Market Access Germany: AMNOG's Effect on Pricing and Access Decisions

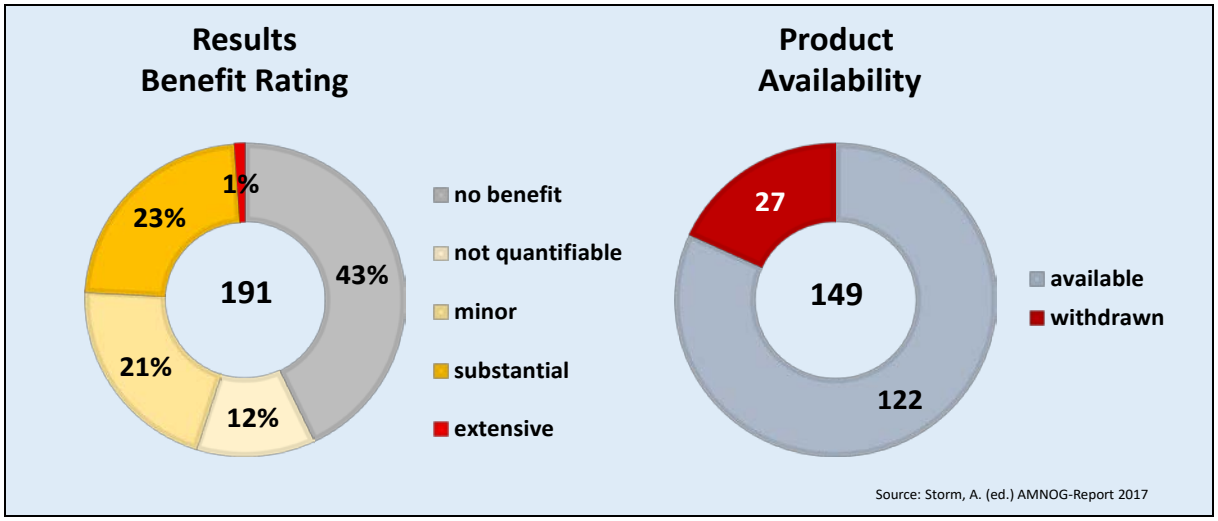
Finally, some good news from Germany: UCB has announced last month to continue marketing its 2016 approved anticonvulsant Brivaracetam (Briviact) in Germany after months of price negotiations between the manufacturer UCB and the National Association of Statutory Health Insurances. The critical issue was that Brivaracetam was rated as not providing any additional benefit over existing meds. An additional benefit rating would be necessary to agree on a reimbursement price above generics level.

Unlike the US, most European countries have already implemented stringent cost control measures for pharmaceuticals, including for newly approved drugs.

In Germany, the largest and most important market for pharmaceuticals in Europe, the AMNOG healthcare reform package, introduced in 2011, has dramatically changed the Germany pharmaceutical landscape.

Until 2011, pharmaceutical companies were free to set the price for new drugs. Now, under AMNOG, the companies can still set a price but must prove to the Federal Joint Committee (G-BA) that the new drug provides an additional benefit over an 'appropriate comparator therapy'. Armed with the G-BA rating on the level of additional benefits, the company then enters negotiations with the National Association of Statutory Health Insurances (Spitzenverband der Krankenkassen) to agree on a reimbursement price. One year after market launch, this reimbursement price replaces the initial list price of the drug.

Since the introduction of AMNOG, some 150 newly approved pharmaceuticals were evaluated in more than 190 assessments by the G-BA. As shown in the Figure below, 43% of assessed drugs were rated as not providing any additional benefit over existing therapies. Pharmaceuticals with no additional benefit will have a low reimbursement price at Reference Price Groups level - typical for generic substances.



As a consequence, 27 (or 1 out of 5) pharmaceuticals introduced since 2011 are no longer available in Germany in order to avoid the negative consequences of having a low German reimbursement level on external reference price systems used by other countries.

The practice of first launching a new drug and then pulling them out of the market is a major problem for patients who need to be switched to a different substance, and a financial loss to the pharmaceutical company who invested considerable amounts of money for launch and dossier preparation.

Some of these new drugs might have had a chance to prove a benefit in case the originator company would have provided the necessary data for benefit evaluation. In particular in metabolic diseases, several 'high potentials' did not receive a positive benefit rating by the G-BA. In some cases, the companies did not provide any data. In other cases, the evidence provided was not considered for evaluation due to methodological problems, mostly related with the definition of the clinical endpoints or the appropriate comparator therapy.

Understanding the European healthcare systems is key for any company planning to enter the European market. Cogent Consulting can help you better navigate the diverse European healthcare systems and to improve the validity of the assumptions for entering and competing in the European markets.