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Healthcare Management Initiative

Current Outlook for Risk-sharing Agreements

102/2014
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Risk-sharing agreements (RSAs), also known as managed entry agreements (MEAs), are contractual arrangements between payers and health technology manufacturers aimed at addressing issues of uncertainty in the context of introducing new therapies to the market. Randomized controlled trails (RCTs) are conducted before a drug is launched; while they demonstrate the efficacy of treatment, they do not necessarily indicate the drug's real-world effectiveness, which is increasingly important to understand given the pressures (stemming from tightening national healthcare budgets) faced by policy makers to demonstrate therapeutic value. RSAs can be used as a mechanism to deal with the a priori uncertainty regarding health outcomes. Moreover, they can also improve patient access and incentivize innovation.

RSAs are implemented in different forms across European countries, ranging from simpler finance-based to more complex outcomes- or performance-based, a common form of classification for these arrangements[1]. Another taxonomy is focused on the objectives countries aim to achieve through these schemes. Some schemes require patient data collection to track outcomes in order to measure cost effectiveness, or to measure utilization to manage the budget impact by lowering the cost/QALY[2] (quality-adjusted life year) at the appropriate utilization threshold; other schemes include simple discounts or rebates which may not be linked to health outcomes.

In addition to these overarching differences, there is significant **heterogeneity** in the governance, level of transparency and systems that support these schemes, as noted by participants at the recent LSE Summit on Risk-sharing and Managed Entry Agreements in London[3], which hosted representatives from Italy, Poland, UK, Sweden, Netherlands, OECD, and the pharmaceutical industry. While the UK and Sweden have been fairly transparent about their experiences with RSAs, Poland is less public about the number of RSAs implemented or details of these agreements. Each country discussed the unique lessons learned from their experiences thus far. The UK's multiple sclerosis risk-sharing scheme, for example, alluded to complexities around issues of governance, model design, and overall management. In Sweden's example of Januvia, economists and policymakers identified nuances in the model in that two different sources were used

[1] See HMI document "Taxonomy of Risk-Sharing Arrangements" for more information (http://centres.insead.edu/healthcare-management-initiative/thought-pieces/index.cfm).
[2] QALY is a measure of health status used to assign a value to health outcomes in cost-effectiveness analyses. It accounts for the quality as well as quantity (years) of life lived. For more information, see http://onlinelibrary.wiley.com/doi/10.1111/j.1524-4733.2009.00515.x/full.
[3] For further information on the conference, please visit: http://www.lse.ac.uk/businessAndConsultancy/LSESummit/riskSharing/home.aspx.

(by manufacturers) for the definition and cost of treatment for mild hypoglycemia, which led to an underestimated cost/QALY calculation. In addition, both Sweden and the Netherlands described difficulties in measuring quality of life (QoL) data, while reiterating that it is an important factor in the cost-effectiveness evaluation process.

These were the views of payers at the national level. As for one **industry position**, Novartis highlighted the need to engage with stakeholders rather than simply focusing on delivering on an agreement, as well as aligning technical solutions with specific needs[4]. In addition, trust among stakeholders and a respect for confidentiality were identified as important factors influencing successful implementation of RSAs. For example, he explained that manufacturers should not be forced to reveal an agreement's contractual details, either publicly or to payers and decision-makers from another country, as a result of country-level nuances around regulatory requirements and market dynamics.

The general consensus to emerge from early experiences was that risk-sharing agreements have the potential to improve access, as well as to alleviate some of the uncertainty at the point of making reimbursement decisions. It appears that RSAs are in use in most of the participating countries, to tackle issues of clinical uncertainty and access despite the initial challenges. As for **longer-term plans**, the question is not whether manufacturers and payers will continue to apply risk-sharing techniques, but how RSAs can be better managed to generate greater value and be less of a burden, particularly from administrative and logistics standpoints. Issues of registries were raised. Although only a few countries have such databases, they are regarded as a helpful tool in collecting data for post-launch cost-effectiveness studies.

Individual countries are pursuing their own initiatives to support RSAs, including evaluating the role of registries, implementing more robust policies, and closer collaboration with other stakeholders, but a number of related initiatives are also in progress at the European level. These include adaptive licensing,[5] developing comparable patient registries (e.g. for rare and chronic diseases), and harmonization of efforts in support of risk-sharing agreements. According to market research conducted by Ernst and Young, the number of RSA implementations has increased in the last five

[4] Novartis presentation at the LSE Summit.

[5] Adaptive licensing, according to the European Medicines Agency, is "sometimes called staggered approval or progressive licensing, is part of the Agency's efforts to improve timely access for patients to new medicines. It is a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine to broader patient populations."

years, with 70% being finance-based[6]. Moreover, the time required for implementation has been reduced to 9 months from 2.5 years.

We are thus seeing growing activity, and the **European Commission** is increasingly asked about the potential for cross-border collaboration such as the ability to share clinical data so as to avoid duplication. It remains to be seen whether there will be better sharing and coordination among the member states.[7]

[6] Ernst and Young presentation at the LSE Summit.
[7] See HMI document, 'Risk-Sharing Agreements: Country Experiences and Challenges' for a more detailed overview (http://centres.insead.edu/healthcare-management-initiative/thought-pieces/index.cfm).