European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

11 March 2005

Dr Hubertus Cranz
Director General AESGP
Association of the European Self-Medication Industry

Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Fachverband der Arzneimittel-Hersteller

European Medicines Agency
Celebrating Ten Years: 1995-2005

London, 11 March 2005

Statement by Dr Hubertus Cranz
Director General AESGP

Congratulations to all those who were preparing and building the EMEA over the last decade and who made it one of the most respected agencies inside and outside the European Union. For the European self-medication industry, this symposium is the occasion to congratulate the Agency on its achievements but also to welcome the new areas the EMEA is now covering.

Following the recent adoption of the EU's revised pharmaceutical legislation, important new elements are about to be put in place which will considerably change the regulatory environment for non-prescription medicines.

First of all, the new provisions make it clear that innovative non-prescription medicines will have the possibility of getting an authorisation through the centralised procedure coordinated by the EMEA. This has the potential of increasing the availability of new self-medication medicines.

By that, those who govern the EMEA have shown the capability of responding to important trends in our society. Many studies indicate that citizens around Europe are nowadays keen to take an active role in health and disease-related matters and that they look for more options in their desire to stay healthy or to treat illness. Policy makers are recognising that better health is

7, avenue de Tervuren • B-1040 Brussels • Belgium • Tel.: + 32 (0)2 / 735 51 30 • Fax: + 32 (0)2 / 735 52 22
E-mail: info@aesgp.be • http://www.aesgp.be

hardly possible without more individual responsibility. How to actively support the move from being an informed patient to becoming involved in the decision-making and finally to being really engaged in health and disease-related matters becomes more and more part of the political debate.

To practise responsible self-medication one needs high quality medicines with an adequate safety profile making them available without a prescription. What is seen as an acceptable indication for self-medication has considerably expanded over the last years. In many countries around the globe, there is a clear move from not only accepting self-medication for minor diseases towards supporting self-medication for the treatment and prevention of chronic conditions, often based on an initial medical diagnosis. Nowadays, the prevention of coronary heart disease and smoking cessation or the treatment of allergic reactions and mycosis are widely recognised as part of the concept of responsible self-medication.

Manufacturers committed to this area are in the process of getting familiar with the EMEA procedures. Provided that good solutions can be found for some pending issues – such as the use of invented names – applications will be filed and European citizens will have innovative self-medication medicines more quickly at their disposal. We are confident that at the EMEA the necessary expertise to deal with the particularities of non-prescription medicines will be available.

In spite of these exciting new developments, the area of non-prescription medicines will continue to be dominated by substances with a well-known safety and efficacy profile, which continue to be seen as the adequate treatment for many of our daily health problems. Often these medicines are produced by small and medium-sized enterprises (SMEs), which form a significant part of our membership.

Without forcing unnecessary harmonisation, the EMEA has shown its willingness to address areas within this field which were in need of more regulatory guidance. The most visible example is the work on herbal medicines. Already shortly after the doors of the EMEA opened an ad hoc group was installed, but it took almost 10 years to establish a real Committee for Herbal Medicinal Products (HMPC) which was inaugurated in September of last year. Thanks to all this good work, we are not really starting from zero, but the next 10 years will show if it is possible to create a true European herbal medicines market. The instruments are now in place, a lot of good will is being felt and – provided sufficient resources are supporting this endeavour – there is a good chance of making it a reality.

This will be of importance for the citizens of Europe who generally appreciate the availability of herbal medicines. It will however be equally important from an industrial policy perspective as it will strengthen the position of many small and medium-sized companies. Provided the scope of application can be well defined, the envisaged SME measures, e.g. with regard to scientific advice or fee reductions, will provide important additional help.

The EMEA is and will continue to be part of a network of national authorities which remain of particular importance for our sector. The mutual recognition system and the decentralised system have a good chance of working well in the future. Efficient interaction between national authorities is necessary to make further progress without imposing unnecessary regulatory burdens that would make future activity difficult for some of our member companies. The debates so far around the implementation of the EU's revised pharmaceutical legislation have been encouraging in that they show that appropriate solutions can be found in difficult areas. Therefore an overall good regulatory system is in the process of being further developed - with the EMEA in a central role - which has the potential of being of service to all medicine manufacturers, and above all to the citizens of Europe.