Redefining Access to Innovative Oncology Therapies: Can Managed Entry Agreements Help?

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At the ISPOR Warsaw 2019 regional conference, a panel examined country experiences with managed entry agreements and their impact on improving access to innovative oncology therapies. This article summarizes the lessons learned from implementing managed entry and multi-year, multi-indication agreements in different regional contexts.

Introduction

Delivering innovative oncology therapies to patients remains challenging in many countries, as payers and industry face pressures to ensure timely access and budget predictability while maintaining incentives for future innovation.[1] Flexible-access agreements, such as managed entry agreements (MEAs), have been identified as mechanisms for expediting patient access to innovative oncology therapies.[2] As one form of MEA, multi-year, multi-indication (MYMI) agreements present further opportunity to address the growing complexity of oncology therapies with multiple indications.

The session *Improving Patient Access to Innovative Therapies: The Role of Managed Entry Agreements* at ISPOR Warsaw 2019 examined country experiences with these agreements and their impact on improving access to innovative oncology therapies. The panel was comprised of representatives from government, the pharmaceutical industry, and patient advocacy groups, who shared their unique perspectives on how MEAs—and MYMI agreements specifically—can be used to improve patient access to innovation. This article provides an overview of lessons learned from the discussion and experiences implementing MEAs, including MYMI agreements in different country contexts.

Managed Entry Agreements Are Valuable Tools

Compared to standard procurement, MEAs have several advantages as longer-term, sustainable purchasing frameworks. These agreements distribute risks between payers and pharmaceutical companies to further their mutual goal of facilitating patient access to new medicines. Specifically, MEAs address the financial risk of overspending on new medicines above expected budgets in addition to the risk of a medicine not performing as well in real life as it did in clinical studies. Moreover, MEAs can help improve budget predictability for payers and reduce the overall administrative burden of assessing medicines, including consideration of multiple indications. In essence, MEAs enable payers to be more strategic health purchasers and generate better value for money for patients.

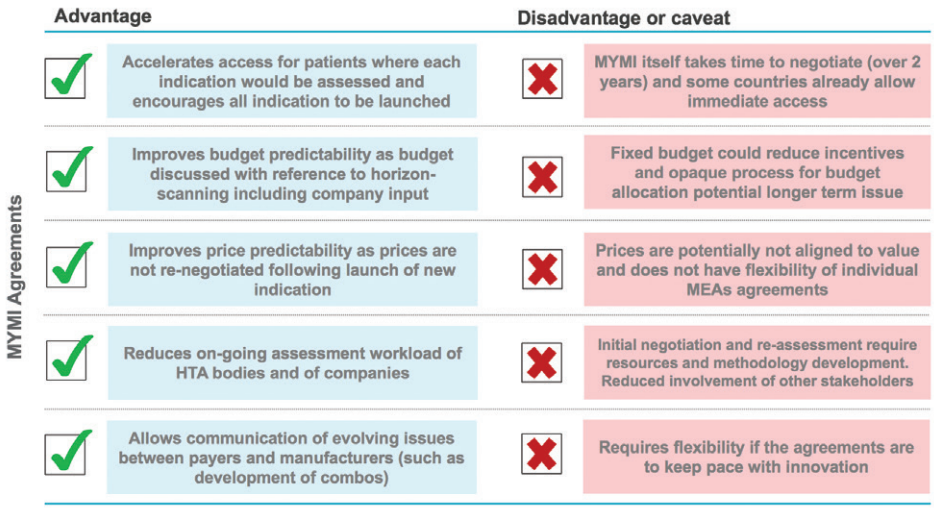
MYMI agreements are a new form of MEA between payers and manufacturers that span multiple indications and years. In the agreements of Belgium, Denmark, and the Netherlands, for example, there are light-touch or no assessments for new indications, and the price and impact on budget of new indications are discussed at the beginning of the agreement. From a theoretical perspective, MYMI agreements have several potential advantages in terms of their impact on speed of patient access, the degree to which they can help payers manage the challenges of affordability, the incentive they provide for companies to register indications, and their relative simplicity. However, it is also clear that MYMI agreements are not the only approach to providing timely patient access to pan-tumor medicines and markets which have adopted alternative approaches (eg, England's Cancer Drug Fund and immediate access in Germany where new medicines are reimbursed right after European Medicines Agency [EMA] approval with assessment one year later) should also be examined.

Strong Data Systems Support Successful Implementation of MYMI Agreements

One of the advantages of MYMI agreements is that they can reduce the administrative burden, which will be increasingly valuable given the predicted number of indications, and they can reduce the pressure on health technology assessment (HTA) agencies.

The existence of MYMI reduces the need for an assessment for every indication. While in the MYMI agreement in Belgium there is automatic coverage without any assessment, although all clinical study reports (CSRs) and economic models have to be submitted, in the Netherlands an evaluation of medical value is

Figure 1: The pros and cons of MYMI agreements – experience from Europe



undertaken, and there is a similar light touch assessment in Denmark. The latter was the case already for all hospital and oncology products and has been integrated in the MYMI agreement. It is noteworthy that even with the light touch, reimbursement can be restricted or rejected.

However, there is still a need to track usage of medicines and develop a process for assessment of the scheme. Governments should invest in strengthening data systems and use data to assess patient population sizes and complementary financing approaches. For example, Belgium is continuing to strengthen data systems and the quality of associated registries. In other cases, the data exists and just needs to be utilized. In Denmark, it was possible to leverage the existing system of patient-level health outcomes registries with the result that the system was able to track treatment performance and disease progress across the country. Showing this system of tracking patient outcomes ultimately convinced the scientific committee and the government that an MYMI agreement would be both possible and beneficial.

Legal Frameworks Need to Be Adjusted

The legal changes necessary to make MYMI possible vary from country to country. For example, previously in Belgium, it was a legal requirement that all new indications would follow the standard price and reimbursement process. While the required legal changes to support the MYMI agreement were minor, the process still took some time to agree and implement. It took a number of years to introduce the agreement, which covered a 2-year period with the option for further extensions (the current agreement expires end of 2019) applying to all I-O products and allowing new companies to be introduced into the arrangement over time.[3]

In comparison, the situation in Denmark coincided with other changes in the value assessment process, and given the company-specific nature of the contracts, did not require specific changes to rules or regulations. The disadvantage of this approach is illustrated by the Netherlands, where negotiations have been specific to each company's product and even though the Ministry of Health is familiar with the concept of a MYMI agreement (after agreeing to an initial contract with Nivolumab[4]), the negotiation process for each new product's MYMI agreement has been lengthy.

Lessons Learned From Implementation

MEAs are increasingly used tools to create budget predictability without affecting list prices.[5] Some Eastern European countries, including Croatia and Slovenia, now have over a decade of experience with MEAs, while others such as Bosnia and Herzegovina, North Macedonia, and Albania are in the initial stages of development. While not much is publicly known about MEA implementation due to confidentiality clauses, many countries appear to face similar challenges. These include establishing legal grounds to regulate MEAs and incorporate them in HTA processes, balancing decision-making transparency and the related perception of corruption, utilizing available epidemiologic data to set budget thresholds, and developing new payer competencies for negotiations with well-versed counterparts and managing the administrative workload these negotiations require.

Looking to MYMI, they can accelerate access to medicines (including indications), bringing significant benefits to patients, particularly in countries that would otherwise assess each indication. Where products would be assessed indication by indication, a process that is resource intensive and delays patient access, MYMI agreements should deliver significant benefits, as outlined in Figure 1. This accelerates patient access, meaning that greater health benefits are delivered, and incentivizes innovation. For example, in Belgium, 5,000 patients became eligible for access to immunotherapy for the lung cancer indication as a result of the MYMI agreements, with significant benefits in terms of saved lives.[5,6]

Second, MYMI agreements improve price and budget predictability. In MYMI agreements, the terms of price and budget are discussed and set based on forecasts rather than actual results, prior to the market access of new indications in the future. The application of preset prices and budgets are important as these features increase price predictability for the manufacturer and budget predictability for the payer.

Finally, MYMI agreements open a channel for the communication of evolving issues between payers and manufacturers. The experience in Belgium and the Netherlands has shown that upcoming developments—such as combination therapies—are discussed.

Although it is clear that agreements in Belgium, Denmark, and The Netherlands >

have reduced the workload and time required for the assessment of new indications, MYMI agreements generally involve a long initial negotiation between the government and the manufacturers, as there is a need to align different stakeholders.

Conclusion

To secure budget for new medicines—sometimes for treatment options that did not exist before—payers in developed countries are increasingly embracing MEAs and MYMI agreements as tools that allow them to continue providing patients with contemporary cost-effective medicines. Payers in less-developed countries are also catching up, challenged by the rising gaps in availability of innovative medicines accessible to their patients compared to those from more affluent countries.

The full potential of MEAs and MYMI agreements, however, has not been reached. The lessons learned should be shared across countries, and all countries should ensure that flexible access agreements are available as an option to expedite patient access to innovative medicines. Multistakeholder dialogues such as the session at ISPOR Warsaw are imperative forums for sharing learnings, discussing challenges, and aligning on future goals to help advance international patient access to innovative medicines.

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