Updates to packaging components and instructions on submissions if the UK leaves the EU without a deal for those marketing authorisations (MA) issued following conversion of EU MA

The steps companies will need to take to register new artwork for medicines packaging as a result of new marketing authorisations being issued in the event of a no-deal Brexit.

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Once you have been issued with your new Marketing Authorisation (MA), you have 21 months to establish and register a UK presence for your MA. This will include submitting amended artwork for approval to accommodate the following new administrative information:

- name and address of Marketing Authorisation Holder (MAH) or representative
- UK MA number
- name and address of product manufacturer for batch release

Actions to take once you have been issued an MA

You will have a further 12 months (33 months in total from exit day) to ensure all stock released to market is in compliant packaging. This additional time allows for assessment of your submission(s) and time for implementation in the production schedule.

You may need to amend the labelling and/or the patient information leaflet (PIL) to take account of new information as a result of a variation between the grant of the new MA and 21 months from when Brexit takes place. In such cases, the changed artwork which accompanies that variation application should include the new administrative information at that earlier time.

If you are making changes to the labelling and/or the PIL as a consequence of a variation application, you should submit the full colour mock-ups as part of the variation submission. These will be assessed and approved as part of the variation procedure. Normal fee arrangements apply.

If you are only changing the name and address of the marketing authorisation and/or the manufacturer for batch release (stated in the PIL) you may do this as part of a Better Regulation of Medicines Initiative, BROMI notification. Normal fee arrangements apply.

If you are making any other changes to the statutory information or the pack design (which are not consequential to a change to the Summary of Product Characteristics (SmPC)), you will need to submit the artwork for full assessment to the Product Information Quality Unit under change code P2. Normal fee arrangements apply.

Multi-language packs

The MHRA will continue to allow multi-country packs, including packs with more than one language on the pack and/or in the PIL, provided that the entirety of the information is compliant with the UK requirements.

National MAs granted after a mutual recognition or decentralised procedure

MAs previously the subject of a mutual recognition or decentralised submission will be considered as purely national licences. Changes to packaging components which previously may have been suitable for submission via an MR 61(3) submission will now be considered under the national rules.

In many cases these changes will be suitable for self-certification under the BROMI scheme. Some changes, however, will need to be submitted for full assessment.

See our information on submission categories, best practice guidelines and the fees which apply.

Submission and best practice

Full details on how to submit applications for assessment, national best practice guidance and the fees.

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019. This guidance follows on from the further guidance note published on 3 January 2019