



The 3Ps of
Digital Endpoint Value
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Quickstart guide: Reimbursement in Europe

How does reimbursement work in Europe?

Discussing every health care market in Europe is beyond the scope of this document, but we will discuss several of the key markets, and examine similarities and differences to the U.S. market.

Germany was the first country to [introduce social health care \(in 1883\)](#) and England and France followed quickly with similar bills. All three countries have a form of universal health care, which allows the high degree of solidary and centralized systems outlined above. All these countries [spend 10% or more of their GDP](#) on healthcare.

While Germany's [health insurance system](#) is similar to that of the U.S. in many ways, Germany uses **collective negotiation** to price new drugs, keeping them substantially below U.S. prices, as well as prices that are more directly linked to clinical benefit.

Since 2011, following market authorisation from the European Medicines Agency (EMA), prices for new drugs are established through collective negotiations between a single buyer (the umbrella organization representing the insurers, also known as **Krankenkassen** or “Sickness Funds”) and a single seller, the drug maker. Both sides are under strong public and political pressure to come to an agreement. If none can be negotiated, the drug's price is established by an arbitration panel with representatives from each side plus an appointed chair. The manufacturer can refuse the arbitrators' price and withdraw its product, but [“then forgoes all sales in the continent's largest market and knows it will enter price negotiations for its next drug with a reputation for being uncooperative”](#).

A unique feature of the German system is that the final negotiated and arbitrated prices are not confidential. Numerous other nations reference the final German prices when administering or negotiating their own rates. [The U.S. administration has](#)

[proposed an analogous system](#) of international reference pricing to cap rates paid for physician-administered drugs under Medicare Part B.

Prior to 2011, all drugs faced the same mandated percentage rebate. Now discounts are large for drugs that offer little or no incremental benefit but small for drugs where the Federal Joint Committee find a [meaningful contribution to patients' health](#).

In **England**, the system is similar to Germany, with reimbursement decision-making highly centralized to the **National Institute for Health and Care Excellence (NICE)**. [NICE processes are based around cost-effectiveness](#), and are extremely rigorous. See [here](#) for a case study. NICE assessments are referenced by many markets in the rest of the world. You can read more about how NICE is thinking about digital drug development tools (DDTs) as a source of RWE in [this presentation](#).

In **France**, following market authorisation from the EMA, the **Haute Autorité de Santé (HAS)** produces an [opinion document](#) which assesses the new drug in terms of its actual benefit (Service Médical Rendu, or SMR; the intrinsic value of the drug, i.e. should the drug be reimbursed? Is the drug clinically interesting?). SMR is based on 5 criteria:

1. Severity of the disease and its impact on morbidity and mortality
2. Clinical efficacy/effectiveness and safety of the medicine
3. Aim of the drug: preventive, symptomatic or curative;
4. The therapeutic strategy as regards to therapeutic alternatives;
5. The impact in terms of public health (burden of disease, health impact at the community level, transposability of clinical trial results).

The HAS also assesses the improvement in actual benefit (Amélioration du service médical rendu, or ASMR) which assesses whether the drug actually improves a patient's clinical situation, as compared to existing therapies? What is the clinical added value?). Both the SMR and ASMR ratings ('major' through 'minor' to 'no improvement') group drugs into classes which are then differently reimbursed. The greater the benefit, the more a drug is reimbursed.

How are list prices set in Europe?

In **Germany**, there is a [two-steps procedure](#) to set the reference prices for medicinal products:

1. The **Federal Joint Committee (Gemeinsamer Bundesausschuss or GBA)** decides for which medicinal product a reference price can be defined and forms the groups of medicinal products. In these groups medicinal products are

combined based on (1) the same active ingredients (2) pharmacologically-therapeutically comparable active ingredients or (3) a therapeutically comparable action.

2. The **National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)** sets the reference price for the medicinal products. The criteria for the setting of the reference price for a medicinal product are regulated by law.

In **England**, as individual regions and hospitals have independent budgets, they are also key stakeholders in setting the final price.

In **France**, following the HAS opinion, the decision is passed to the *Ministre santé et sécurité sociale*, where the Healthcare Product Economic Committee determines the price, including inclusion on lists and the level of co-payment from the National Health Insurance.