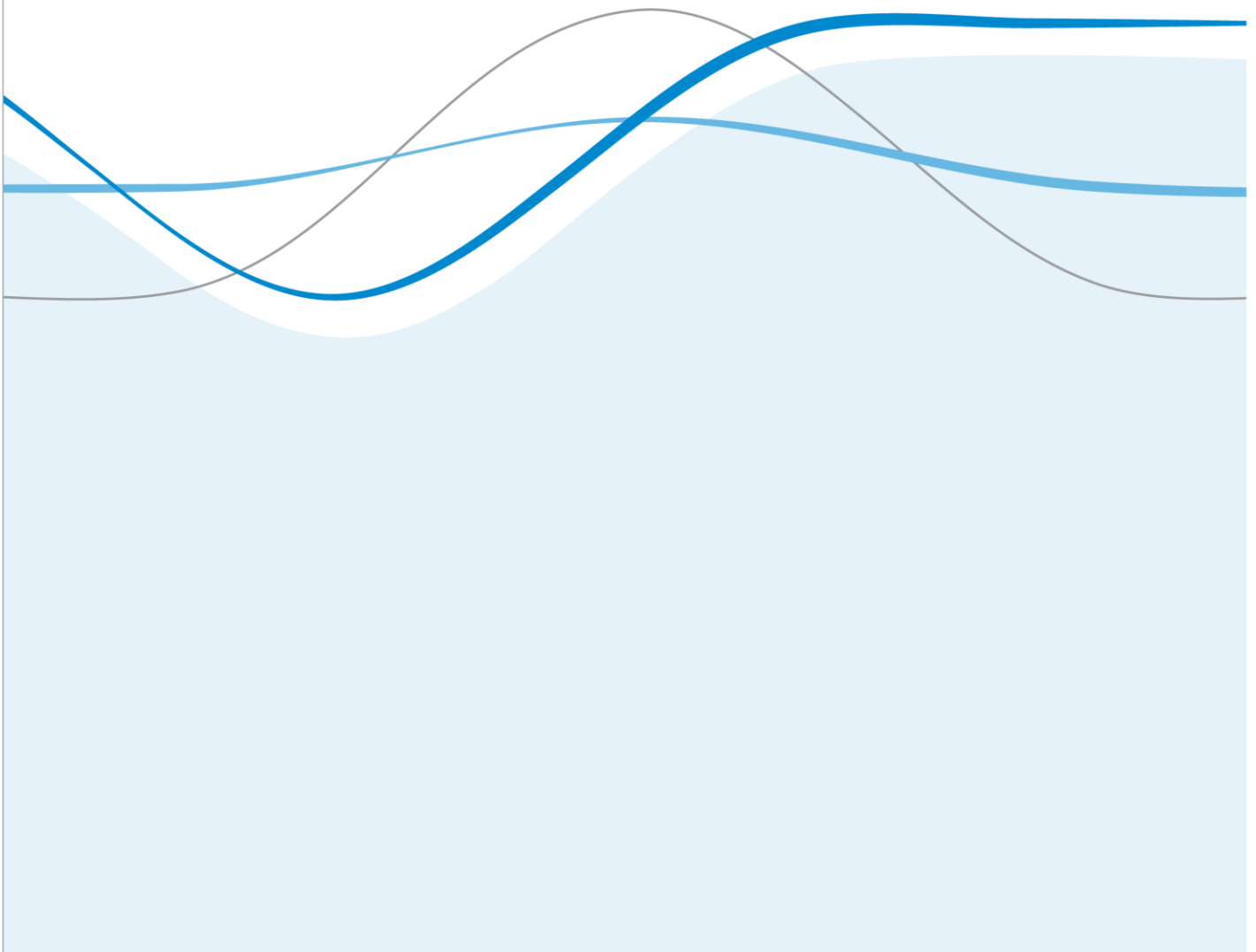


Multi-Indication Pricing (MIP): Practical Solutions and Steps to Move Forward

December 2018

Margherita Neri, Adrian Towse and Martina Garau



Value Assessment of Multi-Indication Pricing (MIP): Practical Solutions and Steps to Move Forward

Margherita Neri, Adrian Towse and Martina Garau

December 2018

Please cite this report as:

Neri, M., Towse, A. and Garau, M. (2018). Value Assessment of Multi-Indication Pricing (MIP): Practical Solutions and Steps to Move Forward. OHE Briefing, London: Office of Health Economics.

OHE Consulting Ltd
(a registered company number 09853113)
Southside, 7th Floor
105 Victoria Street
London SW1E 6QT
United Kingdom

For further information please contact
Margherita Neri
Economist
Tel: +44(0)20 7747 8851
mneri@ohe.org

About OHE Consulting Reports

Many of the studies OHE Consulting performs are proprietary and the results are not released publicly. Studies of interest to a wide audience, however, may be made available, in whole or in part, with the client's permission. They may be published by OHE alone, jointly with the client, or externally in scholarly publications. Publication is at the client's discretion.

Studies published by OHE as OHE Consulting Reports are subject to internal quality assurance and undergo a rapid review by a member of the OHE Editorial Panel.

Funding and Acknowledgements

This briefing was commissioned and funded by Sanofi Aventis Groupe.

Erratum:

06/02/2019: Please note that this copy of the report (originally published 28/11/2018) has been updated to correct an error in Section 3.

Table of Contents

1.	Introduction	1
2.	MIP: Do we want it? Can we operationalise it?	1
3.	How is MIP handled across European countries?.....	4
4.	Is MIP feasible? The UK case	5
5.	A successful application of MIP: the Italian case.....	6
6.	The industry perspective	8
7.	Panel discussion and conclusion	9
8.	References	11

1. INTRODUCTION

Increasing numbers of new drugs (notably biologicals in oncology) have more than one approved indication. If HTA bodies are to assess value, how should they handle multiple indications for the same drug? HTA bodies have experience in assessing value in subgroups of patients, but the addition of new indications after the first presents a separate challenge. Such follow-on indications appear at different times over the lifetime of marketed product. Prices, however, are set or negotiated based on the value of the first indication, which may or may not reflect the value of subsequent indications. To adjust to unanticipated volumes of use, some payers may require volume discounts for subsequent indications. To maximize returns, manufacturers may change the order in which indications are developed or not seek licensing approval at all for some indications. How should HTA bodies, technology developers and payers behave to ensure the best use of effective products at acceptable prices, and in a way that continues to encourage investment in innovation?

This report provides a detailed summary of a panel discussion on these challenges held at the HTAi 2017 annual meeting in Rome¹.

The structure of this briefing is as follows:

- Section 2 summarises the background information on multi-indication pricing (MIP) as presented by Professor Adrian Towse;
- Section 3 outlines the presentation by Dr Ad Shuurman on approaches to implementing MIP that are applied in different countries in Europe;
- Section 4 summarises the discussion by Professor Carole Longson on the case for MIP in the UK about the challenge of aligning the objectives of several stakeholders;
- Section 5 sets out the presentation by Dr Simona Montilla on the approach to applying MIP in Italy and the key factors for success there;
- Section 6 presents a pharmaceutical industry perspective from Dr Katja Berg, discussing the implications of developing additional indications and assessing their individual value;
- Section 7 concludes by summarising the key messages from the panel discussion.

2. MIP: DO WE WANT IT? CAN WE OPERATIONALISE IT?

Adrian Towse, Office of Health Economics, UK

Professor Towse opened the panel session providing some contextual information on MIP. After outlining the theory for its use, he discussed some operational challenges to implementing MIP, as perceived by health care stakeholders.

When multi-indication products are priced with a single price across indications, negative consequences will occur from an efficiency point of view. If the price is set according to a higher-value indication, payers may be reluctant to pay that price for lower-value indications, thus restricting the use of the product to fewer indications and patients (static inefficiency). Conversely, when prices are based on a lower-value indication, the

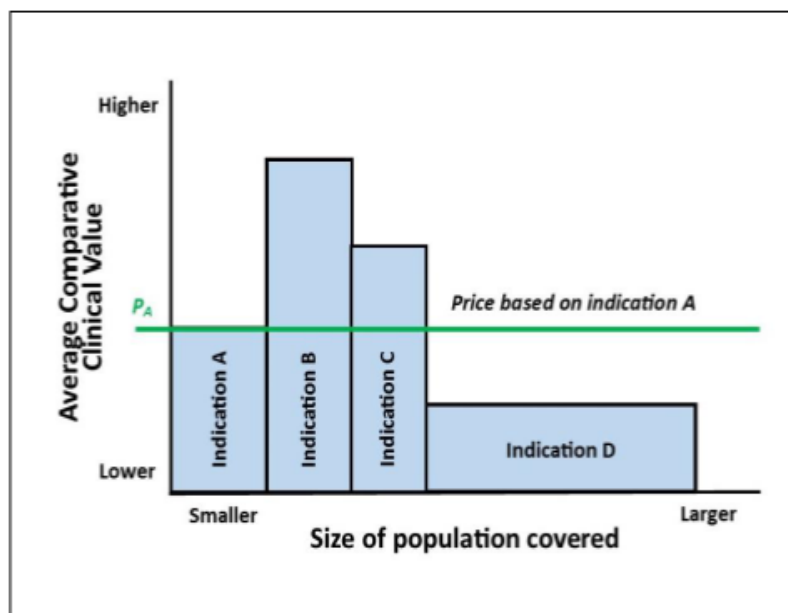
¹ <https://htai.org/interest-groups/pcig/htai-2017/>

industry will be discouraged from investing in research on higher-value indications (dynamic inefficiency). MIP intends to recognise the value for all the indications for which a product is authorised. The same principle can apply to patient subgroups with different characteristics or varying disease severity within the same indication. MIP can increase both static and dynamic efficiency: prices will be set at a cost-effective level from the patient point of view, thus allowing more patients to access the treatment; it also will stimulate future research because manufacturers can expect a sufficient return on R&D expenditures.

The ability of MIP to improve efficiency assumes that the length of the patent period, during which the economic surplus is captured by the manufacturer, provides optimal R&D incentives (Danzon, Towse and Mestre-Ferrandiz, 2015). Some researchers (Claxton et al., 2008) have argued for single pricing across indications, which allows payers to appropriate a larger share of the economic surplus. However, pricing levels can be constrained by in-class competition during patent life (DiMasi and Paquette, 2004; Berdud et al., 2018). Such competition by indication could reduce the price below the actual value-based price, thus transferring surplus from innovators to the payer (Cole et al., 2018).

Figure 1 illustrates the challenge of setting a uniform price for a product that varies in value by indication or patient subgroup.

Figure 1: The clinical benefit of a compound can vary by indication



Source: Hebborn (2014)

The potential efficiency gains from MIP are substantial. More than 50% of major cancer medicines marketed in 2014 were approved for multiple indications; by 2020, the share of these medicines is estimated to reach 75% (Aitken, Blansett and Mawrie, 2015). Treatment for rare diseases is another area where MIP could be particularly relevant.

A common and simple approach to MIP is separate branding by indication, although this involves significant cost and does not completely remove the potential for arbitrage (i.e. use of the drug in a higher-value indication at the price of a lower-value indication). Therefore, alternative strategies to implement value-based pricing are desirable.

Despite the theoretical attractiveness of MIP, health care stakeholders hesitate to embrace MIP because it entails several trade-offs. For instance, MIP can increase demands on the budget if more patients gain access to treatment; but it also can also avoid the risk of overpaying for lower-value follow-on indications. Implementing MIP can be more complex and administratively costly; such costs may be offset by incremental health gains as more patients gain access to treatment and the possible value from the development of additional indications. A strong information system based on electronic health records (EHR) and information, and information and communication technologies (ICTs) can help contain the administrative cost of collecting data for MIP.

A previous workshop led by the Office of Health Economics (OHE) explored the views of stakeholders about the attractiveness and feasibility of MIP in the UK (Mestre-Ferrandiz et al., 2015). The workshop's participants expressed their support for a system of prices that reflects the relative value of each indication, but emphasised that price should not exceed value for any indication. Participants expressed a preference for implementing MIP through (1) a 'blended' price at list level (i.e. single price calculated as the average value of all indications, weighted by expected patient volumes) or (2) schemes based on variable 'net' selling prices (i.e. differential discounts).

The Systemic Anti-Cancer Therapy (SACT) data set, a mandatory chemotherapy dataset of treatment for all solid tumours and haematological malignancies within organisations funded by NHS England, was considered a useful tool for tracking patient data in oncology. However, other disease areas still lack the data capable of supporting implementation of MIP.

The Institute for Clinical and Economic Review (ICER) held a policy summit on the desirability of MIP in the US health care system (Pearson, Dreitlein and Henshall, 2016). The workshop identified a number of challenges to implementing MIP in the US: the complexity of the US system makes it difficult to link price to indication, data collection and analytic capabilities are insufficient, and tiered-pricing formulary structures cannot easily accommodate pricing by indication. The US system also is affected by a number of regulatory and legal hurdles. These include, for example, reimbursing physicians for drugs purchased and administered by them (e.g. in oncology) based on the Medicare average sales price (ASP), which is a weighted average of sales. For higher-value indications, the ASP may not be sufficient to cover the acquisition cost. Use of products off-label also presents challenges because manufacturers legally can negotiate reimbursement contracts only for FDA-approved indications. Despite the numerous operational challenges, however, both payers and pharmaceutical manufacturers in the workshop viewed MIP favourably and did not consider the barriers insurmountable. Table 1 below summarises some of the key points made at the ICER summit.

Table 1: Implementing MIP in the US - insights from the ICER summit

Potential Benefits	Potential Risks
<ul style="list-style-type: none"> ● Offers a new mechanism to facilitate access while balancing affordability and sustainability ● Aligns with value-based pricing and benefit designs ● Supports pricing discussions for multi-indication drugs ● Potential to save the system money ● Demonstrates innovation 	<ul style="list-style-type: none"> ● Administrative burden ● May not address affordability ● Conflict with existing pricing policies (Medicaid Best Price, 340B, and others) ● Payers may not acknowledge added clinical value ● Risk of “arbitrage”

Source: Adapted from Pearson et al. (2016)

MIP, then, is an attractive approach that could provide substantial gains in both economic efficiency and patient health. MIP can be implemented using a variety of approaches, including ‘blended’ pricing, differential rebates, or a combination of the two. To achieve the desired results, however, reliable data from EHRs or disease registries on use by indication and patient subgroup are essential.

3. HOW IS MIP HANDLED ACROSS EUROPEAN COUNTRIES?

Ad Shuurman, MEDEV, The Netherlands

Dr Shuurman provided an overview of the current level of diffusion of MIP in Europe by using country-specific examples.

Most European countries conduct the assessment of individual indications of the same drug separately. However, they vary as to how the pricing of multi-indication products is handled. Three main approaches can be distinguished: (1) application of the price of the first indication across all indications, (2) use of a weighted price across all indications and (3) setting a different price per indication.

Countries following approach 1 tend to fix the price of multi-indication drugs at the level of the first indication that has been negotiated. This is the approach followed by **The Netherlands, Norway and Poland**. If the follow-on indications are not deemed cost-effective at the price of the first indication, a lower price may be negotiated. If no agreement on a lower price can be achieved, the follow-on indications that are not considered cost-effective may not be reimbursed. In practice, the price of the first indication launched is used to anchor the price of all indications.

Germany, France, Belgium and Austria are among the countries that implement a single price weighted by the value of each indication (approach 2). In **Germany**, HTA and price negotiations are different processes and, due to legal requirements, the assessment of each indication triggers a new price negotiation. The outcomes of the multiple negotiations are processed into a unique price that reflects all the therapeutic values. In **France**, each indication is assessed separately and is scored against a five-level scale (Amélioration du Service Médical Rendu, ASMR) according to added therapeutic benefit. The public price reflects the value across indications weighted by the expected volume. If the actual volume by indication does not reflect the volume predicted at the time of the

negotiations, rebates may be claimed. In France, the possibility of reimbursing hospital drugs on top of the flat rate is being considered, although stakeholders raised concerns because this would require disclosure of medical data on patients' diagnoses. In **Belgium**, the extension of reimbursement to larger populations is usually followed by volume discounts. Price reductions are calculated according to the so-called 'rule of one-third': the price percentage reduction corresponds to one-third of the spending increase across the multiple indications divided by the new spending volume. Pharmaceutical companies may try to bypass this by means of financial agreements (e.g. separate rebate agreements) that retain the original list price. Price reductions following the expansion of the patient population also occur in **Austria**, although the extent of the reduction is not formally specified in advance.

Countries following approach 3 set different prices for individual indications using a variety of methodologies. For the application of MIP, **Italy** relies in part on a web-based patient registry where individual level information on prescription and associated billing is collected. The availability of individual patient data is crucial for the implementation of managed entry agreements (MEAs) which determine a different price for each indication.

In **the UK**, the indications are reviewed one by one and recommended only if deemed cost-effective. However, the price of new medicines does not change when additional indications are introduced, as only one Patient Access Scheme (PAS) is usually allowed per product².

The preference of each country for the pricing approach for multi-indication products are influenced by the characteristics of the national HTA system and availability of resources. Setting different pricing options across indications requires substantial effort and resources. Because not all countries in Europe are equipped with the capabilities necessary for embracing a more complicated pricing system, MIP may not be the optimal solution.

4. IS MIP FEASIBLE? THE UK CASE

Carole Longson, National Institute for Health and Care Clinical Excellence (NICE), The UK

Professor Longson discussed the organisation of the pricing system of pharmaceuticals in the UK and the role of NICE within this system. In addition, she reflected on the challenges that could make MIP a suboptimal approach in the UK.

In the UK, the assessment and pricing system of pharmaceuticals is structured on three levels. Prices are set across the UK through the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary scheme that allows manufacturers to negotiate prices directly with the Department of Health. The UK-wide price then is translated into value in individual jurisdictions (the UK nations) which maintain separate HTA processes. In England and Wales, the HTA process is led by the National Institute for Health and Care Excellence

² We note that Managed Access Agreements (MAAs) have been introduced as an alternative mechanism to PAS for managing price and patient access. These have been used to date: as part of the revised arrangements for the Cancer Drugs Fund, where two drugs and three indications have been subject to MAAs, and in the Highly Specialised Treatment programme, where two drugs have been approved with MAAs as well as PASs. However, it is not clear if any of these arrangements amount to de facto multi indication pricing as the detailed contractual arrangements are commercially confidential (Towse et al., 2018)

(NICE), which acts as a price taker and directly feeds the negotiated prices into their evaluations. NHS England (NHSE) (or the NHS operating in the other nations) represent the payer. Discounts on the UK list price can be agreed with the Department of Health (via Patient Access Schemes) and with NHSE (via commercial access agreements). Because of such fragmentation, the outcomes of the HTA recommendations, payers' funding decisions and industry's objectives are not always aligned.

Divergence in objectives is particularly apparent in the case of multi-indication products. Manufacturers want the value of their innovations reflected in indication-specific prices. The challenge is to implement this in a single (list) price per product. More specifically, it can be problematic to link value (expressed in terms of cost-effectiveness) and affordability. As more indications are added to a product and patient access expands, the budget impact can grow significantly while value is not necessarily the same across indications.

A criticism of MIP from the payer point of view relates to who captures the benefits yielded by the introduction of new products. In a system like the UK, where there is an explicit cost-effectiveness threshold, there is an incentive for companies to set prices at the maximum allowed by the threshold and thereby appropriate all the surplus for every indication. The transactional burden associated with negotiating prices for each indication is large; simplicity is a priority for payers.

5. A SUCCESSFUL APPLICATION OF MIP: THE ITALIAN CASE

Simona Montilla, Agenzia Italiana del Farmaco (AIFA), Italy

Dr Montilla described the challenges associated with the price setting of pharmaceuticals given the evolving nature of pharmaceutical R&D. Having explained the advantages of MIP, Dr Montilla outlined the factors that determine the success of MIP in Italy.

One of the key drivers of pharmaceutical spending growth in Europe is early access schemes, introduced to foster access to new medicines and encourage innovation. Early access schemes are available in the form of priority medicine (PRIME) and adaptive pathways schemes by the European Medicines Agency (EMA), conditional marketing approval, and approval under exceptional circumstances. Scientific progress also drives the evolution of expenditures because of the advances in the fields of personalised medicine, curative therapies, orphan drugs, multi-indication drugs and combination therapies. Overall, the pressure exerted by the combination of these factors is posing significant challenges to setting prices for pharmaceuticals.

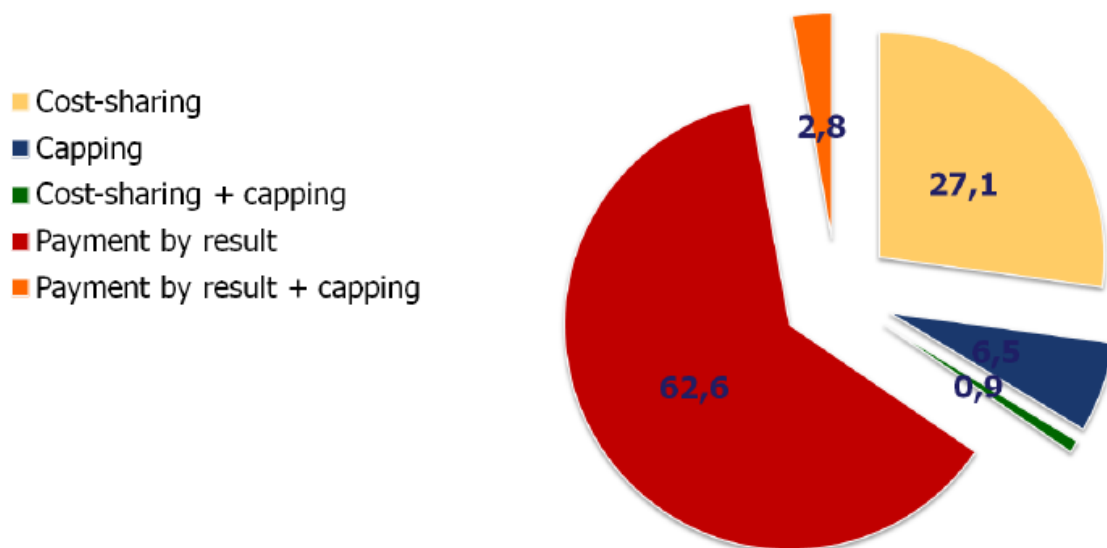
In the case of multi-indication drugs, the price setting process is complicated by the authorisation of follow-on indications, which occur after the approval for the first indication. Manufacturers tend to prioritise the development of indications that target niche populations, leading to the negotiation of prices that reflect the high therapeutic value of the first indication. However, as a consequence of additional drug development, the number of authorised indications will expand. As a result, the renegotiation of prices at a lower level is necessary to reflect the size of larger patient populations.

Combination therapies are the treatment of the same medical condition through the coincident use of two or more medicines. In recent years, significant progress in oncology has been realised by using new and expensive medicines in combination therapies. This has come at a cost: for example, the use of lenalidomide in combination

with newly launched medicines has doubled the price for the treatment of multiple myeloma. In theory, the combined use of individual therapies adds value and should be rewarded because it improves health outcomes. However, the sum of the prices of individual therapies is often high enough to require discounting the price of some combination therapies. This may be hard to implement in practice when individual components of the combination therapy are produced and marketed by different manufacturers.

By setting different prices for different indications (or patient subgroups), MIP aims to reward different levels of clinical benefit. Although clinical benefit may vary by indication, a single uniform price is usually assigned to multiple-indication drugs. In Italy, MIP is implemented through an extensive use of MEAs. Outcome-based MEAs—such as payment by result, risk-sharing, or success-fee schemes—can address the uncertainty around the health and economic impact of each indication (or patient subgroup) because prices can be modulated to reflect the observed performance (value). MEAs not based on outcome, such as cost-sharing, capping and volume schemes, can help contain budget impact, particularly when the patient population of the first indication is small and that of the subsequent indication(s) is large. As shown in Figure 2, of the 107 current MEAs, payment-by-result schemes account for the majority (62.6%) followed by cost-sharing (27.1%) and capping (6.5%) schemes.

Figure 2: Distribution (%) of type of risk sharing agreement (107 MEA of 99 registries)



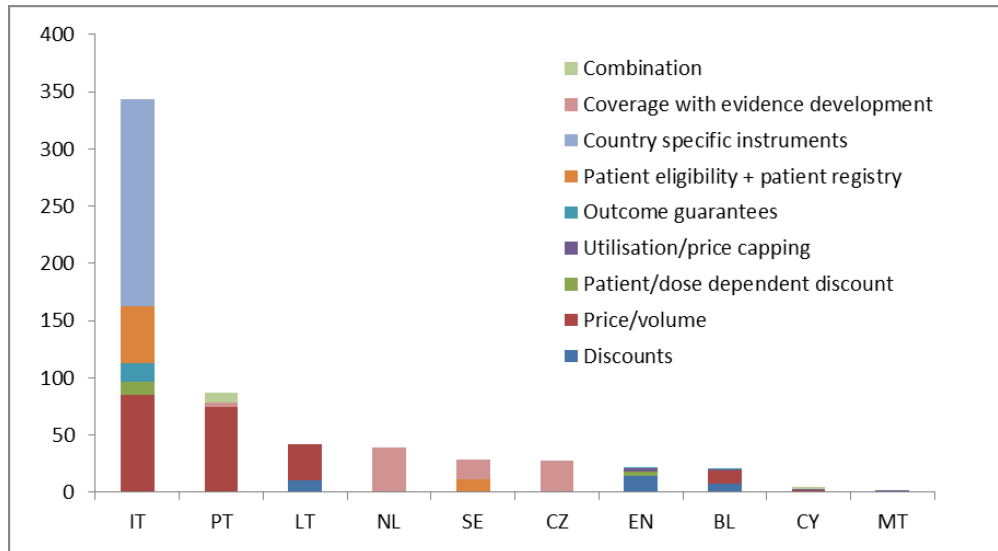
Source: Internal Data AIFA (June 2017)

Bevacizumab, authorised for seven oncology indications, is a notable example of when MEAs linked to outcomes have been implemented successfully and combined with financial agreements on discounts.

As Figure 3 shows, as of December 2012, Italy ranks highest among the European Member States in use of MEAs. A key factor in success in Italy is the online monitoring system of registries through which the Italian Medicine Agency (Agenzia Italiana del Farmaco, AIFA) can track eligibility, adverse events and safety signals of more than one million patients. Patient-level data, collected by health professionals, support decisions for conditional reimbursement schemes that are based on the extent to which health

outcomes meet initial expectations. Research on the value generated for the National Health System in Italy by registries is available in Montilla et al. (2015).

Figure 3: MEAs by type of instrument



Notes: BL = Belgium; CY = Cyprus; CZ = Czech Republic; EN = England; IT = Italy; LT = Lithuania; MT = Malta; NL = Netherlands; PT = Portugal; SE = Sweden.

Source: Ferrario and Kanavos (2013), Figure 9.3 p. 126

Finally, Italy aims to improve access and reward the development of innovative medicines through the introduction of two new funds: an Innovative Medicines Fund and an Innovative Oncologicals Fund, each at €500 million per year. According to the new set of evaluation criteria released in March 2017, AIFA rewards innovation based on a multidimensional approach that, for each indication, takes into account therapeutic need, added therapeutic value and disease severity, and quality and robustness of the evidence.

6. THE INDUSTRY PERSPECTIVE

Dr Katja Berg, Sanofi

Dr Berg discussed the pharmaceutical industry perspective on the value and challenges of MIP. After describing the current situation, she proposed a list of topics for discussion to promote the achievement of a shared position on the optimal MIP approach.

The evolution of pharmaceutical R&D towards targeted drug therapies has led to an increase in the cost of investment and associated opportunity costs. Pharmaceutical research pipelines include medicines that can act via several pathways, providing an opportunity for developing multi-indication drugs. The majority of these drugs are concentrated in oncology and immunology, but examples also exist in other therapeutic areas.

HTA bodies increasingly require evidence to establish substantial added value and differentiation from the standard of care. To optimise market access, the industry is directing research efforts towards narrower segments of the market and more specific patient populations. As volumes and access decline, the potential health gain of a

particular drug cannot be fully captured, but the burden of evidence generation and opportunity costs do not decline.

The industry faces three main challenges in the context of products with multiple indications:

1. Price setting challenges, both within the same therapeutic area and across diseases, where severity and other characteristics differ. Using different comparator drugs, across indications, produces particularly disparate price points;
2. Value creation vs patients' interests. Current pricing and reimbursement practices incentivise companies to prioritise the development of indications for carefully targeted patient populations where the drug's value is potentially high. Without MIP, the incentive to develop lower-value follow-on indications remains low;
3. Implementation challenges. Payment systems have difficulty pricing by indication unless each indication is differentiated by dose regimen, formulation or branding. Given inadequate existing data-capture systems, however, such differentiation makes it more difficult to monitor utilisation and reimbursement.

The risks of adopting a single price for all indications is clear for follow-on indications, which vary in value and appear on the market over a period of time. As an example, a therapy with an assessed high value for its first approved indication may be priced above what the payer is willing to spend for a follow-on indication considered to be lower value. If this results in discouraging reimbursement for the follow-on indication, incentives for developing lower-value follow-on indications will ultimately decline.

Key discussion points to advance the debate on MIP are:

- 'Start small' and engage where feasible: where capabilities are mature and offer an opportunity for MIP, MIP-related reimbursement pathways could be developed in partnership with all stakeholder groups and follow a value-based pricing approach;
- Create a learning system: successful experiences from countries that are able to monitor outcomes through real world evidence (e.g. Italy) should be shared to help facilitate the expansion MIP;
- Evaluate the benefits of refining HTA practices to account for MIP approaches: engage stakeholders in more sophisticated and broader discussions on the value and trade-offs of using an MIP approach;
- Elaborate strategies to foster data capture and governance: implement approaches that can provide evidence that MIP can result in improved patient access to high value indications;
- Share responsibility for price and access consequences vis-a-vis outcomes and performance, which will help increase trust and build long-term credibility.

7. PANEL DISCUSSION AND CONCLUSION

In principle, the implementation of a value-based price for individual indications of the same medicine could achieve improvement in both static and dynamic efficiency. Prices can be set at a cost-effective level for each indication and patient sub-population, thereby expanding treatment to more patients and stimulating future research as manufacturers anticipate a sufficient return on R&D spending. Some critics of the MIP

approach charge that MIP allows the producer to capture all the economic surplus for each indication. In systems with an explicit cost-effectiveness threshold (e.g. the UK), companies will set prices at the maximum allowed by the threshold. In this case, payers may be reluctant to introduce MIP because it can lead to higher budgetary impact from the use of a treatment. In response, they may demand discounts to contain total spending even when adopting MIP as a value-based pricing mechanism.

An optimal patent period during which MIP pricing is implemented can foster R&D for therapeutic competitors, which in turn can contain the level of prices during the patent life period. After patent expiry, prices will decrease dramatically with the appearance of generic competitors, allowing payers to capture most of the economic surplus.

The panel presentations discussed several practical challenges for the implementation of MIP. Previous work by the OHE and ICER has highlighted the concerns of health care stakeholders about inadequate data capabilities to monitor prescriptions by indication, legal and regulatory hurdles, and the inflexibility of formulary structures (particularly in the US) to accommodate multiple prices for the same drug.

Current practice to set the price of medicines with multiple indications in Europe include:

1. a single price for all indications based entirely on the price for the first indication authorised;
2. a single price weighted by the value of all indications;
3. a value-based price for individual indications.

Only the second and the third approaches are designed to reflect the value of the follow-on product indications.

According to some payers, MIP is worthwhile if the approach is simple. Any solution that is too complex or requires too many resources (e.g. staff from the department of health) might not be efficient. Most favour tracking both volume and outcomes, however, to inform re-assessment and address the uncertainty attached to any new product at launch. In Italy, online registries that collect data on patient eligibility and outcomes support the implementation of outcome-based agreements, where prices are modulated to reflect the observed drug performance.

From an industry perspective, without MIP developers will have an incentive to focus on high-value indications for well-defined patient populations rather than expanding use to additional indications both within and outside the therapeutic area. In practical terms, the lack of data capabilities (in most systems) that adequately and reliably monitor different uses of the same medicine is a critical challenge.

Potential steps for facilitating the application of MIP include: sharing successful MIP experiences across countries and improving data governance methodologies that can more easily and effectively monitor both volume of use and health outcomes. Full and continuing stakeholder engagement will be a key factor in determining the success of this process.

8. REFERENCES

- Aitken, M., Blansett, L. and Mawrie, R., 2015. *Developments in cancer treatments, market dynamics, patient access and value*. Available: https://www.keionline.org/sites/default/files/IIHI_Oncology_Trend_Report_2015.pdf.
- Berdud, M., Garau, M., Neri, M., O'Neill, P., Sampson, C. and Towse, A., 2018. *R&D, Competition and Diffusion of Innovation in the EU: The Case of Hepatitis C*.
- Claxton, K., Briggs, A., Buxton, M. J., Culyer, A. J., McCabe, C., Walker, S. and Sculpher, M. J., 2008. Value based pricing for NHS drugs: an opportunity not to be missed? *BMJ: British Medical Journal*, 336 (7638), 251.
- Cole, A., Towse, A., Lorgelly, P. and Sullivan, R., 2018. Economics of Innovative Payment Models Compared with Single Pricing of Pharmaceuticals. *OHE Research Paper*.
- Danzon, P., Towse, A. and Mestre-Ferrandiz, J., 2015. Value-based differential pricing: Efficient prices for drugs in a global context. *Health economics*, 24 (3), 294-301.
- DiMasi, J. A. and Paquette, C., 2004. The economics of follow-on drug research and development. *Pharmacoeconomics*, 22 (2), 1-14.
- Ferrario, A. and Kanavos, P., 2013. *Managed entry agreements for pharmaceuticals: the European experience*. Available: http://eprints.lse.ac.uk/50513/1/Libfile_repository_Content_Ferrario,%20A_Ferrario_Managed_%20entry_%20agreements_2013_Ferrario_Managed_%20entry_%20agreements_2013.pdf.
- Hebborn, A., Value-based pricing across indications: A company perspective. International Society for Pharmacoeconomics and Outcomes Research 19th Annual International Meeting. Montreal, Canada, 2014.
- Mestre-Ferrandiz, J., Towse, A., Dellamano, R. and Pistollato, M., Multi-indication pricing: pros, cons and applicability to the UK. Seminar Briefings, 2015. Office of Health Economics.
- Montilla, S., Xoxi, E., Russo, P., Cicchetti, A. and Pani, L., 2015. Monitoring registries at Italian Medicines Agency: Fostering access, guaranteeing sustainability. *International journal of technology assessment in health care*, 31 (4), 210-213.
- Pearson, S. D., Dreitlein, B. and Henshall, C., 2016. Indication-Specific Pricing of Pharmaceuticals in the United States Health Care System. *Institute for Clinical and Economic Review*. March.
- Towse, A., Cole, A., and Zamora, B., 2018. *The Debate on Indication-Based Pricing in the U.S. and Five Major European Countries*. Available: <https://www.ohe.org/publications/debate-indication-based-pricing-us-and-five-major-european-countries>.