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Letter to the Editor

SOME ADDITIONAL THOUGHTS ON FORTHCOMING AMENDMENTS TO HTA IN POLAND

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Dear Dr. Mäkelä,

In reference to the article A Decade of Health Technology Assessment in Poland by I. Lipska et al. (1), I would like to provide you with some comments and additional information on the changes in reimbursement policies in the Polish healthcare system currently taking place, which is likely to lead to increased number of health technology assessments (HTAs) of medical devices (MDs).

First, let me explain the potential causes of the discrepancy between the recommendations from the Agency for HTA and Tariff System (AOTMiT) Transparency Council/President and the final decision on reimbursement by the Ministry of Health (MoH). At least for the negative recommendation by AOTMiT coupled with the positive final decision by MoH, the reason may come out of the process design. The AOTMiT's critical assessment of the HTA analysis supplied by the Marketing Authorisation Holder (MAH) in the application for the reimbursement forms a basis for following price and Risk Sharing Agreement negotiations between the applicant and Minister of Health (represented by the Economic Council). If negotiations bring the price to an acceptable level (the incremental cost-effectiveness ratio estimated approaches the cost-effectiveness threshold), the final decision is positive. Thus, the critical assessment of health technologies by the AOTMiT puts forward strong arguments for achieving access to the drugs at affordable prices.

The drug reimbursement process issued in Poland, as clearly described by Lipska et al. (1), uses so-called "light HTA model," which ensures its operational effectiveness. In this model, the responsibility for providing an HTA report lies on the MAH, while a public institution deals with the critical assessment. Coming to MDs, from 1 January 2012 based on the Act on Reimbursement (2), they formally undergo the same procedure of application for reimbursement as drugs. However, in practice, only a small number of MD producers apply for reimbursement as other means of funding are available (1 to 10 assessments of nondrug technologies by AOTMiT per year, most of them being procedures rather than MDs, http://bipold.aotm.gov.pl).

In Poland, MD class I including assisting devices are now reimbursed for individuals based on the prescription by a general practitioner. Therapeutic MDs, for example, implantable ones, are financed by DRGs (diagnosis related groups) in hospitals. As a fixed cost of full implantation procedure is set, hospitals tend to buy the cheapest MD in the tender and offer them to their patients. Currently, it is not possible for a patient to apply for a more sophisticated version of MD by paying the difference in costs out of pocket. Thus, for a patient, the only chance to decide on a type of an artificial implantable device is to buy the whole procedure in a private clinic. Due to the shortage of hospital's budgets, lists of patients waiting for procedures involving MDs are unacceptable long (3).

Currently, the MoH is working on the update of the Act on Reimbursement to change the way MDs are financed (4;5). The objective is to redesign rules of reimbursement of MDs to better fit the real-life needs of the society, for example, by increasing availability of MDs, financing them based on an added value as assessed by HTA and give patients an opportunity to choose MD if relevant.

The idea is that only the cost of a procedure will be covered by DRGs, while the price of (implantable) MDs will be counted separately. MDs, similarly to drugs, will be listed as reimbursed up to a limit set, with patient co-payment and, possible, payment of an incremental cost of a preferred MD. At least one MD will be available at the price not exceeding the limit set. In this model, applying for reimbursement status may become

a business strategy for MD producers who would be competing for reimbursement by proposing better prices (e.g., in terms of more beneficial risk sharing scheme). Patients might choose a more expensive MD version, if relevant, and co-finance the incremental cost, just like in the case of drugs.

This financing model may substantially increase the workload of the AOTMiT, which will advise MoH on several levels of the implementation process: (i) MoH will issue a list of MDs for which producers may apply for the reimbursement status by supplying a submission supported by the HTA analyses. This evidence will be critically assessed by the AOTMiT; (ii) Based on available evidence, MoH will determine, supported by the advice of the AOTMiT President, the scope of evidence needed for reimbursement decision for a specific group of MDs, including a clinical effectiveness and safety evaluation, a more or less sophisticated economic analysis, and a budget impact estimation; (iii) Having a list of MDs reimbursed on the individual basis, MoH will review the guaranteed healthcare benefits basket. In case the MD was previously reimbursed, for example, in the specific DRG, the tariff for this DRG should be recalculated. Thus, MoH should trigger the tariff-setting process by the AOTMiT for the healthcare benefits changed.

An individual reimbursement submissions will be assessed in the AOTMiT while a Transparency Council statement, as well as a President recommendation, will be issued in a similar process as described for drugs (1). This process will be of a type of "light HTA model" with the analysis provided by the applicant and relatively quick (90 days long in the case of MDs) assessment/appraisal by the Agency.

On the other hand, the MoH may request the Agency to perform full HTA analysis for selected MDs or procedures. These changes will need a significant effort of the AOTMiT to gain new skills and capacities on assessment of MDs.

Other changes in the rules of reimbursement, for example, of drugs for rare diseases, has been reported by Kawalec et al. (6).

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