on revising the regulations on state aid for R&D&I in the EU’s community framework

Reasons for changing the regulations in the interests of the European pharmaceutical industry, which has a large number of small and medium-sized enterprises, using Germany as an example

Evaluation of the European Union’s research, development and innovation policy
The European Union (EU) recognises the importance of research and development (R&D) as a source of innovations. At the Lisbon European Council in March 2000, the heads of state and governments set a new strategic goal of making the EU “the most competitive and dynamic knowledge-based economy in the world” within the next ten years. Average annual growth of three per cent in gross domestic product (GDP) and the creation of 20 million jobs by 2010 were expected. Another aim was to achieve an employment rate of 70 per cent. The Barcelona European Council in 2002 subsequently set a target to raise overall R&D investment to three per cent of GDP by 2010.

The current Community Framework for State Aid for Research, Development and Innovation (R&D&I) is regarded as a significant improvement over past frameworks and is seen generally rated positively as regards research funding in particular. Although the pharmaceutical industry points out a need for certain changes, these only concern individual aspects where implementation of the framework has revealed room for improvement.

The pharmaceutical industry also highlights some topics that have not yet been sufficiently taken into account in the current R&D&I framework.

Basic information on R&D&I policy in the EU
The idea behind R&D&I policy instruments is to create incentives for more R&D&I in companies in order to reduce the risks involved in R&D projects and to offset market failure and the sector-specific disadvantages faced by small and medium-sized enterprises (SMEs).

Innovative companies should be regarded as a special case. They have to overcome the greatest obstacles in order to enter the market. At the same time, it is precisely these firms that drive structural change and form the European corporate landscape of the future. Hence, they merit special support. Furthermore, they set the tempo and direction for their supplier chain, thus playing a very important role and facing significant risk, and deserve special attention.

1 http://www.europarl.europa.eu/summits/lis1_en.htm
2 http://ec.europa.eu/invest-in-research/action/history_en.htm
Because of their size and, in some cases also because of their corporate culture, innovative pharmaceutical intermediate-sized enterprises (ISE) often have to overcome obstacles in order to gain access to and collaborate with research institutes.

Innovative ISEs in the pharmaceutical industry often find that their access to the capital market is blocked. Overcoming financing difficulties in the phase between development and market entry (the “valley of death”) is often a particularly serious problem for these firms. 

In view of this fact, it is necessary and justified to address R&D&I support for innovative pharmaceutical ISE in a special way in the R&D&I community framework.

Incentives are not only created via support for start-ups. The same applies to established, innovative companies, which often have to set the tempo and direction for their (smaller) suppliers and thus have to bear the largest share of the technological and economic risk of investing in a new technology. Bad investments can threaten the survival of a company and its supplier chain. Hence, companies’ research policy would often be significantly more conservative if there were no state aid for R&D&I.

R&D in the pharmaceutical industry
The pharmaceutical industry spent around €5 billion on R&D in Germany in 2012, thus playing a large role in helping to meet the goal set in Barcelona in 2002 of achieving an R&D investment quota of three per cent of GDP.

The increase in macroeconomic R&D intensity from 2.8 per cent in 2010 to 2.88 per cent in 2011 was largely a result of greater R&D activities in the private sector. With expenditure of €50.3 billion, German companies invested 7.2 per cent more in R&D than they did in the previous year. The pharmaceutical industry invested 14 per cent of its turnover from its own products on internal R&D projects, thus putting it at the top of the list of R&D expenditure, clearly ahead of the automotive, mechanical engineering and chemical industries.

According to the German Federal Statistical Office, there are around 900 pharmaceutical companies in Germany, including SMEs, owner-managed companies (most of them ISEs) and the German offices of international concerns. However, the figures clearly show that the sector is characterised by SMEs and ISEs. Almost 95 per cent of the companies that manufacture medicinal products in Germany have fewer than 500 employees, although the pharmaceutical industry is one of the country’s oldest industrial sectors. Many companies have been in business for 100 years, and most of them were founded at least 50 years ago.

According to many experts there is a large and very important sector in economies which neither belong to the large company category nor to the SME. These companies are defined (e.g. by the National Institute of Statistics and Economic Studies in France) as intermediate-sized enterprises (ISE): a company with between 250 and 4999 employees, and a turnover which does not exceed 1.5 billion euros or a balance sheet total which does not exceed 2 billion euros. A company with fewer than 250 employees but a turnover greater than 50 million euros and a balance sheet exceeding 43 million euros is also considered to be of intermediate size (http://www.insee.fr/en/methodes/default.asp?page=definitions/entreprise-taille-intermedi.htm).

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5 BPI – Pharma-Daten 2012. Calculations by the BPI based on data from 2012 by the German Chemical Industry Association (VCI) and the Federal Statistical Office.
However, this does not prevent these companies from conducting R&D at the latest level, such as in the highly innovative field of biopharmaceuticals. Many pharmaceutical companies research, develop and market their own biopharmaceuticals. In 2011, there were almost 120 such companies. Just under 200 biotechnology-based medical products – around 150 of which are genetic-based – are already licensed in Germany. This amounts to a share of 19 per cent of the total turnover in the pharmaceutical market. ⁶

There is huge potential for further development in the field of medicines manufactured using biotechnological and genetic engineering methods. In 2012, there were around 550 biopharmaceutical compounds in the clinical pipeline. Overall, the number of drug candidates in clinical trials has more than doubled since 2006. ⁷

In 2012, pharmaceutical companies in Germany invested over €4 billion in R&D. This constitutes around twelve per cent of the pharmaceutical industry’s total turnover and around eight per cent of total internal R&D expenditure by German firms. The pharmaceutical sector’s role in creating and safeguarding highly qualified jobs in Germany is essential as regards strengthening and developing Germany as an innovative location.

Conditions that block innovation

Despite these very positive figures, there are some signs that the current over-regulation is having a negative impact, particularly on companies that conduct research. Many such companies are putting innovative developments on the back burner for the time being. In the summer of 2012, the German Pharmaceutical Industry Association (BPI) conducted a survey among its members on the importance of innovations. ⁸ Almost 90 percent of the firms stated that the benefit assessment stipulated by Germany’s Act on the Reform of the Market for Medicinal Products, which came into effect in January 2011, made it impossible to refinance investments in R&D. The situation is very serious for Germany as an innovative location, since 78 per cent of the surveyed companies stated that they would not currently pursue very promising development projects in the field of prescription medicines, including a large number of biopharmaceuticals.

This clearly leads to market distortion in favour of multinational concerns, whose structure and resources allow them to simply move entire R&D departments to a country or continent that offers better conditions.

Moreover, pharmaceutical ISEs often do not qualify for national or European R&D funding programmes because of the sector’s special structure, as described above. Although the sector is clearly characterised by SMEs as regards the number of employees in companies, the firms’ annual turnovers can be in the range of double or triple-digit millions of euros thanks to their (successful) history. For example, an average member company in the BPI, which represents the German pharmaceutical sector, employs around 330 people.

The European Commission’s recommendation of 2003 (2003/361/EC) on defining an SME (as having up to 250 employees and an annual turnover not exceeding €50 million) fails to

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⁷ Ibid.

⁸ BPI member survey on the role of innovations based on proven active substances, June 2012.
meet the aim of facilitating the flow of innovations from companies smaller than “BigPharma”. Neither the number of employees nor the size of annual turnover has been adapted to inflation rates or sector-specific factors in the past ten years. In the case of the pharmaceutical industry, developments that could improve patient care are thus indirectly being withheld from the citizens of the European Union.

A broad ISE segment is essential to a functioning market economy. Experience has shown that ISEs can compete because they are flexible. They can also hold their own against large companies. However, ISEs are at a disadvantage as regards their larger competitors, since increases in company size often lead to benefits concerning procurement, production and sales.  

In order to prevent distortions of competition arising in the entire pharmaceutical market as a result of inappropriate definitions, the definition of an SME should be based on the market structure of the sector in question. This way, the question of whether a firm is defined as an SME would not depend purely on absolute parameters, such as annual turnover or the number of employees, but rather on the size of the firms in the sector concerned. What is decisive for the definition of an SME is its size in relation to the large companies in its sector, that is, the companies against which smaller firms are to become more competitive. For example, in certain circumstances a company with an annual turnover of €100 million can be regarded as a medium-sized enterprise in a market where some companies have sales in the billion euro range.

Pharmaceutical ISEs mostly do not meet the above-mentioned threshold values of the EU's recommendations on SMEs due to their integration of R&D, manufacturing and sales. Such firms often employ more than 250 people and/or have a turnover or balance sheet total above the threshold value. As a result, they face worse funding conditions or do not have access to particular funding measures. However, taking into account the vast size differences of companies in the pharmaceutical industry, which is dominated by large firms with tens of thousands of employees, there can be no doubt that these firms are small enterprises.

On the other hand, an advantage of ISEs is that they fund R&D costs themselves without venture capital financing and have the necessary expertise and market knowledge. However, they do not have the same research budgets as large firms.

It would therefore be useful for the definition of an SME to be based on relative size, in which the threshold values for the number of employees, the turnover and the balance sheet total are defined in relation to the average values of these markers in the 15 largest companies in the sector. For example, small companies would be defined as firms whose number of employees is less than two per cent of the relevant average, while medium-sized companies would be those that employ less than ten per cent of this average.

Alternatively, the BPI calls for the current threshold values to be doubled, for example from 250 to 500 employees and from an annual turnover of €50 million to €100 million.

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10. Ibid.