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| <p style="text-align: center;">EXAMPLES FOR ACCEPTABLE AND NOT ACCEPTABLE GROUPINGS FOR MRP/DCP PRODUCTS</p> |
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For future variation applications comparable to those listed below as acceptable groupings applicants do not have to contact the RMS for acceptance as these grouped applications are already accepted by all EU member states.

1. ACCEPTABLE GROUPINGS

- All minor notifications of type IA and type IA_{IN} may be grouped in one application without any relation to each other, if the group includes only type IA and type IA_{IN}.
- Only notifications of type IA or IA_{IN} may be grouped for more than one MA.
- The update of Module 1 incl. User Test, Braille, Environmental Risk Assessment, DDPS, RMP, QPs declaration etc., e.g. in preparation of a Repeat Use MRP may be submitted as one single application according to type II. The change may be introduced under classification category C.I.z – Update of Module 1 in preparation of a RUP.
- After a transfer of the MA in one or more member states to a new MAH – which itself is an independent purely national application – all other changes related to that transfer, e.g. change in product name in that member state, new DDPS for the new MAH etc. may be grouped in one application according to the highest variation type for the single changes.
- In connection with the introduction of a new manufacturing site other changes, e.g. changes in batch size, changes in batch releaser and controller, changes in the manufacturing process of the finished product including in-process controls etc. may be submitted in one application as a grouped variation according to the highest variation type for the single changes. All these changes are regarded as belonging to the same project as described in Annex III of the Regulation “All variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance”.

2. **NOT ACCEPTABLE GROUPINGS**

- Introduction of a new API manufacturer with a new ASMF may not be grouped with other unrelated quality changes concerning the active substance or the finished product but have to be submitted as separate applications.
- Variations for several minor changes of type IA and type IB though related to each other may not be grouped for more than one MA. In these cases a worksharing procedure should be followed.
- Changes to module 3 may not be grouped with a change in the product name if there is no relation between these changes and a common assessment is not justified. In exceptional cases where the changes to module 3 and the change in the product name are related with each other, e.g. changes in flavour, a grouping would be acceptable. However, the applicant should liaise with the RMS before submission.