The German Reform Act On The Reorganisation Of Market For Medicinal Products (ARZNEIMITTELMARKTNEUORDNUNGSGESETZ - AMNOG)

iPAAC INNOVATIVE PARTNERSHIP FOR ACTION AGAINST CANCER

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TYPE	STATUS	LAST UPDATE	
Legislative framework at the federal level	In force since January 2011	September 2021	GERMANY ● NATIONAL Pharmaceutical market – Diagnostic & Treatment

PROBLEM & OBJECTIVE

PROBLEM One of the primary objectives of Germany's health policy is a comprehensive supply of high-quality medicinal products for patients, especially in the case of life-threatening diseases such as cancer or rare genetic diseases. Due to rising expenditures for medicinal products, the challenge was to create a faire balance between the cost of innovation and the sustainable funding of the health system.

OBJECTIVE Ensuring an efficient supply of high-quality medicinal products by stipulating a value-based reimbursement price in order to control spending/costs, while maintaining financial incentives for innovation.

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KEY COMPONENTS / STEPS

- The AMNOG applies to all medicines with new active substances introduced in the German market, except those with annual SHI expenditure below EUR 1 million.
- According to the so-called AMNOG procedure, as an innovation incentive, manufacturers are allowed to set prices freely during the first year after market entry. However, at the time of market launch, they must submit a dossier with the necessary data to support the "added therapeutic benefit" of the medicine over the appropriated comparator (the current standard of care). The Federal Joint Committee (G-BA) assesses the data and passes a binding resolution stipulating, inter alia, the extent of additional benefit, patient groups eligible for treatment and the cost of treatment.
- For orphan drugs, additional therapeutic benefit is assumed by virtue of marketing authorisation without reference to an appropriate comparator as long as annual SHI expenditure for the drug remains below EUR 50 million. Once this threshold is exceeded, manufacturers are required to submit data on additional therapeutic benefit and orphan drugs are evaluated in the same manner as any other medicinal product.
- The resolution of the G-BA is the basis for price negotiations between the Federal Association of SHI funds (Spitzenverband Bund der Krankenkassen – GKV-SV) and the pharmaceutical company. If the drug has some added therapeutic benefit, a reimbursement price is negotiated based on the prices of appropriate comparators (the current standard of care). If no additional therapeutic benefit is found, the new drug is included in a reference price cluster (Festbetrag) where possible. Otherwise, a reimbursement price should be negotiated that does not lead to higher annual therapy costs than the appropriate comparators.

KEY CONTEXTUAL FACTORS

- Health insurance is mandatory in Germany. The vast majority of Germany's population (90%) get coverage from statutory health insurance (hereafter SHI). The other 10 % are covered by private insurance or special schemes. The basket of pharmaceuticals reimbursed by the SHI is not defined through a positive list. Basically all authorized medicines entering the market are reimbursed. Before the introduction of the AMNOG in 2011 there was a system of free-pricing and full reimbursement in Germany. The AMNOG has retained the principle of free pricing at launch but imposes a systematic and formal assessment of the "added therapeutic benefit" of new medicines in order to negotiate the price according to the therapeutic value of the drug within twelve months after market launch.

MAIN IMPACTS / ADDED VALUE

- For the first time, AMNOG has seriously tackled the price monopoly of the pharmaceutical industry in Germany.
- The AMNOG did not only establish a clear and efficient procedure for manufactures, involving relevant stakeholders and experts, but also leads to transparency regarding the "added therapeutic benefit" of medicinal product for patients and doctors.
- AMNOG has turned out to be an effective tool to control spending in a transparent and meaningful way. In the period from 2011 to 2018, the AMNOG procedure led to some €6.3 billion in savings. In 2019 it was about €3.2 billion.

LESSONS LEARNED

- In a federal system formal approaches (e.g. legislation) are effective to implement programmatic public health policy. Involvement of all stakeholders and levels of decision-making is paramount.

REFERENCES & DOCUMENTATION

- Hyperlink to the legal framework of the reform act
- www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/nutzenbewertung-35a/
- www.gkv-spitzenverband.de/krankenversicherung/arzneimittel/verhandlungen_nach_amnog/rabatt_verhandlungen_nach_amnog.jsp

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