

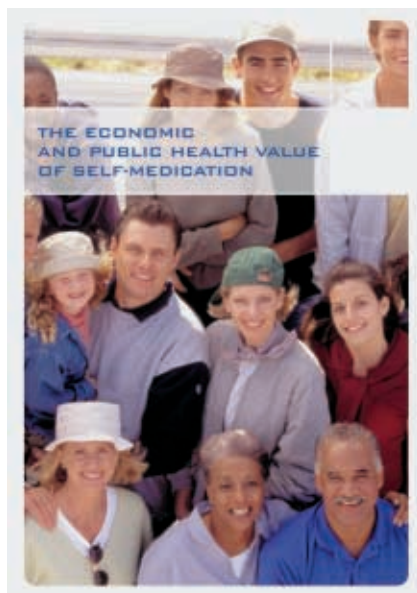
ANNUAL REPORT 2004 2005

HIGHLIGHTS OF THE YEAR

2004 – a year of change

The past 12 months were characterised by many changes, with 10 new Member States joining the European Union in May, the EU's 455 million inhabitants electing new representatives to the European Parliament in June, a new European Commission taking office in November and the challenge of explaining the issues on the AESGP agenda to all these new faces.

New study on economic and public health value of self-medication



The last meeting of the G10 Medicines Group, in which two AESGP



*Pictured from left to right at the AESGP Annual Meeting in Madrid, June 2004 are: **Claudio LEPORI**, President of ANEFP; **Giuseppe NISTICÒ**, Member of the European Parliament; AESGP President **Albert ESTEVE**; European Commissioner **Erkki LIIKANEN**; **Fernando PUIG DE LA BELLACASA**, Sub-Secretary of Health and Consumer Affairs, Spain and ANEFP Director General **Rafael GARCÍA GUTIÉRREZ***

Presidents have been members since the Group's creation in 2001, formed the occasion for AESGP to present a major new study on the **"Economic and Public Health Value of Self-Medication"**. AESGP President Albert Esteve was given the opportunity to demonstrate on 3 June 2004 to an audience including several European Commissioners and national Ministers of Health that a shift to self-medication of a small part of the medicines currently prescribed by medical doctors could lead to considerable savings. The study showed that shifting only 5% of the medicines prescribed for certain self-limiting conditions could yield annual savings of 16.3 billion euros in the enlarged European Union of 25 Member States. Through an analysis of three indications areas – smoking cessation, vaginal mycosis and heart disease prevention – the study, which

was presented on the same day to delegates at the AESGP 40th Annual Meeting in Madrid, demonstrated how responsible self-medication has a positive health impact on the individual and is able to create incremental positive outcomes for society as a whole. The study recommended enlarging the options for education and information on self-care, and in particular on the medicines available without a medical prescription. The study's conclusions could certainly be considered as appropriate in light of the G10 recommendations to facilitate the move of medicines from prescription to non-prescription status through improved switch mechanisms, to allow the use of the same trademark for medicines moved to non-prescription status, to lift current restrictions on the advertising of non-prescription medicines and to abolish price controls on medicines not reimbursed by the state.

Implementation of these recommendations would therefore undoubtedly facilitate the climate for self-medication.

Getting the implementation of the new legislation right

... of the G10 recommendations and of the provisions added to the European Union's pharmaceutical legislation in March 2004 has been taking up much time and attention within the association. Most of the new provisions from the new legal framework should be included in the national laws of the 25 EU Member States by end October 2005. Implementing the spirit of the main new features is in this context therefore extremely important for the self-care industry and is being closely monitored. In general terms, the main features to be incorporated into Member States' national legislation are:

- The possibility for innovative non-prescription medicines to use the centralised procedure

- Improvements to the mutual recognition procedure by, for instance, guidance containing a more precise definition of what constitutes a serious risk to public health
- 12 months of data exclusivity for an innovative switch. This makes it appropriate to revise the existing switch guideline
- 12 months of data exclusivity for a new indication of a known substance
- The abolition of certain restrictions on the categories of medicines which could be advertised to the general public even if the products had non-prescription status
- An appropriate use of tradenames, both for products with a different legal status and for products within the non-prescription category.

In addition, the implementation of new specific issues such as the provisions on Braille, renewal and user testing requested particular attention. AESGP Members had more opportunity to learn about the details of the revision's new provisions and how they

were going to be implemented at a conference in London on 21 January 2005 entitled **"Roadmap to 2010: The future of self-care"**, a direct reference to the **"EMEA Roadmap to 2010"** in which the European Medicines Agency set forth its future plans for the next five years. The meeting also commemorated the opening of the EMEA 10 years earlier, which was officially celebrated on 11 March 2005, allowing AESGP's Director General to convey the congratulations of the association.

New herbal committee at EMEA: a milestone for the self-care industry

The conference **"Changing the Rules for Food Supplements and Herbal Products in Europe"** in Brussels on 28-29 September 2004 – a few days after the creation of the Committee for Herbal Medicinal Products (HMPC) at the EMEA, provided the opportunity for AESGP members to get a comprehensive overview on the political climate for these self-care products and on the implementation of the food supplements and traditional herbal medicinal products directives around Europe. The establishment of the new scientific committee dedicated to herbal medicinal products within the EMEA structure has for years been considered by the AESGP membership as crucial for the development of a true herbal medicines market in Europe. The simultaneous adoption of the provisions on traditional herbal medicinal products has complemented the legal framework for herbal



Pictured at the AESGP reception in London on 19 January 2005 are (l to r): AESGP President **Albert ESTEVE**; Hannes WAHLROOS, Chair of the EMEA Management Board; EMEA Executive Director **Thomas LÖNNGREN**; Daniel BRASSEUR, Chair of EMEA's Committee for Medicinal Products for Human Use; and AESGP Director General **Hubertus CRANZ**



*Pictured at the AESGP conference in September 2004 (l. to r.): AESGP Director General **Hubertus CRANZ**, MEP **Jules MAATEN**, MEP **María del Pilar AYUSO GONZALEZ**, **Paola TESTORI COGGI**, Director for Food safety, production and distribution chain, European Commission and **Rob DORTLAND**, Director for Food and Health Protection, Ministry of Health, the Netherlands (holding the EU Presidency in the second half of 2004)*

products to gain access to the European market.

One of the main tasks for the HMPC will be the establishment of monographs and lists for medicinal plants, including a clarification of a herbal's well-established and/or traditional use. AESGP has already submitted suggestions for a priority list of plants to be covered by monographs/lists.

Food issues remain high on the association's agenda

The discussions around new legislation for nutrition and health claims concerning food were resumed by the newly elected European Parliament in the autumn of 2004. AESGP's priorities during the adoption process are to achieve sufficient flexibility in the wording of claims and to gain protection for research data obtained to substantiate claims.

The implementation of the 2002 food supplement directive continues

taking up much of AESGP's attention in spite of uncertainties around the validity of the directive. The European Commission has to establish "minimum" and "maximum" amounts for each vitamin and/or mineral that will be permitted in food supplements based on a scientific evaluation of the European Food Safety Authority. A report on the advisability of establishing specific rules for other substances

than vitamins and minerals within the scope of the food supplement directive has to be finalised by the European Commission by mid-2007 at the latest and preparatory work is ongoing.

Further developing stakeholder interaction

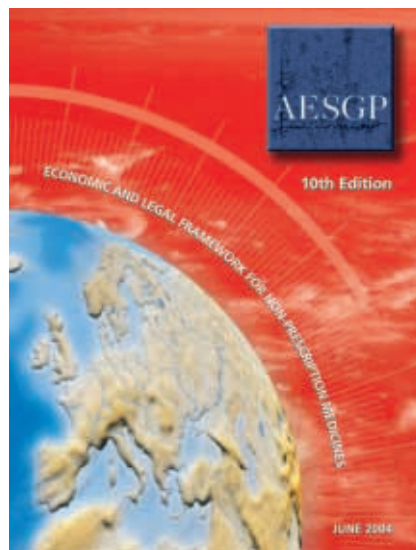
European pharmacists represented by the Pharmaceutical Group of the European Union (PGEU) and AESGP strengthened their collaboration by signing a second **Charter of Collaboration** in November. Since the signing of the first Charter of Collaboration in May 1993, the two associations have collaborated on numerous projects, several of which were supported by the European Commission. In March 2002, the two associations co-organised a workshop on "How appropriate presentation of non-prescription medicines enhances the role of the pharmacist" and agreed on a "Common



*PGEU President **Pedro CAPILLA** (middle right) and AESGP President **Albert ESTEVE** (middle left) present the new PGEU-AESGP Charter of Collaboration in the presence of PGEU Secretary General **Flora GIORGIO** and AESGP Director General **Hubertus CRANZ***

statement" supporting the importance of a good presentation of non-prescription medicines in the pharmacy. As a follow up, a special session at the Geneva conference in June 2005 will look at the best pharmacist education to meet consumer demand in the area of communication and at a good presentation of non-prescription medicines in the pharmacy.

Since the finalisation of the research project on new collaborative care indications in January 2002, contacts with the umbrella organisation of medical doctors in Europe, the CPME, have been ongoing on a regular basis. The importance of explaining the rationale of certain switch applications to the medical profession became evident during the last of these meetings in October 2004, particularly in light of the first statin switch to non-prescription status a few months earlier.



Another witness to development and change in the area of non-prescription medicines was the 10th edition of AESGP's **"Economic and Legal Framework for Non-Prescription Medicines"** issued in June 2004. Starting with only a few European countries, the study has gradually expanded and covered 26 European as well as nine non-European countries last year, with Argentina, China and Lithuania contributing for the first time. Since 2004, the individual country profiles have been available on the AESGP website.

The 2004 edition of the study showed that a great deal of progress has been made in those 10 years with regard to the legal framework of non-prescription medicines. However, the study also showed that many obstacles remain in place at the national level.

Support for AESGP national associations

Supporting AESGP's National Associations in removing obstacles to the development of self-care and self-medication remains a top priority for the association. One of the commitments made in this context is to support the Greek member association EFEX to overcome current restrictions on the pricing of non-prescription medicines. The Greek association is aiming to get this and other issues hampering the development of self-medication in Greece relaxed by the time the self-medication industry will gather in Athens for the AESGP 42nd Annual Meeting, 7-9 June 2006.

As part of the service provided to its members, AESGP recently gave its website a new look. The wealth of information available from the website includes updated information on the classification status of more than 200 ingredients widely used in self-medication and reports of AESGP conferences over the last seven years. The regular newsletter **"AESGP Euro OTC News"** completes the picture by providing up-to-date information on the latest European and worldwide developments.



2004 was also the year in which AESGP celebrated its 40 years. The occasion was marked by a special anniversary brochure **"40 Years Working For Self-Medication"** in which the history of the association was traced back to its creation in 1964. The booklet highlighted the different development stages of the European legal framework for pharmaceuticals, and it may be assumed that many regular AESGP conference participants were moved by the memories evoked.

AESGP · 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 · Web: <http://www.aesgp.be>