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Policy Check: Status and Perspectives of the Pharmaceutical Industry in Germany

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Executive Summary of the HWWI Policy Report No. 7 »Politik-Check Pharmastandort Deutschland: Potenziale erkennen – Chancen nutzen«, commissioned by the German Association of Research-Based Pharmaceutical Companies (VFA).

Overview of the Study Results

As globalisation has progressed, competition between locations to host economic activities has increased, too. Old locations are coming under pressure while new ones are coming into being. In the future, growth will come from those industries that are both capital- and knowledge-intensive. For industrialised countries, the only way to maintain higher prosperity will be through technological progress. This makes investment in education, research and development imperative. Such investment is able to generate new income through innovation and contributes to sustained economic growth. It is companies that make decisions leading to innovations and technical progress, which in turn serve to improve their market positioning. But the research and development activities of companies is heavily influenced by the educational and research policies in place in the different jurisdictions.

For the future, it may be expected that the new technologies – such as biotechnology, nanotechnology and genetic engineering – will lead to a surge in innovations, especially in the area of health care, medicine and pharmaceuticals. The World Bank expects the global population to rise to some nine billion by 2050. Meanwhile, a distinct demographic shift must be anticipated in the industrialised countries, with for instance the proportion of those in Germany aged 65 and above likely to rise from 19.3% at present to 33.2% in 2050. Both these trends will lead to a rise in demand for health-related services and products. The issues will not only be those of medical progress with improved treatment and prevention of disease but also the maintenance of physical and psychological well-being and the ability to work. Nutrition and ergonomics will carry more weight. All in all, health care has the macroeconomic potential to become the major driving force behind innovation, growth and employment.

It is against this backdrop of tougher competition to host economic activity and of increasing demand for health-related services and products that this study has set itself the task of investigating the opportunities for the pharmaceutical industry in Germany. Success will be measured by how pharmaceutical and biotech companies perceive Germany. One major focus of the study will be whether - and if so, how far - the policies pursued by the grand coalition have contributed practically to improving the nation's standing as a location for entrepreneurial activities. A two-fold approach has been chosen. First, an analysis is given of Germany's quality as a pharmaceutical centre in terms of existing surveys and data. Secondly, the results of a survey of decision-makers are presented, including executives of global pharmaceutical and biotech companies, representatives of major research laboratories in Germany, of investors, and of trade unionists. The analysis does not content itself with evaluating the location and the political environment: it also makes practical recommendations on what can be done to improve the appeal of the country.

The analysis of Germany's strength as a pharmaceutical hub shows that Germany has lost ground internationally since 1990, with competing produc-

tion facilities established in Ireland, Sweden, Belgium and Denmark. But it also shows threshold countries such as India and Singapore establishing themselves in research and development alongside the market leaders, which are the United States and the United Kingdom, with the USA leading in research and the UK in development. In Germany, the number of patents registered in pharmaceuticals has climbed more sharply in recent years than in competing countries. Since 2007, Germany has been the leader in Europe for commercial clinical studies and in the production of biotechnological drugs. Germany has also moved up to second place worldwide (with the USA ranking first) thanks to the high level of investment by major pharmaceutical companies in expanding their existing plants.

Both the analysis itself and the survey of experts highlight strengths and weaknesses of Germany as a host country for pharmaceutical and biotech activities. The country's strengths notably include the high quality of its scientists and technicians, a good positioning in selected areas of basic research, great expertise in high-tech production, immediate market access after approval, and its role as an indicator market in determining the prices of innovative drugs.

A significant weakness in Germany is the high level of regulation and sometimes inefficient application and approval procedures, with these weaknesses becoming relevant in various ways at all stages of the value chain. There is some catching up to do in the area of basic research and in the provision of venture capital. All in all, Germany is estimated to be much worse in the surveys of experts than an objective analysis of its strengths and weaknesses should warrant. The very critical assessment that was expressed in some of the interviews derives mainly from the cost-cutting measures arising from the health reforms in Germany. These are largely shaped by budgetfocussed regulation. The influence of the sales market on the image of the country is apparent in two major respects. The discussions about the Institute for Quality and Economy in the Health Sector (IQWiG) and the "Jumbo" groups that were introduced a number of years ago (these include patented drugs in reimbursement groups alongside generics) have, in the eyes of management and experts, steadily impaired the standing of the German sales market. Those surveyed were actually in favour of a macroeconomic cost-benefit analysis of drugs but insisted that any such analysis must conform to international standards. The introduction of "jumbo" groups has greatly damaged Germany's standing as a pharmaceutical hub while failing to lead to any significant savings in the health system. The debate has created an impression internationally that innovative drugs are not appreciated in the German health system, that patent protection is being undermined, and that therefore research and development of such drugs is not rewarded adequately. This is notwithstanding the fact that those surveyed generally saw the protection of intellectual property in Germany as being good. That is, the very debate has succeeded in damaging Germany's reputation as a place to do pharmaceutical business.

All in all, the measures taken by the grand coalition to strengthen the pharmaceutical industry in Germany have been in the right direction and contributed to enhancing the country's image. Of special note are the various research initiatives, the promotion of centres of excellence and the reform of company taxation. However, a number of interviewees thought that the measures had only served to prevent Germany from falling further behind. Some of the interviewees were unaware of these measures, or else they did not consider them relevant to their own decision-making. The main problem identified by national and international decision-makers alike was the lack of any coordination in Germany among those in charge of policy-making. It was thought that the political establishment needs to make a commitment to the pharmaceutical industry, followed by a targeted, long-term policy agreed between the different actors. To this end, the need is to take account of all stages of the pharmaceutical value chain, from basic research through to sales, with a coherent holistic approach by all political players. Measures are needed that take proper account of what makes a business location attractive in the first place, while developing further its perceived strengths.

The first precondition for any action is that the political measures must be developed in an international context. The process of globalisation means that there are hardly any national solutions for macroeconomic problems that can be considered or implemented independently of the increasing interpenetration of the world economy. In terms of the attractiveness of Germany and the competitiveness of pharmaceutical companies operating in Germany, this means striving to maintain or extend the position relative to existing or new competitors. Whatever measures are taken, international perceptions must not be underestimated. For the measures to take real effect, proactive marketing in the framework of a national campaign to attract pharmaceutical investments is needed.

The second precondition follows from this, since it, too, emphasizes the international perception of national policies: although certain individual measures may seem second-best in a closed national economy, accepting them may be a requisite in the global context if the nation is not to fall behind in attracting and retaining investment. In some areas, e.g. fiscal policy or industrial and research matters, international harmonisation of regulatory policy is basically welcomed and indeed necessary. However, such efforts often turn out to be very difficult or are the subject of lengthy and tiring negotiations. As long as harmonisation cannot be reached in certain areas, there is little to be said against Germany adapting to international customs – for instance, in providing subsidies for research.

A third precondition for action is applicable to all political measures, namely that instruments that are not sustainable should generally be kept out of the political toolbox. For the pharmaceutical industry, sustainability of measures is therefore of special importance, since entrepreneurial decisions in this sector are always taken with a wide time horizon and since stable framework conditions are a necessary precondition for decision-making. Two things are meant by speaking of the sustainability of political measures. Firstly, any measures must be reliable in the sense of enabling companies to plan ahead and providing investment security. Hence long-term programmes are preferable to short-term measures. Only against a background of planning security should decisions of a long-term nature in favour of a location be expected. Secondly, measures and programmes need to be consistent and stop-gap measures must be avoided since these only lead to distortions. The evaluation of the interviews showed that Germany's standing as a pharmaceutical location can be strengthened most of all by installing a coherent regulatory framework, which means one that can be understood by decisionmakers abroad.

The study makes concrete proposals to strengthen the pharmaceutical industry based on the three general preconditions for action. In the spirit of a "strengthening strengths" approach, one proposal is an aggressive campaign in the near future to enhance the standing of Germany as a pharmaceutical hub, with a topping-up of state expenditure on research and more state promotion of privately funded research. Furthermore, the campaign to promote centres of excellence should itself be made more permanent, accompanied in the medium term by reform of schools and universities, modification of the company tax reform, more promotion of spin-offs from universities and improvements in the provision of venture capital. In the long term, all political measures should be examined with respect to their effects on the health sector. This would involve eliminating contradictory regulations and cultivating growth potential with measures aimed at increasing competition.

All of these programme points would increase the attractiveness of Germany in general and as a business location for the pharmaceutical industry, with consequent benefits for steady domestic growth.

The key results of the study may be summarised in the following ten points.

1. As a location for pharmaceuticals business, Germany is better than its reputation. It is remarkable that the experts surveyed considered Germany much worse than an objective analysis would warrant.

2. In an international comparison, Germany's strengths are in clinical research, the high quality of its scientists and workforce, in biotechnological and high-tech production, and in exports.

3. Immediate market access and its leading role in determining market prices for innovative products give Germany a pioneering role for therapeutic innovation.

4. Germany's reputation suffers from a certain lack of transparency in health regulations, from overregulation and from inconsistency of regulation.

5. The essential weaknesses, as perceived by the international experts, are the high number of regulations and the inefficient application and approval procedures, which make themselves felt in various ways in all stages of the value chain. There is some catching up to do in the areas of basic research and in the provision of venture capital.

6. The critical judgement is based on a budget-focussed regulation as evidenced by the cost reduction measures in health politics. The influence of the consumer market on the image of the country is apparent in two major respects. The discussions about the Institute for Quality and Economy in the Health Sector (IQWiG) and the "Jumbo" groups that were introduced a number of years ago have, in the eyes of management and experts, lastingly impaired the standing of the German sales market. Those surveyed were actually in favour of a macroeconomic cost-benefit analysis of drugs but insisted that any such analysis must conform to international standards. The introduction of "Jumbo" groups has greatly damaged Germany's standing as a pharmaceutical hub, while failing to lead to any significant savings in the health system.

7. The debate has created an impression internationally that innovative drugs are not recognised in the German health system, that patent protection is not assured, and therefore that research and development of such drugs is not rewarded adequately, despite the fact that the experts surveyed see the protection of intellectual property in Germany in general as being exemplary.

8. What is therefore needed is a transparent, consistent and reliable political framework that would win back trust from investors and thereby direct investment in the global market to Germany.

9. All in all, the measures of the grand coalition have been in the right direction. They have strengthened the location. Of special note are the various research initiatives, the promotion of centres of excellence, and the company tax reform. However, a number of interviewees thought that the measures had only served to prevent Germany from falling behind.

10. If Germany reflects on the advantages it doubtlessly possesses as a pharmaceutical hub and develops a political strategy based on maintaining and growing these advantages, then it has the potential to withstand the increasing competition from the threshold economies and indeed to increase its ranking as a world leader in pharmaceuticals.

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