Reimbursement decision-making and health technology assessment: bridging the gap in non-core pharmaceutical markets

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Introduction
In many non-core pharmaceutical markets, there is a clear gap between health technology assessment (HTA) and pharmaceutical reimbursement decision-making processes. The nature of this gap can be basically twofold: either HTA is not used, or HTA and actual reimbursement decisions are only tangentially aligned. In this essay, I set out to explore the potential reasons of this discrepancy, and I endeavour to give some recommendations on how HTA could come closer to reimbursement decision-makers (payers) and offer them effective support. The thoughts below try to synthesize my previous experiences in a payer role (when I was responsible for pharmaceutical reimbursement in Hungary, a middle-income European Union member state), as well as insights from university research and my market access advisory activities.

Economic evaluation as the mainstream of HTA in non-core pharmaceutical markets
Health technology assessment (HTA) includes all methodologies and processes for the systematic evaluation of pharmaceutical products and other health technologies (e.g. medical devices, surgical procedures, public health programmes) linked to pricing & reimbursement decisions by public and private payers, preceding to admission to the formulary and during formulary management. The broad nature of this definition is crucial, as we sometimes tend to reduce HTA to cost-effectiveness analysis (CEA) and budget impact analysis (BIA). Indeed, these two techniques—which we may call together as ‘economic evaluation’—have until recently constituted the mainstream of thought within health technology assessment. This stream originates from academic institutions in the United Kingdom and is currently hallmarked by England’s National Institute of Clinical Excellence (NICE) as well as the Scottish Medicines Consortium (SMC). This approach has been implemented, for example, in South Korea, Poland and Hungary.

Today, CEA and BIA—which we may call together as ‘economic evaluation’—increasingly constitute only one stream of thought within health technology assessment. Equally important is ‘qualitative assessment’, which usually refers to techniques where the assessment logic is similar to that of regulatory agencies. In many of these approaches, a scoring system is used and the outcome is the classification of the health technology into one of several (typically 4-5) categories based on therapeutic value added. France, Italy, Japan and Taiwan are examples for this approach.

The third main paradigm is what we may call ‘balanced assessment’. This covers methodologies and systems which aim at integrating the strengths of the previous two approaches, offering a balanced (i.e. not too quantitative, not too qualitative, thus unbiased) perspective on medical
technologies (cf. Exhibit 1). Traditionally, Australia and Canada have been seen as countries with balanced assessment, albeit with different methodology focuses. Currently we can already see a convergence between economic evaluation and qualitative assessment in other markets: France has adopted cost-effectiveness analysis, Sweden uses a kind of a societal approach, and the UK is clearly steering away from mainstream economic evaluation.

Exhibit 1. Three paradigms of health technology assessment

- Based on pharmacoeconomics
- Strict quantitative methods applied by dedicated HTA agency
- Attempt to arrive at two economic indicators: ICER, budget impact
- Cost-effectiveness linked to explicit or implicit threshold
- Supported by structured review

- Similarity with regulatory approaches
- Mainly qualitative methodologies based on collective decision making
- No attempt to arrive at ICER: scoring is often used, classification is a priority
- Consideration of non-financial aspects & broader societal impact

- Synergies between economic evaluation and qualitative assessment
- Mainly collective decision making, which is retrievable and publicly accessible
- Cost-effectiveness is one input to a classification/scoring algorithm
- Wide consideration of non-financial aspects & broader societal impact


In those non-cost pharmaceutical markets, where HTA already exists, economic evaluation is still dominant. The reason is mainly institutional: for example, in Central Europe, HTA was conceptualized between 2001 and 2005. When the first Central European scholars brought health technology assessment concepts into Poland, Czech Republic and Hungary, they established contacts primarily with UK universities with health economics focus, and had access to English-language health economics literature. These tended to teem with the mainstream concepts of that time: cost-effectiveness analyses, QALY and ICER.

Such ideas—which offered a huge step forward in non-core pharmaceutical markets compared to the pre-HTA age when non-transparent and over-politicized decision-making was the norm—became the guiding principle for HTA thinking. With local HTA landscapes being heavily influenced by the pioneering health economics scholars, knowledge transfers subsequently took a markedly technocratic trend, and the more pragmatic qualitative paradigm found difficulty in gaining any foothold. This is why most non-core pharmaceutical markets are still in an earlier stage of the ‘economic evaluation lifecycle’ (cf. Exhibit 2), compared to core markets, and this is also why qualitative drug assessment has remained largely unknown and undocumented up to now.
The HTA gap

On the other hand, there are signs that payers are increasingly disappointed with economic evaluation both in core and non-core pharmaceutical markets. Some core-EU countries are in phase 4 of the economic evaluation lifecycle, while others have already stepped into phase 5. For those non-core pharmaceutical markets, which are now in the process of public debate on HTA implementation (e.g. South-East Asia), these instances of disappointment carry crucial pieces of information. In order to understand these, let’s consider the typical flow of the reimbursement decision-making process (cf. Exhibit 3) in an ‘average’ non-core market. First, it is readily visible that there is no such person as ‘payer’; instead, there are many payers at several different layers, and most of them lack the methodology-heavy health economics expertise which could enable them to interpret economic evaluations. What is more, most of them can never realistically be expected to master even those HTA skills which are seen as basic by health economists.
Second, in most non-core markets, budget pressure and the degree of politicization in reimbursement policy shift actual decisions up to ministerial (or sometimes even higher) levels, where the analytical nature of economic evaluation often turns out to be outright irrelevant for decision-makers who are mostly intuitive. Third, budget pressure leads even analytical decision-makers to zoom in on budget impact exclusively, which introduces a large—and dysfunctional—bias into how economic evaluation is applied and interpreted. Fourth, although economic evaluation does not disregard broader clinical, societal and ethical impacts perse, its mere endeavour to condense cost-effectiveness information into one almighty ratio (ICER – incremental cost-effectiveness ratio, i.e. the cost of buying one more quality-adjusted life year) diverts attention away from clinical and societal factors to quantitative, i.e. financial aspects. Fifth, the significant academic uncertainties behind QALY-assessment tend to undermine the legitimacy of economic evaluation with those payers who take the time to dig into technicalities. Sixth and finally, economic evaluation can be disproportionately costly in non-core pharmaceutical markets, because of the infrastructural need it has on the authorities’ side and difficult to implement, as necessary capabilities are missing in part or in total.

To take a simple example: an average HTA agency which carries out primary assessments is said to need at least 30-50 experts to ensure operational continuity and decision consistency. There are not so many trained and qualified experts in the smaller countries, and even if human resources were available, financials still would not be enough to employ so many civil servants for drug assessment.

These anomalies are already visible in everyday practice in some non-core markets: for example, those Central European countries which apply HTA in their reimbursement decision-making processes (Poland and Hungary have separate HTA agencies; Czech Republic, Slovakia and Slovenia perform such evaluations without having set up any dedicated agency) have recently experienced either a public backlash of pro-HTA policies or a loss of influence of health technology assessment. In the meantime, in those countries where there is no institutionalized HTA, there is an ever widening gap between scholars arguing for economic evaluation and pharmaceutical and government decision-makers looking for pragmatic solutions.

**Bridging the gap**

It is highly likely that many non-core pharmaceutical markets cannot, or do not want to, afford the investment need to establish full-scale HTA agencies. It is also clear that those stakeholders who are involved in reimbursement decision-making are—to put it mildly—unenthusiastic about detailed analytical information. What they need is quick and pragmatic answers to their questions (and doubts) regarding the therapeutic value and cost-effectiveness of new drugs, and an algorithm to prioritise completely different products across various therapy areas when there are not enough resources to reimburse all of them.

For this purpose, balanced assessment based on an ‘ultra-light HTA agency model’ may be more appropriate, cost-saving and realistic than implementing economic evaluation. In this model, an independent government agency is established which directly reports to the Ministry of Health or, alternatively, to the
Prime Minister. This agency—which can be set up with as few as 5-10 experts—itself does not carry out either economic evaluation or request economic models to be submitted by manufacturers. Instead, it gathers the transferable elements of appraisals from a selected number of agencies carrying out economic evaluation (e.g. NICE, SMC, PBAC, CADTH) and relies on the guidance that they have provided. At the same time, it adds its own independent assessment covering budget impact (affordability) and 4-5 qualitative criteria such as unmet need, side effect profile, and comparative improvement in key clinical indicators, eventually public health policy priorities and accessibility in other middle-income countries. Thus, the agency is able to provide a quick balanced assessment of all new pharmaceuticals within a reasonable timeframe, and at reasonable costs. The assessment should be provided either as a scorecard (with numerical weights) or an unambiguous verbal statement providing clear and understandable normative guidance for decision-makers. The guidance may refer to the reimbursability, reimbursement rate and/or price, depending on the structure of national reimbursement systems. Idealistically, subsequent decisions themselves are taken not by individual ministries or payers, but by a collective body (committee) in which all stakeholders of the otherwise chaotic reimbursement process (shown in Exhibit 3) are represented at the same table.

This ‘pragmatic balanced assessment’ (PBA) model may provide an implementable and resource-saving way of launching health technology assessment in non-core pharmaceutical markets where HTA capabilities still need to be reinforced and HTA-related costs cannot be high. The main criticism against this model can be that it legitimates ‘free-riding’ on technology assessments carried out by rich countries and that local cost and utility values are disregarded. Although there is some truth in these criticisms, the ethical issues related to ‘free-riding’ can be managed via bilateral agreements, while re-assessing cost-effectiveness with cost values in countries where non-drug costs (e.g. health care salaries) are unsustainably low seems a questionable practice itself. Thus, I believe that balanced assessment based on ultra-light HTA agency may be a pragmatic approach which brings HTA into effective reimbursement decision-making processes in non-core pharmaceutical markets.