Economic factors outpace medical factors – are regulatory authorities brakes to innovation?

The Pharmaceuticals Market Reorganisation Act (AMNOG) of January 2011 aims to limit the rising costs of pharmaceuticals and to create a balance between innovation and the affordability of drugs. For the pharmaceutical industry this means that the price of new pharmaceuticals depends on their proven additional benefit. The 'healthcare industry provider network' (hipnet) invited representatives from Boehringer Ingelheim and SocraTec R&D GmbH to a meeting to enable them to report on their view as to whether AMNOG provides opportunities for innovation for new and optimised drug ingredients.

Speaking at the hipnet meeting to an audience of more than 60 representatives from the pharmaceutical industry, pharmaceutical service providers, universities and various areas of the healthcare system, Dr. Marco Penske of Boehringer Ingelheim spoke about drug innovations following the introduction of AMNOG two years ago.

With 18 percent of the total expenditure in 2012, the cost of medicinal products are the third largest cost item for statutory health insurance funds in Germany. Only treatment carried out by doctors and in hospitals generates higher costs. In order to limit the rising costs of pharmaceuticals, the Pharmaceuticals Market Reorganisation Act (AMNOG), which came into force in January 2011, stipulates that new drugs may only cost more if it is possible to prove any additional benefit in comparison to the comparative therapy identified by the Federal Joint Committee (G-BA). The prices for drugs that demonstrate additional benefit are negotiated between the pharmaceutical manufacturer and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband - GKV-SV) and are based on the reimbursed price of the comparative therapy and the additional benefit demonstrated. The discounts are taken from the list price set by the manufacturer.

AMNOG is aimed at providing patients with the best possible and most effective drugs, achieving the economic and cost-efficient pricing of drugs and creating reliable conditions for innovation, treatment of insured people as well as safeguarding jobs.

"However, two years after the implementation of AMNOG, this objective remains more aspiration than reality," said Dr. Marco Penske, Head of Market Access and Healthcare Affairs at Boehringer Ingelheim Pharma GmbH & Co. KG. "Often, the formalities involved in the benefit assessment prevent the determination of an additional benefit of a pharmaceutical and therefore are more of a brake to innovation than anything else," Penske believes.

In his view, a major problem is that generic drugs are usually used as comparative therapy, despite the fact that they are not always the best therapy option. "Generic drugs are relatively cheap, so the price range for the new drug under evaluation is much lower than could otherwise be achieved," says Penske.

Another problem, as he sees it, is the role of the GKV in the Federal Joint Committee, and the way new pharmaceuticals are evaluated. According to Penske, the GKV is the most powerful representative in the G-BA, which is the highest decision-making body of the joint self-administration of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany. He therefore believes that the GKV has a huge influence on the selection of the comparative therapy and the assessment of drug benefits, amongst other things. "This is comparable to a football player who also acts as referee," said Penske, making his criticism clear. He hopes that in future either an independent scientific assessment of new drugs will be established or that pharmaceutical companies will be able to negotiate prices and reimbursement directly with individual health insurance companies. "You would not ask the TÜV (ed. note: technical inspection association in Germany) to assess your car and then sell it to the TÜV based on this assessment, would you?" commented Penske.

Drugs – more than just active ingredients

From the perspective of small- and medium-sized companies, AMNOG is not the only challenge the pharmaceutical industry is faced with in Germany when it comes to the development of new drugs. "The big pharmaceutical companies are increasingly moving into other markets while smaller companies usually do not have the financial means to carry out research into new drugs," says Prof. Dr. Henning Blume, CEO of SocraTec R&D GmbH.

Prof. Blume believes that the pharmaceutical industry would need to get away from the "substance idea" and instead focus on the potential contribution of a drug form on its actual effect. Here, so-called drug pharmacokinetics plays a crucial role and this includes the study of all the processes to

Prof. Dr. Henning Blume, CEO of SocraTec GmbH clarified whether therapeutic progress resulting from the optimisation of drug forms based on known active ingredients could represent innovation prospects for the pharmaceutical industry in Germany.

which a drug in the body is subject, starting from the absorption of an administered drug in the intestine, its distribution in the body, its biochemical changes and degradation and finally the excretion of the metabolites of the drug.

Blume is sure that this information is in some cases as important as the drug's active ingredient itself. "In some cases, it is not the administered dose alone that determines a drug's effectiveness, but in particular its sufficiently high concentration at the site of action," Prof. Blume explains. "The objective must also be to ensure that a drug is effective and only associated with limited adverse effects by controlling its targeted release from the tablet."

Blume highlighted that some drugs were true innovations and were made possible by merely changing the formulation of drugs with the same active ingredient. "Sustained delivery forms that increase the effectiveness of a drug or so-called targeted drug-delivery systems that enable the release of the drug at the site of action are two such innovations," said Blume going on to add, "different methods of application can also make a considerable contribution to optimising the effectiveness of drugs."

Lack of support for SMEs

From the perspective of SMEs like SocraTec R&D GmbH, the optimisation of known active ingredients not only brings advantages for patients, but also for pharmaceutical companies. Comprehensive information about the effectiveness, side effects and other information is already available for approved drugs and for those that have already been used for patient treatment for an extended

period of time. “In such cases, research and further development is a lot clearer than for new drugs, which leads to a greater chance of success, reduces the amount of money that needs to be invested into drug development, and reduces the risk of failure,” Prof. Blume explains. And this makes drug optimisation particularly interesting for small- and medium-sized pharmaceutical companies.

However, Blume also believes that current legislation has some drawbacks, in particular the regulations that prevent optimised products from being sold at a higher price than existing drugs with the same active ingredient. The companies thus lack the money which they could invest into the development of optimised drugs. “The cost-benefit evaluation required by AMNOG does not take into account a drug’s suitability for application by patients themselves,” says Blume who also believes that AMNOG and the Committee hamper the development of innovative ideas. “Politicians need to support SMEs and adapt conditions to their needs as well,” concluded Blume.

Article

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No new drugs to be placed on the market without clinical trials