Interview with Dorothea Bronner, President, G-BA

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In the last twenty years, Germany has experienced nearly twenty health care reforms. In your opinion, what have been the main reasons for so many changes?

The main reason behind two decades of continuous health care reforms is the persistent federal budget restraint. This ultimately meant that an increased number of drug innovations had to occur with smaller profit margins. This is the collateral consequence of a unique universal health care system that guarantees good coverage to an entire aging population, while also providing great premiums for innovative drugs. Naturally, the combination of a highly profitable industry with a universal health care system represents an unsustainable burden that must be rebalanced in order to guarantee future generations a decent and affordable health care system.

What was the specific impact of the most recent health care reform in 2007 and how has it affected G-BAâ??s role in the German health care system?

The main impact of the Health Care Reform Act of 2007 was to strengthen G-BAâ??s regulatory capacity in quality assurance, which added to the other regulation mechanisms already in place. This enabled the organization to enhance its role as the gatekeeper for new innovations and improved the quality assurance system.When drugs are licensed in Germany, they are in free access to the market. Therefore, insurance companies have to pay the price each pharmaceutical company dictates. Afterwards, the G-BA can try to regulate the prescriptions. In many cases, this regulation occurs by setting reference prices for drugs to reduce costs, such as with hypertension drugs, which are a good example of the many â??me tooâ?• alternatives in the market. Unfortunately, this solution doesnâ??t always work ideally. Another potential option would be the creation of a positive list. However, in Germany, this possibility seems unlikely, given that there have already been efforts to adopt such a system on a trial basis, which were scuttled by the stronger influence and political power of the pharmaceutical industry.The current system is similar to the German parable about the rabbit and the hedgehog. The G-BA always tries to keep up with the pharmaceutical developments, but it can never quite reach them.

How do you collaborate with other governmental agencies in order to guarantee a better affordability of the German health care system?

The G-BA has a very close collaboration with the IQWIG, from which we demand health technology assessments for new drugs and methods. Based on these findings we decide whether or not new drugs and procedures have a real added value and should be reimbursed by the Statutory Health Insurance (SHI). For both the assessments done by the IQWIG and the decisions taken by the G-

BA, there is a legally established methodology in which the companies and other relevant stakeholdersâ?? opinions are taken into account.

In your decisions, how do you balance the different perspectives from diverging interest groups?

The G-BA takes into account only allegations and assessments that can be clearly proven. Statements that are not based on clearly proven data are not of our concern. However, some companies, when faced with contradicting measures, directly pressure the Ministry of Health, which has the final say over reimbursement issues. This harms the overall health care system and G-BAâ??s capacity to build a truly broad and affordable health system in Germany.

How do you take into account the need for a premium for innovation and the costs of research and development?

The premium for innovation has to be based on the benefits over existing drugs and not on anything else. Keeping in mind that we unfortunately do not have a positive list system, but considering its real innovations and substantial improvements for the patients, the current reference price system provides a substantial range of drugs to the German population.The positive list system is already a reality in some specific cases, such as in reference to the OTC products.

Since OTCs are generally excluded from the health insurance refund, some products considered necessary for certain treatments are positively added by the G-BA.As it is today, do you believe that the German health care system is sustainable in the wake of an aging population and increased budgetary restraints?

For the short term the system is sustainable, but it needs further reforms in order to guarantee its long term sustainability. The upcoming elections in September will decide whether or not the following reforms will rebalance the bill through an increased budget or through smarter spending.In the past years, the first option was the answer, but the more one rationalizes costs, the harder it gets to further continue in the same direction. Even though this is the best way to guarantee a high quality universal system for Germanâ??s aging society, surely the costs will keep on rising.

However, as long as the system is rational and cost effective, it will be worth it.What role will G-BA have on the German health care system in the coming years?

Whenever the budget is under restrictions, there will be pressure to rationalize it. Hence, there is more scope for G-BA. This is what happened since G-BAâ??s foundation in 2004 and that is how it shall continue in the coming years.

As the head of G-BA, what would be your final message to Pharmaceutical Executiveâ??s worldwide readers?

What G-BA expects from the pharmaceutical industry is a greater collaboration in order to achieve the common goal of a sustainable and high quality health care system that covers every German citizen. Therefore, the industry has to give more substantial and unbiased data whenever needed. Then, G-BA can reach the best decisions in order to guarantee affordability for the German health care system and profitability for its pharmaceutical companies.

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