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

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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
procedure according to special regulations. The supplementary list of medicines contains drugs with a higher level of prices compared to the prices of essential medicines list. The Fund will cover costs at the price of an equivalent drug specified under the essential list of drugs. The medical devices (dental-prosthetic replacements, orthopedic aids and other medical devices are also on the list through the expert council of the CHIF.

The criteria for inclusion of medicines in the reimbursement list of the Fund, on the basis of which the Commission shall issue an opinion, are: the importance of the drug from the standpoint of public health, the importance of therapeutic drug, relative therapeutic value of the drug and the assessment of the ethical aspects. The basis for determining the comparative price of the drug wholesale is the wholesale price of the same drug (a drug of the same generic name and the same pharmaceutical form) in Italy, Slovenia and the Czech Republic and, if necessary, in Spain and France. MAHs submit the proposal for placing of a new drug or the expansion of indications of the already existing drug into the drug reimbursement list of the Fund. MAH designs a study of the impact on the budget of the Fund. The Budget Impact Analysis (BIA) necessarily contains two scenarios of the analytical model where one takes into account only the direct costs of the drug and the second contains all the additional direct costs arising from placing the drug on the reimbursement list of the Fund. A sensitivity analysis is used to test the robustness and the reliability of the conclusions of the model under different assumptions.

Guidelines for the BIA of the Fund include basic settings; BIA should be made in accordance with the ISPOR guidelines (Mauskopf JA, et al.: Value in Health. 2007; 10(5) : (336-47). The data source must be taken after the data is being reported in the scientific evidence. Primarily considered are the published Croatian data and if none exists, than other published data and expert assessments are to be taken into consideration. All the data must be referenced. The modelling should be also conducted in accordance with ISPOR guidelines (Weinstein MC, et al. Value in Health. 2003; 6(1):9-17), and a validation of the model must satisfy the internal, comparative and foreign types of validation.

The HTA Agency Role

The Agency for Quality and Accreditation in Health Care (HTA) is responsible for the HTA process in Croatia and it conducts the HTA program. The activity of the Agency contains national collaboration, education and the HTA promotion, international collaboration (EU Projects), the establishment of the Croatian HTA Guideline, the creation of the HTA reports and scientific publications. The assessment process starts with a “pre-assessment” of the existing evidence on each selected topic and it is prepared by the HTA department staff (including the existing Core HTA and/or the HTAs from other countries). Furthermore, the final decision about the HTA process and the assessment phase shall be conducted in accordance with the specific algorithm. The type of economic evaluation includes a cost-effectiveness analysis (CEA) or a cost-utility analysis, (CUA), depending on the particularities of the technology. Finally, the HTA also implements BIA and other analysis or procedures, which CHIF than applies for marketing authorization, for the purpose of being included to the list of drugs. Considering the existing facts it is intended that the HTA Agency will take part in the future pricing and reimbursement decisions, because currently its activity is still within the level of recommendation.