ISPOR Warsaw 2019

Improving Patient Access to Innovative Cancer Therapies: The Role of Managed Entry Agreements

27 March 2019
Improving Patient Access to Innovative Cancer Therapies: The Role of Managed Entry Agreements

Educational Symposium
Sponsored by Merck Sharp & Dohme (MSD)
Managed Entry Agreements

Luka Voncina, MD, MSc, PhD
Disclosures

• MSD is sponsoring my attendance for ISPOR Warsaw
• Opinions expressed in this presentation are solely my own
MEAs & Traditional P&R Legislation

• Moving past standards & norms, prescriptive regulation and financing inputs is a general trend in health care governance
  • Strategic health purchasers need more advanced regulatory tools to generate better value for money
    • Productivity, quality and efficiency incentives in primary care and hospital contracting
    • PPPs paid based on KPIs
    • Risk sharing and discounts in medicines

• MEAs provide a wealth of opportunities that standard pricing and reimbursement regulation do not.

• These however require new regulator competencies and a different outlook, one based on partnership and building win-win solutions.

• Some countries in Eastern Europe now have over a decade of experience with MEAs (Slovenia, Croatia, etc.) Few such as B&H, North Macedonia and Albania are only starting.

• Not much known publicly due to confidentiality clauses.
Taxonomy

• The vast majority of MEAs in Eastern Europe are financial agreements:
  • Simple discounts
  • Price volume agreements
  • Pay back or free goods above a financial ceiling

• Some more complex agreements in place also
  • Disease wide agreements
  • Cross product deals
  • Outcomes based (HCV)
Why MEAs? What are the benefits?

• Governments
  • Pass a part of the financial risk to companies
  • Makes sure incentives are aligned and promote rational prescribing
  • Improve cost effectiveness through lower price
  • Improve access, often massively
    • No of newly reimbursed INNs in Croatia > quadrupled as of 2009, Serbia first update to the list in 5 years in 2016, etc.

• Pharma
  • Faster access to innovative products
  • ERP

• Everyone else is doing it (including countries you are price referencing)
  • Implies you are overpaying if you are not
Challenges

• Establishing legal grounds and regulating MEAs and the procedure
• Incorporating MEAs in HTA processes
  • The trees and the forest
• Transparency
• Perception of corruption
• Availability and quality of epidemiologic data
• New competencies required: negotiations with well versed counterparts
• Additional workload for understaffed payers
• Duration of agreements
Issues to be aware of

• Impact on market dynamics and competition
  • Restrictive (administratively) in some countries such as Romania and Hungary
• A future outlook is required: patent status, pipelines, etc.
• Interrelation with external and internal reference pricing over time
• Relying on simple discounts does not tackle risk of over expenditure
• Administratively excluding patients from access based on hard budgets negates the single benefit package concept and is deeply inequitable
• Pricing drugs for different indications
Core issues that remain to be answered in most countries/ payers

- Developing human resources and competencies
  - Institutional memory
- MEA Oversight and evaluation procedures
- Developing infrastructure capable of monitoring Real World Evidence
- Moving towards paying for outcomes/ value for money

Still input based financing.
Alternative approaches to assessing and reimbursing medicines with pan-tumour indications

March 2019

Disclosure: Merck supported the research this presentation is based on and associated travel costs, however, the views expressed are my own
Project objectives and approach

Objectives

CRA was asked to investigate the use of multi-year multi-indication (MYMI) agreements in Europe.

The objectives were to:

• Understand how MYMI agreements have been used in different countries.

• Identify the benefits of MYMI agreements relative to countries that do not use MYMIs.

• Draw lessons for countries exploring MYMI agreements.

Approach

Secondary Research

• CRA has reviewed recent literature on challenges of multi-indication. This includes government reports, initiatives and grey literature.

Primary Research

• CRA has conducted interviews with experts involved in the development of MYMI agreements across selected countries.
The challenges surrounding multi-indication products

Multi-indication product characteristics

- In 2017, there were 765 clinical trials for additional indications across PD-1 inhibitors. Multiple tumours & patient populations
- Multiple new indications expected
- Indication vary in terms of the degree to which there are existing treatments and prevalence

Resulting challenges for stakeholders

- Face delays to treatment as indications work way through P&R process: Patients
- Face budget uncertainty for existing and new indications + need to reflect value for additional patient populations: Payers
- Face significant strain on resources to assess every indication: HTA bodies
- Need to consider alternative pathways or exceptions to meet societal expectations: Policy makers
- Face bureaucratic processes, delays and uncertainty in market access: Innovators

Source: IQVIA (2017), Global Oncology Trends: Advances, Complexity and Cost
There is no formal definition for MYMI agreements, our understanding from the review of EU country experiences is:

New form of agreement between payers and manufacturers that goes across multiple indication and years

<table>
<thead>
<tr>
<th>Agreement component</th>
<th>Description</th>
</tr>
</thead>
</table>
| Value assessment    | • Initial agreement anticipates future indications  
                           • No or light-touch assessment of subsequent indications  
                           • There can be re-assessment using RWE |
| Access              | • Agreement allows for immediate or accelerated access to indications |
| Pricing             | • Agreement includes a pricing arrangement that covers all indications and is set for the agreement period |
| Duration            | • Agreement is for a set duration after the initial P&R approval |
There are multiple dimensions in any MYMI agreement

- **Value assessment for new indication**
  - No assessment vs. Light touch HTA

- **Duration of agreement**
  - Rolling versus fixed terms (2 years + 1 year extension)

- **Budget cap + payback**
  - Flexible vs. 3 year budget cap agreed with payback allocated by market share

- **Application across competitors**
  - Common structure but individual agreements in confidence

- **Value re-assessment after launch**
  - All new indications will be evaluated retrospectively

- **MYMI agreement**

- **We have examined the application of MYMI implemented in Belgium, Denmark and Netherlands**

- **There are some commons elements**
  - Forward looking agreement
  - Involvement and application across multiple companies
  - Overall aim to improve patient access to novel oncology products
  - The initial agreement took some time to negotiate

- **But also some significant differences …**
### The pros and cons of pan-tumour products: Experience from Europe

<table>
<thead>
<tr>
<th>Advantage</th>
<th>Disadvantage or caveat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerates access for patients where each indication would be assessed and encourages all indications to be launched</td>
<td>MYMI itself takes time to negotiate (over 2 years) and some countries already allow immediate access</td>
</tr>
<tr>
<td>Improves budget predictability as budget discussed with reference to horizon-scanning including company input</td>
<td>Fixed budget could reduce incentives and opaque process for budget allocation potential longer term issue</td>
</tr>
<tr>
<td>Improves price predictability as prices are not re-negotiated following launch of new indication</td>
<td>Prices are potentially not aligned to value and does not have flexibility of individual MEAs agreements</td>
</tr>
<tr>
<td>Reduces on-going assessment workload of HTA bodies and of companies</td>
<td>Initial negotiation and re-assessment require resources and methodology development. Reduced involvement of other stakeholders</td>
</tr>
<tr>
<td>Allows communication of evolving issues between payers, patients and manufacturers (such as development of combos)</td>
<td>Requires flexibility if the agreements are to keep pace with innovation</td>
</tr>
</tbody>
</table>
Lessons on the use of MYMI for CEE countries

Drawing from the EU experience to date, there are some key lessons

1. MYMI are valuable where existing rules mean that every indication faces the same process but is not needed in all markets.

2. The nature of the agreements depend on the existing assessment, and pricing and reimbursement landscape.

3. The development of MYMI requires horizon scanning, partnership and may require legislative changes.

4. MYMI can deliver significant benefits in terms of faster access and reduced assessments and improved budget predictability.
Improving Patient Access to Innovative Cancer Therapies: The Role of Managed Entry Agreements
Educational Symposium
Sponsored by Merck Sharp & Dohme (MSD)