



PRICING AND REIMBURSEMENT – KEY PRINCIPLES FROM GSK

Competitive market conditions are the most efficient way of allocating resources and rewarding innovation. Given the absence of genuine market conditions in many countries, GlaxoSmithKline is committed to engaging with governments and other parties to discuss processes and principles that will enable the development of pricing and reimbursement systems that reflect the value of products and reward innovation.

Key Principles:

1. Pricing and reimbursement mechanisms should adequately reward innovation

- Payers wish to receive value for money. However, there should be reciprocity - payers should give money for value.
- Reward for innovation can come in different forms - such as price-setting or readjustment, unrestricted access for the patient population defined as needing new therapy, therapeutic guidelines recognising new therapy, and speed of access.
- The benefits of so-called incremental innovation should be acknowledged. Products that deliver incremental innovation provide alternatives for patients that do not respond well to the first product in class, and create competition, thereby driving price and value optimisation.
- Products should not be punished for success – high volume, and high favourability with prescribers, should not make products the targets for cuts. Payers should not increase volumes for proven value only to reduce price.
- Pricing and reimbursement decisions by authorities should reflect the quality and success in clinical practice of a medicine. Success in clinical practice should be recognised during a product's lifecycle. Reimbursement systems should reward medicines by taking into account measures of success, whether these are available at launch or during a product's life-cycle, that are in line with the way markets function (quality, health outcome evidence, physicians' prescribing etc).
- Payers must also realistically assess when data is available (i.e. pre-or post-launch). Attention needs to be given to the design of new policies that would give payers and industry a flexible partnership approach to handling uncertainty. For example, perhaps products should be able to enjoy early, reimbursed launch, on the understanding that the provision of further clinical outcomes data may lead to changes in reimbursement (which could 'benefit' either the payer or supplier).

2. Pricing and reimbursement mechanisms should be predictable and transparent

- Industry should be able to understand and predict the priority given by payers to types of therapeutic progress identified. This should lead to a better understanding of the 'common good', of what kind of innovation is deemed worth paying for.
- Rather than being dominated by short-termism and ad-hoc measures, pricing and reimbursement systems must allow business planning for long-term supply of medicines and encourage R&D investment in medicines of value.



- Predictability is also created by earlier and more in-depth interaction with healthcare payers to discuss specific data that payers require in order to decide on the reimbursement of a product. At present, dialogue generally starts once a medicine has been approved and the data generated. It is often conducted in a manner that lacks predictability and coherence. What constitutes therapeutic progress, and whether and at what level to fund this progress, should be much clearer.
- Resources should be allocated according to where they make most impact, in a manner that is aligned with long-term health policy goals and aimed at carving out a sufficient and flexible drug budget for a longer period of time.

3. Pricing and reimbursement mechanisms should allow rapid access and meet the needs of all stakeholders

- Patients want to have access to the latest and best therapies available.
- Physicians value being able to choose amongst a portfolio of medicines in order to be able to select the best fit for their patients.
- From a payer/public health perspective, early access to therapeutic improvement allows a choice of medicines to be used to achieve good quality care.
- Industry seeks early market access in order to recuperate the investments into R&D as early as possible.
- Governments should encourage a more demand-oriented pharmaceuticals market by increasing the participation of patients in their decisions. With an expected increase in co-payments and possibly private healthcare schemes, it will be imperative that patients and consumers in general become more aware of costs and choices.

4. Payers must play by the rules

- In order not to delay access of medicines onto markets, pricing and reimbursement processes need to comply with the timelines set by the Transparency Directive.
- Governments should implement Recommendation 6 of the G10, which proposes that member states' price controls should be limited to transactions of medicines purchased or reimbursed by the state. This should allow faster market access after marketing authorisation, more efficient market mechanisms and price competition for non-reimbursed medicines.

5. Governments should improve their financing mechanisms in order to achieve a sustainable medicines policy that is less driven by financial consideration and more by patient outcomes and increased quality of care

- Drug budgets should be viewed in the context of healthcare overall. An end to silo-budgeting is needed because a concentration on the medicines element leads government to seek a disproportionate part of national cost containment from pharmaceuticals.
- Healthcare expenditure management should consider diverse and novel approaches to alleviate budgetary pressures, such as - private health insurance; co-payments; reduced distribution margins; reduced pharmacy margins; and a more competitive generic market



As part of the pricing and reimbursement system, evaluation systems to assess innovation should be more transparent and predictable

- The evaluation process must be independent, transparent and scientifically robust. Evaluation mechanisms should look at the impact of healthcare interventions, including medicines, on the total healthcare system. These evaluations should not be intended purely as a cost-containment or delay mechanism.

Reference pricing on the basis of therapeutic clusters would undermine reward of value and pharmaceutical competitiveness

- Therapeutic reference pricing and reference price clustering of patented and generic products undermines IP; does not allow the level of therapeutic progress achieved, and success with prescribers and patients, to determine the status of a medicine within the reimbursement system; ignores the differences in marginal costs incurred by the generic manufacturer and the R&D-based industry; makes assumptions over the interchangeability of medicines, often without proof; and discourages the development and use of new medicines with additional benefits/improvements (e.g. fewer side-effects, easier administration).
- Reference pricing that includes both generics and patented products erodes the benefits of patent protection, and fails to stimulate competition.

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