ANH PRESS RELEASE: Will supplements be classified as medicines in Europe?

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The ANH identified on 11 December that a Compromise Package developed for the Pharmaceuticals Directive (amending Directive 2003/83/EC), in preparation for its second (and final) reading in the European Parliament **could be particularly disastrous for the leading edge of the supplement industry**.

This was because this Package, prepared in consultation with the European Commission, the Council of Ministers and Rapporteur for the directive, **French MEP Francoise Grossetête (EPP group)**, would be put forward in place of Recommendations made by the the Committee on the Environment, Public Health and Consumer Policy, lead also by Ms Grossetête. These latter Recommendations included most of the key amendments that had succeeded at first reading of the amending directive, but had 'fallen away' in the subsequent Common Position. Indeed, during the vote on 17 December, the key part of the Compromise Package affecting food supplements (including amendments 60, 63 and 65) was adopted as a whole.

Fortunately, **steps were taken before the vote in an attempt to protect the 'medicalisation' of all supplements in Europe**. On 12 December, ANH consulted with its **expert legal Counsel** and commissioned a legal **Opinion** that confirmed the nature of the problem. This Opinion and **ANH's Briefing Note** on the subject (see text below) were delivered on 16 December, both to the European Parliament and the European Commission in Strasbourg, by a delegation from ANH (including Executive Director Dr Robert Verkerk and Legal Director, David Hinde, as well as representatives from Sweden and France).

ANH's key concern is that the scope of the pharmaceuticals legislation is so broad that it completely subsumes legislation on foods, food supplements, cosmetics and medical devices, including the Food Supplements Directive itself. Furthermore, the Commission's attempt to rectify this anomaly **would not firmly delineate medicinal from non-medicinal products in law**. This is because the Commission indicated in a Recital (7) to the amending directive that medicine legislation should not be applied to products that were "...clearly..." foods, food supplements, cosmetics or medical devices.

The new directive would therefore allow **any national authority – whenever it so chose – to consider *any* product that fulfilled the very broad definition of a medicinal product (including a food, food supplement, cosmetic or medical device) as a medicine and so force its manufacturer to comply with a full drugs licensing regime if it wished to go to market! Given that this regime is prohibitively expensive for most food supplement manufacturers, it would effectively amount to a ban on products - at the whim of the legislators!**

Irish MEP Avril Doyle (EPP group) became the key focal point for these issues in the EU Parliament in Strasbourg and raised the issues in the plenary debate on the evening of 16 December. **Extracts from her speech and questions as well as the responses from Commissioner Liikanen**, are given after the ANH Briefing Note below.

We eagerly look forward to a meeting of stakeholders, in which ANH will be represented, in order that the Commission's interpretation of the issue of delineation between medicinal and other products can be clarified. **ANH, together with other interested parties, wishes to continue to influence the situation in such a way that a product which is clearly a food supplement cannot be arbitrarily classified as a medicine.**

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