Medicines & Healthcare products Regulatory Agency

MHRA

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Dear Head of Regulatory Affairs

Conversion of Community Marketing Authorisations (CAPs) to Great Britain Marketing Authorisations (MAs)

At the end of the transition period we will need to put in place arrangements for the continued authorisation of medicinal products. This letter is to inform you of the actions we intend to take concerning CAPs and the actions we need you to take as a Marketing Authorisation Holder (MAH) of a CAP

As set out in the further guidance published in September 2020, transitional provisions in The Human Medicines (EU Exit) Regulations 2019 will ensure that all currently granted Centrally Authorised Products (CAPs) automatically become Great Britain MAs on 1 January 2021, although the holders will have 21 days to opt out of having a Great Britain MA.

To facilitate the grandfathering process, the Medicines and Healthcare products Regulatory Agency (MHRA) will assign a Great Britain Product Licence (PLGB) number to CAPs based on the existing practice for national licences. These are listed in the annex to this letter.

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

1. Review the list of your currently authorised CAPs and advise us as soon as possible of any errors or omissions in that list.
2. Advise us of any CAPs that you do not want to be converted into Great Britain MAs
3. Advise us of the Great Britain marketing status of each of the products (i.e. marketed or not marketed).
4. Advise us of any product/presentations that have been withdrawn or cancelled.
5. Advise us of the MAH company number.
6. If possible, provide us with 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).

Please reply with the number of PLGB numbers you require, if you are intending to do a Change of Ownership (COA) when you submit your baseline submission (see the guidance for COA and baseline submission). Please inform us which company number prefix to use and we will allocate the PLGB number and send an updated list for you to use when submitting the baseline submission.

Please advise by writing to us at capconversion@mhra.gov.uk

To help with our planning, we ask that you advise us as soon as possible at capconversion@mhra.gov.uk if you are planning to opt out and not have a GB licence for a product (i.e. point 2 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.

MAHs can opt-out of the conversion process for all or some of their CAPs by notifying the MHRA in writing by 21 January 2021. If an MAH chooses to opt-out, after 21 January 2021 their product(s) will no longer be licensed in Great Britain. This will mean they can no longer be placed on the market in Great Britain.

MAs for CAPs that are not currently marketed in the EU or Great Britain 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 Great Britain MA.

There is no fee associated with the conversion from a CAP to a Great Britain MA. In line with our existing legislation, the annual periodic fee will be payable for converted CAPs from 1 April 2021.

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

MHRA CAP Conversion Team