Meeting Report

Addressing challenges for sustainable healthcare in Central and Eastern Europe

The Fifth International Conference: Challenges for Efficient Healthcare in Central and Eastern Europe, 9-10 October 2015, Belgrade, Serbia

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Abstract

All European countries face increasing challenges in the provision of equitable and comprehensive healthcare for their citizens in view of a number of factors including changing demographics and the launch of new premium priced medicines. The challenges are even more difficult among Central and Eastern European healthcare systems. Consequently, there is a need for countries to learn from each other to help address some of these challenges and to maintain sustainable systems. This was the basis of the 2-day conference, The Fifth International Conference: Challenges for Efficient Healthcare in Central and Eastern Europe, 9-10 October 2015, Belgrade, Serbia.

Introduction

Central and Eastern European healthcare systems face difficult challenges that need addressing. The main objective of this conference was to discuss these challenges and provide potential ways forward.

Challenges

Wija Oortwijn discussed the use of health technology assessment (HTA) for reimbursement decisions. A key challenge is to achieve and maintain the quality of healthcare including new innovative technologies within constrained budgets, which requires optimal distribution of limited resources. The results of a study conducted in Serbia, Slovakia, Taiwan and Brazil showed that HTA must be adapted to the needs and demands of individual health systems to maximize their usefulness in decision making [1]. This is still at an early stage in a number of these countries, with HTA processes seen as reasonably new and not always robust and transparent. In addition, funds for the implementation of HTA are often limited and in a number of countries there is also limited local information. As a result, a number of countries are forced to use information (reports), as well as HTA methods / procedures from other countries. The exception was Brazil with well-developed national and regional systems versus Serbia where HTA is currently less developed. The main challenges for HTA include political instability and lack of "will", resistance to the HTA process as well as a lack of transparency.

Krzysztof Landa (President, MedInvest Scanner Ltd M.I.S., Poland) discussed HTA as a useful tool for investors and presented the MedInvest Scanner Database (www.medinvestscanner.com). HTA can significantly improve the choice process of health technologies that are most promising, and these, together with other methodologies, can be an important tool in order to reduce investment risk. MedInvest Scanner offers investors access to a database discussing potential new non-drug medical technologies for possible investment. Potential innovations are ranked according to HTA and EBM criteria to inform about their investment attractiveness.

Exemplars

Angela Yu from the London School of Economics discussed experiences with Managed Entry Agreements in China as a basis for recommendations for Central and Eastern Europe. More than 95% of the population of China is covered by one of the three state health-insurance schemes. In 2012, the total contributions for all three schemes amounted to US$115 billion. The urban scheme receives 67% of these funds; however, this covers only 40% of the total population. Yu explained that to date, Managed Entry Agreements have been established in 25 locations (20 individual provinces out of 31 and 5 municipalities). A total of 41 different brands and 37 different molecules have so far been covered by such agreements across China. The situation is being closely monitored to provide future direction.

Tanja Novakovic discussed the role of patient registries in improving healthcare quality and resource allocation, as they are seen as a valuable source of information given concerns with patient selection in Phase III randomized controlled trials [2]. Several patient registries are available in Serbia including registries for melanoma, inflammatory bowel disease and rheumatoid arthritis; however, collecting and utilizing these data requires close cooperation among all key stakeholder groups including the Health Insurance Fund. These issues were explored further by Mark Parker when discussing real-world evidence, as routine clinical practice can be considerably more complicated than Phase III randomized controlled trials when taking into account issues such as co-morbidities. Modern technology has greatly reduced the cost of gathering clinical evidence. While such data are often routinely collected in some European countries [3], this does not apply to all European countries including Serbia. It is important to rectify this to help optimize the future use of resources.

David Danko (Managing Director at Ideas & Solutions, Hungary) pointed out that in Serbia there is currently no formal review of HTA submissions as part of pricing and reimbursement negotiations and limited patient level data. There are potentially two frameworks for assessing the value of new technologies in Serbia; firstly, the value of new medicines for patients and society as a whole and secondly, their financial impact. The first framework takes into account the added clinical benefit of the new technology, its alignment with national health policy as well as social and ethical consideration, whilst the second includes a budget impact analysis [4].

Special diseases and pharmaceuticals

There is growing use of biosimilars across Europe in view of potential savings; however, uptake has been hampered by limited discounts to date, typically 15% to 30% [5], as well as disinformation. The latter has resulted in strategies to address this from the European Commission [6]. The situation is changing with Orion offering the Norwegian Drug Procurement Cooperation a 69% discount for biosimilar infliximab compared with the originator tender price (REMICADE) and 72% compared with its list price [7]. Concerns with potential side-effects are being countered by the Ministry of Health in Norway funding NOR-SWITCH to compare the effectiveness and side-effects of originators and biosimilars [7].

Current prices of orphan medicinal products (OMPs) are also a growing concern given the numbers in development and the increasing number of new targeted cancer medicines seeking orphan status [8, 9]. Prices for OMPs are generally between US$10,000–30,000 per patient, per month or more, with limited reimbursement hurdles, although this is changing [10,11]. High prices have been justified by an estimated US$2.6billion to develop a new medicine; however this figure is criticized [12,13]. Concerns with the attractiveness of the OMP market was also debated; tempered by Sanofi paying over US$20billion for Genzyme [14]. Concerns with the high prices and limited health gain with most new cancer medicines is also resulting in requests for greater price transparency [12,13,15,16].

Bojan Trkulja (INOVIA; Association of Innovative Drug Manufacturers, Serbia) discussed concerns that Serbia has the lowest access to innovative therapies in comparison with other countries in the region. From 2007– 2010, 228 new medicines were registered in the EU. From these, 133 were reimbursed in Italy, 148 in Slovenia, 62 in Croatia, 83 in Bulgaria 83 yet only 12 in Serbia. From 2010, 139 new medicines were registered in EU, of these; Bulgaria reimbursed 44, Croatia 27 and Serbia only 1. The appropriate use of new and existing medicines can reduce disease burden. This requires improved communication between key stakeholder groups, as well as greater transparency and fairness in decision making. It also requires pharmaceutical companies to accept only a minority of new medicines are truly innovative [16].

Neven Lovrin (Consultancy Terminal, d.o.o., Croatia) reviewed the cost-effectiveness of ombitasvir/paritaprevir/ritonavir +/- dasabuvir from a Croatian perspective in patients with chronic hepatitis C (HCV). New HCV therapies are highly cost-efficient including patients with HCV genotype 1 previously treated with other regimes; however, given the prevalence of HCV and high requested prices there are

concerns with their budget impact, leading to considerable discounted prices for reimbursement across countries [17-19].

Timothy Johnston (The World Bank Group, Austria) discussed the challenges and priorities of pharmaceutical policy in middle-income countries. Availability, purchasing, i.e. how to get the best price for quality generics and new medicines, financing - including preventing catastrophic out of pocket payments, and the rational use of medicines are the main challenges facing middle-income countries. This increasingly includes non-communicable diseases. Algorithms for assessing the clinical and economic benefits of new medicines is one way forward, including collecting publicly available data as well as decisions from other countries.. Other issues regarding reimbursement negotiations include identified health priorities, applicability of the data from other countries, available funds for medicines, and healthcare delivery capacity. Optimizing "value for money" requires different strategies for new versus generic medicines. Available data can be used to monitor rational use, track budgets, identify patterns of abuse/ overuse as well as enforcement of any price-volume agreements.

Alan Haycox discussed the importance of the 'patient voice' and other contributory stakeholders involved in the HTA process. NICE actively seeks the widest possible input from clinical experts, patient interest groups and society, with the NICE technical team subsequently summarizing all responses for Committee members prior to producing the Final Appraisal Determination to be discussed at the Appraisal Committee [20]. Such an extensive consultation adds considerable time to the review process; however, it also provides the widest possible opportunity for all interested parties to contribute to decision making. NICE ensures every Appraisal committee meeting has clinicians and patient representatives with direct experience of the disease in question, with patients' voices seen as crucial. However, it is recognized patients may be focused on a particular disease restricting their focus. Consequently, there is a need for HTA groups to address this and reflect the values of society as a whole given the opportunity costs involved. This includes emotive areas including new cancer medicines and OMPs often with limited health gains [21].

There are concerns with HTA submissions and their evaluation within Central and Eastern European Countries in terms of a lack of local skills. Consequently, attendees on the second day of this meeting had an opportunity to address this by taking part in a competitive healthcare "war game" through simulating a patient population with chronic HCV in Serbia treated with new medicines in order to help eradicate the disease combined with central tendering approaches.

Conclusion

There are appreciable differences between countries in terms of access and reimbursement to new medicines and their assessment. HTA is a way forward to enhance transparency in decision making and access. Patient-level data can also improve decision making. These developments are needed in Serbia to enhance access to new valued innovative medicines as well as ensure patients with non-communicable diseases are well treated within available resources. This will require cooperation between all relevant stakeholder groups.

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