Human Development Network

A Framework for Improving Access to Innovative Medicines in Middle Income Countries

Draft for stimulating a discussion with internal and external stakeholders

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Purpose of this framework

- This simple framework is meant to be used as a benchmark to develop and evaluate manufacturer's pricing and access strategies
- It could also provide the basis for a Memorandum of Understanding between a manufacturer and a counterpart in a given country
- It refers to countries with segmented health systems, in which the wealthy part of the population has access to high-end care and, at the other end, many poor people can hardly afford basic care
- Most of these countries offer limited coverage for parts of the population through some form of health insurance or tax-financed health plans
- Such health plans need to make decisions as to which medicines are included in the benefit package

Underlying issues

- Novel, potentially life saving medicines developed by large multinational companies come at a high cost
- Increasing requirements for market authorization and limited patient numbers (sales potential) for initially approved indications make these medicines very expensive
- Manufacturers of such products face an ethical dilemma between shareholder interests (cost recovery, profit) and patient interest (access for all who could benefit from a new medicine)

Stakeholder intent

- Manufacturers do care about and want to maximize access - as long as they can still make profits with the well-off part of the population
- Insurance funds and other payers with pooled funding are interested in offering new technologies but need to contain costs, the relevant factor being budget impact
- Individual patients from low-income households may not be able to afford new medicines even if they are priced far below the developed country price level

Some basic assumptions

- Marginal manufacturing costs of a package of medicines often is much lower than the ex-factory price
- Medicines alone do not treat diseases, they need to be delivered through a system that covers other dimensions of care (diagnosis, provider and patient education, disease management etc.)
- Payers facing trade-offs between including different new technologies in their benefit packages and are often not well equipped to assess, negotiate and decide based on rational criteria
- As a consequence of the previous point, decisions on pricing and funding of new medicines are often delayed or made in a way that achieves neither optimal value for money nor maximum access for the poor
- The characteristics of low- and middle income country markets differ between countries, meaning that different countries need different strategies for market segmentation and price differentiation

International price for the affluent segment

- To encourage manufacturers to offer concessions that make a novel medicine available for the poor, countries should not unduly restrict manufacturers' ability to make money from selling to the rich.
- There is no reason why rich patients in low- and middle income countries should pay less for the same drug than rich patients in rich countries

Reimbursement through social insurance

- It is suggested that budget impact rather than price is used as the main parameter for the decision to reimburse a new medicine with clear benefits
- Manufacturers can potentially accept an agreement to get paid only for treatment of a limited number of patients and provide treatment for additional patients for free
- A steeply discounted price is more difficult to accept for manufacturers, as it may be used as benchmark for administrative price controls in other countries
- Other options for negotiation are confidential discounts or claw-backs from the official list price
- In some situations, payment for outcomes is an option (the manufacturer gets paid only if the patient responds to treatment in a defined way)

Ensuring access for the poor

- Manufacturers should make a commitment to working with their national counterparts on a solution that maximizes access to novel medicines for which there is a need that goes beyond the ability to pay
- Different medicines and different countries will require a range of strategic options to optimize access without eroding profitability in the high-income segment
- If the patient population is small, manufacturers could set up “compassionate need” programs that provide the novel medicine for free to uninsured patients unable to pay
- Another option that can work for conditions with larger patient populations is a collaboration with service providers that treat mainly poor patients and offering the medicine for free, as part of an integrated treatment program, through their facilities
- The low income market segment could also be served through a voluntary license to a generic drug company that allows this company to sell only into this market segment

Global benchmarking

- The industry may consider establishing a multi-stakeholder body for benchmarking access strategies and collecting knowledge about successes and challenges
- In addition to adding credibility and shielding individual companies from unfair criticism, this body could also assist, at arms length from both parties, in solution finding and facilitating negotiations in a given country