

informedhealthonline.org

INDEPENDENT, OBJECTIVE AND EVIDENCE-BASED

What is “off-label use”?

Off-label use is non-approved use. It is the use of a medicine for a purpose or indication for which it has not been licensed by the country's medicine authorities (such as the Food and Drug Administration, FDA (URL: <http://www.fda.gov>) , in the USA).

Off-label use is non-approved use. It is the use of a medicine for a purpose or indication for which it has not been licensed by the country's medicine authorities (such as the Food and Drug Administration, FDA (URL: <http://www.fda.gov>), in the USA).

Every medicine that you can buy from a pharmacy or drugstore must have been assessed and licensed. In Germany the authority is the "Bundesinstitut für Arzneimittel und Medizinprodukte" (BfArM (URL: http://www.bfarm.de/EN/Home/home_node.html) - the Federal Institute for Drugs and Medical Devices). The European-wide licensing authority is called the European Medicines Agency (EMA) (URL: <http://www.emea.europa.eu/>).

A single medicine could be used for a variety of illnesses or groups of people, for example children and adults. The manufacturer needs to apply for the authority's approval for each condition and each patient group. But there is no obligation on manufacturers to apply for the same approvals for their products in all countries. That means that particular medicines can be licensed for a particular indication in one country (country A), but not another (country B). If a person in country B is prescribed that medicine for that purpose, then they are using the medicine off-label.

When doctors prescribe a medicine off-label, they might face liability problems, especially if there are serious adverse effects. For this reason, doctors' organisations are careful about recommending off-label use, and usually rely on some kind of formal guideline or recommendation process to guide off-label prescriptions.

If a patient is receiving a medicine off label, she or he needs to be informed that the use is off-label, and of the possible consequences. Patients need to be informed that there is uncertainty, and that medicines that are used off label may not have been tested as much for that purpose. Another consequence is that an individual may have to bear more costs for an off-label use of a medicine than they would for licensed indications. In Germany, the decisions of health funds on whether they take over the costs depends on factors such as:

1. Seriousness of the illness
2. Availability of other treatments
3. Reasonable expectations that the treatment might be effective (according to BfArM)

If you, a family member or friend want to use a drug off label, please check the potential adverse effects carefully. Check with your pharmacy or health fund to see if the costs will be covered.

Glossary

off-label use

Off-label use is non-approved use, which means that a drug is used for an illness or disease for which it has not been licensed by the country's medicine authorities – for example, a drug that has been tested and licensed for treating people with blood cancer is also used for treating people with stomach cancer. When a doctor prescribes a drug off-label, the question arises of who is liable for possible adverse effects. Usually, liability lies with the manufacturer of the medication. Patients need to be informed about possible consequences. In Germany, health insurances cover the costs for an off-label use of a drug only in exceptional cases. Find out more: [What is "off-label use"?](#)

Sources

The German Institute for Quality and Efficiency in Health Care (IQWiG)

The German Institute for Quality and Efficiency in Health Care (IQWiG) was established by legislation to provide evaluations of the effectiveness, quality and efficiency of healthcare services. This includes the assessment of medicines as well as the publication of health information for consumers and patients.

Evidence basis of our health information

Our information is based primarily on systematic reviews of the effects of health care. Systematic reviews are necessary to gain an objective picture of health care. In order to do this, a clear question is formulated. Researchers then find all the relevant studies that could answer this question. They then evaluate those studies.

You can find a list of the evidence and other scientific literature on which this information is based at **www.informedhealthonline.org**

Disclaimer

This information was prepared and published by the German Institute for Quality and Efficiency in Health Care (IQWiG). It is based on the evidence and other scientific literature available at the time of publication. The information is intended for the use of patients in Germany. It is not intended to for use to diagnose illnesses and the information is not intended to substitute for medical advice.