

Conference Report

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At the reception in the European Parliament in Brussels on 9 October 2007 hosted by **Dagmar ROTH-BEHRENDT**, Member of the European Parliament, AESGP President **Hans van ZOONEN** presented the new AESGP slogan approved that day by the AESGP Board:

Self-care: the first choice in health care

INTRODUCTION

Opening the conference, AESGP President **Hans van ZOONEN** mentioned that since the beginning of the decade the legislative and regulatory environment for herbal medicines and food supplements had made considerable progress in Europe. A new legal framework for food supplements was created in 2002 after an intensive political debate. Two years later, in 2004, a new legal framework for traditional herbal medicines was agreed which established the legal basis for the creation of monographs and a list of medicinal plants as well as a specific Committee for herbal medicines at the EMEA.

In the meantime, the provisions of these two directives had to be transposed into national legislation, which most of the countries had done. How much impact these pieces of legislation have really had and what remains to be done was one of the main topics of the conference.

The challenges posed by the implementation of the regulation of health and nutrition claims made in connection with food were the other main subject to be discussed. Following a bumpy ride through the EU institutions, the final text of this piece of legislation was published in January 2007.

THE SITUATION OF HERBAL MEDICINES IN EUROPE

Commission to push Member States on correct implementation

The Chair of the first session, **Dagmar ROTH-BEHRENDT**, Member of the European Parliament, felt especially close to what is happening with herbal medicines in Europe as she had been fighting for many years to put the current legal framework in place, and to make herbal medicines available as “part of the consumer’s free choice”. She called on the European Commission to put maximum pressure on the Member States that had not yet implemented the provisions of Directive 2004/24/EC on traditional herbal medicinal products “for whatever reason – because they do not believe in herbal medicines or because they want to protect their own market”.

Evaluating the EU herbal medicines legislation: Is there a need for amendments?

Commission proposes to enlarge scope of Directive 2004/24/EC...

Martin TERBERGER, Head of Unit Pharmaceuticals, Directorate-General Enterprise and Industry, European Commission, spoke about the draft report on the experience with the directive on traditional herbal medicines published earlier in 2007 under a legal obligation in the Directive and on which the period for comments was closed on 10 August 2007. The report looked in particular at the situation of certain products with a long tradition in medicinal use which do not qualify as traditional herbal medicinal products. The Commission came to the conclusion in its draft that the scope of the simplified registration procedure under Directive 2004/24/EC could be enlarged to encompass those non-herbal substances with a long-standing tradition, well-documented safety and evidence of efficacy, thereby proposing the removal of the discrimination on the use of these substances whose action can up to now be only “ancillary”.



...but certain other restrictions to remain

However, certain other constraints should not be lifted according to the Commission’s draft: Route of administration (injectables are still excluded), medicinal plausibility and unsupervised use are maintained (although these products may of course also be prescribed by a doctor).

Directive 2004/24/EC in figures

Terberger mentioned that there were still six Member States having failed to transpose the Directive, and when the report was drafted there were less than 100 applications and less than 10 registrations were granted in the whole of the European Union. Terberger wondered what was

hampering progress and warned that the Directive's original intention to make life easier for manufacturers of traditional herbal medicinal products by lessening the requirements should not be turned around by additional requirements, for example emanating from the Committee on Herbal Medicinal Products (HMPC) or from the Member States. "In case the regulatory balance becomes too unfavourable in the area of traditional herbal medicinal products, this will inevitably lead to products being placed on the market under more favourable regimes, for instance as food supplements," concluded Terberger.

Where do we stand with the harmonisation of herbal medicines in Europe?

Number of Monographs has increased in last few months

Konstantin KELLER, the Chair of the Committee on Herbal Medicinal Products (HMPC), looked back on the Committee's first three years as an independent scientific body within the EMEA. A new three-year term will start with the election of a Chair and Vice-Chair on 31 October 2007. Since the issuance of the Commission's draft report earlier in 2007, the number of final monographs had increased from 10 to 18, said Keller. "As of October 2007 there are also 5 pre-final monographs; 10 are under consultation, 7 are being discussed in the Working Party on Community Monographs and Community List (MLWP) and 45 rapporteurships have been assigned. Moreover, 2 final opinions on list entries are now being considered under the Scientific Committee procedure, 4 drafts are under consultation and 2 have been suspended because of genotoxicity concerns."



Undiscovered opportunities

The existence of an approved monograph or list entry allows traditional herbal medicinal products immediate access to the mutual recognition or decentralised procedures as soon as they are published, said Keller, who regretted that not more applications and requests for scientific advice had been received so far. He called this "undiscovered opportunities", especially since the HMPC "has the possibility under the referral procedure for traditional herbal medicinal products with a long tradition outside the EU to overrule the requirement for 15 years of use within the EU". Although there have so far not been any referrals under Directive 2004/24/EC, Keller announced that the HMPC had agreed at its own initiative "to endeavour to issue a reasoned opinion within 60 days of the date of referral".

Framework is now in place

With the installation of the three HMPC sub-committees, the Working Party on Monographs and List Entries (under Heribert Pittner), the Drafting Group on Quality (under Burt Kroes) and the Drafting Group on Organisational Matters / ORGAM (under Emiel van Galen); the secretariat being fully established in 2006 and financial resources being made available for literature in 2007, and guidance documents published on Application Format, Templates, Procedures, GMP, GACP, Testing, Specifications, Combination Products, non-clinical requirements, efficacy, and fixed combinations, Keller confirmed that "the regulatory and scientific requirements have now been clearly addressed". He encouraged companies to submit applications under Directive 2004/24/EC sooner rather than later given that the transitional period will end in March 2011.

Lack of financial resources

Keller regretted that the Committee's three attempts to co-opt an expert in the area of traditional herbal medicinal products had so far remained unsuccessful. The fact that experts are not remunerated if they do not belong to a national competent authority could be at the basis of this failure, said Keller.

As some of the main challenges for the operation of the HMPC, Keller saw the mobilisation of resources, especially within the national competent authorities, as there is currently "no compensation for the investments by these authorities". However, Dagmar Roth-Behrendt thought that some of this work "should be performed under these authorities' public service obligations".

Keller was moreover convinced that through the EMEA's contacts with EFSA, the safety rules for herbal medicines and food supplements would converge considerably in the near future.

The perspective of the upcoming Council Presidency

OK to extend the Directive's scope

The Commission's report on the operation of Directive 2004/24/EC also allows the Member States to express their views on the system in place and possible changes to be made. Their comments will be discussed during the Slovenian Council Presidency in the first half of 2008. The envisaged Chair of the Council Working Party in that period, **Barbara RAZINGER-MIHOVEC**, who heads the Herbal Medicines Unit at the Slovenian Agency for Medicinal



Products and Medical Devices, explained that herbal medicines had a long-standing tradition in her country going back to the 15th century. She called Directive 2004/24/EC "the right step in the right direction" and agreed with the Commission's proposal to extend the scope of the Directive given that "a lot of products containing substances of non-herbal origin are on the EU market that are not regulated as medicines or that are regulated in a non-harmonised way".

Borderline herbals/food supplements needs to be defined

With regard to the borderline area between herbal medicinal products and food supplements, Razingier was of the opinion that a clear differentiation was needed with regard to claims and advertising, and agreed with the European Commission that "it should not be possible that products which cannot be registered because an appropriate quality cannot be proven or because the safety cannot be assured to remain available as a non-pharmaceutical products in a widely uncontrolled environment".

The point of view of the Member States

Germany

Werner KNÖSS of the Federal Institute for Drugs and Medical Devices (BfArM) explained that his country's longstanding experience in the area of herbal medicinal products was confirmed by the fact that Germany was the first Member State to register a traditional herbal medicinal product under the new Directive, and that several more had followed. Moreover, the county finalised one registration under the traditional herbal medicinal product scheme in only eight weeks!



He regretted however that some Member States with a less longstanding tradition were still objecting to certain registrations and proposed pooling his country's resources with similarly experienced countries in the area of herbal medicinal products. Although Knöss thought that Europe should accept traditions from outside Europe, "this should not result in a situation whereby medicines from outside Europe would gain easier access to the European market than those with a European tradition".

Netherlands

Emiel van GALEN of the Medicines Evaluation Board in the Netherlands, who chairs the HMPC's Drafting Group on Organisational Matters, mentioned that his country had received 10 applications for herbal medicinal products in the past year and that two registrations were granted last July. Of the eight remaining applications, one is for a well-established use authorisation. He thought that Directive 2004/24/EC has certainly been of help since the Netherlands had received more applications in the past year than in the 10 years before. Moreover, the Netherlands was appointed rapporteur for two monographs. The fact that two of the HMPC's working groups are chaired by persons from the Dutch agency has certainly contributed to a better understanding of the European scene. He therefore encouraged other national agencies to contribute in an equal manner to the work of the HMPC.



United Kingdom



Richard WOODFIELD of the Medicines & Healthcare products Regulatory Agency (MHRA), acknowledged that his country came from an unsatisfactory situation whereby most herbal products were not licensed before the implementation of Directive 2004/24/EC. In order to bring this market sector into line with EU law, the UK maximised help and encouragement for companies to come within the legal provisions, provided information to consumers so that it would become the norm to choose regulated products; and applied vigorous enforcement where operators were hoping to remain outside the regulation.

As of September 2007, the UK had received 29 applications for a traditional registration from 9 different applicants covering 16 different herbal substances. So far 5 registrations from 2 different applicants had been granted covering 5 different herbal substances.

At the European level, the UK would like the HMPC to make progress on the list entries; publish the assessment reports used to prepare the monographs as this could save applicants significant work on safety and traditional use; make progress on the proposed guidelines on quality control of combination products; permit Member States to decide whether evidence of traditional use from outside the EU is acceptable; and rationalise its efforts in delivering effective pharmacovigilance. According to Woodfield, the existing referral procedure is likely to deter most companies and requires a lot of work for a rather uncertain outcome. In general, he warned against the risk of creating adverse incentives for companies using the traditional herbal registration route through changes in other areas of regulation, e.g. food supplements.

SCIENTIFIC ASSESSMENT OF HERBAL MEDICINES IN THE EUROPEAN UNION



Session Chairs **Giuseppe NISTICÓ**, Representative of the European Parliament on the EMEA Management Board, and **John BOWIS**, Member of the European Parliament

Member States should - and could - do more

The session on the scientific assessment of herbal medicines was chaired by **Giuseppe NISTICÓ**, the Representative of the European Parliament on the EMEA Management Board, who – together with Dagmar Roth-Behrendt - had provided invaluable support in the European Parliament to achieve a comprehensive legal framework for herbal medicinal products in the European Union. Like Roth-Behrendt, he called on the Member States to “show more zeal in the implementation of this framework”.

Nisticó hoped that under the EMEA’s Roadmap to 2010, Member States would take it upon themselves to help the HMPC work out 150 monographs by the year 2010, which would mean that each Member State would have to work on only 5 monographs. He praised AESGP for setting the priorities in this work and was confident that if this distribution of work was agreed, the target of 150 monographs could be achieved.

Progress on monographs explained in detail

Most monographs adopted by consensus

Heribert PITTNER, Vice-President of the Committee on Herbal Medicinal Products (HMPC) at the EMEA and Chairman of the HMPC Working Party on Community Monographs and Community List (MLWP) provided a detailed overview of the progress made so far with the establishment of herbal monographs and the adoption process. Although monographs can be adopted by an absolute majority of 17 votes (out of 31), Pittner reported that most were adopted by unanimity.



Adopted monographs by indication area

The 18 adopted monographs could be grouped into the following broad indication areas:

- laxatives, with well-established use and traditional indications such as “constipation”; “when easy defecation with soft stools is desirable”; “adjuvant in irritable bowel syndrome” and “hypercholesterolemia”;
- expectorants with well-established use and traditional indications such as “expectorant in cough associated with cold”; mild spasmodic gastro-intestinal complaints”; and “minor spasm associated with menstrual period”;

- sedatives, with well-established use and traditional indications such as “relief of mild nervous tension and sleep disorders”; “relief of mild symptoms of mental stress and to aid sleep”; “mild gastro-intestinal complaints including bloating and flatulence

The draft monographs cover indication areas such as expectorants, common cold, diuretics, gastro-intestinal disorders, skin problems, muscle pain, fatigue, etc. For monographs in preparation no indication areas could be reported as yet.

Areas for improvement

As points that could lead to an improved working of the HMPC, Pittner quoted the installation of peer review for monographs and list entries (as is currently the case in the Committee for Medicinal Products for Human Use (CHMP)); a procedure for updating monographs; the establishment of monographs for commonly used combination products, a possible restructuring of the Working Party on Community Monographs and Community List (MLWP) in the next HMPC period (starting 31 October 2007); and possibly financial compensation for rapporteurs / national competent authorities.

Quality requirements for herbal medicines

Background on draft guidelines



Burt KROES of the Botanicals and Novel Foods Department in the Medicines Evaluation Board of the Netherlands and Chair of the HMPC's Quality Drafting Group provided background on the adopted guidelines and reflection papers, on the documents released for consultation and on the drafting group's current work programme. He provided some particular background on the draft Guideline on the declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal / Traditional Herbal Medicinal Products in the SPC and on the draft Guideline on the quality of combination Herbal Medicinal Products / Traditional Herbal medicinal products.

HARMONISATION OF HEALTH AND NUTRITION CLAIMS

Revision of function claims

The harmonisation of health and nutrition claims was addressed in a session chaired by **Dagmar ROTH-BEHRENDT**, Member of the European Parliament. The Regulation on health and nutrition claims was adopted at the end of 2006 with the aim of harmonising the provisions related to nutrition and health claims made on food, ensuring a proper functioning of the internal market and providing a high level of consumer protection. The text was published at the beginning of this year and the claims regulation came into effect on 1 July 2007. However, an amendment concerning claims referring to children's development and health is still pending.

A key element in the implementation process is a thorough review of the 'function claims' based on generally accepted scientific evidence that are currently used on foods throughout the Union (the so-called Article 13 claims). For this purpose, Member States have been asked to submit national lists of claims by 31 January 2008.

Submission of Member States' lists

Austria

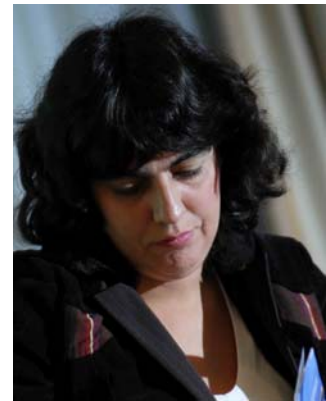
Claims covered

Amire MAHMOOD of the Federal Ministry of Health, Family and Youth in Austria provided background to the process used in her country to gather and classify the claims that would fall under the criteria of the Regulation's Article 13, i.e.:

Health claims describing or referring to:

- the role of a nutrient or other substance in growth, development and the functions of the body
- psychological and behavioural functions
- without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

These claims should be 'based on generally accepted scientific evidence' and be 'well understood by the average consumer'."



Pre-screening

The Austrian list, which is being compiled under the aegis of the Austrian Agency for Health and Food Safety (AGES) from input provided by stakeholders, will be structured according to an industry classification, said Mahmood. The Austrian list, which will not be exhaustive and which provides wordings that are only 'indicative' of the claims they represent, is being pre-screened by the AGES before being submitted to the European Commission by end January 2008. Mahmood explained that general 'wellbeing' claims (described in Article 10.3) may be connected with an Article 13 claim but are not intended for inclusion in the positive list.

No harmonisation of 'other substances'

Moreover, she made it clear that the approval of a claim in the Article 13 list cannot be used for the harmonisation of 'other substances' in food supplements (see the session on food supplements below).

Finland

Submission process started early



In Finland, the gathering of existing health claims is done by the Finnish Food Safety Authority (Evira), the Ministry of Trade and Industry and the monitoring group (authorities, representatives of the food industry, food supplement industry, commerce, research etc.) declared **Kaisa VAIHIA** of the Ministry of Trade and Industry. The process was already started in March 2006 and was given wide publicity through the media and a seminar in December 2006.

Elimination criteria

Vaihia listed the criteria used to screen the submissions: claims that are clearly medicinal were eliminated, as were claims which

clearly state the disease whose risk the product aims to reduce are being removed, e.g. “*compound X reduces the risk of heart disease*”.

Structure

The structure of the list will probably be a combination of proposals by the CIAA and PASSCLAIM. The experts are further categorising the claims into ‘convincing’, ‘probable’ and ‘questionable’. According to Vaihia, it has not been decided whether the last category will also be submitted to the European Commission.

United Kingdom

Much work to be done in a short period

Noel GRIFFIN of the Nutrition Division at the Food Standards Agency (FSA) provided background on the data-gathering process in the United Kingdom, where submission was possible for almost 12 months up to 21 September 2007. Most of the close to 2 000 applications were however received at the last minute, leaving the FSA with the task of pre-screening this vast amount of material in a short period of time in order to eliminate duplications, excluding medicinal claims (contacts are ongoing with the Medicines and Healthcare products Regulatory Agency (MHRA) concerning borderline claims) and novel ingredients, and generally removing questionable references so that the remainder can be properly assessed by EFSA.



Topics for the future

As likely subjects for future discussion Griffin mentioned the level of acceptable science, the differentiation of certain types of claims, consumer understanding and wording differentiation between medicinal claims and reduction of disease risk claims, and the review of available science.

Substantiation of health claims on foods

Tasks assigned to EFSA



The Chair of the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA), **Albert FLYNN**, looked at the area of claim substantiation. The European Food Safety Authority (EFSA) has been assigned the task of carrying out the scientific evaluation of the dossiers submitted in connection with those claims that are subject to an authorisation procedure, i.e. function claims based on generally accepted scientific evidence (Article 13 claims), disease-risk reduction claims and claims referring to children’s development and health (Article 14 claims) and function claims based on newly developed scientific data (Article 18 claims).

Evaluation of Article 13 claims in 2008-2009

In connection with health claims based on generally accepted scientific evidence, EFSA’s evaluation work will start from 31 January 2008, when Member States will have to submit the lists of claims, the conditions applying to them and the references to the relevant scientific justification. In 2008-2009, EFSA will assess to what extent the claim reflects the scientific evidence

taking into account the specific conditions of use of the claim, e.g. the quantity of nutrient / substance required for the claimed role / effect.

Recent guidance on how to apply for Article 14 claims...

As part of its work, EFSA in July 2007 adopted a guidance document for so-called Article 14 claim applications on which Flynn gave a number of details. Although not all information specified needs to be submitted for each claim, Flynn declared that EFSA was aiming for consistency in its evaluation. Criteria for substantiation of an Article 14 claim include:

- Relevance to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of the data for the target population.

...to be updated for Article 18 claims

This guidance should be reviewed and updated for Article 18 claim applications at a later stage, although it was not entirely clear from which date applications for a function claim based on new scientific data could be submitted.

No assessment of consumer understanding

Flynn added that EFSA would not assess 'consumer understanding of the beneficial effects of a claim' as this was neither feasible nor practicable.

Fitting the scientific evaluation in a regulatory framework

Key actions for the European Commission

Basil MATHIOUDAKIS, Head of the Unit Food Law, Nutrition and Labelling at the European Commission's Directorate-General Health and Consumer Protection (SANCO), informed the



conference about the progress made with the key actions foreseen as a follow-up to the two most relevant pieces of legislation affecting food supplements in Europe: the food supplements Directive (2002/46/EC) and the Regulation on nutrition and health claims made on food ((EC) No. 1924/2006).

Under the food supplements Directive, the Commission is charged with updating the list of vitamins and minerals and of their forms (certain applications have been received, but many were of poor quality); setting maximum and minimum levels (to be explained in detail by Fabio D'Atri) and producing a report on other nutrients or substances in food supplements (the so-called 'other substances' – report slightly delayed, probable publication early 2008).

Catalogue of novel foods / updating of food labelling rules

Concerning other relevant EU legislation, Mathioudakis mentioned that the Commission was expected to publish on its website a catalogue of novel foods (which would however not have legal status) and that the nutrition labelling Directive was currently being revised, with a proposal expected to be adopted by the Commission end October 2007.

Careful scrutiny of submitted function claims

Mathioudakis confirmed that the positive list of Article 13 (function) claims will be adopted via the Regulatory Committee procedure involving the Standing Committee on the Food Chain and Animal Health (consisting of representatives of the Member States and the Commission), at the latest on 31 January 2010. Although the Member States are carrying out a pre-screening in order to standardise the high number of submitted claims, Mathioudakis expressed some concern that the Member States' appreciation may differ from that of EFSA, and warned that the submitted lists will be scrutinised carefully.

Two Article 14 submissions received

Mathioudakis revealed that two claim applications under the Article 14 procedure (reduction of disease risk and children's development and health) had so far been submitted. EFSA has the obligation to evaluate these within 5 months, after which they may be granted a Community authorisation prepared by the Commission adopted via the Regulatory Committee procedure.

Other implementing issues

Implementing issues which still need to be addressed are:

- Interpretative guidance on the category where claims belong (i.e. the borderline between claims. Although this is not a legal obligation, interpretative guidance may remove some uncertainty in the market.
- Guidelines for preparation of applications based on the EFSA guidance.
- Transition periods for claims referring to children's health and development. The current limbo will be removed through a proposal currently before the European Parliament which, if it gets a smooth ride from the Parliament (as indicated by Dagmar Roth-Behrendt), may be adopted by early 2008.
- Addition of claims to the Article 13 list based on new scientific evidence (Article 18). As indicated by Albert Flynn earlier during the conference, maybe the possibility of adding claims should be opened up before the final adoption of the positive list foreseen in January 2010 in order not to stifle innovation.

The Commission as regulator

The Commission appreciated EFSA's commitment to ensuring consistency on the Article 13 claim evaluation. Mathioudakis hinted that the Commission would appreciate EFSA allowing it "to play its role as a regulator", i.e. by providing a real choice in its recommendations and not just a "yes" or "no" answer.

No automatic authorisation of 'other substances' in food supplements through claim approval

Finally, Mathioudakis concurred with Amire Mahmood that approval of a particular claim does not automatically authorise the use of the substance for which the claim is made all over the EU in food supplements. The report on 'other substances' (now expected out in early 2008) will provide a picture of how these 'other substances' are used in the Member States. However, Mathioudakis did not expect harmonisation of these substances to occur soon as no Community action has been requested on this point.

NEXT STEPS IN THE HARMONISATION OF FOOD SUPPLEMENTS

Session Chair **John BOWIS**, Member of the European Parliament, mentioned that food supplements are in increasing demand all over Europe from consumers asking for products that can supplement their diet by the intake of nutrients. Until the beginning of the decade, food supplements were regulated only at the national level, resulting in many obstacles to trade. The European Union then decided to take action by agreeing on a harmonised European framework for the manufacture and marketing food supplements, which was finally adopted in 2002 following an intensive inter-institutional debate.

Bowis also commented on the recently modified Comitology rules which allow Parliament the right of scrutiny into certain technical rules adopted under the Regulatory Committee procedure. Individual pieces of legislation had to be adapted by a 'codicil' implementing these new rules, meaning that not all measures are for the moment ready to allow such extended scrutiny by the European Parliament.

Status of food supplement harmonisation

Harmonised elements

Joachim BUG, who chairs the AESGP Food Supplements Committee, explained that as a result of the food supplements Directive, the following elements have been harmonised:



- The definition of what constitutes a food supplements (although there is no definition of what a "nutritional" or "physiological" effect actually means);
- Rules on the vitamin and mineral sources that may be used in a food supplement, with new sources added by Commission Directive 2006/37/EC. If manufacturers applied for a derogation by 1 August 2005, this means that the substance in question may continue to be used until end 2009 unless EFSA has issued an unfavourable opinion.
- Labelling rules.

Non-harmonised elements

So far not harmonised are

- Purity criteria / margins of tolerances. These should be adopted via the Regulatory Committee procedure. In case purity criteria exist for the manufacture of food in general, they also apply to food supplements. In case no purity criteria are specified by Community legislation, generally accepted purity criteria recommended by international bodies shall apply but Member States may maintain stricter criteria. This is only acceptable to industry during the transition period.
- The use of 'other substances', e.g. herbals, fibres, amino acids, essential fatty acids, etc Up to now Member States can set their own rules. However, in case manufacturers would like to innovate, the list of 'other substances' should apply to the whole of the EU, said Bug.
- Likewise, how can manufacturers be expected to develop a pan-European strategy as long as no maximum and minimum levels are set for the use of vitamins and minerals in food supplements? In this context Bug expressed appreciation for the European Commission's Orientation Paper issued in mid 2007 which seemed to favour the safety approach over the RDA-

based approach. He called this a good basis for discussion, especially given the wide disparity in RDA-based levels currently applied by the Member States.

Concerning the screening of the function claim list currently undertaken by the Member States and later by EFSA and the European Commission, Bug asked for a pragmatic approach so that the resulting list would be generally acceptable and not mean that it would only contain the lowest common denominator on every claim.

Setting maximum levels for vitamins and minerals

Fabio D'ATRI, Policy Officer in the Unit Food Law, Nutrition and Labelling of the European Commission's Directorate-General Health and Consumer Protection, explained that under *Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods* the Commission may submit proposals for the maximum amounts of vitamins and minerals added to food by 19 January 2009.



Of the 34 opinions requested and obtained by the Commission from EFSA and its predecessor, the Scientific Committee on Food (SCF), only 16 established a numerical upper level (UL). These opinions refer to the nutrients listed in Annex I of the food supplements Directive.

Interested parties were invited to comment on the Commission's [Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs](#)¹ of June 2006 in which the main issues were identified and 58 contributions were received, including from a limited number of Member States. The Commission's recent *Orientation paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* - summarising the results of the 2006 consultation and indicating the Commission's preferred choice on some of the issues raised - started the formal dialogue with the Member States at expert group level.

The main issues raised were:

- Nutrients for which no numerical upper level (UL) was established, either because of a lack of sufficient data or because no adverse effect was observed even at the highest dose of consumption. The upper level is different from the maximum amount (MA), defined as the maximum quantity of a nutrient that should be supplied in a daily portion of a food supplement or a fortified food. Solutions proposed include the taking into account of values established by other international scientific bodies.
- Given that the risk of adverse effects is so low for some vitamins and minerals, should maximum amounts be set for all nutrients? The Commission regards this as disproportionate and proposes the establishment of maximum amounts following only a risk-based analysis. However, this opinion is not shared by all Member States.
- The Commission has called for all available national intake data to be shared. Moreover, an ILSI project comparing all available European intake data would be ready by early 2008.
- The Commission and several Member States are of the opinion that intake data should apply to all different population groups. In this context, food supplements and fortified foods should not be confused with foods for particular nutritional uses. However, some Member States

¹ http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

seem to think that the intake of the most vulnerable groups should be taken into account. According to D'Atri, a common solution, possibly involving special warnings, can be found.

- On the question whether maximum amounts should be set separately for food supplements and fortified foods, discussion with Member States was at a very preliminary stage.
- As for the minimum amounts of vitamins and minerals to be present in food supplements, there seems to be general agreement to link this to the labelling Directive, which specifies a minimum of 15% of the RDA. Some Member States would however prefer 30% RDA.

The Commission will continue to work with the Member States on the setting of maximum and minimum levels in a step-by-step approach, in order to find acceptable solutions to all the issues raised.

CONCLUSION

Hubertus CRANZ, Director General of AESGP, ended the conference by highlighting some of the main outcomes. He appreciated the positive words of several representatives of the EU institutions on the AESGP contributions and that they were often incorporated into the legislation on herbals and food supplements. No major changes to the legal framework were needed as such. However, how these pieces of legislation are implemented on the national level remains key to facilitating market access for these products.



AESGP will stay closely involved in all developments around herbals and food, in line with the AESGP mission to develop a positive climate for the whole self-care market. In general, maintained Cranz, science and evidence needed to be rewarded in both categories to stimulate innovation. Overall the market is showing a low growth rate, if any, and all efforts should be geared towards improving the competitive situation of companies in this sector.

The next AESGP conference in London on 23-24 January 2008 [Making administrative simplification a reality for medicines in Europe](#)² will look in more detail at the better regulation agenda for the self-care sector. One session will be dedicated to herbals.

Cranz reminded participants of the positive reactions received after the publication of the AESGP study on the Regulatory framework for food supplements in Europe, which was launched at the AESGP 43rd Annual Meeting in Warsaw, Poland, 4-6 June 2007. The study was widely seen as a tool contributing to the work of manufacturers and authorities alike. Copies can be [ordered](#)³ from AESGP at info@aesgp.be.



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² <http://www.aesgp.be/London2008/ProgrammeLondon2008.pdf>

³ <http://www.aesgp.be/ELF/OrderformRFFS2007.doc>