Global Pharmaceutical Risk-sharing Agreement
Trends in 2010 and 2011
Ando G, Reinaud F, Bharath A
IHS Global Insight - London & Paris

Background

With austerity measures being implemented across the world, payers are looking for any excuse not to reimburse any new, innovative – but potentially expensive – therapy. Faced with this reality, pharmaceutical companies are looking creative ways of ensuring that new products achieve at least some form of reimbursement.

The increasing use of risk-sharing in reimbursement decisions across major and emerging markets necessitates that key stakeholders understand the role of this concept in shaping drug development and regulatory decision-making.

IHS Global Insight has previously presented research at ISPOR (and republished in ISPOR Connections September/October issue) on risk-sharing agreements to give a global overview of emerging trends in this area. The current research is an update of this initial presentation to showcase trends in 2010 and 2011. This is a fast-evolving area.

Objectives

With payors increasingly looking at ways of cutting pharmaceutical reimbursement costs, pharmaceutical companies need to consider creative solutions to market access for new compounds.

The objective of this research was to examine the most recent global trends for 2010 and 2011 in pharmaceutical risk-sharing agreements, which are now a critical part of market access strategies in many countries.

It involved careful identification of risk-sharing agreements – whether finance-based or outcomes-based – and examination of what was involved in the arrangement; this was subsequently matched with the taxonomy of risk-sharing agreements in order to see whether certain types of arrangements are more popular than others.

Methodology

Secondary research was conducted examining reimbursement decisions around the world, with a special focus on Australia, Belgium, Canada, China, France, Germany, Hungary, Italy, Netherlands, New Zealand, Poland, Spain, United Kingdom and United States.

Sources were taken from regulatory websites around the world, as well as press releases, news wires, official announcements and conference presentations.

This was supplemented by primary research with payors, government agencies and HTA organisations through interviews in native languages to understand the role which risk-sharing agreements have – or have not – played in their respective markets.

Risk-sharing agreements are often accompanied by significant confidentiality, and there are immediate limitations that were recognised from the outset over precisely how much information and detail would be elucidated, although primary research was designed to capture as much information as possible.

Results

45 new risk-sharing agreements were found under the period of review (January 2010-June 2011), nearly double the total for 2009. Of the new agreements, the majority were finance-based agreements, though there were six new examples of performance-based agreements. 40% of the new agreements were concluded with the UK’s NICE, whilst Australia and Italy remain other important markets in this area.

However, a significant number of newer countries are beginning to see these agreements, including Belgium, Hungary, Poland and New Zealand, and interest is widening in emerging markets.

Around half of the agreements were in the oncology area, but there are signs that risk-sharing is becoming increasingly prominent in other therapeutic areas, including blood disease, mental health, pain treatment, immunology, ophthalmology and cardiovascular care.

Outcomes-based decisions remain rare, but there are still pay for performance deals being signed for drugs such as Votrient and Arzerra in markets such as Italy and the United Kingdom. These do not always lead to positive reimbursement decisions. The Arzerra deal in Italy was also notable for eventually becoming the first risk-sharing agreement that provided a degree of transparency.

Risk-sharing agreements are a reality for pharmaceutical companies in many key markets, and need at least to be considered as an alternative market access strategy in certain therapeutic areas.

In markets where strong patient registries exist – eg. Italy – there is a better likelihood of optimised risk-sharing. For markets considering risk-sharing as a means of partnering with the pharmaceutical industry to make innovative drugs available, such patient registries are a prerequisite.

The results reinforce previous research in this area which points to the fact that achieving “normal” market access for a new treatment, where regulatory approval is followed immediately by drug pricing and launch, is an increasingly rare phenomenon.

Conclusion

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