
EXPANDING THE BOUNDARIES OF SELF-MEDICATION IN A GLOBAL CONTEXT

Chairman's introduction

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This third session will provide examples of how to expand the boundaries of self-medication in a global context, with contributions mainly from the United States, Europe and Japan.

My name is Fernand Sauer and I am the Executive Director of the European Agency for the Evaluation of Medicinal Products (EMEA) created in London some five years ago. In my introduction, I would like to address the following points.

Globalisation

As far as registration requirements are concerned, great progress has been made, especially between the European Union, Japan and the United States in the last 10 years. I am very pleased that the World Self-Medication Industry (WSMI) was able to participate in the process in recent years.

In this same place, six weeks ago, we discussed the outcome of harmonisation of registration requirements with more than 100 different Drug Regulatory Authorities from all over the world at the International Conference of Drug Regulatory Authorities (ICDRA) with the participation of Dr Brundtland and WHO. I am sure that, for all of us, the new brochure "Guiding Principles in Self-Medication" will be a source of inspiration for other aspects of globalisation. The European Agency for the Evaluation of Medicinal Products (EMEA) is itself part of this globalisation effort of drug registration. Its success is recognised worldwide, as is that of the global European marketing authorisation system which encompasses not only the EMEA but also the mutual recognition of registration procedures between national authorities.

Collaboration with AESGP

The Association of the European Self-Medication Industry (AESGP) is a strong and reliable partner as an

"EMEA interested party" alongside the other interested parties which are in constant dialogue with the European authorisation system such as consumers, pharmacists, doctors and the research-based industry.

In the last 12 months since the AESGP Annual Meeting in Athens, there have been several developments in the EMEA's cooperation with AESGP which I would like to address.

- We had a very important "Information Day" in Canary Wharf on 28 January 1999 to discuss the AESGP publication "*Deregulation 2001: The Future of Medicine Regulation in Europe*". Clearly, the OTC industry in Europe is interested in the "revamping" of the mutual recognition process but also in the possibility of having direct access to the so-called centralised procedure run by the EMEA. We are looking forward to discussing these proposals further.
- At a further meeting at the EMEA in March 1999 chaired by Dr Bangemann, AESGP and other interested parties were there when Dr Bangemann launched the 12-month view process of the current registration procedures which will end in 2000 and possibly come forward with proposals to rebalance the whole system. AESGP's suggestions will be an important part of the discussions.
- There was a special wish from the self-medication industry vis-à-vis the EMEA to make the *EMEA Ad hoc working group on herbal medicinal products* a permanent feature of the European Agency for the Evaluation of Medicinal Products. As you know this is not our core business as we are normally engaged in high-tech products. However, we thought that it would be important to prevent any conflicts between Member States in such an important area as herbal medicinal products. The good news is that the EMEA Management Board was convinced by this argument and on 10 February 1999, upon my proposal, decided to make herbal medicinal products the subject of a

permanent working party. Professor Keller will later this afternoon address the new orientations of the working group.

- Another very important issue is the **enlargement of the European Union**. Close partnership with the countries of Central & Eastern Europe started concretely in December 1998 with the signature of an agreement between the EMEA and the so-called 11 CADREAC countries of Central & Eastern Europe about the recognition of centrally approved medicinal products within a rather shortened time period of 90 days. This has been very successful and the agreement works well. The EMEA has of course to provide these countries with all pharmacovigilance data which might be generated.
- More recently, the EMEA has been asked by the European Commission to conduct an important initiative called the **Pan-European Regulatory Forum (PERF)**. A first meeting of the PERF Steering Committee will take place in Brussels in July and will decide on the priority topics for an intense 10-month programme with many meetings being organised both in the EU and in Central & East European countries. On that occasion, we decided to cooperate with the AESGP to co-sponsor the major event of the PERF programme, i.e. an open conference of possible 500 delegates to be organised in one of the Central & East European countries, probably in January 2000.
- This a good example of concrete cooperation based on the good knowledge AESGP has developed over the last 10 years of relations with Central & East European countries. On this occasion I would also like to pay tribute to Jasmina Mircheva who, working at the AESGP, has acted as a special advisor on this programme to the EMEA.

The programme this afternoon will not dwell on registration aspects but more on other relevant topics. It will go into the impact of creating global brands and its influ-

ence on the future of OTC marketing and regulation; the impact of changing legal status and distribution channels in Japan; recent developments and whether there is a trend towards the globalisation of self-medication, including the critical factors; the outcome of the switching workshop held on 9 June as part of this meeting; the specificity of internationalisation of herbal medicinal products; and as the last topic, "Don't forget the consumer."

Farewell to two trusted partners

The EMEA and the AESGP are both going to miss Dr Martin Bangemann for the help and support he has always provided us. I would also like to pay my personal tribute to his influence as an initiator of pharmaceutical harmonisation in Europe and in the world, as a strong negotiator in Council and Parliament and as an enforcer at the top of the Commission. We are very grateful for his role in shaping the European marketing authorisation system and in the creation of the European Agency for the Evaluation of Medicinal Products.

Over the last 10 years, there have been dramatic changes for OTCs in the European Union, and Patrick Deboyser, Head of Unit Pharmaceuticals and Cosmetics at the European Commission, has been an initiator of many new trends such as harmonisation of patient information, classification into OTC or prescription-only medicines, the advertising directive and, more recently, the 1998 switching guideline. Now he himself has decided to "switch" to the food sector and we would like to wish him good luck. I very much enjoyed our direct cooperation over the last 10 years, both when I was in the European Commission and at the EMEA. I know that we will be able to count on him even in the future as he will be close by.

