Opinion on Innovative payment models for high-cost innovative medicines

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

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TERMS OF REFERENCE

- What is the current role of the national pricing and reimbursement authorities to improve access on innovative medicines?
- Is there a scope to explore new ways of setting prices for specialty medicines in terms of improving access, while taking in to account the costs, the benefits, the budget impact and the future return on investment on a transparent way?
- How to deal with polypharmacy/ combination of treatments?
- What are the existing frameworks for such dynamic payment models?
- Any experience from other economy sectors (transport or telecommunications) that can potentially be applied to medicines?

Terms of reference

- How can the use and uptake of medicines impact the health care costs?
- Can this be reflected on price setting i.e. reward for the right behaviour?
- Ways to monitor the adherence to treatment?
- What is the importance of choosing the right outcomes to measure the performance?
- What is the role of RWD for innovative payment models and are there any prerequisites to develop such system?
- Is it possible to develop a common definition for RWD from all different perspectives (regulators, HTA bodies, payers, pharmacovigilance etc.)?

Terms of reference

- Is there a theoretical framework for the interpretation of the results and outcomes?
- Is there a framework of health system performance assessment in the area of pharmaceuticals and possible areas for future work?
- Is there a scope to improve resilience and cooperation between those bodies that are involved in the decision making process?
- What type of synergies can be developed between the payers, HTA bodies and regulators in the EU?

Summary

- The recognition that the current path of growth cannot be continued indefinitely leads to the search of new ways to ensure that innovation “that matters” is produced, that patients have access to innovation and that health systems are financially sustainable.
- It is unlikely that a single payment model will be optimal for all situations.
- broad principles should be observed (taking advantage of many discussions and documents)

The proposed principles

1. Greater price and cost transparency, including the acknowledgement that high prices (high costs to payers) may or may not have underlying high costs of R&D.
2. Use several mechanisms to promote and reward high-value innovations (patent law and market exclusivity are one but not the only way of doing it)
3. Develop methodologies to measure the social value of pharmaceutical products and systematically use such methods (in the context of HTA)
4. Have an assessment of exercise of market power in each price negotiation

5. Set better rewards for higher therapeutic value added, so that innovation efforts are directed to the more relevant areas.
6. Payment systems should evolve in the direction of paying for acquisition of a service (treatment) and not of a product (pill).
7. Explore non-linear payment systems, including bundling, price-volume arrangements, differentiation across geographies and across indications
8. Create dialogue platforms involving all relevant stakeholders

How did these principles emerge?

- Interpretation of current situation
- Identify key elements: objectives and instruments
- Assess advantages and disadvantages of different options
- Make proposals for action in short and medium term

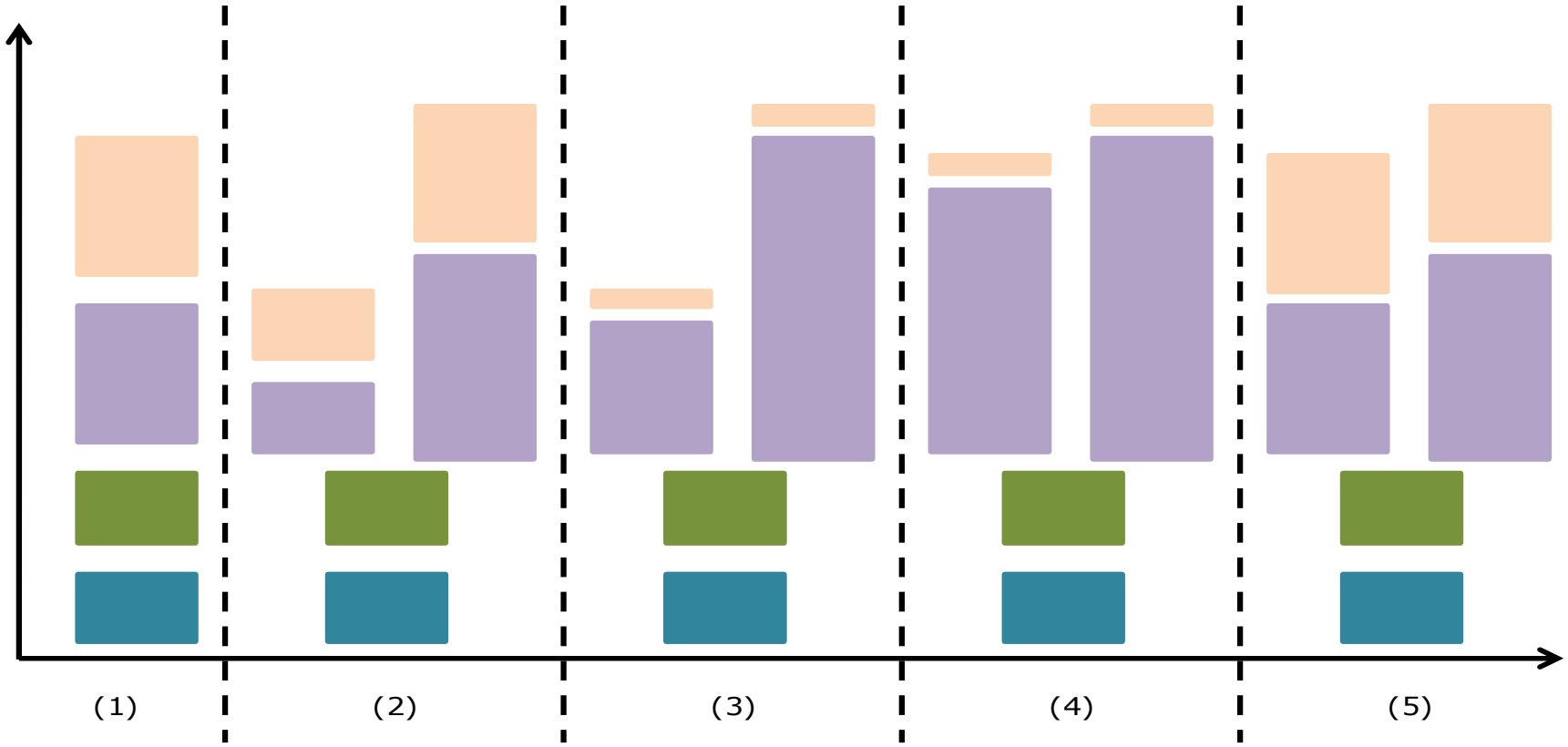
Current practice of pricing new products

- High prices and growing health expenditure create concerns about impact on health systems
- Several arrangements to set prices have been developed
- These arrangements, collected under the term “Managed Entry Agreements”, include one or several of the following features: outcomes-based view, hidden price discounts, assessment of cost-effectiveness.
- MEAs are mainly designed to address issues of information flows.
- They address one important concern: how the new product is going to perform in a population setting.

Current practice of pricing new products

- Overcoming the uncertainty about the value of a new product and setting its prices are two different issues.
- High prices may result from a variety of reasons:
  - High underlying costs
  - High margins due to exercise of market power
  - Higher margins for higher-value products with the objective of providing incentives for R&D
- Current institutional mechanisms do not make an assessment of market power exercise (as demand price elasticity does not perform a limiting role due to the product nature and financial protection to patients)

A graphical view



Legend: Blue – R&D costs; green – production and commercialization costs; Violet – margin to companies; orange – surplus to health care payers

Note: Size of green and blue boxes kept constant for simplicity. Only relative size of Violet and orange boxes are discussed.

Three objectives to be achieved by payment model

- innovation “that matters” - incentives for innovation, with a growing concern with areas in need of new products
- (“that matters” = addresses diseases with a high burden to patients, holds a non-negligible size for the therapeutic benefit)

- that patients have access to innovation as soon as possible in a safe way

- health systems are financially sustainable.

Properties for payment models of innovative medicines

Role of directing R&D

- Under decentralized R&D model based on patents: “compensation for the value of the innovation to encourage the development of products that are more highly valued than others because they address a more important therapeutic gap”
- In case of specific therapeutic gaps being identified, set different procedure (more centralized) to guide innovation on the gap
- Recognize that unplanned innovation will result from decentralized efforts
- Do not pay based on R&D costs incurred, as it stimulates process costs without guiding efforts to therapeutic gap

Affordability to health systems and to patients

- Affordability means ability to pay for products/services in a continued way over time
- The payment is divided between institutional payers (Governments/insurers) and citizens – decreasing the share of one increases the share of the other
- Lower prices are an important part of ensuring affordability
- Avoiding silo mentality and addressing cost-offset effects should be included in affordability assessments

Intergenerational effects

- Innovative products may benefit more than one generation of patients
- Current generation pays the bulk of innovation rewards through the prices set under patent
- On a different direction, antimicrobial resistance to may hurt future generations
- New payment models should recognize this implicit intergenerational transfer when it is expected that innovation will benefit several generations of patients
- There are no such assessments today and no instrument is addressing them

Balance between objectives and instruments

- Linear price model has only one instrument and several objectives requires trade-offs to be made in setting the price
- Another route is to increase the set of instruments available.
- Other ways to reward innovation can be experimented to direct R&D, freeing prices as instrument to pursue other objectives, namely affordability
- Using prizes for discoveries in announced areas followed by immediate-generics decision or procuring innovation are possibilities to be considered in areas of well-identified gaps

Framing health system design options

- Pharmaceutical companies respond and adapt to the economic environment they face
- Measuring benefits is important, but is not the only discussion that matters
- A new framework for price determination of new products that allows for knowledge of full value created (value of benefits to patients – costs of obtaining the innovation) and how it is split between sides under the payment model should be in place
- A payment model should contain mechanisms to promote affordability, timely access and incentives for innovation with value

Governance

- New payment models raises governance challenges that need to be addressed
- Crucial elements are monitoring procedures and negotiation power on behalf of the public good.
- Equally essential is the credibility of publicly announced rules
- This credibility is mostly challenged in delisting products that do not yield the initially expected outcomes
- Governance challenges are typically higher for Governments than for other institutional payers
- Multiple payer health systems face issues of coordination across payers

Governance

- The governance model for new payment models has to provide
  - a clear definition of information to be collected,
  - open standards for outcome measurement,
  - decision rules,
  - openness of information, registries and ownership of data.
- All these matters may require important changes in the legal and institutional settings of health systems.

Instruments

Non-linear prices

- Combination of therapies akin to ”bundles” in other sectors
- Analogies with pricing in other sectors needs to adjust for the presence of financial protection (health insurance)
- Price differentials across geographies and/or indications can be advantageous to patients and payers if a lower (weighted) average price results
- Prices reflecting economic opportunity costs should be pursued, acknowledging the several objectives present

Price transparency

- Knowing how prices are formed provides “better grounds for assessing affordability, equitable access, fairness in pricing and incentives to develop new medicines”
- Having more knowledge about R&D and manufacturing costs does help in the assessment of how a payment system performs relative to value division between all sides
- Such knowledge cannot and should not result in payment model based on costs alone (as it would fail on the objective of guiding R&D and promoting an efficient R&D process)
- Information on R&D and operation costs can be disclosed to payers without being available to market rivals

From paying pills to paying services

- New payment models based on outcomes, including bundled payments, bring the relationship between payers and suppliers to commissioning of health care services
- New payment models in this line will required a closer partnership between pharmaceutical companies and payers, in the sense of requiring a clear strategy from payers and specific expertise by companies
- This move also has governance challenges, namely in defining, commissioning and monitoring services, and on dispute-resolution mechanisms

Innovation procurement initiatives

- Development of relationships with payers in early stages of innovation
- Requires coordination across countries, as more centralized ways of rewarding innovation needs to pool funds from several countries
- Examples of new ways to approach innovation should be encourager and evaluated, such as NGOs/foundations promoting R&D in neglected areas and the triple helix approach

The incentive role of prices

- The role of prices in guiding R&D efforts in a decentralized way (making it more profitable to companies to discover higher value products) is an issue of relative prices
- The level of prices and whether, or not, has an element of too much exercise of market power needs to be explicitly considered
- Current mechanisms do not intend to address it, although HTA does exclude low-value products.
- Defining ways of creating downward pressure on prices without hurting the incentive for to discover higher value products should be an element of new payment models

Searching for a new institutional design

- HTA plays a role in setting a hurdle for a new product to be included in coverage on a sound basis of costs and benefits
- It needs to be complemented with further elements, recognizing that negotiation will be present in many, perhaps most, situations
- Addressing bargaining position of payers in these negotiations should consider elements such as use of TRIPS agreement for public health reasons, delisting of products, credibility in implementing announced decisions, etc.
- Introduction of new payment models need to explicitly address the balance of power they generate.

Real world data and adaptive pathways

- The need for further information, namely on how the new products perform in the population, can be part of new payment models
- The evidence produced by real world data will not be as strong as evidence from randomized control trials, but on the other hand allow for other effects to be factored in
- The political risk associated with delisting may reduce the ability to act upon real world data, and the benefits of earlier access to better drugs by patients needs to be balanced against the costs of too quick introduction of low value products

Patents

- Patents have been the cornerstone of decentralized models of obtaining innovations, and they will continue to have an important role on the future
- Patents, and the pricing power they provide, may not be the only mechanism to obtain and reward innovation (as discussed above)
- Patents may also be used differently by payers (say, a pool of countries buying a patent and licensing it directly for production)

International cooperation

- No single country will be the sole payer of innovation, implying that new payment models that reward innovation may (will) require coordination across countries
- Such coordination should be restricted to creation of “buyer clubs” (joint procurement) and could go to efforts in rewarding and in procuring innovation.
- International cooperation also includes development of dialogues between all stakeholders

- No existing payment model dominates in all relevant dimensions
- Under several objectives and multiple instruments it is unlikely that a single payment model will be the best for all occasions
- Payment models need to be tailored, and basic principles should be used to screen proposals before they are adopted

Proposal of basic principles in design of new payment models

- Greater price and cost transparency
- Consider new rules of protecting innovation (adding, not replacing in all cases the current patent system)
- Consider new ways to fund R&D, namely in well-identified therapeutic gaps
- Adopt governance models adequate to the demands of new payment models
- Improve methodologies to measure value and costs of pharmaceutical products

Proposal of basic principles in design of new payment models

- Have an assessment of exercise of market power in each price negotiation
- Set better rewards for higher therapeutic value added
- Move towards acquisition of service rather than product
- Explore non-linear payment systems, developing the information required and the conditions for its use
- Create dialogue platforms

Proposal for action

- relevant authorities within health systems asking for R&D costs, marketing costs and production costs, even if these are not disclosed to the general public or to other companies (short run)
- select one neglected area and launch international prize initiative with patent being retained by the set of countries participating (medium run)
- check existing payment models used in each country against the principles defined above (short run)
- introduce a competition policy review of high prices asked by companies, with cooperation of competition authorities (short run)

- assess value of new products of uncertain benefit using sound and transparent health technology evaluation methods. (medium run)
- strengthen bargaining power of health systems as buyers by using joint negotiation procedures and consider the use of mandatory licensing in extreme cases of public health risks. (medium run)