Temporary repackaging of medicines with a marketing authorisation

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Occasionally, a marketing authorisation holder (MA holder) will need to repackage a medicinal product for a short temporary period. The Danish Medicines Agency considers that repackaging should generally be carried out by one of the manufacturing sites approved in the marketing authorisation. This should contribute to ensuring a high quality of the repackaging, and the Danish Medicines Agency does not need to be involved.

But sometimes financial and logistical aspects may imply that it is not always possible for the MA holder to use one of the manufacturing sites authorised in the marketing authorisation.

If the marketing authorisation holder (MAH) temporarily needs to repackage medicinal products at a new location, the MAH must submit a variation of the type IAIN, no. B.II.b.1.a application under the purely National Procedure. This also applies to medicinal products authorised under MRP and DCP. The assessment time is the same for a temporary repackaging variation and for a type IAIN variation. The application form is available via the link “EU variation application form (human and veterinary)” in the box to the right, from where you will also find further information and guidelines on variation applications.

Once you have filled in the application form, please send it to the Danish Medicines Agency, Sagsstyring, Axel Heides Gade 1, 2300 Copenhagen S, Denmark.

In connection with 'applications for a secondary packaging site', it must be decided whether the secondary packaging site should also be responsible for releasing the medicinal products or whether this should be arranged by the batch release site used so far. If the new secondary packaging site is to release the medicinal products, the package leaflet must be changed. Alternatively, it is necessary to apply separately for exemption from the Danish executive order on labelling etc. of medicinal products (in Danish titled: “mærkningsbekendtgørelsen”).

Regardless of whether it is the batch release site used so far or the secondary packaging site which appears on the package leaflet, GMP agreements must be arranged between the involved Qualified Persons (QP agreements). It is furthermore

assumed that technical agreements between the MA holder and the secondary packaging site have been made.

For more information concerning

- Repackaging: **Send a mail**
- Exemption: **Send a mail**
- GMP: **Send a mail**

Did you get answers to your questions?

Yes | No

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Danish Medicines Agency
Axel Heides Gade 1
2300 København S
Email: dkma@dkma.dk

Contact the Danish Medicines Agency
+45 44 88 95 95 (9am - 3pm)

Contact DKMAnet
+45 44 88 96 94

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