Dear Nicolas Rossignol,

At the Icelandic Medicines Control Agency (IMCA) we have been discussing the Revision of Variation Regulation and would like to make the following comments:

Main conclusion:
- The current variation system is a good system.
- If national variations were covered by the new Regulation would be a benefit for all.
- Guidelines instead of Regulation is a major step in the right direction, enabling flexibility in classification of changes.
- Worksharing, within the CMDh/v field, would be an important step forward.

Worksharing:
IMCA would recommend that CMD should be the platform for worksharing in the area of DC/MR and national procedures.

Grouping:
IMCA is in favour of grouping concerning one marketing authorisation. Grouping of several marketing authorisations is however likely to add to the administrative burden on NAs.

Annual report:
“Do and tell” IA variation applications which affect SPC, Labelling, PIL could lead to disharmonisation in the EEA market and misleading information for patients.

IB reclassified as II:
The IMCA points out the possibility of disharmonisation if NAs have the option to reclassify.

On behalf of Rannveig Gunnarsdóttir, forstjóri/Executive Director

Thorbjorg Kjartansdottir

Head of Licencing Unit