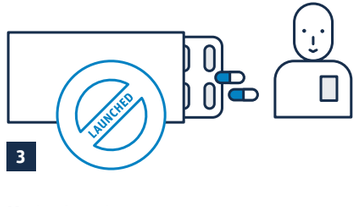
How does a new drug enter the market?

1

Testing
Drugs are tested for efficacy, safety, and technical quality before being submitted for approval. This includes required tests with cell cultures and animals, then on healthy individuals, and finally on patients.

2

Approval
Experts at the relevant authorities examine the results of all laboratory tests, animal tests, and studies as well as the technical quality (e.g. purity) of the drug. If the result of their review is positive, the drug is approved.



3

Market launch
The drug enters the market and can be prescribed to patients. Doctors, manufacturers, and authorities monitor for any possible, rare side effects. The package insert is constantly updated.

4

Benefit analysis
A scientific review determines whether a drug has any additional benefits over and above comparable therapies as well as the extent of these additional benefits.

5

Price setting
Within six months after receiving a decision in direct negotiations with the National Association of Statutory Health Insurance Funds, pharmaceutical companies must agree on a SHI refund as the discount on the pharmaceutical manufacturer price for drugs that have been deemed – through a benefit analysis by the Federal Joint Committee (G-BA) – to have an additional benefit as well as for drugs that have no additional benefits and cannot be assigned to any particular reference price group.

Source: vfa