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European Comission, DC
G Enterprice & Industry, Unit F2 "Pharmaceuticals"

B1049, Brussels, Belgium

Riga, 21.12.2007.
Nr. 2031

Dear Mr. Rossignol

Our Company – the biggest pharmaceutical company in Baltic countries - with enthusiasm accept the work carried out by European Commission to make variations regulations simpler, clearer and more flexible.

EC Regulations 1084/2003 and 1085/2003 had been adopted in the legislation of Latvian Republic without delay. However, in the process caused by implementation of GMP and Ph. Eur. requirements (equipment modernization, change of previous API, starting materials, reagents and excipients manufacturers and suppliers to the new – audited and qualified, it appeared that the complicated and slow official variation procedures in high degree delayed progress of Latvian pharmaceutical manufacturers.

Supporting proposals from Prof. Dr. B. Sickmüller and Mr. M. Wilken (BPI, Germany), Latvian pharmaceutical manufacturers addressed to Mr. Terberger in year 2006 with the request to incorporate the best from German legislation in the new version of Variations Regulation. The proposals based on the newest trends and requirements of EU legislation (risk assessment, marketing authorizations holder responsibility about API used, involving of Qualified Person in development and clinical trials processes, Site Master Files constantly actualizations, Annual Product Reviews and trend analysis). According to the legislation, much of the present supervision work is charged to pharmaceutical inspectors, to manufacturer and to Marketing Authorizations Holder..

As the consequence, we support inclusion of some additional proposals taken from German legislation in the Regulation. It will reduce amount of documents and alleviate work for Medical Agency, too, without any threat to patients.

The main idea of our proposals: