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January 4, 2008

Nicolas Rossignol
European Commission
DG Enterprise and Industry
Unit F2 - Pharmaceuticals
B 1049 Brussels, Belgium

Re: Proposal for a Commission Regulation 'Concerning the Examination of Amendments to the Terms of the Marketing Authorisations for Medicinal Products for Human Use and Veterinary Medicinal Products' (Version 24 October 2007)
(by e-mail)

Dear Mr Rossignol,

Wyeth appreciates the opportunity to provide feedback on the EU Commission draft proposal for a new Variations Regulation (referenced above). Our detailed comments are provided in the table enclosed.

In brief, we strongly support the:

- General principles which hold the promise to make the variation system significantly 'simpler, clearer and more flexible'. We are also supportive of the pragmatic separation of classification guidances from the regulation to facilitate a more frequent updating.

- Extension of the Community system to national MAs - and we would urge the process to be implemented as soon as possible.

- New procedures for Type 1A and 1AIN variations which we view as being extremely positive and would simplify the management and supervision of changes which are not expected to have any negative impact on the quality, safety or efficacy of the medicinal product concerned.

- Principle that unforeseen variations default to a Type IB - although we want to express a concern that the guidance might (i) be so comprehensive that there will be few cases of a default to a 1B and (ii)

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result in too many other cases where a Type II will be required because of an inability to comply with all the conditions for a foreseen variation and (iii) it is unclear how an unforeseen Type 1B variation will be processed.

- New possibility of 'grouping' variations together - although we believe the scope for grouping should be further widened.

- Option to use a 'Worksharing' procedure

- Incorporation of the 'Design Space' concept as a separate type of Type II variation (for introduction or amendment). We recommend an explicit reference to the Design Space concept in the main body of the Regulation and a statement that a change within an approved Design Space will not trigger a variation.

There will inevitably be instances where it will not be possible, or appropriate, to comply with all of the conditions of the change classification. Such situations may not impact on the quality of the product to such an extent that a Type II variation is motivated. A pragmatic way of handling such changes should be addressed in the Regulation.

Last, we could understand if there were concerns about the potential financial implications of a new framework for the handling of variations, in particular if national licences are to be included. Any such concerns should in our view be approached in a constructive manner by the stakeholders involved and should not be a hindrance for the implementation of more rational, harmonised, rules.

We trust that DG Enterprise and Industry will find our written feedback helpful and constructive and will take it into consideration when developing the future legal framework for variations.

Yours sincerely,

Mats Ericson, Ph.D
Director Global Regulatory Affairs Europe
Wyeth Research

[Attachment: Wyeth detailed comments table]