



European Commission
DG Enterprise & Industry
Unit F2 „Pharmaceuticals“
Mr. Nicolas Rossignol
45 Avenue D`Auderghem, Office 10/128
BE - 1049 Brussels

Brussels, 21 December 2007

Consultation Paper “Better Regulation of Pharmaceuticals: Towards a Simpler, Clearer and More Flexible Framework on Variations”

Dear Mr. Rossignol

ECHAMP E.E.I.G. represents 52 small and medium sized pharmaceutical companies active in the field of homeopathic and anthroposophic medicinal products in most of the EU Member States.

We gratefully welcome this ongoing consultation on the important topic of the variations. Referring to the public consultation paper version 24th October 2007 we ask for consideration of our attached comments.

We have also made some remarks on the Draft Commission Regulation version 24th October 2007. This includes a preliminary comment on the detailed draft guideline for which we expect further consultation later on in parallel with the procedure for the adoption of the legislative proposal reviewing the variations regulation.

Sincerely yours

A handwritten signature in black ink that reads "Nand De Herdt". Below the signature is a horizontal line.

Nand De Herdt
General Secretary

A handwritten signature in black ink that reads "Gesine Klein".

Dr. Gesine Klein
Chairperson Subject Group
Regulatory Affairs

Encl: ECHAMP Comments on European Commission Consultation on Variations of
24.10.2007