Policy Pillars of Pharmaceutical Innovation

The four interdependent strategies needed to sustain medicines innovation

Produced by the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)

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Nurturing innovation for better health

Achieving top performance in any discipline is difficult. Even more challenging is the ability to sustain it over a long period of time, as is the case with pharmaceutical innovation.

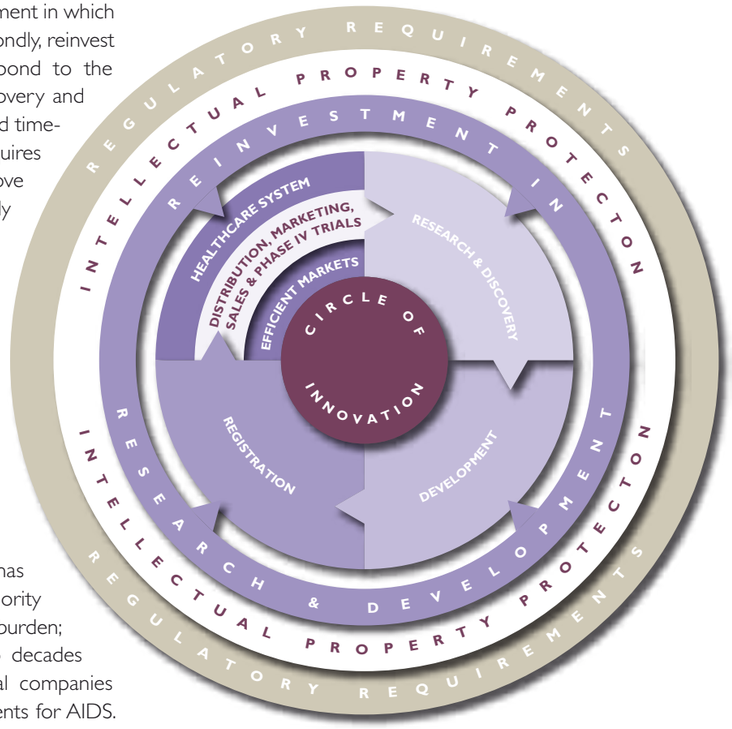
To sustain top performance, the research-based pharmaceutical sector needs a 'circle of innovation' – an environment in which companies are able to, firstly, generate and, secondly, reinvest capital. Only in this way can this sector respond to the evolving needs of public health. Medicines discovery and development is a uniquely resource-intensive and time-consuming process. Even a new medicine requires continuous innovation post launch to improve its utility for patients, which is an increasingly expensive part of the research process.

The overwhelming majority of medicines on the global market today – in excess of 90 per cent – were developed with private research and development expenditures. Government funds may assist the discovery process at the basic research stage, but only the private sector focuses on the critical path of medicine development where compounds are tested and certified for safe and effective use in the human population.

The research-based pharmaceutical industry has brought to market medicines for the vast majority of diseases that make up the global disease burden; yet more is needed. For example, in the two decades following the discovery of HIV, pharmaceutical companies have developed more than 20 effective treatments for AIDS.

Unfortunately, to date, there is still no cure for AIDS, nor medicine nor vaccine to prevent it. Likewise, the "war on cancer" has resulted in impressive advances in treatment, but a cure remains elusive.

The Circle of Innovation



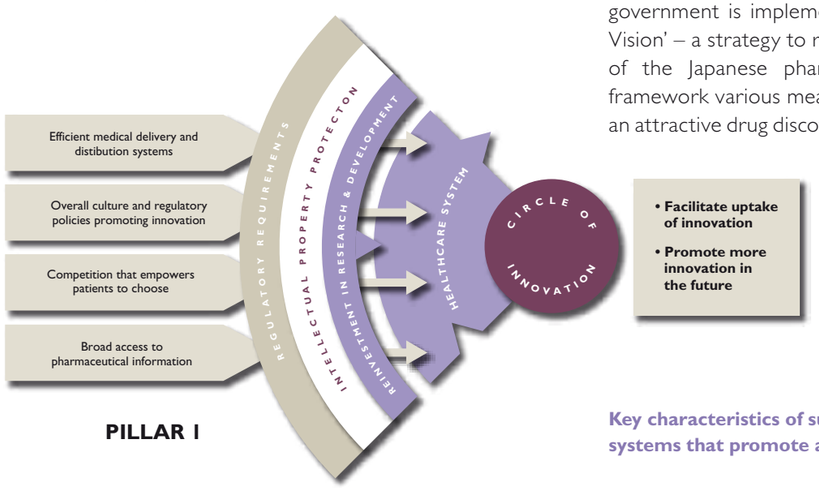
Four pillars of innovation

To sustain itself pharmaceutical innovation requires four fundamental pillars that together provide the incentives needed for investing in research and development:

1. **sustainable healthcare systems,**
2. **effective markets,**
3. **intellectual property protection and,**
4. **a conducive regulatory environment.**

The four pillars depend on each other and also complement each other in the innovation process.

Fostering innovation is fundamental for realizing public health objectives. This requires implementing policies critical to driving the decision-making process of innovative pharmaceutical companies in a way that generates a positive return for society. They represent a mix of healthcare and industrial policies and are the pillars of the 'circle of innovation'. Each pillar is significant for the R&D process and together they safeguard the social value, integrity and sustainability of pharmaceutical innovation.



Key characteristics of sustainable healthcare systems that promote a 'circle' of innovation

Pillar I
Sustainable healthcare systems that cater for patients

Healthcare systems are complex mechanisms through which health products, services and care are delivered to patients. They involve a variety of stakeholders whose objectives may differ significantly – governments, citizens, healthcare providers and funders. The pharmaceutical industry is an important stakeholder as the principal provider of innovative medicines.

Healthcare systems influence the uptake of medicines and have an important impact on future innovation. They both 'push' and 'pull' innovation through encouragement and reward at the same time. 'Push' mechanisms come into play when enlightened public policy stimulates science and innovation, serving as a source of added value that bolsters independent private research. The figure below illustrates the most important preconditions for an effective healthcare infrastructure – one that facilitates innovation.

Japan provides an example of how a broad healthcare environment can influence medicines innovation. The government is implementing its `Pharmaceutical Industry Vision' – a strategy to reinforce the global competitiveness of the Japanese pharmaceutical industry. Within this framework various measures have been initiated to create an attractive drug discovery environment in Japan, including

the creation of the new Pharmaceutical and Medical Devices Agency (PMDA) to help speed up diffusion of new medicines. More work is needed on price system reform to improve the global attractiveness of the Japanese pharmaceutical market.

The role of the healthcare system is particularly significant in the level of uptake of innovation and its diffusion – the 'pull' function. Healthcare systems should encourage appropriate innovation and the prompt introduction of innovative pharmaceutical products for the benefit of public health. It is often the case that the potential of a drug or a vaccine is hampered by the lack of an effective healthcare infrastructure and a consequent inability to treat patients who might benefit.

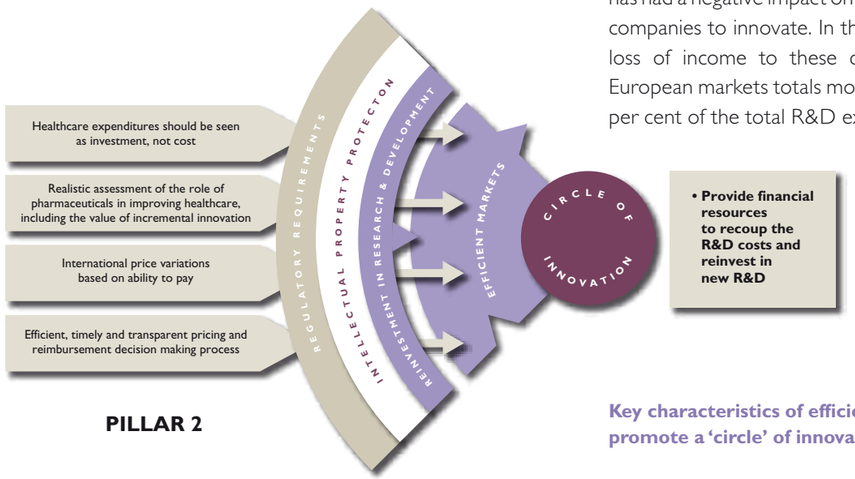
For instance, in many European countries uptake of new drugs is hampered by inefficiency and bureaucratic controls on healthcare infrastructure that limit effective price competition between patented and generic medicines. This is combined with a lack of information to enable easier access for patients to useful pharmaceutical product information.

Pillar 2
Effective markets for innovative products

In theory, effective markets should allow for an efficient allocation of resources. However, this is generally not the case for pharmaceutical markets, which are distorted by inadequate health funding and government pricing, as well as reimbursement policies.

Modern healthcare systems are characterized by a complex cost structure whereby many of the costs tend to be indirect, or, at least, difficult to identify. Yet, policymakers tend to focus on pharmaceuticals as the primary source of budgetary savings because their costs are the easiest to identify and make the easiest targets for cost-reduction policies. Fostering access to innovation is important, but critical is the need to also reward innovation. In other words, in order to maintain the 'circle of innovation' a company must obtain the financial capacity to innovate, which is realized through the price at which a new medicine is sold. The figure below outlines the key aspects of effective markets that would promote the innovation process.

Europe is an example where the failure to reward innovation has had a negative impact on the capacity of its pharmaceutical companies to innovate. In the last three years, the estimated loss of income to these companies in the seven largest European markets totals more than €16 billion, or roughly 80 per cent of the total R&D expenditure in Europe in 2004.



PILLAR 2

Key characteristics of efficient markets that promote a 'circle' of innovation

As a result, companies are relocating R&D activities from Europe to the US, where medicines innovation is better rewarded.

Price controls on pharmaceutical products are becoming prevalent around the world and threaten innovation by undermining the long-term financial viability of the research-based pharmaceutical sector. Concern is also raised by the focus on cost effectiveness and the use of arbitrary methodologies like QALYs (quality-adjusted life years) to determine incremental cost effectiveness ratios for new treatments. This is a very narrow way to estimate value that fails to account for the patient interest or the informed judgment of clinicians.

> ***'To maintain the 'circle of innovation' a company must obtain the financial capacity to innovate, which is realized through the price at which a new medicine is sold'***

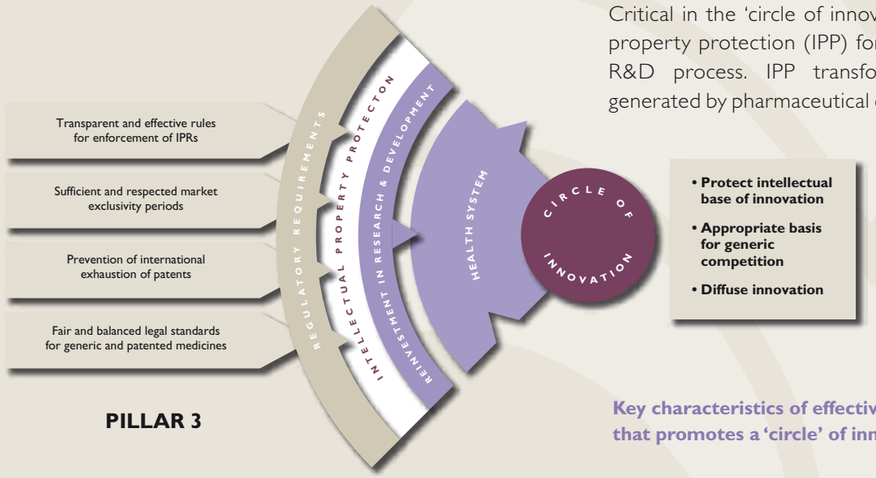
Even the best innovation is useless if not used. Healthcare systems play a critical role in making sure that innovation in healthcare reaches and benefits patients.

Healthcare systems need to provide for efficient delivery and distribution of healthcare resources, and to facilitate healthcare professional and patient access to information about innovations and their therapeutic benefits. These key stakeholders should play the principal role in the healthcare allocation decision-making process.

Looking at various countries, differences can be quite significant. In the US, some 60 per cent more medicines are launched annually compared to Canada or Japan. In many countries in Europe, the delay between the time when a medicine is approved for marketing and when patients finally get access to the medicine exceeds one year. This also limits the effective rate of return to the inventor, who faces a fixed patent term and the prospect of immediate competition from rival products.

Pillar 3
Intellectual property protection to award innovators

Critical in the 'circle of innovation' is effective intellectual property protection (IPP) for inventions generated in the R&D process. IPP transforms the intangible capital generated by pharmaceutical companies during the process



PILLAR 3

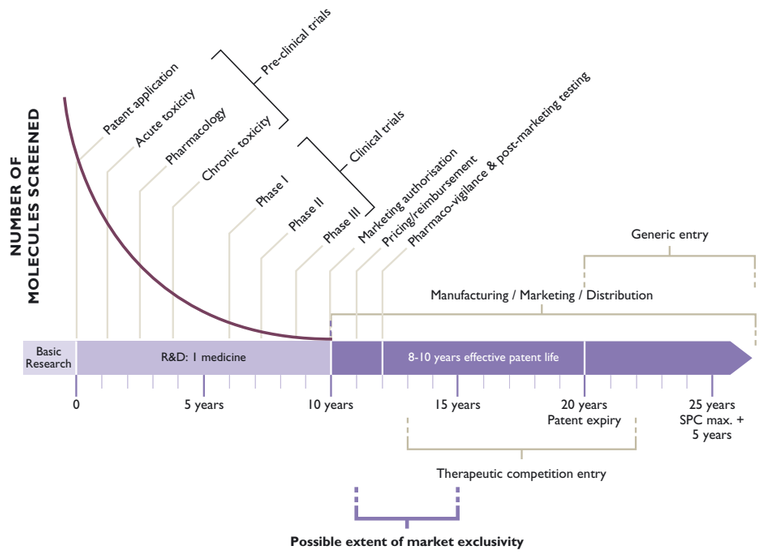
Key characteristics of effective use of IPP that promotes a 'circle' of innovation

of R&D into a financial flow, which is indispensable to the cyclical process of innovation. As such it should be regarded as the heart of the whole system of pharmaceutical innovation.

Intellectual property protection and, in particular, the temporary period of exclusivity granted by patent protection is of critical importance to the pharmaceutical industry. The reason is simple: once the value of a molecule for treating a particular disease has been established by the innovator and satisfies regulatory requirements, it is relatively easy to imitate manufacturing processes and commercialize generic copies of medicines.

A patent does not confer a monopoly. In recent years, the time during which a company can realize a return on investment has been shortened despite a fixed patent term for pharmaceuticals and data exclusivity protection. The average time before therapeutic competition enters the market is now only three to four years; i.e. the introduction of competing products in the same therapeutic class comes shortly after the launch of the breakthrough product effectively ending the market exclusivity conferred by a patent. This has important implications for companies, as their long-term financial projections are largely based on anticipated exclusivity periods. The figure right shows the shrinking period of market exclusivity for the life of patents. In reality the pharmaceutical market is highly competitive. The growth of the global generics market will also have a major impact on the future business models of R&D based pharmaceutical companies.

Shrinking period of market exclusivity



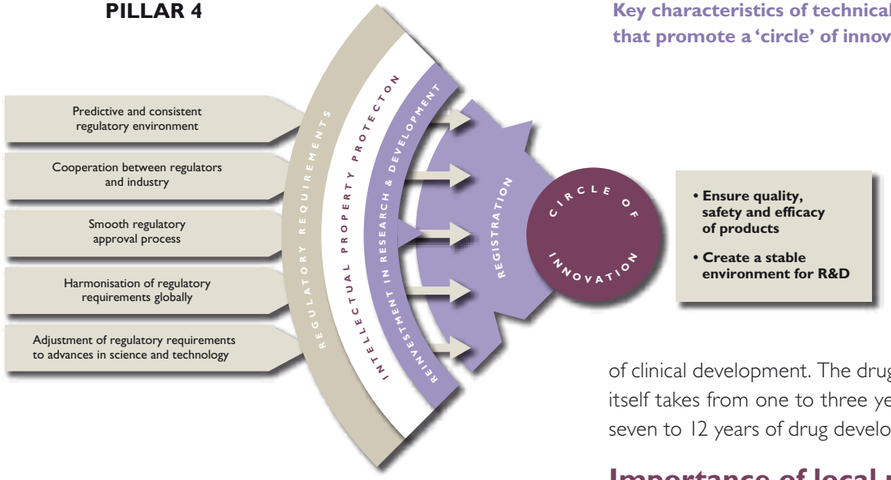
Source: Adapted from The Pharmaceutical Price Regulation Scheme, Office of Fair Trading (2007)

Pillar 4
Regulatory environment that adequately balances risks and innovation

Effective regulations are the key feature to every aspect of the pharmaceutical business cycle: in setting requirements and shaping the all-important drug development process, in establishing quality standards for manufacturing, and in ensuring that the medicines that reach patients are effective and safe.

The growing tendency among regulatory authorities to make the process of drug approval more stringent contributes to the upsurge of R&D costs. Significant benefits could be achieved if drug regulatory authorities

Key characteristics of technical regulation that promote a 'circle' of innovation



applied a more consultative and flexible approach to their processes and procedures, thus keeping up with the latest scientific and technology advances in the R&D process. This could result in a faster and less costly development process as well as more productive and efficient manufacturing of pharmaceuticals.

Ever more burdensome regulatory requirements may have contributed to disrupting R&D efforts needed to produce new generations of antibiotics. Increasingly stringent regulations contribute to more complex, longer and more expensive R&D. A dossier requesting regulatory approval for a new medicine now consists of up to 100,000 pages with reports on the safety and efficacy profile of the drug based on many years of clinical development. The drug regulatory approval process itself takes from one to three years, added to the average of seven to 12 years of drug development and testing.

> ***'IPP transforms the intangible capital generated by pharmaceutical companies during the process of R&D into a financial flow, which is indispensable to the cyclical process of innovation'***

Importance of local policies for patients worldwide

The policy pillars for innovation represent a universally applicable policy mix that creates a nurturing environment for innovation. Whilst medicines are increasingly global goods, local policies also need to promote an environment conducive to pharmaceutical innovation. Policy makers on a country level contribute to a global climate that promotes innovation, even if that innovation is not generated directly in their home country. The realization of the importance of an inter-country policy environment for innovation is crucial to sustain and intensify R&D efforts to address the health needs of patients worldwide

Recommended reading

Abbott T (1995), Price regulation in the pharmaceutical industry: prescription or placebo? J. of Health Economics, Vol. 14, pp. 551-565

IFPMA (2004), Pharmaceutical Innovation Platform

Imperial College, Tanaka School of Business (2007): Innovation in Life Sciences