

CMD(h)-(v) SUB-GROUP ON VARIATION REGULATION

BACKGROUND

The Variation Subgroup is a joint subgroup of the CMD(h) and CMD(v) meeting monthly in the margins of the CMD meetings to facilitate the implementation of the revised variation legislation.

MANDATE

The mandate of the Sub-group on Variation Regulation will be:

1. Prepare proposals for
 - a. new CMD guidance and documents to the revised Variation Regulation, and
 - b. adaptation of existing CMD guidance and documents to the revised Variation RegulationThese proposals will be forwarded to the CMD(h) and CMD(v) for endorsement.
2. Input to EC proposals, e.g. for Guidelines
3. Common interpretation of the revised Variation Regulation in order to ensure a consistent approach with variation procedures in the future.

For common topics such as recommendations on classification of unforeseen variations and work sharing, a joint discussion with the EMEA should take place in the subgroup.