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HTA SYMPOSIUM 2019

3-4 JUNE

KRAKOW

POLAND

SUMMARY

The 7th Cracow HTA Symposium was held on the 3 and 4 June 2019. It featured a team of experts from various backgrounds, including the Ministry of Enterprise, Trade and Employment, National Health Fund, AHTAPol, URPL, the Polish Parliament, PZPPF and Supreme Audit Office who touched on numerous important issues regarding systemic changes in the Polish healthcare system and medical devices.

WHAT NEW DEVELOPMENTS IN REIMBURSEMENT CAN WE EXPECT?

Experts representing the Agency for Health Technology Assessment and Tariff System have indicated that future challenges include joint clinical assessments. It is still unknown what the result regarding EU HTA will be. There are ongoing discussions regarding, among others, the criteria for assessing applications and appointing experts. It is important to define the methodology assessment strictly and precisely.

In Poland, we have been observing an increase in the number of drug programmes (including in the area of oncology), in the number of patients and in NFZ'S spending on drug programmes. In the context of works on the Reimbursement Mode for Development (RTR), numerous demands and expectations have been mentioned, i.e. Automatic renewal of reimbursement decisions, exempting Partners of the Polish Economy from the payback obligation, diversification of applicants in the area of partnership with the PL and EU economy.

In health economics we are mostly dealing with increased importance of real-world data. FDA has established that real-world evidence will be used in the regulatory context, and furthermore payers also try to define the scope of reimbursement based on the analysis of these retrospective data resulting from the patient's electronic records.

Ageing of the society results in the need to look for new solutions and savings in healthcare expenditure. One of the solutions is digitisation, aimed at supporting the effectiveness of treatment and preventing medical staff shortages.

According to the experts participating in the discussion, electronic records and registers will enable us to collect data on the effectiveness of treatment and support decision-making. Re-assessment of the benefits basket and the list of reimbursed drugs, in turn, stimulates the introduction of new technologies and removal of obsolete, ineffective ones, while the risk of removing an effective therapy or introducing ineffective technologies is described as not significant, since all available evidence is taken into account.

HOSPITALS AND THEIR FINANCING

Health technology assessment is always associated with the comparison of costs and effectiveness. In hospital settings, the adopted HTA approach is to lead to cost optimisation. The HB-HTA methodology is aimed at increasing the possibilities of managing the healthcare system by assessing health technologies, adapted to the context of a given hospital, used to support decision-making about investments in the assessed technologies.

Cost accounting is extremely important to AOTMiT (due to the tariff processes). Its purpose is to improve management of individual entities, as well as the entire healthcare system, by providing the Agency with highest-quality, detailed information. The main assumptions of the draft regulation on recommendations regarding cost accounting standards are: cost-effectiveness of cost information, reality (implementability of the proposed solutions) and implementation of changes (regarding the list of cost and calculation accounts) in two stages.

Medical rehabilitation funded by the national payer (NFZ) is subject to various organisational and procedural limitations (including waiting times and availability of benefits). The NFZ undertakes certain activities aimed at general promotion of quality. Implementation of benchmarks allowing to review hospitals in terms of basic quality indicators has been announced. At this point, we are not quite ready to evaluate the quality of the service after the fact/following the performed surgery. Integrating billing data with medical registers can be the turning point.

According to the invited experts, the service providers' performance should primarily be assessed by patients. Of course, there is also a need for professional evaluation by external entities using appropriate tools. It is very important to take indicators related to the assessment of the processes and effects of the healthcare system into account. It is also worth considering what can be done in the field of effective investment of funds in prevention, and motivate healthcare providers to adapt to the value-based healthcare concept.

The experts agreed that the projects are evolving quite smoothly and we can expect that, over time, the aspects of quality assessment and optimisation of benefits and paying for them will develop in the right direction.

NON-DRUG HEALTH TECHNOLOGIES

Currently, the boundaries between drugs, medical devices or tissue transplants are becoming blurred. When developing new technologies, one should also think about how they will be classified in a formal and legal way. Medical devices are supported by a smaller number of studies, and thus less evidence, which can be problematic when the manufacturer applies for reimbursement. The complicated regulatory environment also constitutes a challenge. Next year in Poland, we will face a major reform of the legal system regarding medical devices, as the EU regulation regarding a larger group of medical devices comes into force. In connection with that, the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) is preparing a law which will implement these provisions into the Polish legal system. A public register/list of devices entered into the market or imported into Poland is to be created.

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Most of the funds for the development of new technologies in Poland come from the European Union. When observing financing models in various countries on the hospital market, one can find examples where, based on HTA analyses, the guaranteed benefits basket is supplemented with new products. In Poland, work on the guidelines for the evaluation of medical devices, which are very much expected by the industry, is under way.

According to the speakers, the registers are also very important because they show us the effectiveness of a given technology. However, opinions vary as to whether the registers should be made available to the public or, in the case of strictly medical data, one should take into account what the patient is able to understand and learn from such information.

MULTIPLE-CRITERIA DECISION ANALYSIS IN THE REIMBURSEMENT OF ORPHAN DRUGS – WHOSE PREFERENCES?

The prevalence of rare diseases generates difficulties in obtaining high-quality data and often we have only limited knowledge. Hence the idea of using multi-criteria decision analysis (MCDA), which is increasingly used in pharmacoeconomics. The analysis is a response to the lack of an appropriate tool that would measure additional benefits from the use of a given health technology and take into account socio-economic aspects. What constitutes the premise for the success of using MCDA on a daily basis in reimbursement decisions is involvement the payer / decision maker in the process. It is very important to determine who is to be the source of preferences (decision-makers or their representatives, experts, patients or their representatives, the society). The choice of the MCDA model must be practical and dependent on the list of respondents. Respondents, in turn, must be competent from the perspective of the entity using MCDA to support decision making. The growing number of rare diseases, the development of new health technologies and the high costs of orphan drugs constitute a significant burden to the healthcare budget. Clear criteria for pricing and reimbursement decisions are therefore needed.

There is no reason to completely abandon using ICER for drugs used in rare diseases, as cost-effectiveness is an important criterion which should not be devalued and which constitutes an important point of reference.

From the perspective of clinicians, the following conditions should be applied in financing rare disease therapies:

- severe course of the disease,
- inhibiting the progression of the disease thanks to treatment
- lack of alternative treatment.

At present, in the case of many rare diseases, the treatment exists, but is not available. One might ask about the point of diagnosing diseases if we cannot cure them. There is therefore an urgent need for systemic solutions which will improve the availability of orphan drugs (for example using MCDA).

According to the invited experts, there is no reason to completely abandon using ICER for drugs used in rare diseases, as cost-effectiveness is an important criterion which should not be devalued and which constitutes an important point of reference. Currently, the value of the drug in clinical trials is not determined by how much therapeutic effect it brings, just how rare the disease is. However, we should be able to pay for efficacy and not just for the fact that the disease is rare.

MODERN DATA MANAGEMENT IN HEALTHCARE

The benchmark we refer to when we introduce a technology to the market are randomised clinical trials, the results of which may be subject to errors. Therefore, one should take into account the uncertainty of evidence; the best way to manage it is through registers and post-marketing supervision.

In Poland we do not collect adequate (and digitised) data which should be used and analysed in detail to determine the annual incidence/mortality trends, and based on which, in turn, we could be able to say what the needs (in the context of modern technologies) are. Only "big data" gives us the power to make the right decisions. Telemedicine still does not really work in Poland. The greatest revolution we will be facing in this area (provided that the legislators opt for it) will be the possibility to open the teleconsultation market in the area of primary healthcare and secondary outpatient care.

Modern procedures and technologies are being introduced gradually, but their availability remains insufficient against the background of other countries. Experts agree that new technologies should be implemented under a long-term strategy and that both direct and indirect costs should be taken into account. After all, the key result is the overall impact on the population in a long-time horizon (in accordance with value-based healthcare principles).

It is necessary to increase spending on reimbursement and to introduce more rational distribution and allocation of funds. Experts were not unanimous on the issue of paying for new technologies. Some felt that public funds should also be applied to technologies characterised by proven efficacy and cost-effectiveness (also taking into account their impact on the budget).

There is therefore a need for innovative services and developing a model for assimilating new technologies by the ministry.

However, in the initial stages, new health technologies should be paid from research grants, and then by NFZ, as the public payer. Others voiced their concerns on the fact that excessive waiting for thorough testing of every technology would leave us behind in the technological race. Modern technologies will become widespread and the tested technology might as a result become obsolete in comparison.

There is therefore a need for innovative services and developing a model for assimilating new technologies by the ministry. It seems important to develop technological programmes (similar to drug programmes) and a general decision-making process for reimbursement, similar to the one applied to drugs (taking into consideration that the level of evidence in new technologies is much alike). Experts on new technologies also suggest organising NFZ registers and using innovative solutions, such as Horizon Scanning.

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