
CONCLUDING PERSPECTIVES ON SELF-CARE IN HEALTH POLICY

Closing remarks

Dr Gerhard Stummerer, President, Association of the European Self-Medication Industry (AESGP)

Let me briefly summarise the results of this session on the eve of the new Millennium with all the upcoming changes related to the information society. As shown in the most recent edition of our book “Economic and Legal Framework for Non-Prescription Medicines”, the regulatory framework for self-medication has made a lot of progress both inside and outside Europe. However, the economic development of the OTC market has been behind the development in the prescription medicines market, but also behind the development of healthcare products in general. To really activate the economic and social benefits of responsible self-medication, we have to make additional efforts. We put together a master plan in the form of our document entitled “Guiding Principles in Self-Medication”, which we see as our worldwide credo on how to make progress to provide better service to the people. Hopefully this document will create a better understanding of the most important regulatory conditions.

On the European side, the problems are of a more specific nature. The publication “Deregulation 2001 – The future of medicine regulation in Europe: To create an efficient system for self-medication” which AESGP launched at a Members’ Meeting in January 1999 near the premises of the European Agency for the Evaluation of Medicinal Products, provides the recipe for the European application, taking very much into account the need to

improve the European marketing authorisation system for non-prescription medicines. The functioning of the so-called mutual recognition procedure is far from being ideal and we very much hope that the principles embodied in the legislative provisions are finally put in reality. Particularly important would be a clarification of what constitutes a serious public health risk, which the EU legislation defines as the only reason not to practice mutual recognition.

We have noticed with interest the progress made in the area of herbal medicinal products, on the scientific as well as on the legislative side. AESGP is pleased with the reactions on the study we carried out for the European Commission on herbal medicinal products, which provides more transparency on the situation in Europe and we hope that with the support expressed by the European Commission and the European Parliament, we can really come to a European herbal medicines’ market. If a pragmatic system e.g. through monographs or standard authorisations can be established, I think everybody will support it.

In the area of switching we have made considerable progress in the European Union by the adoption of the new guideline on the change of classification status. We will monitor with great interest how this guideline is used in reality and to what extent it will facilitate and also harmonise the move from prescription to non-prescription status. Those of you who had the occasion to participate in the Pre-Assembly workshop on Wednesday afternoon have certainly realised how much the situation has changed in this area over the last years and how the availability of non-prescription medicines has indeed improved for people around Europe. In the future, I assume that we will have more debates on new indications suitable for non-prescription medicines in line with the concept of collaborative care. It is my feeling that more and more people understand that the need for an initial medical diagnosis and the availability of medicine as non-prescription do not exclude each other.

In this context, one of our major problems are the current restrictions with regard to tradenames. We have appreciated the efforts made by the European Commission to get clarification, at least for the issue of tradenames related to products moved from prescription to non-prescription status and were very disappointed that a few Member States were not prepared to accept this. We still very much hope that consensus will be possible in the European Union to come to a reasonable system for the whole continent. Maybe the Regulators' Forum tomorrow morning is an occasion to create a better understanding for the importance of this issue and also for the use of the same tradenames for different forms of non-prescription medicines, an area often described as umbrella tradenames.

Pharmaceutical regulation is the result of a complex procedure involving all stakeholders and in particular also the health professionals. Therefore we have seen with great satisfaction that the charter of collaboration of the European pharmacists' organisation, PGEU and AESGP which was signed six years ago has led to most interesting projects such as, for example, in the area of telematic systems. We still hope to create a better understanding with our friends and colleagues in the pharmacist organisations for the need to better present OTC medicines in pharmacies.

Last year's AESGP Annual Meeting saw the presentation of the joint brochure on self-medication between the Standing Committee of Medical Doctors and AESGP which was supported by the European Commission and which has now been distributed in all 11 EU languages. I personally feel very much encouraged by the words of the representatives of the World Medical Association, Dr Anders Milton and Dr Delon Human and I am pleased to see the very concrete co-operation we have established for example in the area of smoking cessation.

Many challenges remain ahead of us. AESGP believes it is well prepared for the debates in relation to information technology and that it has a very reasonable policy for areas such as electronic commerce. While we fully respect the particularities of the medicinal products we produce, we have to monitor carefully that the European Union is not putting itself in an disadvantageous position with regard to other countries inside and outside Europe. We are very well aware of the potential dangers which the new possibilities may bring with them, but all debates have shown that straightforward bans will hardly be the winning concept for the future.

In this area, but also in other areas such as food supplements, our overall objective is to find a balance between the need for consumer protection and freedom to

act. The upcoming proposal of the European Commission for a directive on food supplements will draw particular attention in our organisation. Together with the debates related to functional food and fortified food, it will be our overall strategy to ensure that products with a nutritional value can be bought on the marketplace with claims related to health once they have proved their safety. Products with medicinal claims, but also products which are clearly taken with a therapeutic purpose, should be classified as medicinal products requiring a marketing authorisation procedure, which of course may be adjusted to the long-term or traditional use. This kind of balance will certainly require very intensive debates and AESGP is prepared to fully participate in the whole process. In this area, certainly Mr Patrick Deboyser, the new head of unit Food in the European Commission, will play an important role. It is an occasion to thank Mr Deboyser for the ten years of constructive dialogue, first as administrator, then as Deputy Head of Unit and finally as Head of Unit Pharmaceuticals and Cosmetics. We are a little bit proud of the fact that the first public meeting Patrick took part in after he entered the pharmaceutical sector was the AESGP Members' Meeting in January 1990 in Bonn and that his last one, at least for the moment, is our Annual conference. I am sure the choice of the European institutions could not have been better and I wish you, Mr Deboyser, and your new team all success for the important work to come in the field of food products. As you may imagine, you will not really get rid of us in light of our particular interest in the above-mentioned dossiers.

At the end of this session, I would also like to express my gratitude to all persons who helped to further develop the concept of self-medication and all who made this conference a success. In particular, I would like to express AESGP's and my personal thanks to the departing chairman of WSMI, Mr Anthony Jamison. He is a person who has made a great contribution to the ideas and ideals of self-medication in Europe and throughout the world. He was President of AESGP from 1981-1984 and has been President of Roche Consumer Health since 1991. Tony, we do not only wish to remember you, but to see as a guest and adviser at future events.

We are coming to the end of this morning's session. However, tomorrow morning we will have an important forum with representatives of regulatory authorities to digest the messages of this conference and we are very much looking forward to this. There will be a Round Table for the representatives of the authorities and a few industry spokespersons. Let me now thank all the panelists of this morning and all of you for your attention.