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

Draft for stimulating a discussion with internal and external stakeholders

Andreas Seiter, March 20, 2013
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