data at national level in the Czech Republic, and potentially wider across the CEE region depending on available data sets.

Antony Martin (Liverpool University) emphasized the importance of ensuring equitable access to innovations in health care. Minimizing modifiable health disparities is fundamental for an equitable and progressive achievement of health care coverage (14). However, there

are concerns that there can be differences in uptake of new innovative medicines in terms of both speed of access and the number of patients treated, which may be different in different populations and CEE countries due to challenges in access, ability to pay, availability and understanding of health information (15). This needs to be addressed where possible (14). Moreover, an assessment of how innovations in medicine translate within different subgroups is paramount to enhance their potential funding (16), as well as ensure that the beneficial aggregate population effects do not conceal widening disparities (17).

Health care financing considerations

Simo Vukovic (Ministry of Health, Serbia) discussed major reforms which have been conducted related to the introduction of diagnosis-related group (DRG) systems in Serbia. The new payment system will help with auditing, introduce new types of payments, and increase fairness of payments. The current payment system has been based on the traditional healthcare payment fee-for-service model that requires patients or payers to reimburse the healthcare provider for each service performed. Consequently, there has been no incentive to implement preventative care strategies, prevent hospitalization or introduce cost-saving measures. The objective of DRGs is to develop a classification system that identifies the "products" that the patient receives rather than inputs. Moreover, hospital revenues will more closely reflect the cost of good care. DRGs provide an opportunity to better control health care expenditure, increase activity levels and standardise care. In addition, the DRG system provides valuable data for the analysis and comparison of hospital performances across the system.

Nikolaos Kotsopoulos (University of Athens) described the public economic consequences of health and investments in health care using a number of case studies (18-20). Dr Kotsopoulos discussed how a 'government perspective' framework that accounts for transfer costs and lost tax revenues might be suitable for quantifying the benefits of healthcare in tax-financed public health systems. To address the value of health and health care investments for governments, a fiscal health analytic framework that captures how changes in morbidity and mortality influence tax revenue and transfer costs, e.g. disability, allowances, ongoing health costs, was described. The framework can be used to evaluate the marginal impact of discrete investments or a mix of interventions in healthcare to inform budgetary consequences. In this context, the framework can be considered as a fiscal budget impact, and/or cost-benefit analysis model that accounts for how morbidity and mortality linked to specific programs represent both ongoing costs and tax revenue for government.

Conclusions

Innovations can drive increased spending in health care as a result of substitution of lower priced products with new higher priced technologies, complementarity effects, i.e. new and old products used concurrently, and by providing treatments for conditions for which previously no treatments were available. To achieve financial stability, two key challenges need addressing. Firstly, deciding on the level of available resources; secondly, ensuring optimal resource allocation within finite budgets. To be relevant to decision making in the CEE region, governments and HTA agencies must address these key challenges.

MEAs may be one part of addressing financial stability in the region. But to be effective, MEAs should be applied together with HTA, so they can help address clinical and economic uncertainties and provide a transparent and timely framework for deliberative decision-making. However, a current challenge is that most MEAs implemented in the CEE region involve confidential pricing arrangements, and there are few publications assessing their

impact. Further, there can be a reluctance among companies to make decision making more transparent as seen in Poland.

Conflicts of interest

The authors declare that they have no relevant conflicts of interest.

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(*of importance; **of considerable importance)

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