



CRA Insights: Life Sciences

CRA Charles River
Associates

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A comparative analysis of the role and impact of Health Technology Assessment

To understand how the role of health technology assessment (HTA) is evolving in international markets, Charles River Associates was asked to update its assessment first undertaken in 2010/11.¹ The new study, commissioned by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and Pharmaceutical Research and Manufacturers of America (PhRMA) describes recent changes in the use of HTA, widens the assessment to cover 16 countries, including emerging markets that have recently implemented HTA, and further develops the analysis of the impact of HTA (examining 185 individual assessments), particularly how HTA is used in decision-making and its impact over time on health system efficiency.

In this edition of *Insights*, we summarise and compare the progress relative to the earlier study and identify trends regarding scope and priorities, methodology, process and the overall impact of HTA.

In terms of headlines, we find some areas of progress but also ongoing concerns.

- The scope of many HTA processes remains focused on a subset of technologies, particularly new pharmaceutical products.
- Overall, many HTA agencies display increased transparency in the prioritisation of technologies for assessment and in terms of the supporting rationale for subsequent recommendations.
- An increasing number of countries include societal costs in their HTA guidelines, but it is still difficult to observe any tangible impact resulting from the consideration of societal costs.
- It is widely recognised that different stakeholders should be included in the HTA process; some progress has been made to incorporate patient views.
- HTA is being undertaken in a more timely fashion than before, but in some countries more innovative medicines face the longest delays. As a result, the impact of access restrictions imposed by HTA remains significant.

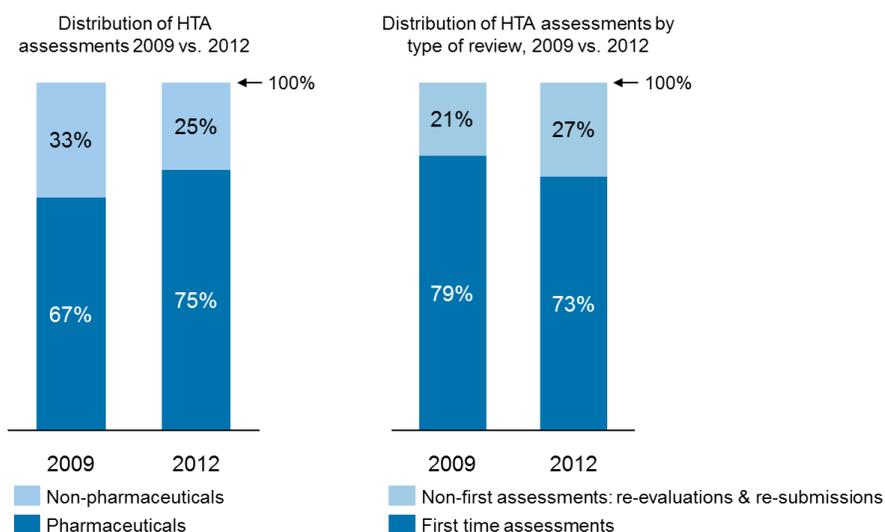
¹ "A Comparative analysis of the role and impact of Health Technology Assessment," a report commissioned by EFPIA, PhRMA, Medicines Australia and EuropaBio. Available here: <http://www.phrma.org/node/741>.

- The impact of HTA varies by therapy area and the type of HTA process. In particular, HTA processes based on formal cost effectiveness approaches are significantly more restrictive; in particular, limiting patient access to oncology medicines.

The products included in the HTA process and prioritisation

In principle, HTA can be applied to a wide range of technologies, allowing healthcare systems to allocate scarce resources in the most valuable way. Nonetheless, a key criticism of our first report remains, many HTA processes focus on a narrow set of technologies—75% of the technologies reviewed are pharmaceutical products as compared to 67% in the 2009 assessments. Equally, the majority of the assessments are focused on assessing new technologies as compared to re-assessing existing treatments (see Figure 1). Sweden, for example, has a process in place to assess old technologies,² but in 2012 more than 70% of the reviews were first time assessments.

Figure 1: Distribution of HTAs in a given year by type of technology and review type, total reviews in 2009 and 2012



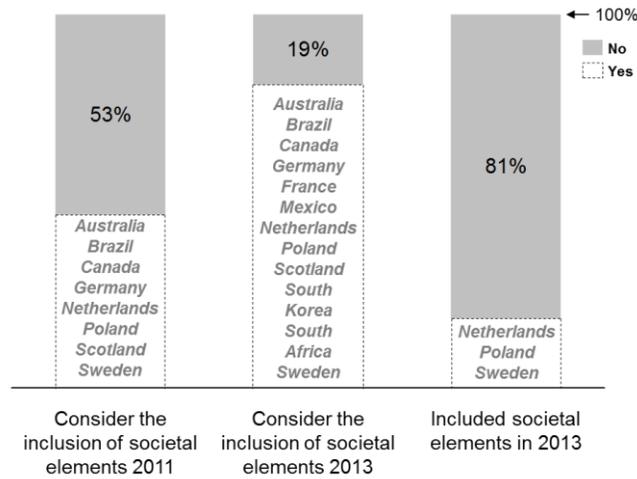
Source: CRA analysis

Methodological issues

There has been significant improvement in the level of transparency. This can be seen in terms of the decision-making process determining which products are assessed, the methodology applied and the rationale for the recommendations. However, significant differences remain among the stated methods and how the assessments are applied in practice. Additionally, many more markets now recommend the inclusion of societal elements in the assessments: in the 2013 report, 80% of the markets studied consider societal elements, compared to less than half in the 2011 report (see Figure 2). Notwithstanding the recommendations to consider societal costs, however, we found that only the Netherlands, Poland and Sweden were including societal elements in the assessments.

² Ulf Persson, "Value based pricing in Sweden: Lessons for design?," OHE Seminar Briefing, November 2012.

Figure 2: Inclusion of societal elements in the sample of case study assessments, 2011 v. 2013

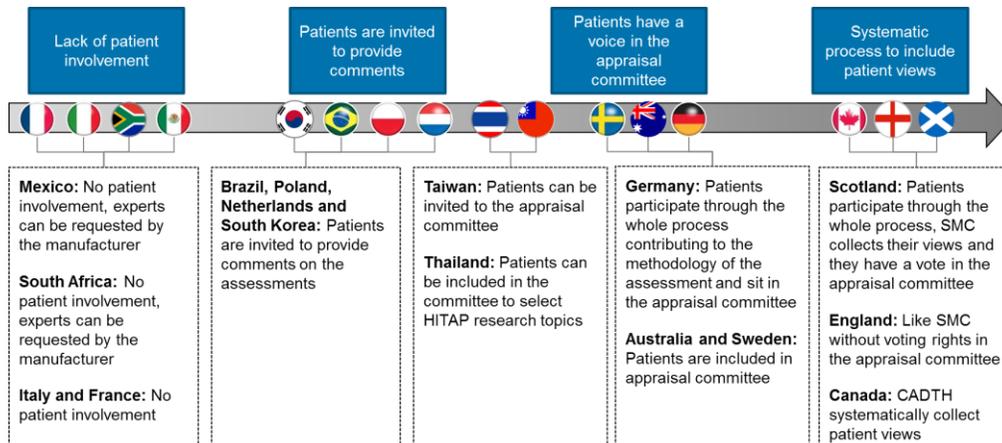


Source: CRA analysis

Accounting for the patient perspective

We observe progress in terms of an inclusive process. The HTA agencies in Canada, England and Scotland are seen as leading in this area, with systematic processes and structured forms for patients to document and submit their experiences of living with the condition under assessment and the value of the technologies being studied. However, concerns remain. In some countries patients sit on the appraisal committee without a vote (Germany or Australia), in others they are mainly invited to provide comments (Netherlands or Brazil) and in some developed systems such as France, patients do not have a role at all. Perhaps unsurprisingly, the role of patients is less structured within emerging HTA systems, partly because patient groups are less developed.

Figure 3: The role of patients within the HTA systems analysed

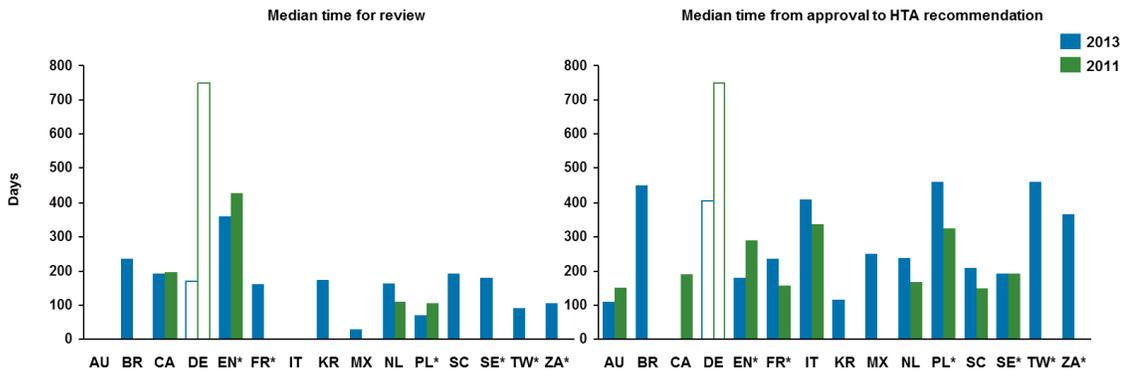


Source: CRA analysis

The impact on patient access

Compared to three years ago, the HTA process is being undertaken in a more timely fashion. In the 2011 review, the length of HTA processes varied significantly among markets, reflecting different processes and levels of stakeholder engagement. Looking at those markets included in the 2011 and 2013 assessments, we find that the average length of the process decreased from 317 days to 179 days. In particular, there has been an improvement in those markets where a defined timescale was established for the review process.

Figure 4: Median duration of the HTA by length of the review and the time from regulatory approval to HTA recommendation, 2011 and 2013



Source: CRA analysis.

Note: *Reflects numbers collected through interviews with industry and HTA representatives as data were not always available; In Germany, time reflects the HTA review and approval to recommendation time and is not indicative of access.

Using the assessments reviewed in the 2011 report, we also consider what happens after the HTA process is completed. Looking at IMS sales data, we examined the delay between the publication of the assessments and observed market entry. In some markets, a subsequent negotiation of price can significantly delay entry. For example, Australia and Italy have the longest delay for more innovative products, which may reflect the administrative hurdles of the system (in particular, the negotiation over the level of prices). In other markets, this has been mitigated by allowing a fast-track approval process so that products are on the market during the assessment period (as in France). In terms of diffusion, we find that the more innovative a product is assessed to be (in terms of the assessment of added therapeutic benefit), the slower the diffusion in many markets. Although, this may represent the inevitable challenges of introducing a significant therapeutic advance, this does not suggest HTA accelerates market uptake.

Given the number of oncology products being assessed, we have also looked at this therapeutic area in more detail. We find that oncology drugs face more restrictive recommendations than other therapy areas. This is the case, even in those markets, such as Canada, where oncology drugs are reviewed by a separate entity. In particular, oncology drugs receive more restrictive recommendations in markets that use some form of QALY with threshold to make HTA decisions.

Conclusions

The use of health technology assessment continues to rapidly develop in terms of where it is applied and the influence it has on access to innovative medicines. Over the last three years, there has been some progress in terms of transparency, the inclusiveness of the process and a recognition of international best practice principles; in other areas, the picture is more mixed and the way that HTA is intended to be applied continues to differ from how it is applied in practice.

To read a copy of CRA's full report, entitled "A comparative analysis of the role and impact of Health Technology Assessment: 2013," click [here](#).

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