

## **EUROPEAN COMMISSION**

Cabinet of Commissioner John Dalli Head of Cabinet

> Brussels, Ares D(2011)

Dear Mr Verkerk,

## Subject: Open letter concerning the THMPD

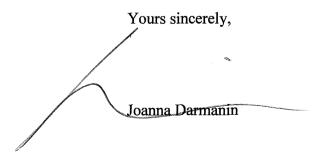
Thank you for your open letter to Commissioner Dalli dated 24 June 2011 including your views on the Question and Answer Forum on Directive 2004/24/EC held on 21 June 2011 in the European Parliament.

Let me stress again that above Directive was adopted precisely with the objective to facilitate the placing on the EU market of traditional herbal medicinal products. The simplified procedure allows the registration of traditional herbal medicinal products without requiring safety tests and clinical trials, which the applicant is obliged to provide under the full marketing authorisation procedure.

I can reassure you that the Commission, together with the European Medicines Agency, is determined and working hard to ensure the appropriate implementation and application of the Directive. In fact, the Commission services have multiplied their efforts to explain in detail all the questions related to the Directive on Traditional Herbal Medicinal Products, which was adopted in 2004 by the European Parliament and the Council.

I would therefore like to express my surprise at the biased way in which the Alliance for Natural Health has presented on its website the outcome and the video of the above mentioned forum. I also consider that your reference, in an open letter, to individual Commission officials is not appropriate.

As regards the questions posed in your open letter, I welcome your transparency in informing us that they will be formulated as formal questions to be asked in the Committee of Environment, Public Health and Food Safety (ENVI). Therefore, from an institutional point of view, it is appropriate to await the answers from Members of the European Parliament.



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