GERMANY

22
new medicines were **withdrawn from Germany** due to unfavorable terms from 2011 to 2016[1]

only 53%
of medicines launched globally between 2008 and 2012 were **available in Germany by 2013** [2]

From 2014-16, it took an average of
106 days
following marketing authorization for **patients to receive access** to a new medicine [3]

Access Restrictions in Germany

Germany's price setting scheme was established in 2011, by the Act on the Reform of the Market for Medicinal Products (AMNOG). [4, 5] As part of the process outlined in AMNOG, during the first year a medicine is on the market, the Institute for Quality and Efficiency in Healthcare (IQWiG) and the Federal Joint Commission (G-BA) conduct a comparative clinical benefit assessment and rate the added benefit on a five-point scale. Just one percent of new medicines are rated as providing a major clinical benefit over a comparator therapy.[4] For example, a medicine granted breakthrough status by the U.S. Food and Drug Administration (FDA) and awarded American Society of Clinical Oncology "Advance of the Year" was determined to be of "no added clinical benefit" by IQWiG.

After the assessment ends, medicines that receive a negative rating (about 56 percent of new medicines) are priced in line with the lowest cost medicine on the market that the government determines is comparable.[4, 6] If the manufacturer of the medicine does not accept the proposed reimbursement rate, they must enter arbitration in order for the product to be available in Germany. If manufacturers do not accept the rate and decline arbitration, they may withdraw the medicine from the German market.

"Cancer patients must be treated according to the current state of knowledge. Negotiating results that do the opposite harm the patient […] patient-oriented solution[s] must be found for such … situations."

German Oncology Association

Statement in response to the market withdrawal of a cancer medicine following a negative clinical benefit assessment

Between 2011 and 2017,148 drugs were subjected to comparative-effectiveness assessment by IQWiG and G-BA.

The G-BA is led by a board comprised of representatives from the national insurer, physicians, and hospital organizations who vote on the outcome of the assessments. Patient advocacy organizations are permitted a nonvoting seat on the board.[7]

[1] Staab TR, et al. "'Market withdrawals' of medicines in Germany after AMNOG: a comparison of HTA ratings and clinical guideline recommendations." *Health Economics Review,* (2018) 8:23.
[2] IMS Institute for Healthcare Informatics. Global Outlook for Medicines Through 2018.
[3] Deloitte, Patient access to innovative medicines in Europe, January 2019.
[4] IQVIA. Pricing & Reimbursement Concise Guide Germany. 28 September 2018
[5] IGES. Reimbursement of Pharmaceuticals in Germany. 2018
[6] OECD Pharmaceutical reimbursement and pricing in Germany 2018
[7] Commonwealth Fund. "Reference Pricing in Germany." February 2019.