

AESGP Conference focuses on food claims and herbal (medicinal) products

AESGP CONFERENCE PARTICULARLY WELL ATTENDED

Upcoming legislation and implementation of food supplement Directive discussed

Almost three years to the date after organising the first [conference on food supplements, fortified food and health claims](#) in the same meeting place, AESGP on 7-8 October 2003 hosted an important conference in Brussels to give an update on the state of play on the most relevant dossiers for the self-care sector in the area of herbal (medicinal) products and food supplements. With over 250 participants, the conference was particularly well attended. Topical dossiers included the upcoming Directive on traditional herbal medicinal products and the activities of the Committee on Herbal Medicinal Products (CHMP) to be created within the structure of the European Medicines Evaluation Agency (EMA), upcoming legislation in the area of food, including in particular the proposal on nutrition and health claims and the measure on the addition of vitamins and minerals to food which is expected to be put forward by the European Commission in the near future as well as the implementation of the 2002 food supplement Directive.



Pictured at the AESGP conference (left to right):

Dr Konstantin KELLER, Chair, EMA Herbal Medicinal Products Working Party; **Dr Hubertus CRANZ**, Director-General AESGP; **Professor Roberto BENZI**, Representative of the European Parliament on the EMA Management Board; **Professor Giuseppe NISTICÒ**, Member of the European Parliament and Rapporteur for the directive on traditional herbal medicinal products; **Dr Paul WEISSENBERG**, Director for the single market, management and legislation for consumer products, Directorate-General Enterprise, European Commission; **Professor Vittorio SILANO**, Chair of the Council Working Party on Pharmaceuticals - Director of the Pharmaceutical Department, Ministry of Health, Italy; **Mr Roy ALDER**, Medicines & Healthcare products Regulatory Agency, United Kingdom; and **Mr Albert ESTEVE**, President AESGP

MEMBER STATES CLOSE TO AGREEMENT ON TRADITIONAL HERBAL MEDICINES

Legislation and assessment of herbal medicinal products

Parliament, Council and Member States discuss “traditional use” procedure

The conference started with a session on herbal medicinal products chaired by **Professor Giuseppe NISTICÒ**, who is the European Parliament’s Rapporteur on the proposed provisions for a simplified registration procedure for traditional herbal medicinal products.

Of major importance was the revelation of the state of play in the Council of Ministers on these provisions by **Professor Vittorio SILANO** who, as Director of the Pharmaceutical Department at his country’s Ministry of Health, currently chairs the Council Working Party on Pharmaceuticals under the Italian Presidency. Together with **Mr Roy ALDER** of the UK’s Medicines & Healthcare products Regulatory Agency (MHRA), he provided an insight into the text as it now stands and on which a common position is likely to be adopted by the Member States early November 2003.

As Professor Nisticò assumed that Parliament would not bring many changes to this text during its second reading, participants in the conference were able to discover the gist of the final provisions on traditional herbal medicinal products.

“Better to accommodate than to hide”

AESGP study at root of new Directive

As the Pharmaceutical Committee’s Rapporteur on the new Directive on traditional herbal medicinal products during the consultation stage, the United Kingdom was in the forefront of its supporters, confirmed **Mr Roy ALDER** of the UK’s Medicines & Healthcare products Regulatory Agency (MHRA). Mr Alder praised the excellent *Study on the situation of herbal medicinal products in Europe*¹ which AESGP carried out for the European Commission in 1998 and which has indicated very clearly the different cultural traditions that existed in the Member States. Rather than hide before these differences and drive the products concerned into illegality, the UK encouraged the Member States to be flexible and accommodate these different traditions through the adoption of the new Directive.

MHRA to support UK companies

The main cause for dissent on the proposal in the UK was, according to Mr Alder, the addition of vitamins and minerals as there is a big market for this type of products in Great Britain. Nevertheless, MHRA was able to defuse the fear on the part of consumers and manufacturers that “the shelves would be cleared”. So long as a product is not compromised, said Mr Alder, all products should be allowed to remain on the market. From a survey conducted among UK companies, it appeared that out of the 70-80 products threatened with exclusion only about 5 would have to disappear.

The cost element for companies had also been considered though consultation with trade associations, said Mr Alder, and if costs are likely to be high MHRA will try and help companies to deal with this.

¹ <http://pharmacos.eudra.org/F2/pharmacos/docs/doc99/Herbal%20Medecines%20EN.pdf>

Mutual recognition encouraged

Mr Alder concluded by encouraging the competent institutions to work on the positive list and establish monographs wherever possible to facilitate mutual recognition.

New Directive will support SMEs

Continued availability of traditionally used products guaranteed

Dr Paul WEISSENBERG, the European Commission's Director for the single market, management and legislation for consumer products at Directorate-General Enterprise stressed the importance of this new legal framework for traditional herbal medicinal products for the companies operating in this area, many of which are small and medium-sized enterprises. They will guarantee the availability of these herbal products for consumers, and was pleased with the understanding that had been created for these products among all stakeholders. Ten years ago, he said, these discussions would have raised more than a few eyebrows.

Commission supports self-care industry's G10 objectives

Dr Weissenberg indicated the European Commission's continued support for the self-care industry's objectives set out in the various [G10 Medicines](#)¹ documents, in particular that switching from prescription to non-prescription status should be stimulated through data exclusivity and tradename flexibility, and that manufacturers of non-reimbursed medicines should enjoy pricing freedom. "The momentum is now with the Member States to take action and should be maintained", concluded Dr Weissenberg.

Proposed procedure to complement the well-established use procedure...

The "traditional use" procedure will complement the provisions in **Title III, Chapter 2, Article 10 (a) ii of the *Community Code***, i.e. the so-called "well-established use" procedure, which states that the applicant for marketing authorisation "shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate ... that the constituent or constituents of the medicinal product have a well established medicinal use, with recognised efficacy and an acceptable level of safety, by means of a detailed scientific bibliography".

...for herbal products not fulfilling the "well-established use" requirements...

However, a significant number of herbal medicinal products, despite their long tradition, do not fulfil the requirements of a well established medicinal use with recognised efficacy and an acceptable level of safety and are not eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted different procedures and provisions.

...through a simplified registration procedure...

The proposed amendment of the *Community Code* has as main objective to harmonise the Community's legislative framework for medicinal products by introducing a simplified registration procedure for these traditionally used herbal medicinal products.

Under the new procedure, no particulars and documents on tests and trials on safety and efficacy will be required. Instead of this, the applicant will be allowed to present "plausible" bibliographical or expert evidence on the "traditional medicinal use" of the product as well as a bibliographic review of safety data, together with an expert report.

¹ <http://pharmacos.eudra.org/F3/g10/g10home.htm>

...to be used only in absence of well-established use data

The text makes it clear that this simplified registration procedure should be eligible only where no marketing authorisation under Directive 2001/83/EC can be obtained, in particular due to lack of sufficient scientific literature demonstrating a well established medicinal use with recognised efficacy and an acceptable level of safety.

Likely shape of the new Directive on traditional herbal medicinal products

Silano: “Current text close to Parliament’s wishes”

Professor Silano explained that the current text of the provisions on traditional herbal medicinal products had taken over many of the changes suggested by the European Parliament in first reading, which were in part already reflected in the Commission’s amended proposal. The most relevant points are mentioned below.

Scope of the “traditional-use registration”

A simplified registration procedure (“traditional-use registration”) is established for herbal medicinal products which fulfil all of the following criteria:

- (a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
- (b) they are exclusively for administration in accordance with a specified strength and posology;
- (c) they are an oral, external and/or inhalation preparation;
- (d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;
- (e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

This is virtually the same wording of the European Commission’s amended proposal. Parliament had simply wished for point (a) to say that: “*they are classified as available without medical prescription*”.

Inclusion of non-herbal ingredients

On the possibility of combining herbal with non-herbal ingredients, the Member States, together with the European Parliament and the European Commission, are in agreement that a herbal medicinal product will also be eligible for the “traditional use” procedure if it includes vitamins or minerals for which there is well documented evidence for their safety “provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients”. The Council text says here that:

“the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the product from being eligible for [traditional-use] registration [...], provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication(s)”.

Acceptance of non-EU tradition

There has been quite some discussion on the period of time a product must have been available within the EU to count towards the “30 years” of traditional use. The Member States are now in

agreement that this period should be at least 15 years.

Also, with next year's enlargement the EU's pharmaceutical market will be composed of countries with a longstanding herbal tradition such as Poland, the Czech Republic and Hungary. This means that from 1 May 2004, many years of traditional use experience will become available for products qualifying for the new traditional use provisions. In case there is no 15-year experience in the EU, the text foresees that the request for simplified registration will be referred to the Committee on Herbal Medicinal Products (CHMP), which should decide on the product's eligibility for the simplified procedure.

Possibilities for mutual recognition

The original proposal by the European Commission did not foresee that mutual recognition would be possible for products registered under the simplified registration procedure as a product's traditional use is usually linked to a national tradition. However, the European Parliament asked for Member States to *recognise* registrations or authorisations granted by another Member State. In its amended proposal, the Commission implemented this change.

The Member States have now qualified this by making mutual recognition possible on condition that there is a Community herbal monograph or in case the product consist of preparations or combinations included in a positive list. In other cases, Member States should take "due account" of registrations granted by other Member States.

Labelling / leaflet statement

Products registered in accordance with the "traditional use" procedure will have to carry a qualifying statement on the label and in the leaflet. However, the three institutions have agreed on a much softer and more positive wording than in the Commission's original proposal:

"any labelling and user package leaflet shall contain a statement to the effect that:

(a) the product is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use; and

(b) the user should consult a doctor or a qualified health care practitioner if the symptoms persist during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur.

A Member State may require that the labelling and the user package leaflet shall also state the nature of the tradition in question."

Advertising statement

A similarly soft wording has been retained to appear in advertising statements for products registered under the "traditional use" procedure:

"Traditional herbal medicinal product for use in specified indication(s) exclusively based upon longstanding use".

Role of the new CHMP

The provisions on traditional herbal medicinal products further define the role of the new Committee on Herbal Medicinal Products (CHMP) which will officially be set up as a new Scientific Committee of the EMEA by the new Regulation on the EMEA that will be adopted as part of the revision proposals.

The Member States have agreed that this Committee will:

- facilitate simplified registrations by drawing up opinions and deciding on the validity of the

documentation submitted to it in case a product has been available in the EU for less than 15 years

- prepare a draft list of herbal substances, preparations and combinations thereof
- establish Community monographs for traditional herbal medicinal products
- establish Community herbal monographs for herbal medicinal products [with well-established use]
- arbitrate in case of referrals
- give an opinion on the herbal substance in case other medicinal products containing herbal substances are referred to the Agency
- perform any other task conferred upon it by Community law.

Co-ordination with the Committee for Human Medicinal Products (currently the CPMP) will be ensured by the Executive Director of the Agency.

Composition of the new CHMP

As for the composition of the new Committee on Herbal Medicinal Products (CHMP), the Member States agree that:

“Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Herbal Medicinal Products.”

Other appropriate data sources

In the absence of a Community monograph, other appropriate monographs, publications or data may be referred to in order to decide on registration:

“When Community herbal monographs within the meaning of this paragraph have been established they shall be taken into account by the Member States when examining an application. Where no such Community herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to.”

Future extension of scope

Member States have agreed that the European Commission, in its report after three years of experience with the new “traditional use” procedure, should assess whether the procedure should be extended to other categories than the herbal medicines currently covered.

New Committee to endorse guidelines for herbals

Working Party already busy on preparatory work for list

[Dr Konstantin KELLER](#), who chairs the EMEA Working Party on Herbal Medicinal Products, gave an update on the work carried out so far by this Working Party, mainly in the area of guidelines on quality, safety and efficacy. For the moment, these guidelines are made available on the EMEA website with a disclaimer that they have not been endorsed by the CPMP. This should be resolved once the Committee on Herbal Medicinal Products is operational as this Committee will have full competence in the area of herbal medicines.

However, Dr Keller stressed that the new Committee’s decisions will be totally independent of those taken by the current Working Party.

Dr Keller mentioned that the Working Party is already collecting national lists in preparation of a proposed structure for the positive list to be established under the new provisions. This list will

include minimum information; otherwise, a monograph will be established. Also in preparation is an online database and work to allocate existing core-data to the “well-established use” or the “traditional use” procedure.

Dr Keller said the Directive’s new aspect was that a framework harmonised at EU level was in fact going to be implemented at the national level. He speculated that this model might even be of interest to the non-herbal area.

Last WP meeting next February?

As for the future timetable, Dr Keller predicted that the February 2004 meeting of the Herbal Medicinal Products Working Party would probably be its last.

Implications for Austria, Ireland and the United Kingdom

The Member States’ point of view

Implications at the national level for Austria, Ireland and the UK were reviewed in a panel discussion by, respectively, **Univ. Doz. Dr Heribert PITTNER**, of the Austrian Ministry of Health and Women, **Dr Dairine DEMPSEY** of the Irish Medicines Board and **Mr Richard WOODFIELD**, of the UK’s Medicines & Healthcare products Regulatory Agency.

AESGP welcomes new provisions on traditional use

AESGP President pledges continued support

AESGP President [Mr Albert ESTEVE](#) stressed that AESGP overall regards the new provisions as an appropriate and welcome legal framework for this category of products in the European Union. He was proud that the association had been able to provide full support during the adoption process and said that AESGP member companies looked forward to a rapid adoption of the new provisions, which will complete the picture for manufacturers of herbal medicinal products wishing to get their products to market through a procedure adapted to their specific needs.

Professor Nisticò was confident that the new Directive would put an end to a long period of confusion and that the dignity of many ingredients used in traditional herbal medicinal products would be preserved.

RAPPORTEUR ON REVISION PROPOSALS ADDRESSES AESGP RECEPTION

All parties wish rapid adoption

Addressing the AESGP Board and a large number of invitees at the Annual AESGP Reception - which was this year held in the premises of the European Parliament in Brussels on 7 October - **Mrs Francoise GROSSETÊTE**, the European Parliament's Rapporteur on the changes to the *Community Code* said that the European Parliament is now making all possible efforts to get the three revision proposals finally adopted by the Parliament and the Council before Parliament dissolves next year in advance of the upcoming Parliamentary elections in June 2004.

The Rapporteur also mentioned that informal debates have already taken place between the two institutions involved in this final adoption, i.e. the European Parliament and the Council of Ministers (the Member States).



CLAIMS AND FORTIFIED FOOD DISCUSSED BY KEY PLAYERS

Two initiatives are closely linked

Under the chairs of **Mrs Dagmar ROTH-BEHRENDT** and **Mr Mauro NOBILIA**, MEPs, the conference examined the European Commission's recent proposal on food claims as well as its upcoming initiative on fortified foods. The Commission's Director for Food safety, production and distribution chain at the Directorate-General Health and Consumer Protection, **Mrs Paola TESTORI-COGGI**, informed the audience that an official proposal on fortified foods is likely to be presented by the Commission in November 2003. She confirmed that the two initiatives were closely linked as manufacturers had to have the certainty that their investment in the development of innovative food would be rewarded by their ability to claim certain properties for their products.

Claims proposal generally welcomed

Brief outline of proposal

All speakers welcomed the Commission's [proposal on food claims](#)¹, although many had individual comments on certain parts of the text. Mrs Testori gave an outline of the main points of the proposal. Echoing the words of Commissioner David Byrne before the European Parliament's Environment Committee a few days earlier, Mrs Testori said that consumers should be able to

¹ Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods of 16 July 2003

make choices based on clear and accurate information. Therefore, the Commission was proposing a science-based validation of food claims to ensure that every claim can be properly justified. The proposal covers nutrition claims, for example -"rich in vitamin C" or "low in fat" - and health claims, that is, claims of a positive relationship between a specific food and improved health. It establishes the framework for making such claims and also allows health claims - including "reduction of disease risk" claims - that were previously prohibited. The latter will be allowed if they can be scientifically substantiated and authorised at EU level, following a thorough risk assessment by the European Food Safety Authority. In that case, the Commission had proposed to grant manufacturers a 7-year data exclusivity period to recoup their investment.

Some individual comments on the claims proposal

Mrs Roth-Behrendt made it clear she had some reservations concerning the ban on general or "generic" health claims.



Discussing the new food initiatives, 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, Spain; **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 HEIDE**, 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)

Mrs Beate KETTLITZ, the Food Officer of the European Consumers' Organisation BEUC, pointed out the importance of scientific substantiation of claims and underlined her position by showing some examples of claims which are currently used in some Member States but can

hardly be regarded as scientifically be proven – most of them very vague and some even misleading.

[Mr Bas van der HEIDE](#) of the Food Department at the Ministry of Health of the Netherlands informed the audience of the current system where two voluntary codes exist. Under one of the codes, only the “plausibility” of the claims was being checked, while the second (from 2000) had up to now not been used very often by industry. He declared that the Netherlands would have preferred for each country to be able to decide on the precise wording of each claim in its own language(s).

[Mr Oscar HERNÁNDEZ PRADO](#), who heads the Food Risk Management Division at the Spanish Agency of Food Safety, showed the audience some examples of the current situation in his country which he described as “clearly chaotic”. The Commission’s proposal was therefore more than welcome, although he had some doubts concerning certain proposed restrictions.

[Ms Melanie RUFFELL](#), the Executive Director of the Joint Health Claims Initiative in the United Kingdom, explained that her organisation is a unique joint venture between consumer organisations, enforcement authorities and industry trade associations in the UK, which was established to draw up a voluntary Code of Practice for the use of health claims on food, beverages and supplements. It does this by providing an independent scientific opinion about the validity of health claims and by helping to ensure that claims do not mislead consumers or contravene food law. She explained in detail how companies are expected to substantiate their claims. She also highlighted a recent initiative called the ‘Well-established Health Statements’ project in which the JHCI received funding from the UK government to develop a process to identify and define ‘well-established’ health statements and to produce a list of ‘well-established’ nutrient function statements for the nutrients listed in annex to the 2002 food supplements directive. She announced that the list is due for publication in the coming weeks on the UK government’s website (www.food.gov.uk).

The industry viewpoint on the new food claims proposal and the other food measures under discussion at the conference was represented by [Mrs Sheila KELLY](#), a Member of the AESGP Board and the Executive Director of the Proprietary Association of Great Britain (PAGB). Following a brief description of where the claims initiative fits, Mrs Kelly cautioned that the procedure for the establishment of the EU list of well established claims foreseen by the new Regulation needs to be transparent and involve all stakeholders. She said that there needs to be discussion and agreement on supporting data as well as on claims that are not yet agreed by the EU but are in use in the Member States.

She added that claims that are not on the established list will be prohibited even if they are true. Therefore, AESGP is proposing that a mechanism should be established to allow existing national claims to continue and extensions to these claims to be approved nationally and then forwarded to EFSA for addition to the list. She was convinced that the misleading advertising directive would control them until there is EU consensus on the claim.

Concerning new claims that have to be approved by EFSA and published by the Commission before they can be made, the industry – although strongly welcoming the proposed exclusivity period – was of the opinion that there may be problems with the confidentiality of the data. Also, industry questions the need to get the claim approved in all Community languages and proposes to submit it only in the languages where marketing of the product is planned. She also made a plea for co-ordination between all the bits of regulation and directives now under discussion in the food area.

Commission wants to dispel certain misconceptions on claims proposal

Mrs Testori announced that the European Commission had recently published a [document](#) which is intended to dispel some of the mythology that has emerged recently in connection with the claims proposal. The document says, for example, that slogans for non-food products will not be affected at all. Nor will the proposal affect in any way advertising slogans for sweets or confectionery where clearly no nutrition or health claim is being made.

Short discussion on food fortification

No major discussion on draft Regulation

As mentioned earlier, this measure¹, which has as aim to harmonise the rules on the *voluntary addition* of nutrients to foods in the European Union, will probably be put forward by the Commission in November 2003. Generally speaking, there was little discussion about this initiative. After Mrs Testori had exposed the main purposes the Commission wants to achieve with the new Regulation, Mrs Kettlitz was the only party wondering whether consumers really needed it.

IMPLEMENTATION AND FOLLOW-UP OF FOOD SUPPLEMENT DIRECTIVE

The Implementation and follow-up of the [2002 food supplements Directive](#)² was discussed in a session chaired by **Mrs Emilia Franziska MÜLLER**, Member of the European Parliament and Rapporteur for the directive during its adoption process. She said that she was glad that the difficult stage of the adoption process – when she and other MEPs were troubled by an irrational lobby campaign against the Directive – was now part of history. The main outcome of the Directive had been the classification of food supplements as food, and that maximum levels were in the process of being set.

[Prof. Robert ANTON](#) of the “Université Louis Pasteur” in Strasbourg is at the same time a Member of the ‘Committee on Human Nutrition’ at the French Food Safety Agency AFSSA and of the ‘Committee on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food’ of the European Food Safety Agency (EFSA). He informed the audience about the French experience with herbal ingredients in food supplements and mentioned some of the claims allowed in French in connection with these herbal ingredients. He also explained the guidelines issued by the French Medicines Agency AFFSAPS for manufacturers wishing to market herbal ingredients as medicinal products.

[Dr Ariane TITZ](#), the AESGP Manager for Food-Related Issues, then gave an [overview](#) of the state of implementation of the food supplements Directive. She also reiterated the manufacturers’ fears that they would have to relabel their products several times over the next few years as a result of the different food-related measures currently being discussed.

The principles of quality assurance for food supplements were explained to the audience by **Dr**

¹ Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods

² Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements
http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_183/l_18320020712en00510057.pdf

Joachim BUG of Merck Consumer Healthcare, who is a Member of the AESGP Committee on Food Supplements.



Discussing the implementation of the 2002 food supplement directive, from left to right:
Prof. Robert ANTON, Université Louis Pasteur, Member of the Committee on Human Nutrition, AF-SSA, Member of the Committee on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food of the European Food Safety Agency, President of the Ad Hoc Committee on Food Supplements with Herbal Ingredients of the Public Health Committee at the Council of Europe; **Dr Hubertus CRANZ**, AESGP Director General; **Mrs Emilia Franziska MÜLLER**, Member of the European Parliament and Rapporteur for the directive on food supplements; **Mr Patrick DEBOYSER**, Head of Unit, Food legislation and biotechnology, Directorate-General Health and Consumer Protection, European Commission; **Dr Ariane TITZ**, AESGP Manager for Food-Related Issues; and **Dr Joachim BUG**, Member of the AESGP Committee on Food Supplements, Merck Consumer Healthcare

Future legislative measures planned by the European Commission to implement the food supplements Directive were presented by **Mr Patrick DEBOYSER**, the Head of Unit Food legislation and biotechnology at the Commission's Directorate-General Health and Consumer Protection. Implementing measures for food supplements include the setting of maximum/minimum amounts. These should be finalised by 1 September 2004, with publication about one year later, although this may happen in several instalments. Other implementing measures include the setting of purity criteria; modification of the Directive's Annexes and a report on other ingredients, possibly followed by a legislative proposal. Mr Deboyser also announced a reform of the novel food Regulation in 2004 as well as a comprehensive review of the food labelling rules. This will include a consultation on making nutritional labelling mandatory for all foods, with a possible limitation to five or six values such as energy, sugar, fat, salt and proteins, reflecting the final recognition by the European Commission of the link between food/diet and health.

In his concluding statement, AESGP Director General **Dr Hubertus CRANZ** summarised the state of play of the main pieces of legislation discussed at the Conference. He expressed the hope that, at the end of this whole process, these initiatives would lead to a reasonable balance in the classification of products whose status is currently not clear as medicines or as food.
