



Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU

Head of Regulatory Affairs

gov.uk/mhra

2nd January 2019

Dear Head of Regulatory Affairs

Preparations in the event of a No-Deal Brexit :

Conversion of Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs)

Delivering the deal negotiated with the EU remains the Government's top priority. This has not changed. However, the Government must prepare for every eventuality, including a no deal scenario. This letter is to inform you of the actions you are requested to take as a Marketing Authorisation Holder (MAH) of a CAP in the event of a 'no deal' scenario.

To facilitate the grandfathering process, the MHRA has assigned a Product Licence (PL) number to CAPs based on the existing UK practice for national licences. These are listed in the annex to this letter.

To ensure that the grandfathering process runs smoothly, actions you are requested to take concerning the attached list of products are:

1. Check the list of your currently authorised CAPs and advise us as soon as possible of any errors or omissions in that list.
2. Review the list of assigned UK MA numbers and contact us as soon as possible if you have a query in relation to the number of different UK MA numbers allocated.
3. Advise us of any CAPs that you do not want to be converted into UK MAs.
4. Advise us of the UK marketing status of each of the products. ie marketed or not marketed
5. Advise us of any of the product/presentation that have been withdrawn or cancelled.
6. Advise us if the MAH company number assigned to the list of products is incorrect.
7. If possible advise us of a single point of contact for all your products. (In the case of a company group, we need a contact for each MAH affiliate within that group)





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MAHs can opt-out of the grandfathering process for all or some of their CAPs by notifying the MHRA in writing by 22nd April 2019. If an MAH chooses to opt-out, after 22nd April 2019 their product(s) will no longer be licensed in the UK. This will mean they can no longer be placed on the market in the UK.

However, to help with our contingency planning for the event of no deal, we ask that you advise us by the end of January if you are planning to opt out and not have a UK licence for a product (i.e. point 3 in the above list), ideally as part of your full return, or if not via a separate communication to the MHRA using the contact information listed at the bottom of this letter

MAs for CAPs that are not currently marketed in the EU or UK can still be converted to UK MAs. For the purposes of operating the Sunset Clause, the period of three years will be restarted from the date of conversion to a UK MA.

There is no fee associated with the conversion from a CAP to a UK MA. In line with our existing legislation, the annual periodic fee will be payable for converted CAPs from 1 April 2019. Guidance on these fees can be found at: <https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees>

In the meantime, if you have any questions about this conversion process, please send them to **capconversion@mhra.gov.uk**

MHRA CAP Conversion Team

