

# ANALYSIS OF REIMBURSEMENT DECISIONS AND IMPROVING THE APPRAISAL METHODS OF INNOVATIVE MEDICINAL PRODUCTS

**Ph.D. thesis**

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# 1 INTRODUCTION

Innovative pharmaceutical products are essential in enhancing the ability of health systems to tackle previously incurable diseases, but they usually come at a high cost, which puts further pressure on the budget of publicly financed healthcare. The reimbursement decision on innovative pharmaceutical products may depend on certain parameters concerning the direct financial environment of each submission. Confidential risk-sharing agreements (RSAs) between the MAH and the payer, or the uptake of the technology preceding its reimbursement in routine practice through individual funding requests (IFRs) are factors that create information asymmetry and can possibly influence the outcome of the reimbursement decision.

Reimbursement decisions should ideally consider the information generated by health technology assessment (HTA) which is an evidence-based scientific method used to assess the added value. The local HTA body in Hungary produces a non-binding assessment report for each submission dossier, serving as a basis for the critical appraisal of the submitted clinical and economic evidence. The assessment reports are covering clinical (health problem and current use of technology; clinical effectiveness; relative efficacy) and economic (costs and fiscal aspects, including budget impact) domains, although other (most frequently, organisational) aspects can be presented occasionally.

Due to the lack of a holistic value framework covering both clinical and economic aspects in the assessment procedure, as well as the confidentiality of some aspects of reimbursement decisions, evidence is extremely sparse and indirect on the outcome of reimbursement decisions and the interaction between the outcome of the critical appraisal procedure, IFRs, RSAs.

Only anecdotal evidence is available on how the assessment reports, their quality, or other financial and procedural circumstances outside of the core assessment procedure influence the outcome of decision-making on the reimbursement submissions of innovative pharmaceutical products in Hungary. It seems that the assessment reports do not have the desired impact on reimbursement decisions, potentially due to the lack of solid methodological foundations. To some extent, the lack of relevant research may be as well due to the difficulty of operationalising the added value of assessment reports alongside a reliable methodology and the confidentiality barriers to accessing assessment reports in full detail.

The overarching aim of this research is to explore the impact of external factors on the reimbursement decisions to position the role of intrinsic factors in the reimbursement process, as well as to design, implement and evaluate some improvements to the local critical appraisal methodology.

## **2 OBJECTIVES**

The first objective of this research is to analyse the association of exogenous factors on the reimbursement decisions on innovative

medicinal products in the social health insurance system of Hungary. The research question related to this objective is which, if not all of the evaluated exogenous factors are associated with reimbursement decisions, and how can their relationship be characterised. The hypothesis related to this objective is that all of the evaluated exogenous factors have a statistically significant association with the outcome of the decision on reimbursement.

The second objective is to develop a methodological approach to conclude on the clinical added benefit of an innovative medicinal product, and also the implementation of a framework to identify, quantify and interpret the sources of uncertainty in economic evaluations as part of the assessment report. The research question related to this objective is to find out if viable methodological improvements are possible to design in alignment with the current assessment procedure of the submitted clinical and economic evidence. The expectation is that a methodological improvements created by an iterative development process need to acknowledge and if possible, take full advantage of specificities arising from the broader legal framework of health technology assessment, as well as resource constrains.

The third objective is to test the implementation of these methods on actual reimbursement submissions and produce more coherent assessment reports where the appraisal methodology was improved. The research question related to this objective is whether the novel methods can be scaled up and implemented to the day-to-day routine of critical

appraisal, and if so, to see if any organisational improvements can help the implementation process.

### **3 METHODS**

In order to analyse the potential association between the outcome of the reimbursement procedure and the anecdotal contributing factors exogenous to the clinical or economic assessment of the health technology, the latter were operationalised as independent variables in a multivariate logistic regression framework (Objective 1).

Following the analysis of exogenous factors, a complex methodological development of the critical appraisal procedure is designed and implemented. Methodological improvements directly related to the clinical domains of HTA are addressed first as part of this research. The designing of the framework on CAB can be divided into the steps of drafting, testing, feedback assessment from stakeholders and implementation. Proceeding with presenting the methodological improvements, the procedure to critically appraise economic evaluations follows. This improvement relies on identifying, quantifying and interpreting the sources of uncertainty in economic evaluations (Objective 2).

To assess its applicability in the routine practice of producing assessment reports, the new methodology is tested and findings are presented using case studies of new oncology medicines (Objective 3).

## 4 RESULTS

### 4.1 Impact of exogenous factors on reimbursement decisions (Objective 1)

The total number of reimbursement submissions between 1<sup>st</sup> of January 2018 and 7<sup>th</sup> of June 2021 was 1,390. Among these, 486 were submitted in the full procedure, of which 162 did not conclude at the time of analysis. Of the remaining 324 submissions, 92 applied for a price increase, or was already reimbursed and proposed changing the reimbursement technique.

The results showed that having an RSA in place at the time of submission was positively associated in both univariate and multivariate models with a statistically significant higher chance of a positive decision (adjusted OR=3.49, 95% CI: 1.56–7.82,  $p=0.003$ ). However, the average biennial expenditure exceeding 200 million HUFs did not show statistical significance, although it was positively associated with the decision outcome being supportive (adjusted OR=1.04, 95% CI: 0.92–1.19,  $p=0.54$ ) in both univariate and multivariate models. Neither did the overall aim of the submission show statistically significant association with the outcome of the decision procedure (adjusted OR=1.32, 95% CI: 0.65–2.69,  $p=0.45$ ); moreover, the direction of the association was not consistent between univariate and multivariate models. A consistent and significant negative association can be observed between needing a legal act for the positive decision and the odds of the procedure arriving at a positive decision (adjusted OR=0.05, 95% CI: 0.02 – 0.11,  $p<0.001$ ).

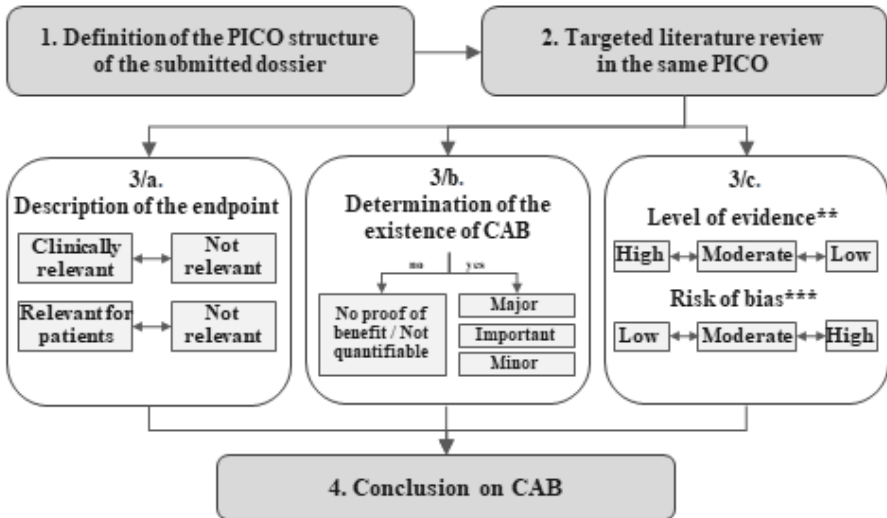
## **4.2 Results regarding the conclusion on clinical added benefit (Objective 2)**

The procedure of concluding on the clinical added benefit (CAB) facilitates the standardised description of endpoint relevance, level of scientific evidence and accompanying risk of bias (RoB), as well as determining the existence and extent of CAB (see Figure 1.).

Two technical steps precede concluding on the CAB: the first is defining the assessment scope, that is, the PICO (patient population, intervention, comparators and health outcomes) structure of the submitted dossier (1. on Figure 1.). A targeted literature review follows to decide whether higher quality scientific evidence is available (2. on Figure 1.) than what was submitted by the MAH in the dossier.

To align the current practices with the formulation of the conclusion on the CAB, the four domains in the developed framework are considered as equal contributors to the conclusion (as appearing on Figure 1.):

- (3/a) information on the relevance of the considered clinical endpoints;
- (3/b) the existence/extent of the added benefit, and
- (3/c) the quality of evidence supporting it; which has two subdomains: LoE and RoB associated with it in the cases of clinical trials.



**Figure 1: Schematic presentation of the process of formulating conclusion on CAB.**

### **4.3 Results on assessing the sources of uncertainty (Objective 2)**

The pilot exercise that had been carried out for assessing the sources of uncertainty was conducted for the reimbursement submission of darolutamide for treating non-metastatic castration-resistant prostate cancer (Table 1). For context, the submitted base case cost-effectiveness results indicated darolutamide generating an incremental health gain of 1.31 QALYs alongside incremental costs over ADT; the calculated ICER is marginally below to the local cost-effectiveness threshold.



**Table 1.: Sources of uncertainty in the submission of darolutamide**

Source of uncertainty	Quantifiable?	Significant?
Time horizon of the analysis (BC: time horizon is 27 years; ScA: time horizon is 10 years) [Type of economic analysis]	✓	✓
Restriction of the efficacy analysis population to mITT (BC: censor patients who develop metastasis before starting treatment; ScA: patients who develop metastasis before starting treatment count as events) [Evaluation of the economic model - transition probabilities]	✓	✓
Long-term effectiveness of darolutamide on overall survival (BC: assume benefit in mortality over the entire analysis time horizon; ScA: do not assume benefit in mortality after 10 years) [Evaluation of the economic model - transition probabilities]	✓	✓
Resource use patterns (comparator and subsequent therapies) (BC: assume equal distribution of degarelix, goserelin, leuprorelin, triptorelin and buserelin as part of ADT; ScA: differentiate the distribution of compounds used as part of ADT: higher share for degarelix, goserelin and leuprorelin, lower for triptorelin and buserelin) [Evaluation of the economic model – cost inputs]	✓	✗
Price discount on subsequent treatments (BC: use the public list prices of abiraterone-acetate, enzalutamide, degarelix; ScA: assume 30% discount on abiraterone-acetate, enzalutamide, degarelix list prices) [Evaluation of the economic model – cost inputs]	✓	✓
EQ-5D value set used to estimate utilities (BC: use the UK value set when estimating utilities; ScA: use the Hungarian value set for estimating utilities) [Evaluation of the economic model – utility inputs]	✗	NA

## 4.4 Implementation to routine practice (Objective 3)

### 4.4.1 Case series analysis

Between the 1<sup>st</sup> of January and the 16<sup>th</sup> of July 2022, a total number of 66 reimbursement submissions for 42 product-indication pairs were assessed, of which 33 were evaluating treatments of other diseases than solid tumours. Of the remaining 9 product-indication pairs, 3 were re-

submissions of earlier dossiers (as the previous procedure ended without a legally binding decision), and there was one submission requesting a price increase. Therefore, a total number of 5 product-indication pairs fell within the scope of the current analysis.

Regarding the exogenous factors to the medicinal products covered in this analysis, all compounds were already reimbursed for a different indication at the time of submissions. Rather unsurprisingly, a legal act was needed for all but one submission (as these medicinal products aimed to treat a group of patients without a targeted therapy), whereas having an RSA in place was reported for only one medicinal product. Expenditures on IFRs were either not reported at all, or were relatively low, making it difficult to interpret the association of this factor with the outcome of the reimbursement decision (Table 2).

**Table 2.: Exogenous factors to reimbursement submissions**

Product	Indication	Reimbursed in a different indication?	Legal act needed?	RSA in place?	Expenditure on IFRs
Nivolumab	NSCLC	Yes	Yes	Not reported	Not reported
Nivolumab	MPM	Yes	Yes	Not reported	Not reported
Osimertinib	NSCLC	Yes	Yes	Not reported	Not reported
Dabrafenib / Trametinib	NSCLC	Yes	Yes	Not reported	45.29 mn HUFs
Abemaciclib	eBC	Yes	No	Yes	7.66 mn HUFs

Contrary to the observations made on the exogenous factors, the conclusions on CAB, LoE and RoB were quite heterogeneous among

submissions, however, this seems to be reasonable in light of different assessment scopes and maturity of clinical data. In one case, the risk of bias could not be determined due to the lack of assessment report from IQWiG (Table 3).

**Table 3: Conclusions on clinical added benefit, level of evidence and risk of bias**

Product	Indication	Comparator	Clinical added benefit	Level of evidence	Risk of bias
Nivolumab	NSCLC	Platinum-based chemotherapy	Important	High	Low
Nivolumab	MPM	Platinum-based chemotherapy	Important	Moderate	High
Osimertinib	NSCLC	Routine surveillance	Major	High	Low
Dabrafenib / Trametinib	NSCLC	Pembrolizumab, platinum and pemetrexed	No proof of benefit	Low	High
Abemaciclib	eBC	Placebo (endocrine therapy)	Major	High	N/A

As for the critical appraisal of economic evaluations, the highest number of major sources of uncertainty was identified for the section *Input parameters for the economic evaluation and Costs*, whereas no sources of uncertainty were identified for *Results of the economic evaluation and Sensitivity analyses* sections.

In two cases out of five, the assessment included an alternative base case that combined multiple quantifiable sources of uncertainty. Both alternative base-cases yielded less favourable cost-effectiveness results for the technology assessed. Although proposing an alternative set of

base case cost-effectiveness results did not occur for three assessments, it is difficult to determine whether doing so could have delivered added value for these reports.

**Table 4: Sources of uncertainty in the economic evaluations.** Numbers indicate the identified sources of uncertainty per section as [significant/non-significant].

Product	Indication	Type of health economic evaluation	The economic model used for the assessment and its key assumptions	Input parameters for the economic evaluation	Health outcomes	Costs	Results of the economic evaluation	Sensitivity analyses	Alternative base case proposed?
Nivolumab	NSCLC	1/0	0/0	0/0	0/0	1/0	0/0	0/0	N
Nivolumab	MPM	0/0	1/0	1/1	0/2	0/2	0/0	0/0	N
Osimertinib	NSCLC	1/0	0/0	1/1	0/0	0/0	0/0	0/0	N
Dabrafenib / Trametinib	NSCLC	0/0	0/0	1/0	0/1	1/0	0/0	0/0	Y
Abemaciclib	eBC	0/2	0/1	0/2	0/2	1/0	0/0	0/0	Y

#### 4.4.2 Practical application of the research findings knowledge repository

These methodological improvements assume essential core professional competencies to the assessment procedure in the public administration, complemented by awareness of legal acts, instructions or databases. These heterogeneous pieces of information can be described as organisational knowledge which has the potential to be turned into a

formalised know-how that can be handed over to newcomers in the organisation. The imbalance of expectations in terms of quality and consistency towards the deliverables of public administration processes as well as respective resource constraints to meet these expectations implied the need for novel tools for knowledge management and supportive approach to quality assurance.

#### **4.4.3 Practical application of the research: organisational improvements**

First of all, the assessment report template was revised to create sections that represent mutually exclusive topics of the submission dossier, so the identified sources of uncertainty can be presented along the report structure. Second, a set of common phrases (and even templates for tables) were developed for the assessment report template that can be used to describe the contents of the reimbursement submission in the appropriate section, regardless of the technology or the disease to be treated. Third, as an attempt to have a direct impact on health policy, we published a handbook in Hungarian that laid down the expectations towards reimbursement submissions and presented the detailed methods used by the Department of Health Technology Assessment for creating assessment reports on the website of NIPN. Finally, the SOPs of the Department of Health Technology Assessment were updated to cover the implications of the updated methodology on the core assessment procedure.

## 5 CONCLUSIONS

The analysis of exogenous factors showed that there is an association between having an RSA on the medicinal product at the time of submission and the reimbursement procedure concluding to a positive decision for the same compound. However, if a legal act is needed for the reimbursement of a medicinal product, the odds are significantly less favourable for a positive decision for reimbursement. There is no evidence of a statistically significant association between the reimbursement decision and expenditure on individual funding requests, nor between the reimbursement decision and the overall aim of the submission (objective 1).

The assessment of clinical added benefit, accompanied with a framework for identifying, quantifying and interpreting the sources of uncertainty are methodological improvements that were possible to design in alignment with the current assessment procedure of the submitted clinical and economic evidence. These improvements take advantage of local specificities arising from the broader legal framework of health technology assessment, even in light of resource constraints (objective 2).

After testing the implementation of methods in the day-to-day routine of critical appraisal, it is believed to be shown that the proposed methods can be scaled up for routine use in the local decision-making on innovative medicinal products, and in particular for treatments of solid tumours. The methodological improvements are accompanied with the introduction of knowledge management tools and process developments,

revised document templates, better quality assurance which can be characterised as organisational improvements (objective 3).

Using both of the presented frameworks in the daily routine of the assessment procedure is expected to increase the efficiency of decision-making and also to amplify the impact of assessment reports on the outcome of decisions. The efforts on methodological developments and their implementation contribute to taking the local critical appraisal process to the next level; they also facilitate realising the vision of an active, responsible and responsive health technology assessment body in Hungary.

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