Determining the prices of the medicines in the absence of superiority over alternative medical technology

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Problem Statement

When there are randomized clinical trials (RCT) which prove that the new technology is better than the drug or non-drug medical technologies currently financed, the price of new technology can be negotiated based on the clinical effectiveness, cost effectiveness and budget impact. But when there are no RCT, which prove that the new technology is better than the currently financed by the public payer drug or non-drug medical technologies, on the basis of art. 13 sec 3 of the Reimbursement Act (RA), Marketing Authorisation Holder (MAH) is obliged to perform the price equal to the cheapest reimbursed alternative.

Art. 13 sec 3 of the RA the exact wording: "If the clinical analysis, (...), does not contain RCT proving the superiority of the drug over the medical technologies (…) currently financed in this indication, the official sales price (net price + VAT) of the drug, must be calculated in a way that, the cost of using it would not be higher than the cost of the cheapest alternative, which has the best ratio achieved health outcomes/cost".

Objectives

Presentation of a method offered by the RA (from 2011), which allows to determine the prices of the medicines in the absence of superiority over alternative medical technology. This price is calculated by the Agency for Health Technology Assessment and Tariff System and must be presented in the Recommendation of the President of the Agency for Health Technology Assessment and Tariff System.

Methodology

The primary goal of the RA is to implement the principle of economical production. This should be kept in mind, while interpreting its content, because while maintaining the standard described in the act, it allows one to approach to each drug individually.

At the beginning one needs to find all the comparators currently financed in this indication and set their outcomes/cost ratio. Then, to choose the one that has the best result. Next step is to search for RCT proving the superiority of the proposed drug over the designated comparator. In cases, where there are no such RCT in MAH's submission, the official sales price of the drug, must be calculated in a such way, that the cost of using it would not be higher than using the designated comparator. This has significant consequences because Ministry of Health is obliged to use the calculated price in final reimbursement decision.

The poster presents the most complex cases we have searched through Recommendations of the President of the Agency for Health Technology Assessment and Tariff System from 01.2012 to 04.2015. We selected two most interesting cases where the calculation of the price based on the Art. 13 sec 3 Reimbursement Act was not so obvious.

First example is polipill compared to the separate tablets with the same substances. There were no studies that demonstrate the superiority of the polipill in comparison to monotherapies. The law says that, the cost of therapy with polipill proposed by the applicant cannot be higher than the cost of therapy with the same substances in separate tablets.

Second example is an add-on therapy. There were no conclusive results, which proves the superiority of the proposed added drug to the standard therapy over the standard therapy alone, so the cost of the drug cannot be higher than the comparator. This price was proportionally calculated to the share of the total cost of the treatment, which was equal to the cost of the treatment with the exception of add-on therapy.

Results

First example: polipill

Drug A and drug B were financed in the same indication as new submitted drug (polipill) (Tab. 1). Two tablets (one with drug A and another with drug B) and one tablet of polipill contains the identical amount of the same active substances. So according to art. 13 sec 3 RA the calculation was simple, price of the drug A plus price of the drug B. Price from the reimbursement submission was higher than the calculated one.

Tab. 1. Prices for two drugs in separate tablets and in a one polipill.

Item description	Price (€)
Drug A (30 tablets)	14
Drug B (30 tablets)	20
Maximum price of the polipill (30 tablets) according to the RA	34
Price proposed by MAH (30 tablets)	58

Second example: add-on therapy

One cycle of financed standard therapy costs 1032 € (Tab. 2). According to reimbursement submission the new technology should be used with standard therapy (add-on therapy). MAH didn't show RCT proving that add-on therapy is better than the standard therapy. So there was a necessity to calculate the price according to art. 13 sec 3 Reimbursement Act.

Cost of one cycle of the therapy (standard+add-on), taking into account the price of a new drug from application, was 10 032 €. Cost of add-on therapy accounted for 90% of the whole cost. So according to art. 13 sec 3 RA the maximum cost of one cycle of add-on therapy was 926 € (90% of one cycle of standard therapy). On this basis, price of the new drug was 239 €. The price proposed in the reimbursement submission was almost 10 times higher than the calculated one.

Tab. 2. Price and cost for for standard therapy and its alternative proposed by MAH.

Item description	Value (€)
Standard therapy (cost per cycle)	1 032
New add-on therapy proposed by MAH (cost per cycle)	9 000
Maximum price of the drug calculated according to the RA (add-on therapy)	239
Price of the drug proposed by MAH	2 350

Conclusion

The price is easy to set if there are few comparators or RCT. It is more difficult when the number of comparators is much higher and there are a lot of RCT with different outcomes. In these cases calculating the price is labour-intensive. The new Reimbursement Act offers the tool to set the maximum price for the drugs without superiority proven in RCT, by a comparison their cost with the cost of the cheapest comparator or a comparator with the best cost-effectiveness ratio. This price can be used as the starting point in the price negotiations from the payer's perspective. This price, presented in the Recommendation of the President of the Agency for Health Technology Assessment and Tariff System can provide the Ministry of Health stronger negotiating position.

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