
WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

Chairman's introduction

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Good afternoon, ladies and gentlemen, and thank you very much for the opportunity to chair this seminar on switching principles and about the basic requirements for safety and efficacy of self-medication products.

Self-medication is a reality

In Germany last year more than 40% of all units of medicines were sold without a medical prescription and purchased directly by the patient. This figure was increasing for many years.

What is in my view the task of the regulatory affairs agency in this respect? The major responsibility of the agency is to assure safety, efficacy and quality of the medicaments in question for the benefit of the patient. In this connection, I will raise four questions.

1. What is the patient's benefit from self-medication?

A basic principle in a modern democracy is that people can do everything, which is not forbidden. Therefore, it's consequent for the patient to have access to medicines they are able to use safely.

A second principle is that people take over responsibilities. These two principles together lead to one of the megatrends of our modern life: People's desire to take over responsibility for their own health. Self-medication products are an important tool here. This trend may have some by-effects: Faster relief of symptoms of illnesses is one - if treated early enough. Another one is less time off work, the patient feels better. A third one is to save health costs. In all European economies (and I guess also in the world) the financial resources for health care are decreasing. In order to maintain a sufficient health system in the future the community services have to be concentrated. This also means more responsibility has to be

given to the patient, i.e. in addition to the possibility to go to the doctor he has to have the opportunity for self-medication in all justified cases.

It is your responsibility to supply the patient with products appropriate for self-medication and our responsibility to assure the suitability.

2. What is the patient's risk from self-medication?

Sometimes objections against self-medication are raised. The spectrum of objections is from general ones to more specific ones. A general concern raised mainly by medical doctors is the question if the patient has enough knowledge to interpret symptoms in self-diagnosis. Other objections are it is not sure whether or not OTC products are of comparable efficacy to prescribed medicine, people tend to overmedicate and ignore the instructions, and the information in the advertising may not be justified.

We, in the regulatory affairs agency, and you, in the pharmaceutical companies, have to take this arguments very seriously. Because if they were true the patient will be at risk. We have to do everything to avoid this.

We have to make sure that all medicines, whether Rx or non-Rx, meet the same high standards of quality, safety, efficacy and information.

3. What is the basic requirement for self-medication?

It is information, information, information, which needs to be communicated properly to the patient.

This is also emphasised by the EU's Council of Health in its Programme of Community Action of Health Promotion and Information, dated 1996. It reads:

"The trend towards self-medication must be accompanied by a strengthening of information measures. Thus giving people more choice and responsibility

must also involve ensuring that they are equipped to make sensible choices.”

A major instrument for information is the package leaflet. This underlies also our direct responsibility – in close cooperation with the pharmaceutical company. Both company and agency use this tool in order to give a full, comprehensive and clear information. The patient has a right to know everything not only about the benefits but also about the risks of a specific medicine. The public must also be aware and properly informed of the need to consult a doctor if symptoms persist or any doubts exist. In this respect also, advertising is playing an important role provided it is done properly.

I would like to encourage you to take all practical steps to inform the patients and the general public about the correct use of medicines. Don't forget modern media.

It is a function of information where the boundaries of self-medication are drawn. The boundaries can be expanded if the level of information and knowledge of the patient is raised.

A recent development is after the advice given by the WHO in their “Guidelines for developing national drug policies” to expand self-medication also to:

“some chronic or recurring illness, after initial diagnosis and prescription, with the doctor retaining an advisory role.”

Also, the EU-Council follows this approach to open self-medication to new indications where an initial diagnosis and prescription is required and afterwards the doctor delegates control to the patient while retaining an advisory role.

I know your name' for this approach is “Collaborative Care”. It's an interesting development. But steps in this direction have to be taken slowly and sensibly. Self-medication can loose much if the steps in this direction are going too fast and are not accompanied by adequate information level. Provided the information level is high enough, an Rx-to-OTC switch is justified in our view:

- if the illness has in general no tendency for a sudden worsening
- if the illness has the tendency to keep steady over a long time or, in the case of recurring diseases, the symptoms must be clear and always be similar
- the treatment regime is simple
- and the product has a wide therapeutic margin.

In Germany, we have only few examples of this part of self-medication up to now. One example is the OTC-treatment of vaginal mycosis by clotrimazole and miconazole containing products. They have been successfully

switched in 1994 under clear and strict conditions and limitations. Since that time, my agency has no information that any additional risks occurred.

4. What is the European switch climate like?

The regulatory system in today's world is to control only in cases where it is necessary and justified. Therefore, no regulation in the world denies the right for a company to apply for a switch. The agency, expert committees and government then check whether a switch is justified. Risk of the substance, the indication and the patient's ability to treat himself are the main points to consider. A switch should also be possible for newer substances, provided enough information is available.

But a switch could also be a reverse one if a product turns out to have new so far unknown risks. We have had some examples in the last years

The tools for managing switches are already available. Directive 92/26/EEC defines criteria when a product has to be classified as Rx. Non-prescription medicines are “defined” as the difference position to 100% of the market. In Germany, we adopted this system already more than 40 years ago, and our experience is good.

The EU's “Guideline for Changing the Legal Classification”, which is two years old by now, provides further explanations and the data requirements. In Germany, we have for a long time had a clearly structured procedure how to handle Rx-to-OTC switch applications, and – as I may add – vice versa. Our procedure also includes a time frame. The overall experience of this procedure is good.

5. Conclusion

My conclusions are:

- Self-medication is a need for the patient in our health care systems today
- Self-medication is a must for saving health costs
- A close control of self-medication products and the conditions of their use is absolutely necessary
- The boundaries of self-medication can be expanded, provided this is done slowly and sensibly, and under defined conditions
- The information level of the public needs to be improved constantly
- Under these conditions, Rx-to-OTC switches should be continued, preferably within a clear procedure.

