GERMANY

23 months
Average delay between application to launch oncology medicine and approval of coverage [1]

57
Number of medicines to treat rare diseases that were approved in the U.S. but not available in Germany between 2004 and 2018. [2]

112 days
Average delay in approval of new medicines compared to the U.S. [2]

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).[3, 4] 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.[5] 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.[5, 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

A report on "The German Health Care System and its Impact on Patient Access – Lessons for the U.S." found that the German HTA system adherence to rigid guidelines for admissible data, poor comparator choices, and failure to meaningfully engage patients has the impact of evaluating the benefit of drugs to the average patient – without accounting for differences among patient needs and preferences within subpopulations – and structuring assessments in ways that do not appropriately represent or account for patient needs. "Due to these flaws, 60 percent of new medicines have received negative assessments from G-BA, including products that patients view as major treatment advances like CDK4/6 inhibitors and PIK3CA inhibitors for breast cancer."[7]

1 Health Division, OECD Directorate for Employment, Labour and Social Affairs, "Addressing Challenges in Access to Oncology Medicines," www.oecd.org, pg. 57.
2 Blankart, Katharina, et al, "Availability of New Medicines in the US and Germany From 2004 to 2018," JAMA, Aug. 30, 2022.
3 IQVIA. Pricing & Reimbursement Concise Guide Germany. 28 September 2018.
4 IGES. Reimbursement of Pharmaceuticals in Germany. 2018
5 OECD Pharmaceutical reimbursement and pricing in Germany 2018
6 Commonwealth Fund. "Reference Pricing in Germany." February 2019
7 Partnership to Improve Patient Care, "The German Health Care System and its Impact on Patient Access – Lessons for the U.S." Dec. 12, 2022.