
EXPANDING THE BOUNDARIES OF SELF-MEDICATION IN A GLOBAL CONTEXT

Rx-to-OTC switch: a global perspective

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The global-perspective scenario for the Rx-to-OTC switch is that self-medication should be generally possible for minor illnesses and for chronic or recurring illnesses which are well known to the patient. There should be no differences between countries.

The question is whether harmonisation has already been reached or whether further harmonisation of self-medication is necessary.

The table below shows an overview of about 40 substances / products in four countries which are important for self-medication in the world. It is clear that a great deal of harmonisation has already been achieved for quite a few of substances but that other substances still present a totally different pattern.

The question is whether we really have a global perspective for self-medication. The conclusion from these tables is that:

- more and more substances succeed to switch from Rx to OTC worldwide
- more and more initiatives are addressing the Rx-to-OTC issue worldwide
- harmonisation still has not been reached
- the level of Rx to OTC in different countries is still not the same.

What are the differences in Rx to OTC status from country to country?

1. Different traditions
2. Different situations for initiating a switch
3. Different procedure
4. Different political support

5. Different level of information / education of the patient

What can we do to improve the situation for the switch of Rx to OTC in different countries?

1. Different traditions

Tradition is individual per country. Tradition helps to find individual arguments for the communication in switching procedures. Companies and other interested parties should carefully check what influence the tradition in their country has and how to put the right arguments from the traditional source and knowledge.

2. Different situations for starting a switch

A switching consciousness started to develop in many countries in the world in about the 1980s. Owing to different traditions in these countries as well as the differences in information levels of the patient, it is obvious that the starting point for switches is different.

But, the more countries having been successful in switching the better the start in remaining countries.

Why? There is much to learn from the experience with already switched substances and products in another country. To make the best use of information an international network is important and should be encouraged.

3. Different procedure

A number of countries where successful switches were achieved in the last decade have an established switching procedure. Examples are the United States, the United Kingdom, Germany, and also Spain and Mexico. It is obvious that a well-established switching procedure is a basic requirement for a successful switch. Therefore, my recommendation is to ask and to fight for a transparent

switching procedure. The EU switching procedure is a good example.

- Medicines are divided into two categories: Rx and non-Rx
- It is very important that the European Union only provides a definition for Rx products (according to Council Directive 92/26/EEC), meaning that non-Rx products are not specifically defined and therefore non-Rx is the default classification.
- A change of classification whether from Rx to OTC from OTC to Rx, is generally possible upon the decision of an authority (Ministry, Parliament).

The requirements for these decisions are laid down in an European Union Guideline. It is also a big step forward that this guideline defines only risk/benefit criteria. No other issues such as reimbursement status should be the subject of an assessment.

In order to concentrate resources in industry and the authorities, a clear timetable seems to be mandatory. But so far, timetables have only been implemented only in the UK (12 months) and Germany (9 months).

4. Different political support

Another important reason for differences in the Rx-to-OTC switching procedure in different countries is the different level of political support. Moreover, there is already strong political support on a supranational level

- from the World Health Organization (WHO)
- from the EU's Council of Health Ministers.

One outstanding example for political support for self-medication is laid down in the "Programme of Community Action on Health Promotion" adopted by the EU's Council of Health Ministers in 1995, and thereafter also adopted by the European Parliament in 1996. As far as self-medication is concerned, the programme states that:

"The increasing trend towards the use of over the counter medicines is partly a result of people's desire to take responsibility for their own health

Sensible self-medication may help to reduce health expenditure by cutting the number of medical consultations

The trend towards self-medication must be accompanied by a strengthening of information

Self-medication is of particular benefit in the treatment of minor ailments and can provide relief from these for the persons concerned

The public must be made aware and properly informed of the need to consult a doctor if symptoms persist or doubts exist."

In very similar words, political support was given by the World Health Organization in its "Guidelines for developing national drug policies" (first adopted in 1995), which states that:

"Self-medication is widely practised for the prevention or treatment of minor ailments or symptoms which do not justify medical consultation. Responsible self-medication can:

- help prevent and treat symptoms
- reduce the increasing pressure on medical services

- increase the availability of health care
- enable patients to control their own chronic conditions."

The criteria for selection are common for all and should be based on demonstrable efficacy:

- the criteria and process should be transparent
- products should include complete information
- attempts should be made to ensure the appropriate use of self-medication.

In my view, this political support from the European Union and the WHO gives an excellent entree for collaboration with:

- governments
- doctors/ doctors' associations
- pharmacists / pharmacists' association
- patients and consumers

in order to facilitate Rx-to-OTC switches and to give self-medication a more prominent status in countries' healthcare.

A very interesting development in the past years was the additional political support for the expansion of self-medication for all switches resulting in indications previously not available for self-medication. Again this political support came primarily from the EU Council and the WHO.

The EU Health Council said in its above-mentioned Community programme on health promotion:

"After initial diagnosis and prescription, self-medication is possible with the doctor delegating control while retaining an advisory role such as in the case of diabetes and asthma.

Information must be easily accessible and understandable."

The WHO, in their programme for developing national drug policies, said exactly the same in different words:

"In some chronic or recurring illnesses, after initial diagnosis and prescription, self-medication is possible with the doctor retaining an advisory role."

This new field of self-medication is commonly called "Collaborative Care", meaning:

- Diagnosis and first prescription by a doctor
- Self-medication in following episodes.

A comparison of selected indications illustrates where this new approach of collaborative care seems to be justified.

- **Established self-medication:**

- cough / cold
- headache
- constipation
- diarrhoea
- interdigital mycosis

- **Collaborative care-indications**

- vaginal mycosis
- rheumatism

- prostatic hypertrophy
- elevated cholesterol
- oral contraception
- Crohn's disease
- peptic ulcer
- herpes genitalis
- gout.

The basic requirement for "established self-medication", and especially for the new field of collaborative care, is mentioned in the next point.

5. Different levels of information / education of the patient

The basic requirement for self-medication is information. Prof. Überla, the former President of the German Drug Authority, stated this very clearly in 1985:

"The limits of self-medication are knowledge and information of the consumer on the one hand, and the individual's ability of action on the other hand. The more informed and educated the consumer is, the more extensive the limits of self-medication can be drawn."

How do we get information about the consumer's education level?

Industry and our partners in healthcare should make every attempt to increase the level of information and education of patients as well as the general public about health issues, especially how to use medicines correctly.

The screening of consumer behaviour after a switch is necessary in order to get proof of the switch conditions. Patient studies after switching are also necessary to prove whether a switch was justified. Many studies have been conducted. I would like to give two examples of different types of studies.

Example one is a patient study for the indication vaginal mycosis. The switch applicant conducted a study before the submitting his switch application. This study showed that 80% of women with vaginal mycosis suffer repeatedly from this disease – and had a previous diagnosis by a doctor. 90% of patients reported that the symptoms are always similar and many women hesitated for one week before consulting a doctor.

Ingredient	F	UK	I	D
<u>Analgesics oral</u>				
Acetylsalicylic acid	+	+	+	+
Paracetamol	+	+	+	+
Ibuprofen	+	+	+	+
Ketoprofen	+	Rx	Rx	Rx
Naproxen	Rx	Rx	Rx	Rx
<u>Antirheumatics topical</u>				
Ibuprofen	+	+	+	+
Piroxicam	Rx	+	+	+
Diclofenac	+	+	+	+

The switch application was sent to the German authorities as well as to those in other countries like the UK and the US. The switch application was adopted and the product was released from prescription control with certain limitations on pack size and duration of treatment.

Some years later, the same company conducted another study in order to examine whether the switch was justified or not. The results were that 97% of women reported relief of the symptoms after 4 days, and that 90% of women were satisfied with the OTC treatment. The question what to do when the next episode occurred was answered as follows: 88% of women would again practise self-medication and 12% would visit the gynaecologist.

The second example is a self-medication study with more general aspects. The main results of this German self-medication study were that:

- 76% of the German population buy the medicine previously recommended by the doctor.
- 65% have a good or very good knowledge about medicines.
- 97% go the doctor believing they are seriously ill. This trend has increased over the last few years.
- Only 8% do not read the package leaflet, the trend for this figure being on the decreased in the last year.

Rx-to-OTC outlook

The major trends for the future are that:

- Self-medication will become more important
- The education level of patients / consumers will grow. Industry has the obligation to contribute significantly.
- Collaborative care will play a greater role, an adequate education level of the patients being even more important for this area of self-medication. And collaborative care has to be justified via patient / consumer research.
- The switching of substances / indications will, despite the international trend, remain a national issue in the coming years.
- In order to participate in the experience of other countries, an International Network seems to be essential for the success of Rx to OTC worldwide.

Ingredient	F	UK	I	D
<u>Laxatives</u>				
Bisacodyl	+	+	+	+
Lactulose	+	+	+	+
Sodium picosulfate	+	+	+	+
<u>Smoking Cessation</u>				
Nicotine gum	+	+	+	+
Nicotine patch	+	+	+	+
<u>Antihistamines</u>				
Diphenhydramine oral	+	+	+	+
Doxylamine oral	+	+	+	+
Terfenadine oral	n.m.	Rx	Rx	Rx

Ingredient	F	UK	I	D
Astemizole oral	Rx	Rx	Rx	Rx
Loratadine topical	Rx	+	Rx	+
Cetirizine topical	+	+	Rx	+
Azelastine topical	Rx	+	n.m.	+

<u>Cough/Cold</u>				
Dextromethorphan	+	+	+	+
Acetylcysteine	+	Rx	+	+

<u>Sympathomimetics</u>				
Naphazoline	Rx	+	+	+
Xylometazoline	n.m.	+	+	+
Oxymetazoline	Rx	+	+	+
Ephedrine topical	+	+	+	+
Pseudoephedrine	+	+	+	+

<u>Antifungals topical</u>				
Nystatin	Rx	Rx	Rx	+
Clotrimazole	+	+	+	+
Bifonazole	Rx	n.m.	+	+
Miconazole	+	+	+	+
Isoconazole	+	+	Rx	+
Ketoconazole	+	+	+	+

Ingredient	F	UK	I	D
Econazole	+	+	+	+
Terbinafine	Rx	Rx	Rx	Rx
Amorolfine		Rx		+

<u>Antifungals vaginal</u>				
Nystatin	Rx	Rx	Rx	+
Clotrimazole	+	+	Rx	+
Miconazole	+	+	Rx	+

<u>Gastrointestinals</u>				
Loperamide	+	+	+	+
Ranitidine	+	+	Rx	+
Famotidine	+	+	Rx	+
Domperidone	Rx	+	+	Rx
Sucralfate	+	Rx	Rx	Rx

<u>Antivirals</u>				
Acyclovir topical	+	+	Rx	+

<u>Corticosteroids</u>				
Hydrocortisone	+	+	+	+
Beclometasone (nasal)	Rx	+	Rx	+

+ = OTC / Rx = prescription only / n.m. = not mar-

