Key Aspects of a Sustainable Healthcare System

Introduction

Governments across the world are looking for ways to bring into balance a number of competing policy goals: economic growth; industrial development; attraction of foreign direct investment; advances in education, science and technology; overall budgetary control; complex and evolving healthcare needs. Balancing options is especially hard in the area of healthcare.

Market-based pricing for reimbursed pharmaceuticals, in which companies are free to set prices and there are no supply-side or demand-side controls, remains the industry's preferred solution to meeting the needs of patients and society's demand for better medical treatment. However, markets in Europe and the International region tend instead to be characterized by monopsonistic payer structures, over-regulation, poor resource allocation, slow access for new medicines, and a focus on cost rather than value.

Against this background, this paper outlines the elements which GSK believes most effectively deliver sustainable and efficient healthcare systems. Not all of these elements may be relevant or appropriate to every country. However, governments are urged to review some, if not all of them, as they consider how best to meet the challenge of establishing a healthcare policy that meets the needs of all key stakeholders, namely patients (who want rapid access to the best treatments), payers (who want to deliver good healthcare to their citizens and manage budgets) and the industry (which wants to secure a return on investment that will incentivise further innovation).

Key Elements

1. Healthcare priorities should be identified through improved and earlier dialogue

National healthcare systems and policies should ensure that the right capabilities are put in place for defining treatment priorities within each individual disease area and for identifying disease management targets.

Industry and government should discuss these health priorities and targets as part of a 10-20 year strategic agenda and not just as part of cost containment measures over the next 6 months. This will enable the development of new medicines, to help ensure that unmet need is addressed, disease prioritisation is clear and patients get access to the medicines that will improve their lives.

Predictability is 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.

2. Healthcare funding should be adequate and sustainable

Resources should be allocated where quality is achieved and outcomes are maximised. Ways of achieving this include:

- *improved prevention*. Chronic diseases are among the most prevalent, costly and preventable of all healthcare problems. By encouraging prevention, healthcare will be improved and huge healthcare spending avoided.
- *driving out waste*. Efficient practice (prevention, diagnosis, treatment, rehabilitation) will lead to savings for the healthcare system as a whole. With respect to pharmaceuticals, policies for proper usage of medicines in both qualitative and quantitative terms should be promoted and implemented, with a view to freeing up resources for use elsewhere in the system.
- *integrating care of chronic diseases and viewing drug budgets in the context of healthcare overall*. Silo-budgeting should be eliminated because a focus on medicines expenditure leads governments to seek a disproportionate contribution to cost containment from pharmaceuticals.
- *developing a greater awareness of the cost-effectiveness of innovative medicines*. For example, an increase in medicines spending in the treatment of Alzheimer's can lead to greater overall savings. Governments should identify and target savings and redirect expenditure towards innovative drugs.
- *recognising the importance and value of comprehensive vaccination programmes* in the context of investing in cost-effective preventative care
- *taking account of the existence and benefits of new technologies.* The benefits can refer to their cost-efficiency in relation to hospital-based interventions or to advantages for patients in terms of convenience, improved quality of life etc. A focus on cost, rather than value, will not meet the budgetary goals of governments.
- *strengthening/establishing primary care services and avoiding misuse and overuse of medical services;* an ambulatory care system should be developed. This includes a GP referral system, the development of community care centres with focus on health promotion and disease prevention, and further development of the role of pharmacists.
- *reassessing the organisation of hospitals and the number of acute hospital beds in light of current medical needs and available technologies*; innovative therapies and medicines can reduce the length of stay or avoid hospitalisation and should therefore be encouraged.
- *promoting appropriate use of over-the-counter/self medication products*: Governments should encourage the appropriate use of self medication products as a means of relieving pressure on public healthcare systems (ie. physician appointments) and of freeing up financial resources for innovative products.

New funding sources for healthcare should be considered:

Systems in which the government is the sole purchaser of medicines are likely to be unsustainable in the medium to long-term. Governments should look at new funding options, including;

- a greater role for private health insurance
- increased patient co-payment, in a way that encourages compliance and cost-effective use of medicines while ensuring that low-income and other vulnerable groups are not excluded or discouraged from seeking and receiving medical care. Any move to a situation where people are prepared or required to contribute more to healthcare costs will require a process of education and communication, especially in view of the fact that currently patients remain reticent to pay additional charges to their prescription. There is a clear risk that patients perceive that a medicine's value is somehow questionable if the Government does not fully reimburse it.
- new or increased taxation on products and behaviours, like fast foods and smoking, which increase healthcare costs. Tax revenues from these sources should be dedicated to healthcare budgets.

An acceptance by citizens that they need to pay more for healthcare is critical. Shifting more costs onto consumers of healthcare will make them more demanding, hungrier for information and more sensitive to value. Together patients and doctors can work on adopting the most cost-effective treatments and thereby help to reduce the inefficient use of healthcare facilities.

3. Pricing and Reimbursement policies should reflect the true value of "innovation".

Society is on the brink of a new era in which pharmaceutical research in genomics and pharmacogenetics will yield an entirely new class of medical interventions with respect to prevention, detection, treatment and cure. This will throw a radically new light on the concept of effectiveness (tailored medicine with much higher rates of success) and cost (tailored medicine instead of one-size fits all).

The nature of drug development, however, remains highly unpredictable. There is no guarantee that the first drug to market will be the best. Some new medicines will be revolutionary breakthroughs. Others will deliver incremental benefits over existing treatments, be it in efficacy, improved tolerability or improved mode of administration. Products that deliver incremental innovation provide alternatives for patients that do not respond well to the first product in class. They also create competition, thereby driving price and value optimisation and provide the path to more radical change

Where payers seek value for money, pharmaceutical companies require money for value. The reward society gives to an innovative medicine must reflect its added therapeutic value. Reward for innovation can come in different forms, not just a premium price - e.g. unrestricted access to the patient population defined as needing new therapy, therapeutic guidelines recognising a new therapy, and speed of access.

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.

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) and that are in line with the way markets function ie. quality, health outcome evidence, physicians' prescribing etc.

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 that count.

4. Tools for measuring "innovation" should be appropriate

The evaluation of a medicine's value must deliver a reasonable balance between the interests of payers (better management of budgets), patients (better access and outcomes), physicians (better outcomes), and industry (appropriate reward for innovation).

Health technology assessment (HTA) is one of the tools, when appropriately defined and applied, that can contribute to an assessment of clinical effectiveness and cost-effectiveness of new medicines and new technologies (including medical devices). Certain key principles should underpin any HTA system.

- the process should be inclusive and involve early dialogue with industry around the aims and priorities of the process.
- there should be clarity and consensus on the criteria against which therapeutic progress (or value) can be measured throughout a product's lifecycle. The measures of value can include: mortality and morbidity data, side-effects, tolerability, predictive surrogate parameters, pharmaceutical form, route of application, compliance, ease of use, impact on the healthcare service, disease severity, medical need, quality of life, and patient preferences.
- the evaluation process should be independent, transparent and scientifically robust. Where HTAs are focussed on delivering guidance, the evaluating body should be independent of the payer.
- evaluation systems should be clear and consistent with regards to methodology, criteria used and data required – this would include clear timeframes for the evaluation and for any decisions arising from it
- patients, physicians and the industry should be involved in the assessment process, to allow for a better evaluation of the balance between benefits, costs and risk.
- pharmaceutical companies should be able to submit health outcomes information to the relevant government bodies throughout a product's lifecycle. This evidence should then receive appropriate attention and reward from payers. A 'one size fits all' approach to the timing of appraisals fails to take account of the complexity of conducting assessments and ignores differences in treatments and therapeutic areas.
- the HTA should be separate from the regulatory review for the grant of a marketing authorisation. Regulatory review must be based on objective and scientifically verifiable criteria of efficacy, safety and quality. HTA should not become a fourth hurdle in marketing authorisation.

5. Increased access to information for patients should be actively encouraged

Citizens and patients should be at the centre of many key aspects of healthcare as well as medicines policy – such as assessments of value, decisions on access, and allocation of funding. This can only work, however, if there is sufficient information available to them - patients should be given the ability to make choices, and should receive the information to choose wisely.

Industry should be involved in this initiative. Disease education and vaccines information campaigns are an example of how responsible, approved information from the industry to the public can fulfil a number of objectives: raising public awareness of the existence of a safe and effective vaccine; educating the public of the risks attached to non-vaccination; allowing important savings to be achieved for healthcare systems by preventing disease; and contributing to the overall "wellness" of society.

6. Free pricing for non-reimbursed medicines should be allowed

When governments negotiate, they should only negotiate for the prices of what they purchase or reimburse; sales outside the state system should be subject to the normal rules of market pricing.

7. Generics should play an appropriate part in treatment options

Appropriate use of generics can deliver savings in healthcare expenditure and free up resources to reward innovation. However, a more competitive market is required to enable generics to yield the savings they promise. It is estimated that if the OECD utilised generics at the same rate and prices as in the US, savings of $5-30bn annually could result. To this end:

- *generics should be commoditised, reflecting the limited innovation and investment that goes into their development.* Price differences between generics and branded medicines should be visible and sufficiently large to allow healthcare systems to fully benefit from savings created by the use of generics.
- *generic substitution should be used by governments and other payers to free up resources to reward innovation.* Provided that physicians can make exceptions on medical grounds, a generics policy, including a system that encourages competitive generic prices, will free up resources that should be used to reward innovation.

8. Use of OTC products should be encouraged

Policies encouraging the use of over-the-counter medicines should be actively implemented where medicines provide a clear health benefit to patients and are sufficiently safe to warrant OTC status. These policies should include Government support for products with a long history of safe use being switched from prescription to non-prescription. The advertising and promotion of these products should also be liberalised.

9. Effective regulatory systems should be established

A well-regarded registration process for new pharmaceutical products that enables medicines to gain international credibility by passing stringent criteria on quality, safety and efficacy will encourage pharmaceutical companies to conduct clinical trials and launch innovative products early. Key regulations should be conducive to the development and early adoption of innovative new drugs.

10. IP should be respected

A strong legal framework on intellectual property rights creates a desirable environment for research and development. Enactment and enforcement of international patent protection and registration data exclusivity to reward innovation and allow funding of R&D in an era of escalating technology development costs is a key factor.

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