CRA Insights: Life Sciences

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An update on the use of therapeutic reference pricing

In 2006 Pfizer commissioned CRA International to review the impact of therapeutic reference pricing and the impact it had had on incentives to innovate. Therapeutic Reference Pricing (TRP) involves grouping products together for the purpose of reimbursement decisions; it does not require all products in a cluster to be based on the same active ingredient, but it does require that the products are judged to be similar. We concluded that TRP could harm the incentives to innovate. We found that *"the mechanisms that make TRP most attractive as a means of achieving cost savings (in particular, the inclusion of generics with branded patented products and adding new patented products to existing clusters) are also the areas that are the most challenging for innovation. Therefore, if widely adopted, there is a considerable risk that this would significantly deter innovative activity, which evidence suggests by its very nature consists for the most part of multiple incremental steps."* Over the last three years, TRP has remained one of the most contentious issues in the pricing and reimbursement of pharmaceutical products in Europe. Recently, Pfizer asked CRA to look back on this assessment and see how the use of TRP had evolved.

The use of therapeutic reference pricing

In the 2006 report, CRA looked at the use of TRP in Germany and contrasted this with the use of TRP in the Netherlands and in Italy. The system in Germany was clearly the most ambitious and of the most concern to industry. In the intervening three years, the Italian system has not been developed at a national level. In the Netherlands although the TRP systems remain in place, the main development has been the introduction of tenders for off-patent medicines. This has had a dramatic impact on off-patent prices but does not influence the reimbursement level of therapeutic groups. The German system has continued to be developed (there are currently 71 therapeutic groups); however, there is an ongoing debate regarding the role of reference pricing given the development of rebate contracts. Rebate contracts have resulted in discounts/rebates being provided to individual sick funds, with the result that the reference price system caps the reimbursement level but the price of products is often based on negotiation with individual sick funds. Arguably, it therefore could be said that the concern regarding therapeutic reference pricing has receded.

However, although the use of therapeutic reference pricing has not increased at a national level in the largest markets (and its impact may even have reduced where it was previously being used), it has been developed in a number of ways:

- **Regional markets**: In Italy, regions such as Puglia in the south-east of the country and the central region of Abruzzo implemented therapeutic reference pricing for proton pump inhibitors (PPIs). The northern region of Liguria went even further and set homogenous groups for four therapeutic categories (PPIs, statins, SSRIs and treatments for benign prostatic hypertrophy). However, the 2008 Finance Law prevented the formation of further therapeutic groups by the regions.
- **Eastern European markets**: Therapeutic reference pricing has been actively used in some CEE markets, for example, Czech Republic, Hungary and Poland, building on the German example.
- **A new threat of clustered tenders is emerging**: In Germany, tenders for therapeutic clusters have been proposed by sickfunds, effectively introducing therapeutic reference pricing in a different way.

Table 1: The extent to which therapeutic clustering is used in Eastern European markets

Country	Existence of therapeutic groups and ATC level of classification
Bulgaria	Majority of pharmaceuticals are grouped at ATC Level 5 by pharmaceutical form. There are very few grouping at ATC-4 level, i.e. EPOs
Czech Republic	Yes. Widely used therapeutic grouping at ATC Level 4, i.e. anti-hypertensive products
Hungary	Yes. Widely used therapeutic grouping at ATC Level 4
Latvia	Grouping is applied using ATC classification at the aggregation levels 3, 4 and 5; however, limited to less than five groups, i.e. sartans
Poland	Therapeutic groups of substances are based on ATC levels 4 and 5, i.e. statins, proton pump inhibitors

Source: PPRI Reports, country policy regulations, CRA interviews

Avoiding the negative impact of therapeutic reference pricing going forward

The concerns identified in the 2006 paper remain. Once a product has been allocated to a reference pricing group, it is inevitable that it will be difficult to re-assign the product, even in the face of convincing data supporting that the product can be differentiated from the rest of the group.

Recommendations

The design of the TRP system can clearly have significant impact on the incentives to innovate. The method by which prices inside and outside the cluster is determined and the way that new information is made available is central to this assessment. Unless a way can be found to change the behaviour of patients and physicians in order to retain incentives to innovate, it is clearly beneficial to:

- Allow for a reasonable period of time after launch before a product is placed into a cluster
- Set out clearly defined terms by which products will be excluded from the reference price system or maintain a separation between the pricing and reimbursement system for patented and generic products
- Develop a mechanism that allows adjustment of the price of products at any point in the life cycle when new evidence regarding their superiority (in terms of clinical benefits or cost-effectiveness) becomes available
- Have clear separation between the process for assessing which products are included in the cluster and the implementation of cost containment measures

About CRA's Life Sciences Practice

We provide life sciences companies, law firms and regulatory agencies across the globe with the industry experience and analytical expertise needed to address the industry's toughest issues. Our reputation is for rigorous and innovative analysis, careful attention to detail and the ability to work effectively as part of a wider team of advisers.

CRA has offices throughout the world including European offices in London, Brussels, Hamburg and Amsterdam; United States offices in Boston, New York and Washington DC; and offices in Toronto, Bahrain and Hong Kong.

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