
WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

Switching around the world: Germany

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Germany is the leading European pharmaceutical market, with 26.4% of all European pharmaceuticals sales taking place in Germany. Interestingly, the two leading countries, Germany and France, make up about 45%.

In the two categories of non-prescription and self-medication products, Germany has a market share of about 1/3 each. The European market in both categories is concentrated in four countries (Germany, France, the UK and Italy), which together hold about 75% of the European market.

1998 German market

The German market shows totally different aspects if considered in value on one hand and in selling-units on the other. As far as value is concerned, Rx-products have a market share of about 70% and OTC-products only about 16%. This picture changes significantly if selling units are concerned. Here OTC-products are number one with 41%. This shows the significant importance of self-medication products in our society. Every package unit is a contact to a patient, and thus there are more contacts for self-medication products than for Rx medicines.

Switch-climate in Germany

The switch climate in Germany is traditionally very liberal. This is also demonstrated by the high market share of package units in self-medication.

Many medicines which up to now are prescription-only in other countries, were never Rx in Germany. Examples are the indication of rheumatism for oral acetylsalicylic acid; the indication of prophylaxis against heart attack, also for oral acetylsalicylic acid; the indication of vaginal mycosis for nystatin; and the indication of heart insufficiency according New York Heart Association Type II (NYHA II) for hawthorn. Although these products were mainly prescribed by doctors in the past, there were no reports about risks even though the market share in self-medication is more or less unknown.

Additionally, Germany has been rather successful in switches. Nearly all the main switch candidates have now been switched successfully in our country. Sometimes we even have been among the first three countries in the world. But every switch requires a deep and thorough scientific discussion. A switch procedure is never automatic in our country.

The definition of Rx in the German Medicines Law

§ 48 of the German Drug Law provides a definition of prescription-only conditions in Germany. Rx conditions have to be established for medicines:

- when even under correct use directly or indirectly jeopardise human or animal health, if they are administered without medical, dental or veterinarian supervision or
- which are frequently administered in considerable quantity not for the intended purpose, if they may thus lead to a direct danger to human or animal health.

The underlying principle is that every Rx-to-OTC switch is a case by case decision considering

- risk / benefit-evaluation
- estimation of the consumer's ability to treat him/herself.

It is important to mention that the decision is not related to other factors such as for instance reimbursement conditions.

Criteria for an Rx-to-OTC-switch

The examination of a Rx to OTC-switch application is done under four main criteria.

1. The first criterion is efficacy. The two questions being asked are:

- Is the medicine effective?
- Is it adequate for self-medication?

2. The second criterion is safety

Under this headline, general pharmacology and toxicology, severity and frequency of side effects and the possibility of misuse and dependency are examined. Points of consideration in this respect are: Is the patient's knowledge about the illness, about the symptoms of side effects and about the contra-indications high enough?

3. The third criterion is experience

The experience in the practical use of the medicine, if available in self-medication use, is considered.

4. The fourth criterion is a clear and understandable package leaflet in consumer terms as the basis for all information about the product.

The examination in detail of a switch application follows the criteria laid down in the EU guideline on changing the legal classification, dated September 1998.

The switch procedure in Germany

In Germany, we have a clear switch procedure.

1. The first step is an application via a pharmaceutical company to the Federal Institute for Medicines and Medical Devices (BfArM).
2. The second step is the check of the application by the BfArM
3. The third step is that the BfArM puts the issue on the agenda of the prescription committee with a proposal for a decision.
4. The fourth and most important step is a discussion in the prescription committee followed by the committee's decision. The decision of the committee may be acceptance or rejection of the application, and in some cases, the subject is postponed to the next meeting.
5. Step five is the submission of the decision to the Minister of Health, who is empowered to set the decision in force.
6. Step six is the publication of a draft order, including the transformation of the committee's decision.

7. Seventh and final step is the publication of the order in the Federal Law Gazette, after which the order comes into force.

Rx to Switch target time table

The target timetable of the switching procedure in Germany is also very clear.

Two meetings of the prescription committee are held per year. These two meetings are, in most cases, in the third week in January and in the fourth week in June. Therefore, March 15 and September 15 are the deadlines for the filing of the application to the authority, accompanied by the complete documentation.

After a decision in favour of a Rx-to-OTC-switch is made in the committee, the procedure to set into force needs another half year. The effective date will thus be January 1st and July 1st.

Provided a decision is not postponed in the prescription committee, the whole procedure needs a minimum of nine months for an Rx-to-OTC-switch in Germany.

The Expert Committee on Prescription

The German Expert Committee on Prescription, as the main body to make decisions on Rx-to-OTC-switches, consists of 15 voting members.

- five members are coming from universities.
 - three from pharmacology
 - one from medical statistics / epidemiology
 - one from pharmacy
- six members are practitioners:
 - one general practitioner
 - one for internal medicine
 - one paediatrician
 - one dentist
 - one veterinarian
 - one *Heilpraktiker* (natural practitioner)
- four members are delegated from "interested parties":
 - one pharmacist
 - one for the veterinary pharmaceutical industry
 - one for the human pharmaceutical industry.

The decisions in the committee are made by a majority vote of the members attending the meeting. No written votes are expected.

The most significant switches in Germany

About 60 switches from Rx to OTC were achieved in the last 20 years.

My selection of the most significant switches in our country is:

1989 ibuprofen – the first "big" switch of a new substance

1992 aciclovir – an example of an active treatment in a new OTC indication (herpes simplex / cold sore) and Germany was Nr. 2 in the world (after New Zealand) to switch this substance

1994 nicotine patch and gum – the most significant issue with this switch was the long discussion about the medical and social justification. Smoking cessation was considered by many to be a “lifestyle” and not a “medical” indication

1994 clotrimazole against vaginal mycosis – the first active switch into an indication defined as “collaborative care”

1996/1997 hydrocortisone and beclomethasone – the switch of a corticoid was a “big jump over a high hurdle” in Germany.

Do we already have collaborative care?

After the definition of the EU-Council of Health in their “programme of community action on health promotion” collaborative care is defined as:

“after initial diagnosis and prescription, self-medication is possible with the doctor delegating control while retaining an advisory role”.

In addition, there are also WHO guidelines with similar definitions.

The European Union and WHO with their definition are opening a discussion for an expansion of the boundaries of self-medication to areas which were formerly the domain of doctors prescription and supervision.

Self-medication in these new areas and indications is justified provided the patient has an adequate level of information and education. In Germany, collaborative

care is not an official political issue, but in practice we already have it in some cases.

Examples:

- Rheumatism – treated with oral acetylsalicylic acid or external non-steroidal anti inflammatory drugs
- Herpes labialis (cold sore) – treatment with e. g. aciclovir
- Vaginal mycosis – treated with clotrimazole, miconazole, and nystatin.

Conclusions for the Rx to OTC-switch climate in Germany

1. Germany is a country well developed for self-medication
2. Germany has a well-structured Rx-to-OTC switch procedure
3. A switch of new substances into already established OTC-indications is possible
4. An Rx-to-OTC switch for new indications is very difficult. Excellent consumer research is necessary
5. There is only little political support for switches
6. The principle of collaborative care is not yet implemented - despite already existing examples

