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BY E-MAIL and COURIER

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Reporting Members

High Level Group of Independent Stakeholders on Administrative Burden

European Commission
1049 Brussels

Subject: Variations Regulation

Dear Madam, Sirs,

Following the implementation of the new EC Variations Regulation one of the undersigning associations has recently had two very disturbing experiences, demonstrating that there is a very high increase in costs and workload, in contrast to our understanding of the aims and intentions of the implementation of the European Commission (EC) Variation Regulation 1234/2008/EC and its guidelines. PPTA has previously written to you reporting these two cases (DGSanco10001, 25. May 2010, copy attached)

The first example is specific for the industry PPTA and IPFA represents, i.e. the Plasma Master File (PMF) second step procedure. The second case relates to grouping of variations which is relevant for all pharmaceutical industries submitting variations. The EMA and several EU member states (at national level) have recently published their updated fees according to the implementation of the EU Variation Regulation 1234/2008/EC.

It clearly appears that in contrast to previous arrangements each change now submitted in a grouping and which makes the same change across several products/presentations/pharmaceutical forms or which is related/consequential to the main change is charged individually. In fact, there is no longer a fee reduction when

variations are submitted in a group. We believe that the principle and obvious advantages of grouping (and also worksharing) disappear both in view of the new fee structure and also due to the eCTD structure, which also does not reduce workloads when compiling grouping applications.

The circumstances described above raise very critical issues for the whole of the pharmaceutical industry. For smaller companies with a large portfolio of products these developments and dramatic increases in costs will have a major impact on the economics of their activities and in some cases may act as a disincentive for product or quality developments. We are convinced that this is not the intention of EMA and the EC and therefore EuropaBio, PPTA and IPFA consider it important to inform the relevant European authorities about our experience and concerns as early as possible in the implementation process the of the EU variation Regulation 1234/2008/EC.

We would be very pleased to meet with the EC, the Agency and the CMDh to present further examples from our membership and bring them to your attention and will be happy to provide further clarification of our concerns..

Meantime we would be grateful to receive your comments and views in response to our observations and concerns described above.

Yours sincerely,

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