



Annual Report ^{2002/2003}

HIGHLIGHTS OF THE YEAR

Legislation, legislation...

The last twelve months were characterised by an unprecedented level of activity in the context of modifying and/or establishing pieces of legislation relevant for the self-care industry on the European level. In the pharmaceutical sector, debates were dominated by the revision of the regulation for the European Medicines Evaluation Agency (EMA) / centralised procedure and the codified text on pharmaceuticals for human use covering a wide range of legislative provisions including areas such as marketing authorisations, advertising, labelling and classification. AESGP was particularly active in the European Parliament up until the vote in first reading in October 2002, and afterwards with the Member States in preparation of their common position. Close contacts with the European Commission are ongoing.

Top goal: data exclusivity for switch

In a new and unique campaign for the self-care industry in Eu-



*AESGP President **Albert Esteve** welcomes the European Commission's Director-General Enterprise, **Jean-François Mingasson** at the **AESGP Annual Reception on 8 October 2002 in Brussels**, where the new European Commission's policy on data exclusivity for switch applications was unveiled.*

rope, AESGP advocated the establishment of data exclusivity provisions for scientific work around known substances. The European Parliament backed a three-year data exclusivity provision for new indications of known substances as well as for switch applications. As announced at the AESGP Annual Reception on 8 October 2002 by Jean-Paul Mingasson, Director-General DG Enterprise, the European Commission supported a two-year data exclusivity provision for switch applications and

defended this in the Council of Ministers Working Party. AESGP continues to argue that at least a three-year provision is necessary for switches and for new indications of known substances to initiate innovation in self-care.

Free movement of self-medication medicines

Through numerous discussions on the political as well as regulatory level, AESGP strongly argued in favour of a better functioning

of the mutual recognition system in the European Union to allow easier access for non-prescription medicines to all European markets. AESGP was pleased to see that both the European Parliament and the European Commission gave support to the establishment of guidelines to better define serious risks to public health, which are the only grounds that Member States can raise when not accepting the authorisation issued by the Reference Member State.

More freedom for advertising

As still quite a few countries in Europe do not allow public advertising for all categories of non-prescription medicines, AESGP appreciated modifications to this area suggested during the revision of the EU's pharmaceutical legislation. It is working with the member associations in the countries concerned to overcome such restrictions. This issue was also very much referred to in the so-called G10 Medicines recommendations, which were put together by a High Level Committee of health and industry ministers, the European Commission, patient and health insurance representatives and four representatives of the pharmaceutical industry including the AESGP President (Alessandro Banchi until 30 June 2002 and Albert Esteve from 1 July 2002 onwards).



Pictured at the **G10 Medicines Forum on 7 May 2002 in Brussels** (l to r): **Alessandro Banchi**, President of the Association of the European Self-Medication Industry, **Jean-François Dehecq**, President of the European Federation of Pharmaceutical Industry Associations, **Philip Hunt**, Parliamentary Under Secretary of State for Health, United Kingdom, **Françoise Grossetête**, Member of the European Parliament, Rapporteur for the European Parliament on the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, **Erkki Liikanen**, Commissioner for Enterprise and Information Society.

G10 supports switching

The G10 Medicines Group also suggested amending the switching concepts and procedures, which can be seen as support for the results of the study AESGP carried out for the European Commission with regard to new indications for self-medication. In particular, indications going beyond minor illnesses but often based on an initial medical diagnosis have moved to the centre of current considerations. Allowing the same tradename for medicines moved to non-prescription status was also part of the recommendations, and AESGP is working with all its members to make this a reality all over the European continent.

No price control for OTC manufacturers

Part of the G10 Medicines activities was a workshop in December 2002 involving all interested stakeholders to discuss ways to overcome price controls for manufacturers of medicines not reimbursed by the State. Without this freedom, manufacturers are not able to finance their communication activities, and an appropriate self-medication market cannot develop. Other G10 Medicines activities with strong AESGP involvement included the development of performance indicators ("pharma-barometers") to measure the competitiveness of the Europe-based pharmaceutical industry – including the self-care industry.

Umbrella tradenames

The use of the same tradename for different forms of non-prescription medicines is restricted unnecessarily in some European countries. However, European consumers are used to umbrella tradenames and no prohibition exists in the European legislation. There is even a balanced EMEA guideline for central authorisation. The emphasis of AESGP's work was and is therefore related to supporting member associations in their efforts to overcome national restrictions by sharing best practices and putting together a catalogue of arguments.

Herbal medicines in Europe

These activities were complemented by work on a new legislative framework in the European Union concerning traditional herbal medicines, which went through the European Parliament in first reading in November 2002 and which is now being discussed between the Member States. Complementing the status of herbal (and other) medicinal products of well-established use, a new category of traditional herbal medicines will lead to more clarity in the European legislation. It is of great importance for current but particularly also for future European Union Mem-

ber States. AESGP was particularly pleased to see the support of the European Parliament and the European Commission for a new Committee on Herbal Medicinal Products at the EMEA, which will inter alia be responsible for arbitration procedures related to herbal medicines.

will to a considerable extent harmonise food supplements with vitamins and minerals. All other ingredients, e.g. herbals, will primarily be regulated by national legislation. However, a proposal for a regulation on fortification for food is expected to clarify conditions for those herbal sub-



Mogens Bjørnbak-Hansen, Director Legal Affairs, Danish Medicines Agency, Chairman of the Council Working Party on the revision of the pharmaceutical legislation, 2nd semester 2002 and **Paul Weissenberg**, Director, Single market, management & legislation for consumer goods, Directorate-General Enterprise, European Commission, discussing the EU pharmaceutical legislation at the **AESGP Members' Meeting on 17 January 2003 in Vienna**.

New legal framework for food supplements

After a long period of campaigning, Europe saw the adoption of the directive on food supplements in July 2002. This directive has to be transposed into national legislation by July 2003. Together with upcoming implementing directives e.g. with regard to upper limits, the directive

stances which are not allowed to be used in any food products, including food supplements.

Hot issue: food claims

AESGP has been very much involved in an intensive debate on a new European Union legal framework for nutrition and health claims. Of particular importance is the European Com-

mission's intention to establish an authorisation process for all health claims, including in particular so-called disease-risk reduction claims. Following AESGP campaigns, it seems that the principle of establishing a data exclusivity provision for scientific work around the proof of such claims will be part of the European Commission's proposal.

Close stakeholder interaction ongoing

Progress on the legislative and regulatory front would not have been possible without the well-established strategic alliances AESGP enjoys with many stakeholder groups including in particular the European umbrella organisations of medical doctors, pharmacists, patients and consumers, health insurers and pharmaceutical wholesalers. The constructive interaction was particu-



Stakeholder Panel at the **AESGP Annual Meeting in Dublin** on 7 June 2002, from left to right: **Dagmar Roth-Behrendt**, Member of the European Parliament; **Léon J. S. Wever**, Director, Department of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, the Netherlands; **William Darling**, President, Pharmaceutical Group of the European Union (PGEU); **Seppo Morri**, President, European Association of Pharmaceutical Wholesalers (GIRP); **Olivia O'Leary**, Journalist, Ireland; **Alessandro Banchi**, President, AESGP (until 30 June 2002); **David Byrne**, European Commissioner for Health and Consumer Protection and **Rainer Brettenthaler**, President, Standing Committee of European Doctors (CP).

larly visible at the AESGP 38th Annual Meeting held in Dublin from 5 to 7 June 2002 entitled: "Meeting great expectations for self-care: Let's ask the people", and on a worldwide level at the World Self-Medication Industry (WSMI) General Assembly held in Tokyo from 13 to 15 November 2002 to which AESGP made numerous contributions. This is expected to be further intensified during the AESGP 39th Annual Meeting entitled "Innovating self-care – An opportunity for consumer and public health" to be held in Cannes from 4 to 6 June 2003.

Service, service, service

AESGP continues to provide comprehensive information services to its members. Beside the intensive and detailed personalised service to members of the different committees, relevant developments for the self-care industry are summarised in AESGP Euro OTC News issued ten times per year. A general overview on the market situation is provided by the annually updated study "Economic and Legal Framework for Non-Prescription Medicines". Questions and remarks may always be addressed to the AESGP team at the Brussels offices.



AESGP Director General **Hubertus Cranz** welcoming European Commissioner **David Byrne** at the **AESGP Annual Meeting in Dublin**.