



Annual Report ^{2003/2004}

HIGHLIGHTS OF THE YEAR

Successful revision of EU pharma legislation

AESGP's activities over the last year were dominated by the debates on the revision of the EU's pharmaceutical legislation and the establishment of other new pieces of EU legislation, e.g. with regard to herbal medicinal products and food claims. The outcome of these debates is overall a big success for AESGP, as many of the key proposals made in the AESGP document "Deregulation 2001" have finally been integrated into the new legislation. Of particular importance are:

- The optional use of the centralised procedure for innovative non-prescription medicines.
- Provisions to make the mutual recognition procedure work better through changes in the decision making and through the establishment of guidelines to define serious risks to public health.
- Decisions on the classification status in the mutual recognition procedure to be taken nationally. However, same classification status for products going through the centralised procedure, thereby providing manufacturers with an option for a harmonised classification status.
- Deletion of categories of indications which could not be advertised even if the product had non-prescription



Pictured from left to right at the AESGP Annual Meeting in Cannes, June 2003 are: Professor Jean-Pierre REYNIER, the European Parliament's Deputy representative on the EMEA's Management Board; Mr Patrick BLOCK, President of the French self-medication association AFIPA; Mrs Françoise GROSSETÊTE, Member of the European Parliament; and AESGP Director General Dr Hubertus CRANZ

status. This confirms the general policy that in principle all non-prescription medicines may be publicly advertised.

- Acceptance of the principle of data exclusivity both for scientific work related to the change of classification status and for new indications of known substances.
- Abolition of the 5-yearly renewal system for well-established substances; reinforcement of the pharmacovigilance system.

These achievements were complemented by other significant changes with regard to the legislative and regulatory environment for herbal

medicinal products that are in line with AESGP recommendations made in a study for the European Commission back in 1998. These include:

- Establishment of a category of traditional herbal medicines (in addition to the existing category of medicines with a well-established use). This makes it clear that there are primarily two categories of herbal medicinal products.
- Adequate legal provisions for traditional herbal medicines, including the possibility of combining them with vitamins and minerals.
- Establishment of a new Committee on Herbal Medicinal Products at the European Medicines Agency.

Focus now on implementation

In order to have a positive impact for the people around Europe as well as for business operators, each piece of European legislation needs to be implemented properly. Bearing in mind the need for an adequate interpretation of the new legal provisions, AESGP organised a Members' Meeting near the premises of the European Medicines Agency (EMA) on 22–23 January 2004 entitled "New legislation – New opportunities? What the new pharmaceutical legislation will mean for the self-medication industry in an enlarged Europe". At this meeting, the European Commission's intentions in the context of the new legal provisions were clarified and the implications for the European Medicines Agency and for the future Committees for Human Medicinal Products and Herbal Medicinal Products were analysed. The meeting provided the opportunity to clarify the details of the future use

of the centralised procedure for innovative non-prescription medicines.

This conference, held in cooperation with the European Medicines Agency, formed the follow-up to many constructive interactions with the European agency in charge of the evaluation of medicinal products since its foundation in 1995. Part of this cooperation was the support provided by AESGP in the organisation of two conferences in the framework of the Pan European Regulatory Forum (PERF), in Budapest in February 2000 and in Ljubljana in July 2003. Both events made important contributions to a smooth preparation of the enlargement process, which allowed the self-medication industry to be well prepared for the entry of ten new Member States on 1 May 2004. The important legislative and regulatory parameters (classification of medicines as prescription or non-prescription, advertising of all non-prescription medicines and free pricing for manufacturers) were established



AESGP meetings held in the EMEA premises on 22 January 2004

in most countries of Central and Eastern Europe during the 1990s and have created a comparable environment for the industry in the whole of Europe.

Political support for self-medication

The successful termination of the review process would not have been possible without a positive attitude towards non-prescription medicines. This became particularly evident during the so-called G10 Medicines process which brought together leading representatives from the European Commission, national health and industry ministries as well as from patient groups, insurance organisations and the pharmaceutical industry. Once the recommendations of the G10 Medicines Group were presented in May 2002, the European Commission issued a Communication reflecting its official position on 1 July 2003, just a few days before a conference related to this Communication organised by the Italian Council Presidency in Rome. The Communication in particular recommends:



Pictured at the opening session of the AESGP Members' Meeting in January 2004 in London are (l to r): AESGP President Mr Albert ESTEVE; Associate Professor L'udevit MARTINEC, Director of the Slovak State Institute for Drug Control; Dr Paul WEISSENBERG, Director, single market, management & legislation for consumer goods at the European Commission's Directorate-General Enterprise; Dr David LYONS, Member of the CPMP, Irish Medicines Board; and Mr Thomas LÖNNGREN, Executive Director of the EMEA

- Removing price controls for manufacturers of non-reimbursed medicines
- Allowing the same tradename for medicines moved from prescription to non-prescription status
- Permitting advertising for all non-prescription medicines
- Making full use of the legal provisions concerning well-established use in the new legislation on traditional herbal medicines with regard to the assessment of existing products.

G10 recommendations to support AESGP member associations

These recommendations should be helpful for AESGP national associations to argue their case in countries where the legislative provisions are so far not in line with the recommendations. Supported by AESGP, the abolition of price controls for manufacturers of non-prescription medicines has been a key priority in countries such as Greece and Belgium but also Turkey and more recently Hungary. In addition, AESGP has been active in providing support for problematic developments outside Europe – for example in South Africa – by referring to the G10 recommendations.

The recommendations were endorsed by the EU ministers in the form of Council Conclusions which underlined the need to reinforce the competitiveness of the Europe-based pharmaceutical industry with appropriate measures, including those for the development of the non-prescription sector in the European Union.

No growth without innovation

...was the key conclusion from the considerations at the AESGP Annual Meeting in Cannes in June 2003. For the first time this whole event was dedicated to the need to innovate self-medication concepts in order to bring more benefits to people around Europe. Taking into account recent experience from the United Kingdom on an open debate on new indications for self-medication, representatives from authorities, health professionals – including in particular medical doctors and pharmacists – as well as from patient and consumer organisations and pharmaceutical wholesalers looked at concrete ways of how to make this happen.

The meeting was part of the ongoing stakeholder interaction which led in 2003 to the signing of a *Charter of*

Collaboration between the European Association of Pharmaceutical Wholesalers (GIRP) and AESGP. The charter advocates an active presentation of non-prescription medicines in pharmacies and appropriate space / category management. Also promoted will be the training of pharmacists and their staff in their role of communicators of the benefits of non-prescription medicines to their customers. Back in 1993, AESGP signed a *Charter of Collaboration* with the European umbrella organisation of community pharmacists, the Pharmaceutical Group of the European Union (PGEU), which has led to a number of joint activities in particular with regard to appropriate training and education of pharmacists and a better presentation of non-prescription medicines in the pharmacy environment. A strong AESGP delegation attended the opening of the new PGEU offices in Brussels in November



The stakeholder panel at the AESGP Annual Meeting in Cannes, June 2003, from left to right: Mr Erkki LIIKANEN, European Commissioner for Enterprise and Innovation; Mrs Dagmar ROTH-BEHRENDT, Member of the European Parliament; Dr Rainer BRETEN-THALER, President of the Standing Committee of European Doctors (CPME); Dr Philippe BRUNET, Head of Unit - Pharmaceuticals: regulatory framework and market authorisations at DG Enterprise, European Commission; Mr Jeff HARRIS, Incoming President of the European Association of Pharmaceutical Wholesalers (GIRP); Mr Paul BUNDGAARD, President of the Pharmaceutical Group of the European Union (PGEU); and Mr Albert ESTEVE, the President of AESGP.



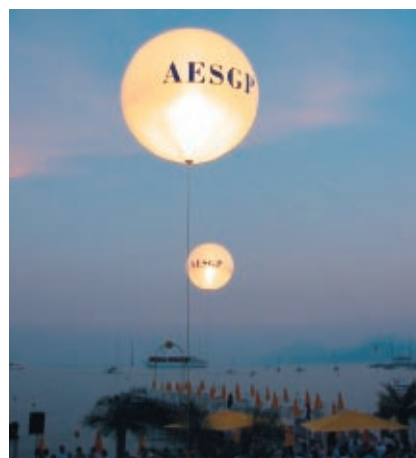
Discussing the new food initiatives in Brussels, October 2003, are from left to right (seated): Mrs Beate KETTLITZ, Food Officer, European Consumers' Organisation (BEUC); Mr Oscar HERNÁNDEZ PRADO, General Subdirector of Food Risk Management, Spanish Agency of Food Safety; Mr Mauro NOBILIA, Member of the European Parliament and Rapporteur for the proposed regulation on food claims; Mrs Paola TESTORI-COGGI, Director, Food safety, production and distribution chain, Directorate-General Health and Consumer Protection, European Commission; Mr Bas van der HEI-DE, Department of Food, Ministry of Health, the Netherlands – (standing): Ms Melanie RUFFELL, Executive Director, Joint Health Claims Initiative, United Kingdom; Mrs Sheila KELLY, Member of the AESGP Board, Executive Director, Proprietary Association of Great Britain (PAGB).

2003 held around the theme "Community pharmacists in Europe – A resource for public health".

Food claims

AESGP has been closely involved in the discussions around new legislation for nutrition and health claims which is likely to have a direct impact on promotional activities for food supplements. This issue was discussed in a comprehensive way at an AESGP conference in October 2003 at which key representatives of the European institutions participated, including in particular the European Parliament's Rapporteur for that dossier and key persons from the European Commission.

In spite of many efforts by the European institutions, this dossier did not clear the first step in the European Parliament during the current legislature and will therefore continue to stay high on the agenda once the new European Parliament with mem-



AESGP beach party at the end of the AESGP Annual Meeting in Cannes, June 2003

bers from the enlargement countries will have been elected in June 2004.

Also high on AESGP's agenda were all activities around the implementation of the food supplements directive including the preparatory work for the setting of maximum levels of vitamins and minerals used in food supplements.

Competence and service

...continue to be guiding principles in AESGP's day to day activities. A huge number of messages are being sent to the members of the AESGP committees in charge of positioning the association in numerous matters of a more technical nature. The overall policy orientation is determined by the AESGP Board, which has followed the development of an important new document on the economic and public health value of self-medication over the year. This document will be presented at the AESGP 40th Annual Meeting in Madrid. Together with the compilation of the widely appreciated reference document on the economic and legal framework of non-prescription medicines (in its 10th edition in 2004) and the "switch list" with around 200 OTC ingredients, AESGP continues to provide comprehensive information services for the benefit of its members and the public at large. In addition, all the meetings and conferences organised by AESGP facilitate human relationships – an element that has always been at the forefront of AESGP's considerations.