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# WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

## Basis for switching

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***It is a particular pleasure to have the occasion to give the first presentation at this conference in which WSMI and AESGP have invested a lot of time and effort. I hope that you will enjoy the event as well as the city and please do not hesitate to call upon all my colleagues at the registration desk if we can be of any service.***

It is not by coincidence that the topic of effective switching from prescription to non-prescription status has been put in the form of a pre-Assembly workshop at the beginning of this conference. Without question, the change of classification status has become one of the most important elements in the development of self-medication. Some call it the fuel for the development of the OTC market. For others, it is the logical consequence of the increasing willingness and capability of people around the world to take more responsibility for their own health, which needs appropriate adjustments in the regulatory environment.

At the eve of the new Millennium, it is evident that the experience with and the upcoming changes through health information technologies have a further impact on this area. As information on all medicinal products is becoming more easily available, a clearer concept for those medicines obtained without the obligation for a medical prescription is needed. However, not only the developments related to information technology and access to information have an impact in this context. The growing interest in direct-to-consumer advertising for prescription-only medicines will further question traditional boundaries.

Even without the increasing role of health technology, we have seen hundreds of changes from prescription to non-prescription status all over the world which have considerably changed the face of self-medication. In all the debates, there has been one common element to determine

the status and this is safe use without a medical prescription. Various efforts have been made to formalise the requirements for the legal classification and for the change from prescription to non-prescription status. The most important pre-requisite is a clear definition of the classes, and it has turned out that the best approach to do this is to clearly define the prescription only status of medicinal products. In spite of quite a few differences between the United States and Europe in the OTC market, there has been a very wide consensus on this point for many years, resulting in similar legal requirements on both sides of the Atlantic.

Let me just briefly remind you of the requirements related to prescription-only status in the European Union, which have been laid down in the directive for the classification of medicinal products adopted by the European Union's Council of Ministers in 1992.

According to Article 3(1) of this directive, "a medicinal product shall be subject to medical prescription where

1. it is likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or
2. it is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health, or
3. it contains substances or preparations whose activity or side effects need further investigation, or
4. it is normally prescribed by a doctor to be administered parenterally."

It is important to note that the Directive does not say anything specific about self-medication. However, Article 4 states that all other medicinal products, not classified in the prescription category will be classified as non-prescription.

In spite of the Directive's positive impact, the situation in the European Union has remained unsatisfactory due to continuing differences between Member States and the

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still quite different detailed requirements remaining in force at the national level. Therefore, it was of great importance that the European Parliament expressed a clear view on future developments in a resolution for an industrial policy in the pharmaceutical sector in 1996, the relevant part of which reads as follows:

“[The European Parliament]

Considers that responsible self-medication should be further promoted, which will foster the growing desire of the European Union's citizens to take responsibility for their own health and to reduce health expenditure. In recent years, responsible self-medication has been identified as an important element in long-term health policy by the institutions of the European Community. As part of the process of improving the legal environment for non-prescription medicines, it will be important to establish more transparent procedures which define the method by which prescription medicines can be transferred to non-prescription status.”<sup>1</sup>

This political message has been taken up by the European Commission as well as the Member States and finally led in September of last year to the adoption of a guideline on changing the legal classification for the supply of a medicinal product for human use. The main purpose of this guideline is to clarify the regulatory requirements for carrying out a switch, and by that it complements the more basic legal requirements related to the classification status laid down in the above-mentioned directive.

This guideline is divided into two parts:

1. classification criteria
2. data requirements

Part One particularly elaborates the safety profile necessary for a medicinal product to move from prescription to non-prescription status by explaining in detail the directive's four criteria and clarifying what they mean for the applicant.

Part two looks at the data requirements which should, through an expert report, provide a critical analysis of the proposed availability of a product without a medical prescription with a dose and indications as stated in the application. Again, particular emphasis is put on the safety requirements while it is stated that the evidence of a product's efficacy is not normally considered when applying for a change in the classification unless this application also includes changes to the indications or posology. Throughout the document, references are made to the importance of comprehensive and well-understandable product information, an overall essential element for responsible self-medication.

Generally, we believe that the European Union now has an appropriate legal and regulatory framework for switching, and we will see during this year and the years to come what the concrete impact will be. Certainly, Europe will continue to learn from experience in other countries and therefore this meeting here today is a good

occasion to go through a benchmarking exercise and compare the situation in major European countries with developments in other continents, taking into account the growing interest within the pharmaceutical industry to get worldwide standards for the move from prescription to non-prescription.

It is very much in this context that AESGP and WSMI appreciate the initiative of the World Health Organisation to develop a worldwide applicable guideline for the regulatory assessment of medicinal products for use in self-medication. An informal consultation on this guideline was held in Geneva in mid-April, and WSMI had the occasion to send observers.

As far as we can judge the situation so far, the expected guideline could provide a reasonable basis with regard to the classification of medicinal products and the change of legal status on a worldwide level. The draft guideline will be forwarded to the WHO Expert Committee on the use of essential drugs in December 1999 for further discussions, and is therefore for the time being not yet available as a document upon which applications can be based.

Again, all these efforts to clarify the regulatory requirements related to switching are appreciated by our industry. However, the basis for switching is not only related to the regulatory considerations. Many other factors are of vital importance when deciding whether a switch application makes sense and what the impact of the switch will be.

The most important issue in this context is presumably that there should be no restrictions with regard to the use of trade names for medicinal products with different legal status. The principal argument against using the same brand name for both the Rx and non-Rx version of the same active ingredient is the risk that the prescription sales will increase as a result of the advertising linked with the launch of the OTC product. Thanks to some practical examples, AESGP concluded in its publication “The Value of the same Trademark for Medicines with a different Legal Status” that this argument is not sustained by facts.

Consumer-friendly information through leaflets and labels as well as the possibility to advertise in all media are important to make the public aware of a newly introduced OTC medicine. In this context, it should be kept in mind that the successful self-control instruments established in many countries around the globe are also competent for clearing the advertising of switched products. We remain convinced that the best way to inform the public through OTC advertising is to mention only the name of the product, the indication and an express invitation to read the label or the leaflet.

Concerning pricing, it is evident that existing price controls in a few countries around the world, including three European Union Member States, are an important disincentive for manufacturers of non-prescription medicines to carry out switches. It is virtually impossible, in particular in those countries where the price level is extremely low, to finance the communication to make people aware of a switched product.

All decisions with regard to reimbursement continue to be taken on a purely national level due to their strong

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<sup>1</sup> Resolution of the European Parliament for an industrial policy in the pharmaceutical sector adopted on 16 April 1996

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interdependence with the social security system. It is however evident that reimbursement considerations are often influencing switch considerations although they may formally be separated from each other.

Most important for the success of a switch is certainly its appropriate presentation once a product is available without prescription. This means in many countries, particularly in Europe, that there is a need for good or improved visibility of self-medication medicines within pharmacies. This should be seen as a natural and logical part of the movement towards more consumer orientation in the pharmacy and as giving customers wider possibilities and also control over the management of their health. Evidently, this should not be seen as diminishing the role of health professionals, including in particular the pharmacists.

Indeed, the attitude of health professionals is the last but certainly not the least important element I would like to mention in this context. Based on comprehensive information for doctors and pharmacists the OTC manufacturers are certainly pleased to provide, the guidance medical doctors and pharmacists provide to the public is extremely important to make a switch a success. It is also very much in this context that AESGP appreciated the signing of a charter of collaboration with the European Pharmacists Organisation, PGEU, back in 1993. This has been followed up on the European level by a common position as well as the publication of a joint brochure on self-medication agreed between the Standing Committee of European Doctors and AESGP. On the

worldwide level, we will see during this conference the signing of a similar document between the Worldwide Pharmacists' Organisation, FIP, and WSMI. Very fruitful discussions are also ongoing between the World Medical Association and WSMI.

For the future perspectives of switches, it seems important to embark on an open-minded discussion on the suitability of indications that go beyond the traditional concept of self-medication related to minor and self-limiting illnesses. The capability and willingness of people around the world to take more responsibility and the ongoing pressure on the budgets of the social security systems have already inspired a debate to what extent certain indications requiring an initial medical diagnosis might also be suitable for self-medication once the patient has become fully informed about the disease. This may be particularly true for recurring illnesses without a life-threatening character but which need permanent management by the sufferer. The organisers of this meeting hope that this issue can be further discussed this afternoon as well as in different presentations over the next few days, and we think that it is also worth embarking on a kind of brainstorming when the regulators sit together on Saturday morning.

We do not expect to reach any final conclusions at this meeting, but we would be happy if we could get more understanding for the consideration that the need for an initial medical diagnosis and the availability of a medicine as non-prescription are not mutually exclusive.

