Policy principles for a competitive healthcare environment

Pharmaceutical Research and Development Industry Malta Association (PRIMA)

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

The research-based pharmaceutical industry understands the pressures on European governments to ensure effective management of the limited resources allocated to healthcare, including pharmaceuticals. However, these pressures frequently result in short-term, and often punitive, pharmaceutical cost-containment measures, which bring only temporary relief, while reducing patient benefit and undermining the industry's R&D efforts.

The industry has an important contribution to make to Europe. Innovative medicines contribute enormous social benefits and reassurance for individual citizens through improved healthcare - as seen in increased life expectancy and the treatment of cancer, diabetes, asthma and other diseases. Innovative medicines also enable healthy working populations to work longer, and healthier elderly populations to make fewer demands upon social security systems; and they enable more efficient use of healthcare budgets. The pharmaceuticals sector provides substantial investment in research and development, leading to high quality jobs for science graduates, unrivalled job multiplier benefits, and support for the academic research community. This contribution must be nurtured.

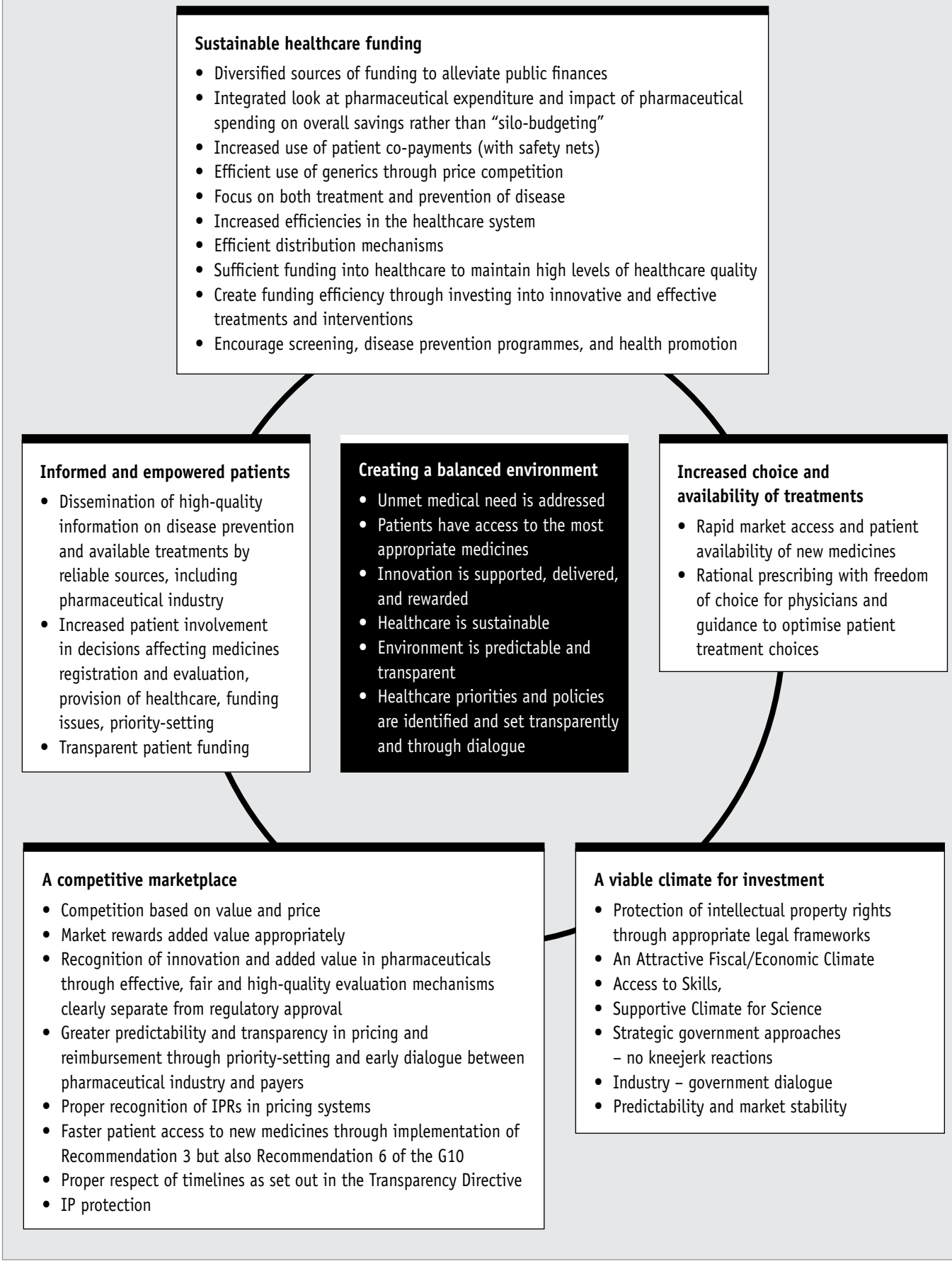
Market-based pricing for reimbursed pharmaceuticals, in which companies are free to set prices and there are no supply-side or demand-side controls, remains the industry's preferred solution to meeting the needs of patients and society's demand for better medical treatments. At the same time, industry also recognises the challenges involved in finding approaches that can function within the context of social healthcare systems.

Industry believes better balance between competition in the pharmaceutical marketplace and government regulation is both possible and necessary. The aim is to identify how the market structure for pharmaceuticals can work in a manner that encourages competitiveness; is adapted to future, more personally-tailored medicines; and ensures patient access to innovative medicines. There are a number of elements that effectively deliver sustainable and efficient healthcare systems. Governments and industry should work together to identify steps that should be taken to strike a better balance.

Industry believes that only a collaborative and concerted multi-stakeholder approach can enhance progress in medicine for the best benefit of patients, who should be at the heart of healthcare systems. Sustainable solutions need to be weighed against three key objectives for improving patient outcomes: (1) optimal use of resources to maintain sustainable financing of healthcare, (2) access to medicines for patients and (3) reward for innovation. In each country, these goals will be addressed differently. However, industry believes that a set of core principles can guide policy approaches.

This paper sets out elements for a more balanced environment. Not all of these elements may be relevant or appropriate to every country. However, governments should be encouraged 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

Figure 1. Creating a competitive healthcare environment for the pharmaceutical industry – Overview



rapid access to the best treatments), payers (who want to deliver quality healthcare to their citizens and manage budgets) and the industry (which wants to secure a return on investment that will incentivise further innovation benefiting patients).

A vision for a balanced environment - key elements

1. Government efforts in meeting healthcare priorities should be supported by improved and earlier dialogue

Governments should ensure that the right infrastructure is in place for defining treatment priorities within individual disease areas and for identifying disease management targets. Industry and government should discuss these health priorities and targets as part of a long-term strategic agenda for the industry and not just as part of short-term cost-containment measures. This will enable the development of new medicines that address unmet need, clarify disease prioritisation, and ensure patients get access to medicines that improve their lives.

Increased predictability for all parties will be delivered through earlier and more in-depth interactions to discuss evidence that payers require in order to support reimbursement discussions. At present, dialogue generally starts once the indications for a medicine have been approved and the data generated. It is often conducted in a manner that lacks predictability and coherence.

2. Industry and government should establish more structured forms of dialogue

Industry believes that dialogue platforms should be launched at national level, bringing together the pharmaceutical industry, government, patients and other stakeholders to address issues of relevance to healthcare as well as pharmaceutical industry competitiveness. Industry believes that current approaches fail to address the more fundamental problem of how to maintain current quality of healthcare provision and treatment with innovative medicines in a context of demographic change and increased demand. Structural change is needed, and measures can best be identified in cooperation between the key actors involved.

3. Healthcare funding should be adequate and sustainable

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

- **Improved prevention** - chronic diseases are among the most prevalent, costly and preventable of all healthcare problems. While prevention is an investment that can incur up-front costs, evidence shows that over time health care outcomes will be improved and significant new spending avoided.
- **Improving efficiency** - efficient practice (prevention, diagnosis, treatment, and rehabilitation) will lead to savings for the healthcare system as a whole. Policies for appropriate 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 and delivering better outcomes.
- **Integrating care of chronic diseases and viewing drug budgets in the context of healthcare overall** – a more comprehensive view of the contributions of various components of the health care system to efficient health care interventions should be adopted. Governments currently tend to focus on medicines expenditures.
- **Developing greater awareness of the cost-effectiveness of innovative medicines** - governments should identify savings and redirect expenditures towards innovative drugs. The key objective should be to allow access to advanced health care technologies, while ensuring that usage is targeted and cost-effective.
- **Recognising the importance and value of comprehensive vaccination programmes in the context of investing in cost-effective preventative care.**
- **Strengthening/establishing primary care services and avoiding misuse and overuse of medical services** - an efficient ambulatory care system should be developed. This includes a general practitioner referral system, the development of community care centres with focus on health promotion and disease prevention, further development of the role of pharmacists and the nursing profession, and the creation of effective incentives for all healthcare actors to deliver the highest standards.
- **Promoting appropriate use of over-the-counter products.**
- **New funding sources 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, appropriate tax-based measures, and greater pressure on the generics and distribution sectors to increase efficiency.

4. Pricing and reimbursement policies should reflect the true value of "innovation"

Where payers seek value for money, pharmaceutical companies require reward for delivering value. The reward society gives to an innovative medicine should reflect the value it delivers to patients, healthcare systems, and society at large. This reward can come in different forms, e.g. price level, unrestricted access to the patient population defined

* 'generic' being defined as a medicine based on an active substance that is out of patent and which is marketed under a different name from that of the original branded medicine.

as needing new therapy, therapeutic guidelines recognising a new therapy, and speed of access.

The nature of drug development, however, remains highly unpredictable. There is no guarantee that the first drug to market will be the best (nor how any individual patient will respond to any particular drug). 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. Reward for value must therefore be provided for stepwise advances in therapy.

5. Tools for measuring "innovation" should be appropriate

The evaluation of a medicine's value must deliver a reasonable balance between the interests of payers, patients, physicians, and industry. 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). The goal of the HTA process should be to improve patient care and physician decision-making. Certain key principles should underpin any HTA system.

- HTAs should be based on a clear, sophisticated and clinically differentiated view of what constitutes value
- HTAs should be transparent and balanced
- HTAs should be based on early and inclusive dialogue, including with patients
- Evaluations should allow new data to be considered
- Comprehensive understanding of the benefits of a drug in disease management is needed
- Payers should commit to rewarding added value and HTA outcomes should be implemented
- HTA should apply to all healthcare interventions
- Assessment should take place at the national level
- HTA should remain separate from regulatory review
- HTA bodies should have a process to handle appeals of their decisions by stakeholders efficiently.
- Evaluations should take into account the full range of value, including indirect benefits (societal view)
- HTA should use different types of evidence

6. 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; encouraging proper compliance with courses of treatment; and contributing to society's overall "wellness".

7. Market pricing for non-reimbursed medicines should be allowed

Governments should only negotiate for the prices of what they purchase or reimburse; sales outside the state reimbursement system should be subject to the normal rules of market pricing. This will help to manage problems of market distortion and parallel trade. Market distortions, and potential safety hazards for patients, can also be addressed through improvements in the integrity and security of the supply chain.

8. Off-patent/generic medicines should play an appropriate part in treatment options

Appropriate use of multi-source products (off-patent and generics*) can deliver healthcare savings and free up resources. However, a more competitive market is required to enable multi-source products to yield the savings they promise. Prices of multi-source products should be competitive, reflecting the limited innovation and investment that goes into their development. Policies encouraging the use of multi-source products should be implemented in full respect of physicians' prescribing freedom.

9. Distribution systems should operate efficiently

Distribution margins can have a large impact on the dispensing behaviour of pharmacists, the creation of competitive off-patent markets and the savings created for healthcare systems. As a general rule, we believe that free market dynamics are the best way to 'regulate' prices along the pharmaceutical value chain, including ex-factory prices. Free market conditions for distribution services should always go hand-in-hand with free market conditions for pharmaceutical manufacturers. Where controls are imposed on margins, the structures of the wholesale and retail margins should reflect economic reality as much as possible when compensating for the services provided.

10. 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 for minor, self-limiting indications or diseases where medical supervision is not needed, 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, to realise cost-savings for the healthcare system.

11. Effective regulatory systems should be enhanced

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.

12. 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. Therapeutic reference pricing – which groups patented medicines with older off patent medicines for purposes of setting a single reimbursement price – represents an infringement on basic IP rights because of its impact in curtailing the effective period of protection offered by a patent.

13. Strong anti-counterfeiting laws and enforcement should be put into place

There are increasing examples of counterfeit medicines entering the legitimate supply chain, an issue of increasing concern for the Community. Measure should be put in place to prevent counterfeit medicines from reaching patients. The European Commission should issue a Regulation for ensuring the safety and integrity of the supply chain including measures such as a ban on repackaging, an unique system of identification and coding of pharmaceutical products throughout Europe, a notification of corrupt products and strict liability rules for all distributors and retailers of medicines.

14. Support for the science base

There needs to be a more concerted effort at EU level to encourage cooperation and research in the pharmaceutical field. There are a number of broader environmental issues that should be addressed in Europe in order to maintain attractiveness for R&D investment:

- Europe must deliver appropriately skilled staff. The speed of the change in R&D has translated into essential skills being in short supply. Training in leading-edge technologies is key if the right quantity and quality of scientists is made available.
- EU should provide funding to develop academic expertise in biomarker and surrogate technologies and the application of these technologies in drug development.
- Access to new ideas and technology through links with the academic research base and with biotech SMEs is important. Clusters of research and training institutions, suppliers of key inputs (e.g. software), venture capital providers and other related entities are essential to facilitate linkages and partnerships.