# Updates to prescribing information for centrally approved medicines and other medicines from 1 January 2021

The MHRA has issued guidance regarding the process for the conversion of centrally approved products (CAPs) to UK marketing authorisations (MAs) from 1 January 2021.

On 1 January 2021 the MHRA became the UK's stand-alone medicines and medical devices regulator, taking any decisions and carrying out any functions which were previously taken or carried out at a European Union (EU)-level except for decisions on MA applications made through European procedures to market medicines in Northern Ireland (NI).



**PMCPA Press Release 16 February 2021 to replace guidance published on 10 April 2019**

A number of companies have contacted the PMCPA about the end of the transition period on 31 December 2020 and its impact on activities covered by the ABPI Code of Practice for the Pharmaceutical Industry. From 1 January 2021 changes to marketing authorisation (MA) numbers are required for many products. Companies may also change the marketing authorisation holder's (MAH) name and address as part of this process. There will be implications for ensuring compliance with the ABPI Code including requirements that prescribing information in advertising is up-to-date.

The MHRA guidance refers to the automatic conversion of CAPs into MAs effective in Great Britain (GB) only and issued with a GB MA number on 1 January 2021. This is referred to as 'Grandfathering' and these UK MAs are referred to as 'converted EU MAs'. As a result of the implementation of the Northern Ireland Protocol, existing CAPs will remain valid for marketing products in Northern Ireland.

To support the ongoing regulation of these converted EU MAs, the MHRA requires essential baseline data and companies will have a period of 12 months from 1 January 2021 to submit this information.

There is agreement in relation to decisions made by the European Commission between 1 January 2021 and 31 December 2022 whereby the MHRA may adopt approvals leading to a GB licence.

Clause 4.1 of the 2019 ABPI Code requires that prescribing information be provided and this includes the number of the relevant marketing authorisation and the name and address of the holder of the marketing authorisation, or the name and address of the part of the business responsible for the sale or supply of the medicine. Clause 7.2 of the 2019 ABPI Code requires that materials are up-to-date.

Pharmaceutical companies with centrally approved medicines should update the marketing authorisation numbers and any change to the marketing authorisation holder name in promotional material as soon as possible after 1 January 2021, and by

no later than 1 January 2023, and prior to 1 January 2023 must do so when other changes are needed.

For the period from 1 January 2021 until 1 January 2023, a complaint that the prescribing information for a previously centrally approved medicine does not have the new marketing authorisation number or any new marketing authorisation holder's name and address as required by Clause 4.2 (vii) of the 2019 ABPI Code will not be considered to be in breach of that clause and potentially any other relevant clause provided that:

- other changes to the prescribing information have not been needed
- the prescribing information includes the previous information about the marketing authorisation number and
- any new marketing authorisation holder can be contacted via the address given in the prescribing information.

This will also apply to medicines (other than those centrally approved) if the marketing authorisation numbers and marketing authorisation holder name and address are changed from 1 January 2021 as a result of the departure of the UK from the EU.

**Opting-out**

MAHs could have chosen to opt-out of the conversion process for all or some of their CAPs by notifying the MHRA in writing by 21 January 2021. Such products are no longer licensed in GB and must not be promoted in GB.

**Applications for new products from 1 January 2021**

From 1 January 2021 companies will be able to apply to the MHRA under new arrangements for UK licences. This includes procedures to prioritise access to new medicines, an accelerated assessment procedure and new routes of evaluation with a view to issuing a UK licence.

**Arrangements for all licences from 1 January 2021**

There will be a range of licences for medicines in the UK from 1 January 2021. A medicine will have one of the following: separate GB and NI licences (Grandfathering); a single UK licence; a GB only licence: or a NI only licence. The NI licence may be a national NI licence (as described above for new products from 1 January 2021) or a centralised EU licence. Such medicines will be available and can be promoted in all parts of the UK where the product is licensed (ie GB and/or NI).

Given the prohibition on promoting prior to the grant of a marketing authorisation in the ABPI Code, the PMCPA is working on amendments to the agreed 2021 ABPI Code and guidance in relation to the 2019 ABPI Code to help companies ensure that their medicines are promoted appropriately. Both the GB marketing authorisation number and the NI (NI or EU) marketing authorisation number will need to be included when medicines are licensed in both territories and promoted across the UK (ie GB and NI). This is likely to be the most common approach. However companies need to start to take account of where in the UK the medicine is being promoted.

The table below sets out the current position and will be updated if necessary:

| **Valid marketing authorisation** | **UK countries where such a medicine can be promoted** | **Can one advertisement comply with all UK requirements?** |
|---|---|---|
| GB and NI (or EU pre 31 December 2020) marketing authorisations (most common situation) | UK-wide - England, Wales, Scotland and Northern Ireland | Yes. Both marketing authorisation numbers and holders' addresses needed<br><br>(preferred approach wherever possible) |
| UK marketing authorisation | UK-wide - England, Wales, Scotland and Northern Ireland | Yes. One marketing authorisation number and holder's address needed |
| GB marketing authorisation only (available from 1 January 2021) | England, Wales and Scotland | No, as product is not licensed in Northern Ireland.<br><br>Material will need to state that the medicine is licensed in GB. |
| EU marketing authorisation post 1 January 2021 with a GB marketing authorisation (following a GB application) | UK-wide - England, Wales, Scotland and Northern Ireland | Yes. Both marketing authorisation numbers and holders' addresses needed<br><br>(preferred approach wherever possible) |
| EU marketing authorisation post 1 January 2021 without a GB application or NI marketing authorisation only | Northern Ireland | No, as product is not licensed in GB. |



Currently the above table applies where the marketing authorisations are essentially identical in GB and NI (other than administrative differences such as MA numbers or holders' names and addresses). If in future there is divergence between the terms of the licences in GB and NI, companies will need to ensure that any UK-wide advertising is not misleading and not inconsistent with the terms of both licences. Further guidance will be provided on this at a future date as needed.

Where a company is promoting a product with only a GB licence then this should only be promoted in England, Wales and Scotland. Similarly where a company is promoting a product with only a NI (NI or EU) licence then this should only be promoted in Northern Ireland. Companies must take reasonable precautions to ensure that advertisements do not appear in the territory where the product is not

licensed. When promoting a product that only has a GB licence a statement is also required that the product has a GB licence. UK-wide promotion is only permissible where a product has separate licences in both GB and NI, or a UK licence.

**Q and A**

**Can a company have material that is suitable for both GB and NI?**

This is the most likely and simplest approach. From 1 January 2021 the medicine will either have both GB and NI (NI or EU) licences or a UK licence and thus UK-wide advertising with the necessary marketing authorisation numbers (and both marketing authorisation holder details if different) will be possible and will meet the requirements of the Code in this regard.

When a medicine has a marketing authorisation in both GB and NI, it is acceptable and helpful to include details of both GB and NI marketing authorisations in materials for any UK audience.

**Can a GB only licensed medicine be promoted in a UK-wide health professional journal?**

Companies will need to ensure that they consider the circulation of such UK publications to ensure that the medicine being promoted is licensed for use by the intended audience. If the medicine does not have the relevant licence (ie UK or both GB and NI (NI or EU)) then advertising is not permitted in a UK-wide publication that is distributed in NI.

**Why is there a requirement to state in advertising for a GB licensed medicine to a GB audience that the medicine is licensed in GB?**

The requirement is to ensure that the audience is clear and to address any inadvertent spill-over into NI for an advertisement aimed at a GB audience.

**Can an NI (EU) only licensed medicine be promoted in a UK-wide health professional journal?**

It is unlikely that such advertising would meet the requirements of the Code as the audience would not be wholly or mainly in NI and therefore the advertisement in a UK journal would be seen as promoting a medicine without a marketing authorisation in GB.

**What about promotional meetings?**

Companies will have to ensure that materials used at meetings are geographically suitable. So if a representative is visiting a pharmacist in NI, the materials etc will have to comply with the relevant marketing authorisation in that territory. Similarly if a meeting is being held in Wales for Welsh and English health professionals the materials etc will have to comply with the relevant marketing authorisation in GB.

When a medicine has a marketing authorisation in both GB and NI, it is acceptable and helpful to include details of both GB and NI marketing authorisations in materials for any UK audience.

**What about the required adverse event reporting statement?**

There is no need for any changes to the requirements in the Code for this to be included in promotional and other materials used in the UK.

**When will the PMCPA issue more details?**

The position as set out above will be included in the 2021 ABPI Code and the PMCPA will issue more guidance in due course if needed.

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The PMCPA position as outlined above has been discussed with the Advertising Standards Unit, Vigilance and Risk Management of Medicines, MHRA and the Code of Practice Appeal Board.

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