

Opinion on Innovative payment models for high-cost innovative medicines

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

Summary

- The current path of growth cannot be continued indefinitely leads => search of new ways for:
 - innovation “that matters” is produced,
 - patients have access to innovation
 - health systems are financially sustainable.
- It is unlikely that a single payment model will be fit for all situations.
- broad principles should be observed

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
3. Develop methodologies to measure the social value of pharmaceutical products and systematically use such methods (in the context of HTA)
4. Have price negotiations recognizing that "too high prices" may result

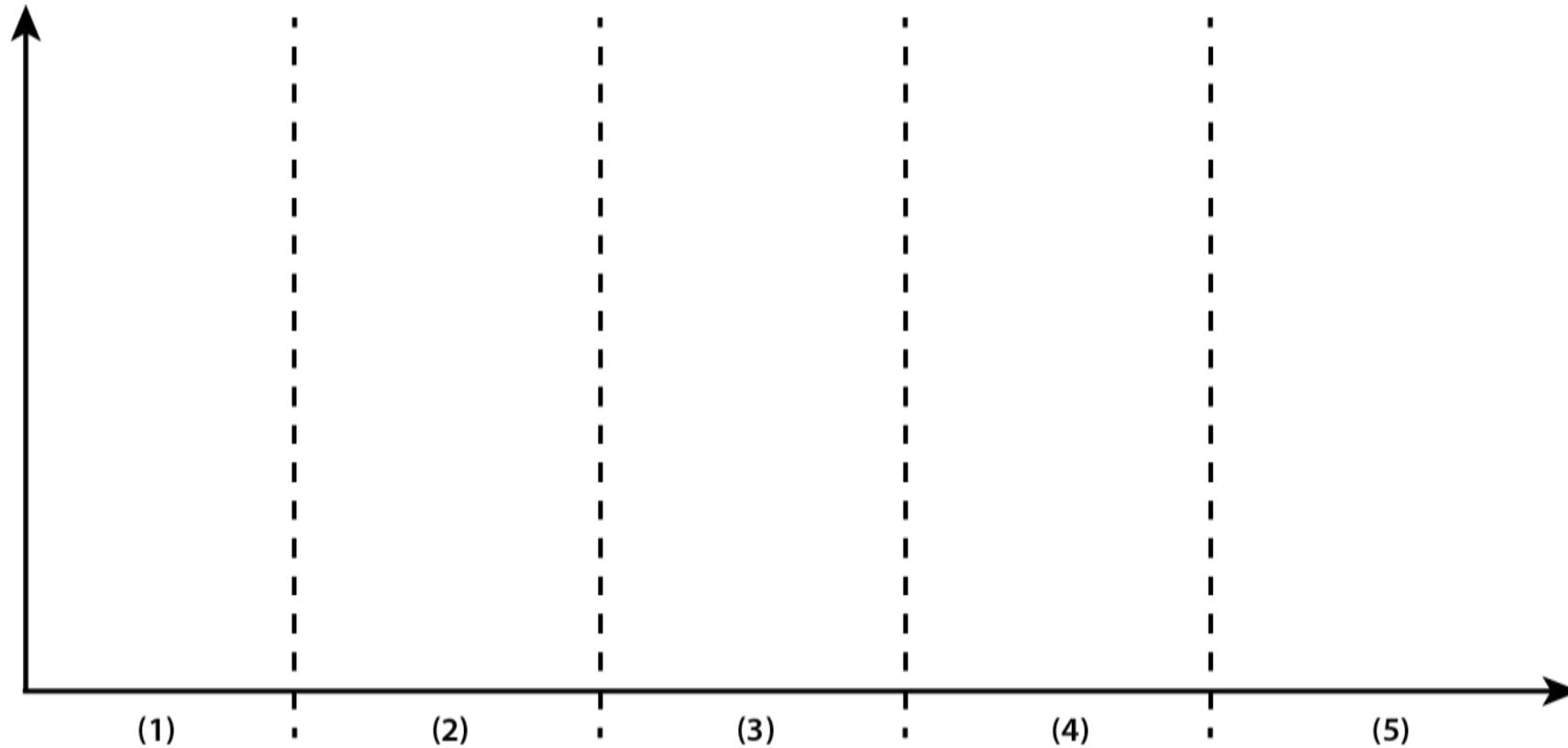
The proposed principles (2)

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

Current practice of pricing new products

- Several arrangements to set prices have been developed recently
- “Managed Entry Agreements”: outcomes-based view, hidden price discounts, assessment of cost-effectiveness => designed to address issues of information flows.
- 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
 - Higher margins for higher-value products to implicitly guide R&D efforts

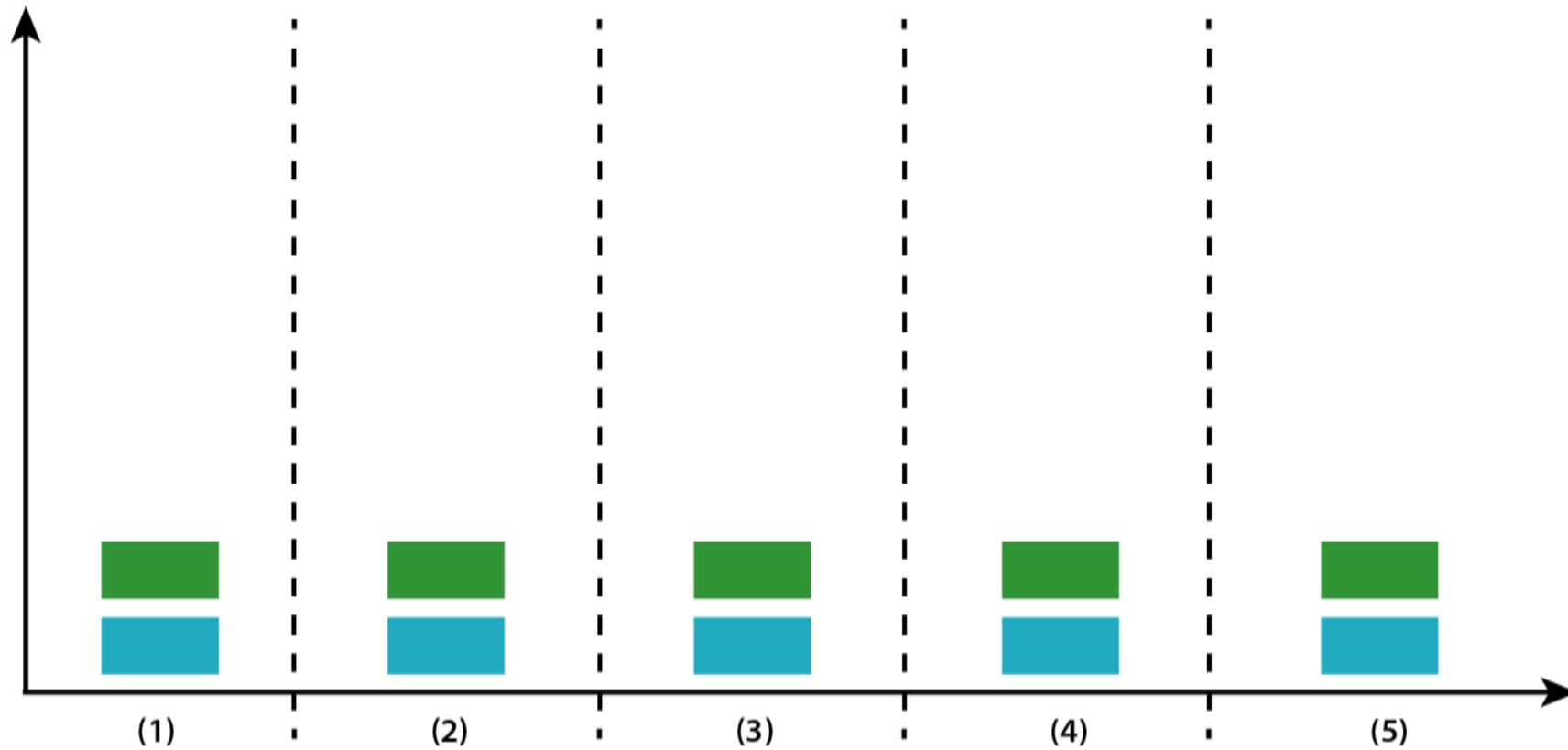
A graphical view



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.

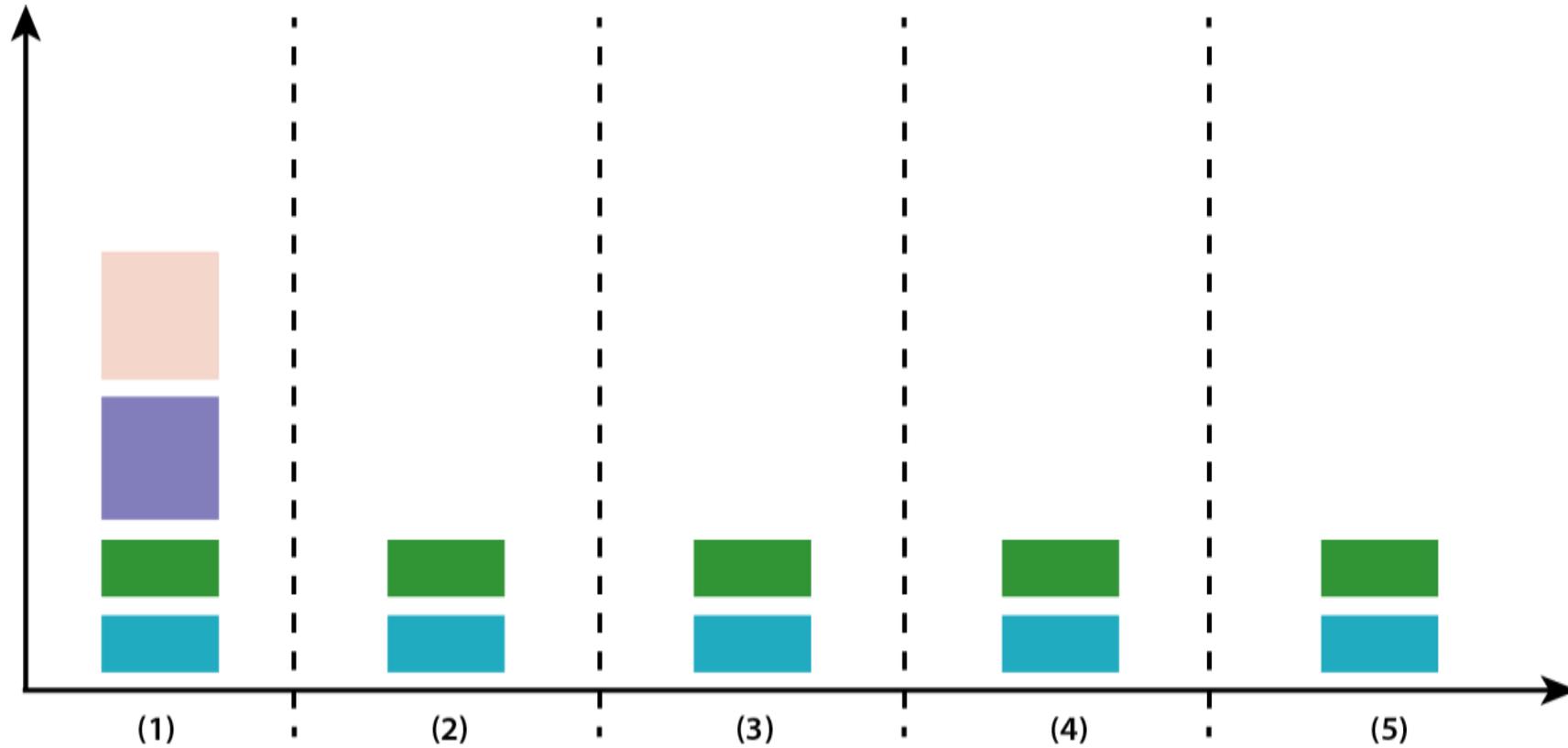
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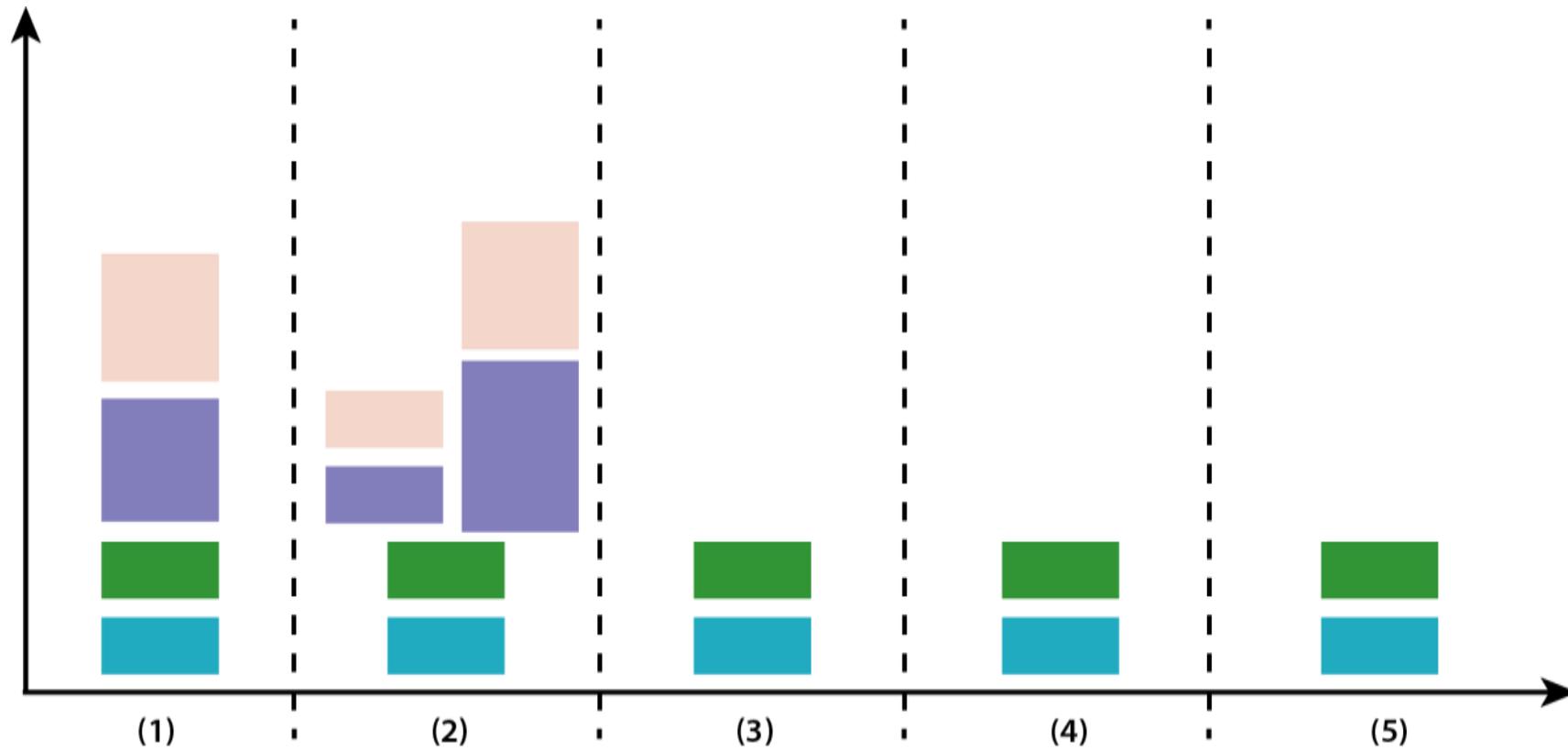
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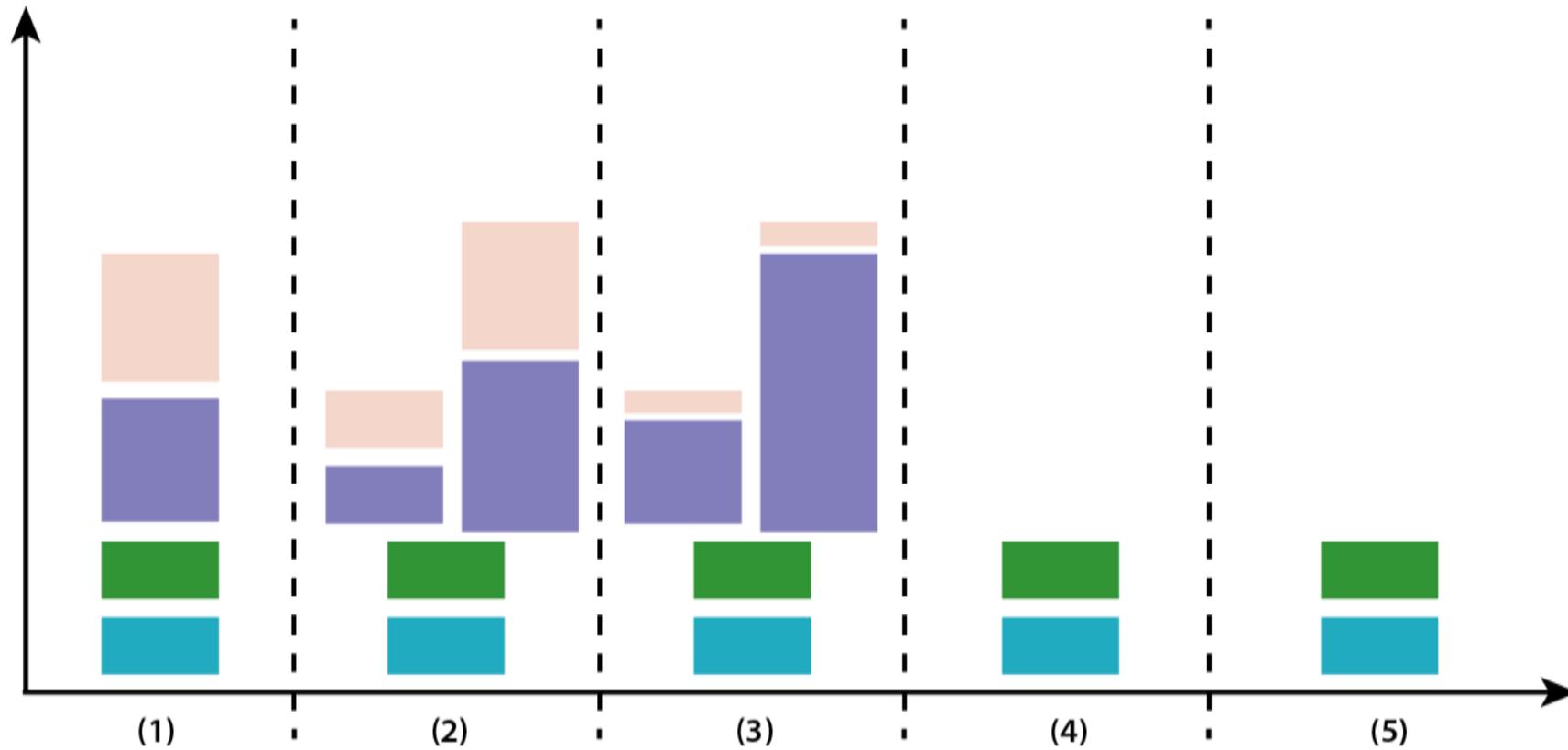
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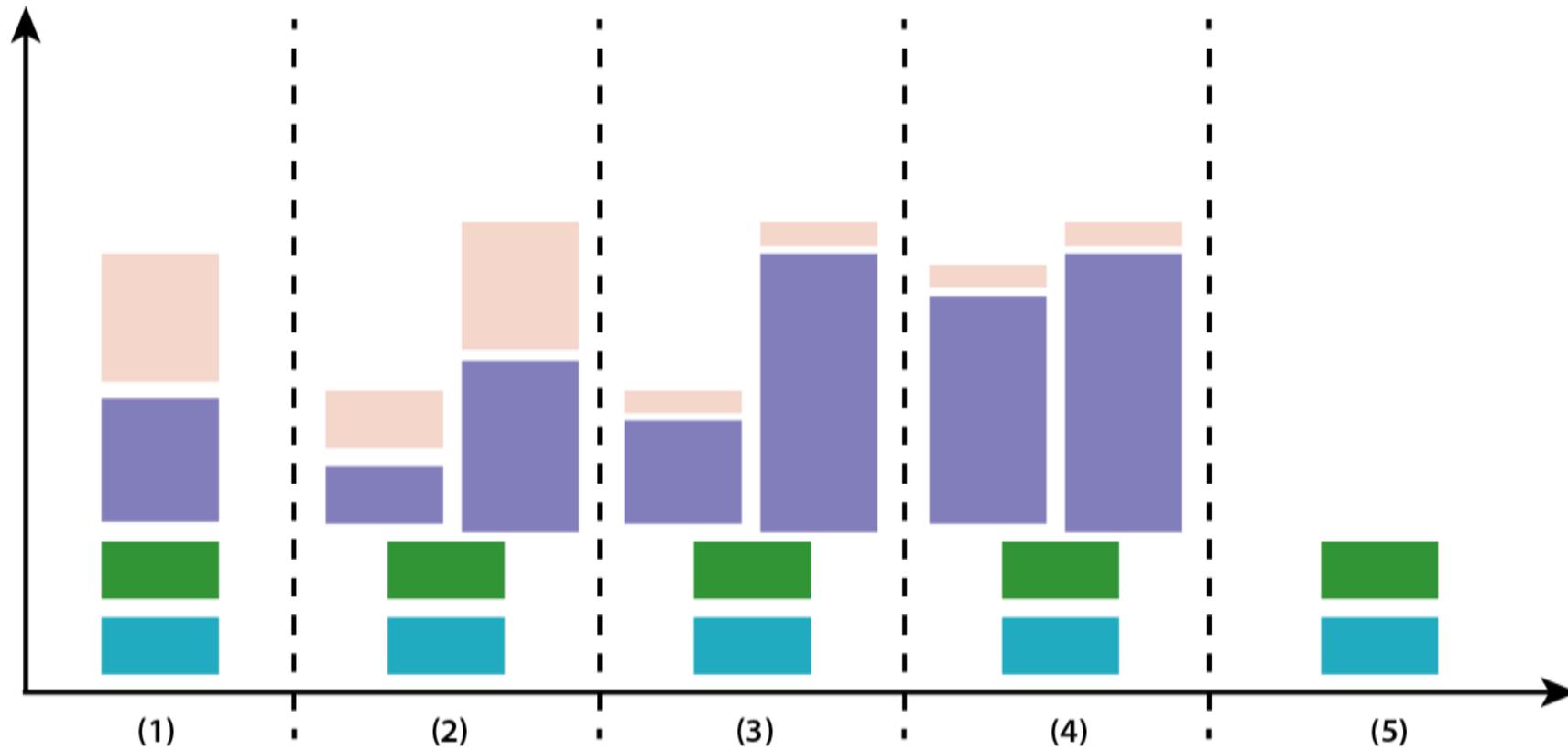
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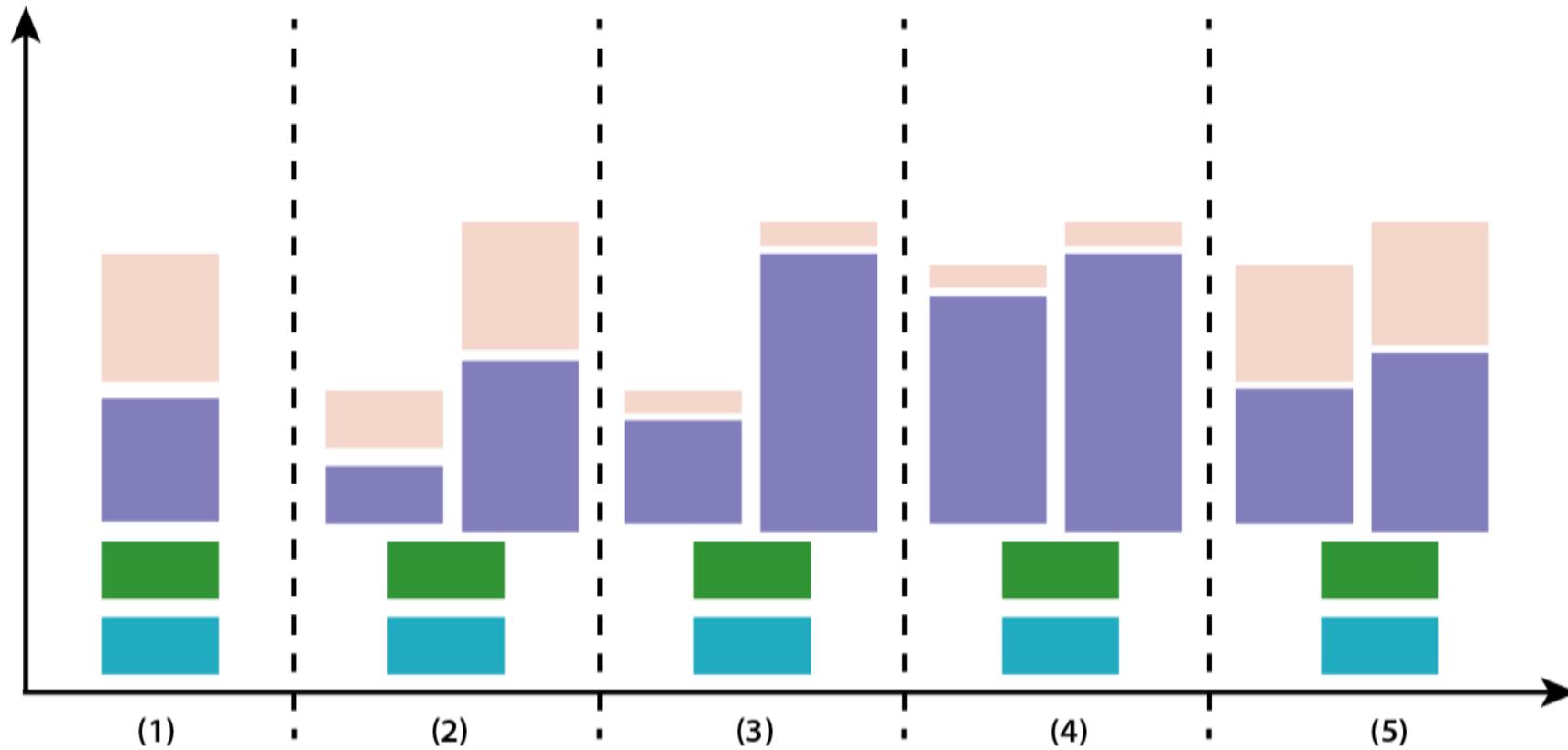
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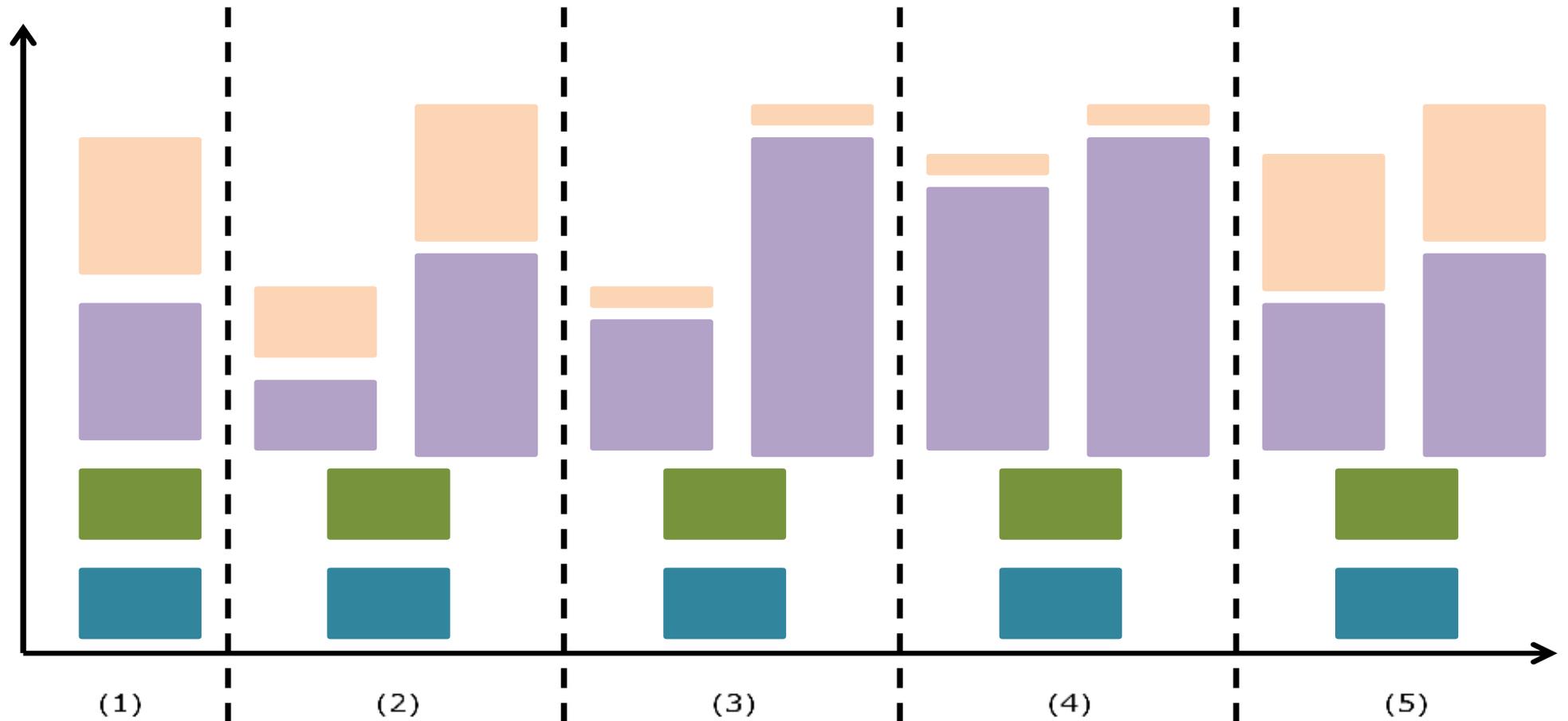
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Property: Role of directing R&D

- Under decentralized R&D model based on patents, pay better for higher-value drugs to keep incentives for such development
- In case of specific therapeutic gaps being identified, set different procedure (more centralized) to guide innovation
- Do not pay based on R&D costs incurred, as it stimulates process costs without guiding efforts to therapeutic gaps

Property: 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 (saving in one area allows spending more in another area of health care)

Property: 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
- We do not have such assessments today and no instrument is addressing it

Property: Balance between objectives and instruments

- Linear price model has only one instrument (price per quantity)
- Several simultaneous objectives requires trade-offs to be made in setting the price
- Another route is to increase the set of instruments available – more objectives require more instruments
- Other ways to reward innovation can be experimented to direct R&D to therapeutic gaps
- Examples:
 - Using prizes for discoveries in pre-defined areas followed by immediate-generics decision;
 - Procurement of innovation

Property: Framing health system design options

- 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

Property: Good Governance

- Crucial: monitoring procedures and negotiation power on behalf of the public good.
- Equally essential is the credibility of publicly announced rules (credibility is mostly challenged in delisting products)
- Governance challenges are higher for Governments than for other institutional payers
- Multiple payer health systems face issues of coordination across payers
- The governance model for new models of payment 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.

Prices

- 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
- The incentive role of prices
 - prices guide R&D efforts in a decentralized way (should make more profitable to companies to discover higher value products)
- Price transparency
 - Information on R&D and operation costs can be disclosed to payers without being available to market rival, but do not move to “pay for costs”
 - Have an assessment of “too high” prices in the decision process

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
- 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 encouraged and evaluated, (examples: NGOs/foundations promoting R&D in neglected areas; the triple helix approach – payer, provider of care, industry working together)

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 not 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

Proposals for action

- relevant authorities asking for R&D costs, marketing costs and production costs, even if not disclosed to the general public or to other companies
- select one neglected area and launch international prize initiative with patent being retained by the set of countries participating
- assess value of new products of uncertain benefit using sound and transparent health technology evaluation methods.
- introduce a competition policy review of high prices asked by companies, with cooperation of competition authorities
- strengthen bargaining power of health systems by using joint negotiation and consider mandatory licensing in extreme cases of public health risks
- check existing payment models against the principles defined above