CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

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European Commission
Mr Nicolas Rossignol
Enterprise Directorate-General
Avenue d'Auderghem, 45
1040 Bruxelles
BELGIUM

Dear Nicolas,

Subject: Re: Co-ordination Group for Mutual Recognition and Decentralised Procedures – human (CMDh) response to the Public Consultation Paper - Better Regulation of Pharmaceuticals: towards a simpler, clearer and more flexible framework on variations

Introduction

Thank you for the opportunity to respond to draft proposals for a new Variations Regulation. The CMDh has reviewed the proposal and welcomes the Commission initiative to contribute to the Better Regulation policy agenda in the field of pharmaceuticals. In this regard we support the objective of making the Variations Regulation simpler, clearer and more flexible.

The new legislation will be deemed a success if it reduces administrative burden for both the pharmaceutical industry and the competent authorities, without compromising human health. We emphasise the need for simplicity of procedures and workable, practical arrangements. CMDh does have some concern that the current draft involves a level of complexity that may hinder the achievement of these objectives.

CMDh is therefore keen to progress development of the draft legislation in aspects where it can play a direct role in achievement of these objectives.

From discussion within CMDh it is apparent that individual Member States will be responding in detail to the contents of the full Regulation from a national perspective. We have therefore focused our comments on those parts of the Regulation that concern the group as a whole.

Article 16 of the Regulation specifically concerns the Co-ordination Group. We believe that the role of CMDh could be further clarified both in this Article and within the Regulation. Specifically:

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Article 5
Scientific recommendation on unforeseen variations
The current proposal for the classification of unlisted variations is for the EMEA to provide a scientific recommendation. CMDh believes there is a role for it in delivering such a recommendation. CMDh members have extensive experience of processing variations and will have knowledge of the products authorised nationally and through MRP/DCP. These will be the majority of variations processed. There is an existing variations sub-group comprising representatives of CMDh, CMDv and EMEA and this working model could be an option for delivering a recommendation.

Article 6
Guidelines
Article 6.1(b) provides for the Commission, in consultation with member states, the EMEA and interested parties, to prepare detailed guidelines on the operation of the procedures. CMDh has a good track record of preparing procedural guidance and best practice recommendations. These are updated regularly in consultation with interested parties and are made available in a transparent and timely manner. CMDh regards this activity as key to efficient functioning of the group and processing of applications and would wish to maintain this role without the formality of transforming the guidance into Commission guidelines.

Article 12
'Do and Tell' procedure for Type IA variations [MRP]
Article 12 includes the new concept of a Type IA annual report for notification of those 'Do and Tell' minor variations not requiring immediate notification. We foresee a role for CMDh and/or its secretariat in the administrative processing, scientific check or audit of annual reports connected with MRP/DCP authorised products, including how this information should be incorporated in databases such as CTS.

Article 16
Co-ordination Group and arbitration
Article 16 reflects that where an NCA is not in agreement with the opinion or the draft decision of the RMS, the matter should be brought to the Co-ordination Group, within which member states are encouraged to reach agreement on the action to be taken. Where there is disagreement with the final outcome the MAH or the NCA may refer the matter to CXMP for arbitration.

We believe that the role of CMDh should be further clarified in the context of a referral procedure and on the grounds for disagreement.

- **Referral procedure.** When setting up CMDh we had anticipated that procedures and operations would apply by analogy to variations. This approach was endorsed by the Heads of Medicines Agencies (HMA) in their vision paper. However Directive 2001/83/EC as amended did not provide for the 60 day extension of timetable necessary for a CMDh referral procedure. Instead, use of CMDh to facilitate agreement has to take place within the specified timeframe of a variation. In practice this has caused some difficulties and we are aware that interested parties have asked for a similar referral procedure for variations.

For a CMDh referral procedure to be introduced for variations there needs to be a clear provision in legislation with timeframes. In order to avoid unnecessary extension of timelines and ensure timely decisions are taken we propose that a variation referral would apply to Type II variations only. Articles 14 and 16 of the draft Regulation would require amendment. Provision for a CMDh referral when considering an extension of a MA must also be allowed for, as applying under current legislation.

- **Grounds for disagreement.** A referral to CXMP is foreseen in the legislation where there is disagreement with the final outcome by the MAH or a Member State. However the grounds for disagreement are not specified. CMDh believes there would be merit in introducing consistency between a variation and a new MA and would propose that the same principle of a "potential serious risk to public health" included within Directive 2001/83/EC applies to the Variations Regulation. This would be of particular importance if a CMD referral procedure is to be introduced.

Article 24
Worksharing procedure
CMDh regards this optional procedure as an important new provision to the Variations Regulation. However it has the potential to be complex in practice, particularly as grouped variations are eligible for worksharing, and the majority are likely to comprise national and MRP/DCP approved products. The NCAs have the expertise of these products. CMDh believes that it could play an important role in delivery of an opinion on worksharing for variations to national, MRP and DCP authorisations, and this should be considered as an alternative model to the current EMEA proposal.

A CMDh worksharing role would incorporate the following features:

- evaluation of variations to national, MRP and DCP authorisations
- simple procedures with clear conditions for eligibility
- fair distribution of work amongst member states
- use of CMDh and member state expertise in working with disharmonised dossiers
- agreement of consequences if not all concerned MS are in agreement with the outcome of worksharing
- an administrative co-ordination role for the EMEA CMDh secretariat
- development of a tracking system
- support of HMA to ensure the necessary NCA resources are available.

Conclusion
We see this new legislation as an important opportunity to maximise the potential role of CMDh in the post authorisation field of product development and implementation of product information to reflect the latest knowledge of the risk / benefit of the product.

Our points are addressed as high level principles and we would be pleased to discuss detail and expand our views further with you. A meeting at a convenient location involving me and one or two CMDh members could be arranged if that would be helpful.

With kind regards.

Yours sincerely

Mrs Truus Janse de-Hoog
Chairperson, CMDh

Cc.: *- All CMDh members*
- Esther Werner, Chairperson CMDv
- HMA Management Board