Interview with Henning Fahrenkamp, Chairman of Board of Directors, BPI

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What role does the German Pharmaceutical Industry Association (BPI) play for the German pharmaceutical industry?

BPI is the oldest industry association of the German pharmaceutical industry, dating back to 1951. Today, it represents around 260 members. These members come from all segments of the pharmaceutical spectrum: start-up companies, small and medium sized companies and multinational companies alike.Regarding the tasks of the association, BPI has two pillars. The first one is the classic task of associations: the representing and defending our members' interests in the political and administrative arena. The other pillar is to support our members with technical advice regarding some of the most important issues the industry faces. For instance, BPI has more than 30 groups of experts specializing in different areas such as OTC, innovation, healthcare policy, clinical research, biotech, national and international regulatory affairs and so on.The members of BPI are involved in a wide spectrum of activities, ranging from innovative to generic companies. Furthermore, we also represent a considerable number of biotech companies and have a large membership of pharmaceutical companies producing drugs from plant-derived materials, as well as homeopathic companies. This membership covers the whole range of the industry and therefore gives BPI a true understanding of patient and industry needs.Our diverse membership gives us an important advantage, since it forces us to find common ground between different interests that, once achieved, represents the common goals of the whole spectrum of pharmaceutical companies.

Hence, it increases our chances to be heard in the political arena and lends legitimacy and credibility to our demands.

How do you think the German government can guarantee the development of a sustainable healthcare system and, at the same time, incentivize innovation?

In the last 20 years Germany has undergone 20 healthcare reforms, averaging one reform every year. For instance, in 2004 all non-prescription drugs were excluded from reimbursement. This resulted in a massive decrease of investments in the OTC segment.The impacts of this measure were especially damaging in Germany, because in contrast to other countries, if a prescribed drug is on the market for more than five years and has proven to be free of relevant side effects, it may be classified as OTC. As a result, this governmental policy affected an enormous range of products. In a country where 90% of the population is covered by statutory health insurance and benefits from reimbursement, it’s easy to understand why pharmaceutical companies weren’t very satisfied.This unpredictability of the development of the legal framework is a great discouragement for the development of a sustainable healthcare system since it puts investments at risk that would benefit the German economy and improve people’s access to medication.However, the struggle of the government to deal with the increased budget constraints and rising healthcare costs is understandable. The demographic ageing of the population, the continuous decrease in numbers of young tax payers in coming years, the dramatic increases in some chronic diseases such as diabetes, all are good reasons for concern. Having said this, the answer to these problems cannot be found by cost management alone. On the contrary: an increase in the health expenditures of government, healthcare insurers and pharmaceutical companies is needed in order to finance the structural increase of health-related expenses.

Unfortunately, for politicians it is hard to accept the economic reality when it means legislating against the short-term interests of their voters. And how is BPI helping its members to overcome this challenge?

Our role as an association is to ensure that our companies are still able to invest in innovation. Naturally, their needs are determined to a large extent by the kind of company they are in terms of activity and size. Therefore, a major challenge is to make sure that pharmaceutical companies in Germany – whatever their size – can conduct R&D to generate innovative advances, to have opportunities to benefit from the rewards of innovation.

What have been the main impacts of the Competition Enhancement Act on the German pharmaceutical industry?

For more than 20 years Germany has been using a price reference system – where competition between companies is purely price-based. It affects especially generics producers. As a result of fierce competition, prices have been decreasing every year. This process gave companies time to adapt and alleviated government healthcare expenditures.The introduction of the Competition Enhancement Act ended up enormously accelerating price cuts by introducing artificial competition. Now, healthcare insurers can agree on contractual rebates directly with pharmaceutical companies. The government believed that by doing this, increased competition would accelerate the drop in prices and guarantee the financial sustainability of the healthcare system. It certainly alleviated the burden on the statutory health insurance system, and the governmental budget in the short term, but they didn't take into account the survival of most of the players in the pharmaceutical industry, especially smaller generics producers.The main issue regarding the new competition clause is that, in Germany, healthcare insurers are organized in groups, such as the AOK, which controls more than 40 per cent of the healthcare insurance system. The disproportional bargaining power of these groups when negotiating directly with the pharmaceutical industry forced the price level in some cases below production cost levels.To prove the success of its measures, the government uses the argument that the Competition Enhancement Act generated a 50 per cent cut in health insurance medication costs. However, once the number of pharmaceutical companies is drastically reduced by the drop of prices, the government and insurers will struggle to find the appropriate level of competition that guarantees the excellent quality expected from drugs at a fair price. When dealing with healthcare and an innovative industry, politicians have a short-sighted approach and this is definitely not the best strategy.This is especially true given the fact that the pharmaceutical industry is a constant target of cost-containment measures while its products are responsible for only approximately 10% of the expenses of the statutory health system – in other words: cost control is hitting particularly hard a sector which is exceptionally effective.

How has this governmental act affected German innovative pharmaceutical companies?

The innovative sector was mostly affected by the provisions regarding reimbursement. The G-BA (joint committee representing health insurers and doctors) is responsible for deciding which products will be reimbursed or not. Under the new rules a benefit and a benefit-cost assessment must be in place for these decisions. To that end, G-BA commissions assessments from the IQWiG (NE: Institute for Quality and Effectiveness in Health Care), which advises whether a new product has real benefits compared to existing products. The transparency of the procedures of the IQWiG has been frequently questioned by the scientific community. This new structure creates a situation where innovative patent-protected drugs can be rebated as well. For instance, we recently had a

case of a new type of insulin that allowed patients a longer period between the injection and the next meal. This would be a great advantage for patients who work and can't have a meal at a defined period of 15 minutes after taking the insulin – the time stipulated for the existing drugs covered by the healthcare system. However, IQWIG did not view this as a substantial benefit and advised G-BA not to cover it. This forced the producers of the new drug to engage in rebates and match the price of their innovative product to the one already on the market. Obviously, this is a recipe to prevent investment into innovations and a great discouragement to innovate at all.

In your opinion, what's the future of the pharmaceutical industry in Germany and do you think the upcoming elections are going to impact the industry?

We have seen in the past 20 years that irrespective of which parties are in power – be it the Socialist Democrats or the Christian Democrats – the measures taken towards the pharmaceutical industry were always quite similar. Politicians are unwilling to pay the political price of implementing unpopular reforms that will give long-term sustainability to the healthcare system for fear of losing the next elections.Germany should apply a smarter system such as the one in Switzerland, with co-payments by patients. In this system, people have access to high-quality treatment and only need to pay 10% of the costs; health insurance covers the rest. Besides, there should be competition between different healthcare insurers.Today, our country has more than 200 healthcare insurers in the statutory system and this number shrinks continuously due to the new regulations – instead of generating true competition.

What is it going to take for Germany to regain its position as the pharmacy of the world?

The framework for pharmaceutical companies has to be more attractive. The legal framework has to be more predictable in order to generate new investments: we need a transparent long-term political strategy to cope with the challenges of the future. If you compare Germany with other OECD countries you will see that most of them actively support R&D by, for example, giving write-offs on taxes once companies invest in innovation. Unfortunately, Germany is an exception. With the current economic crisis the German government had to support many industries massively. But this is not the case for the healthcare sector, which is responsible for one out of every ten jobs in the country. Germany wants to continue advancing as a research-based economy and a leader in the international pharmaceutical industry.

Now, more than ever, it needs to move in the right direction. How can Germany achieve that?

Germans have to leave behind particular interests and work together to find solutions supported by the whole society. For example, today, 20% of the population is over 65 years of age. Since most of

them are already retired, they pay very low contributions into the healthcare system, but they generate very high demands on the system. The result is that young people today will have to pay a huge bill in the future and will lack appropriate coverage once they get older and start needing it. In the year 2030, the fee for social insurance will have to be around 25% of a person’s income in order for the system to remain solvent – this is unsustainable.Different interest groups have to come together and find common ground to find intelligent answers that will bring real long-term sustainability to the healthcare system and the pharmaceutical industry. Unfortunately, the current rebate system is far from adequate to deal with the real needs of society and does not deliver the sustainability the industry demands and the people need.

To help the industry take on such challenges makes BPI’s work even more valuable and interesting. In your opinion, what is the most exciting thing about working for BPI?

Our team at BPI understands that the very existence of the pharmaceutical industry is essential for the sustainability of the healthcare system, and as a representative of the whole spectrum of pharmaceutical companies we understand the whole complexity of the healthcare system. This is why we strongly believe that helping to stabilize the pharmaceutical industry will allow the social security system to survive and truly support the whole society when it is needed.BPI has a unique team of experts that work hard to make the demands of our members heard by policy makers. Our members invest significant amounts of capital and hard work in innovation and providing high-quality drugs – which ultimately will provide a better quality of life for all of us. Making their work possible is what drives us every day.

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