Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Fachverband der Arzneimittel-Hersteller

AESGP Position Paper on the European Commission's discussion paper on Nutrition Claims and Functional claims (SANCO:1341/2001)

The Association of the European Self-Medication Industry (AESGP) represents the manufacturers of non-prescription medicines and food supplements in Europe. Its membership comprises 23 national associations as well as the leading multinational companies operating in this area.

AESGP welcomes the initiative of the European Commission for having released a discussion paper on claims for foodstuffs as announced in the European Commission White Paper on Food Safety of January 2000. AESGP considers this document as a starting point in order to initiate a wider debate on this topic, in which AESGP is most interested.

The discussion paper provides a comprehensive overview on the debate with regard to nutritional and functional claims. There are only a few issues on which we would like to comment:

Point 31 reflects correctly the current debate with regard to the minimum amounts of vitamins and minerals necessary to justify a claim. As mentioned in the discussion document, there are indeed concerns if 15 % are not slightly too high, however it is not seen as a real problem for our industry.

Concerning point 34, we would appreciate some clarifications on the specific conditions that may be necessary for vitamins and minerals.

Most comments received from our membership were made on point 47, which is related to the substantiation of claims. We would appreciate clarification on what references, such as "where available", mean in the context of totality of evidence. Further on, we believe that it would be appropriate to clarify the intellectual property rights of companies who carried out supportive studies for certain claims. Another point needing clarification would be to what extent substantiation of claims is related to specific dosages respectively strengths and to what extent certain studies may be used for different dosage levels. Also the issue of self-regulation needs to be addressed in this context.

Most importantly in this context will certainly be an overlapping debate on the area of health claims in relation to the evidence required to substantiate these claims and the systems and procedures for their assessment. We understand that the European Commission intends to initiate a separate consultation on this topic at a later stage. Evidently AESGP will be most interested in participating in this debate since food supplements are regarded as foods and should be regulated in the same way as regards claims. In anticipation of these discussions, AESGP is currently in a consultation process with its member associations and companies.

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