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# Introduction

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## 1. Background

The pharmaceutical industry represents an important branch of western economies. In 2008, the total world market for pharmaceutical products amounted to US$ 773 bn (Table 1). Moreover, the industry implies also important economic stimuli in terms of national income and workplaces. Due to the pharmaceutical companies' demand for investment goods and other supplies, for Germany, it was found out that for each direct employee 1.63 indirect workplaces are created.[1] In several countries the industry looks back on a very long and prosperous history of developing new drugs.[2] Not for nothing, especially Germany boasted itself for a long time to be the "world's drugstore". This is also true for other countries with a stronghold in innovative pharmaceuticals such as Switzerland, the UK, or the US.

Table 1
Global Pharmaceutical Sales, 2001–2008

| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|---|---|
| Total World Market† | 393 | 429 | 499 | 560 | 605 | 648 | 715 | 773 |
| Growth Over Previous Year‡ | 11.8% | 9.2% | 10.2% | 7.9% | 7.2% | 6.8% | 6.6% | 4.8% |

†Current US$ in billions; ‡Constant US$ Growth; Source: IMS Health Market Prognosis, March, 2009.

However, since the mid 1990s there is an international deterioration of the underlying conditions fostering pharmaceutical innovation.[3] This can also be measured empirically in the declining number of admissions of chemical or biological drug agents.[4] Beyond this development the public discussion in some countries stresses that the own losses as a worldwide leading research- and development site of the pharmaceutical industry are attributable to legal and political weaknesses of the host country. The successful companies in terms of profits as well as the number of innovative medicines benefit from their privileged location.

[1] Source: Fraunhofer Research 2005.
[2] For the history in the US refer to Gambardella [3].
[3] See also e.g. Pisano [9, p. 51], Sykes (1994).
[4] See also DiMasi [1, p. 286].

Conversely, there must be factors for legal and political competitiveness. These can be identified throughout the whole pharmaceutical value chain, from drug discovery, r&d, authorization until the marketing of an existing drug. Taken together, they define the friendliness of the environment:[5]

1. Health care systems that provide incentives for innovation,
2. Effective markets for innovation,
3. A regulatory environment that enables innovation.

### *1.1. Health care systems that provide incentives for innovation*

In the mid 1980s, many economies experienced high price flexibility for innovative medicines because most physicians disregarded the costs of the medication and prescribed solely the 'best' pharmaceuticals.[6] Caused by the monopoly during the duration of a patent, the companies were not only able to recoup their r&d costs but were also rewarded with a superior profit margin on their invested capital. This changed by the health care systems' cost reduction efforts that evolved globally since the scientific progress has put significant pressure on expenditures.

Since then, price levels of patented and generic innovative drugs have been focused due to the financial situation of the respective health care system. Therefore, in most countries the pricing is not only influenced by the usual competitive strengths but also by national interventions like price or profit controls, budgets, or additional payment regulations. Pharmacoeconomic studies have, in some countries, been built up as a fourth hurdle for expensive drugs whose innovativeness should be evaluated against their medical utility. Especially, NICE of UK has led this development by defining a clear price for life years gained.

In order to provide incentives for innovation the reimbursement processes has to be transparent, fair, swift and predictable. It is quite understandable that the European Court of Justice asks in several verdicts for a common market to be implemented in this sector. This common market is seriously hampered by 27 different health care systems, driven by their own traditions, legal provisions and price setting. National pricing and reimbursement policies do not provide for higher rewards for innovative products compared to older ones in certain diseases areas (e.g. therapeutic reference pricing).

However, health care policy is also economic policy and vice versa. Therefore, retroactions are to be expected for industrial research as well as the competitiveness of pharmaceutical companies. Because such health politic measures will determine the incentives offered to companies for their research, short-term savings while supplying pharmaceuticals might have to be "bought" in the long-term with higher, additional costs.

[5] See IFPMA (2009), p. 2.
[6] See also Pisano [9, p. 56].

### *1.2. Effective markets that constitutes promoters for innovations*

Besides the customers', i.e. the health care systems' incentives for innovation, there are further environmental variables that provide supportive conditions.[7] For instance, for the US the existence of spillovers, i.e. the diffusion of knowledge among different organizations, could be shown for research clusters such as Boston, MA. Spillovers are necessary for innovation because they constitute pathways for the exchange of knowledge besides licensing patented inventions through r&d cooperation or the fluctuation of scientists between companies and research sites.

In regard to the legal conditions, there are close connections with the protection of industrial property as well as closely related topics like inventor's bonus and the right to human components. Furthermore, the hitherto discussions have hardly paid any regard to the fact that health care is not disconnected from the macroeconomic development.

Intellectual property rights (IPRs) are a key pillar as incentives for innovation. Effective protection of IPRs (through patents, trademarks and protection for all pharmaceutical registration data) is, therefore, essential for quality healthcare based on innovative pharmaceutical products.

### *1.3. A regulatory environment that enables innovation*

Since the early 1960s and the tragic thalidomide epidemic of abnormalities which caused worldwide almost 10,000 victims in the years 1959–1962, the development stage has been constrained by a strict regulation. Among other, the US "Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act" from 1962 and the Declaration of Helsinki by the World Medical Association mark the beginning of an unprecedented stream of regulation. By now, every state has its own pharmaceutical law with the corresponding legal and scientific guidelines.

Through the supranational and international harmonization, the shape of the regulatory environment is changing. Within the European Union, a wide variety of acts and regulations emphasized the creation of a common code for human pharmaceuticals. In addition, since more than two decades there has been a tripartite convergence within the International Conference for Harmonisation (ICH). Its members are the drug agencies of the EU (DG III), the US (FDA), and Japan (Health Departments) as well as representatives of the four pharmaceutical industry organisations (EFPIA, PhRMA, JPMA, and IFPMA). Although the ICH aims at the facilitation and simplification of reciprocal acknowledgement of clinical trial data, the convergence has not led to a faster market access. Moreover, the research costs increased to more than $ 802 mn. per active ingredient.[8]

[7] See also Henderson [4]; Henderson/Cockburn [5]; Henderson/Cockburn [6]; Henderson/Jaffe/Trajtenberg [7]; Henderson/Orsenigo/Pisano [8].

[8] Cf. DiMasi/Hansen/Grabowski [2].

The purpose of the orphan Drug and pediatric medicinal products regulation is to introduce incentives to develop and market medicinal products for the prevention, diagnosis and cure of rare conditions ('orphan medicinal products') and pediatrics product. Among the most important incentives provided for by the regulation are: One of the main incentives included in the legislation for the development of orphan drugs is market exclusivity for a period of 10 years after the grant of marketing authorization. During this period, directly competitive similar products cannot usually be placed on the market. This exclusivity is a substantial competitive advantage, which mainstream pharmaceutical products do not enjoy. Lower fees are reduced for all the steps of the market authorization centralized procedure at the EMEA (European Medicines Agency).

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