Windsor Framework – PMCPA guidance for promotional material

This guidance was produced in consultation with the MHRA. If a complaint is received under the ABPI Code about any matter referred to in this document, it would be considered in accordance with the PMCPA Constitution and Procedure; the Appeal Board would make the final decision if a case went to appeal. Each complaint is considered upon its own merits and based upon the allegations raised by the complainant.

1. Background

Since 1 January 2021, the Northern Ireland Protocol has meant that medicines in Northern Ireland ("NI") were authorised by the European Commission ("EC") as a Centrally Authorised Product with an EU licence number.

From 1 January 2025, the Windsor Framework[1] comes into effect and will mean that all medicines in the UK will be licensed by the Medicines and Healthcare products Regulatory Agency ("MHRA").

One of the effects of the Windsor Framework is that marketing authorisations ("MAs") that were issued by the EC (for a product approved through the European Medicines Agency centralised procedure) will no longer be valid for NI from 1 January 2025. Instead, the MHRA will issue UK-wide MAs for these products.

2. Licence numbers

From 1 January 2025, the EU licence number that was assigned to licences applicable in NI will no longer apply.

Companies will need to ensure that their promotional material refers to the appropriate licence number(s) with the prefixes outlined below:

- **UK-wide MA:** a product licensed by the MHRA, across the whole of the UK (which may include MAs with a PL or PLGB prefix).
- **NI MA (PLNI):** a product licensed by the MHRA that covers NI only as the territorial application, with PLNI as the MA number prefix.
- **GB MA (PLGB):** a product licensed by the MHRA that covers Great Britain ("GB") only as the territorial application, with PLGB as the MA number prefix.

3. Prescribing information

Prior to 1 January 2025, UK-wide advertisements may have listed a PLGB number (for GB) and an EU number (for NI) in the prescribing information ("PI"). This may have been within one combined PI or as separate PIs.

[1] https://www.gov.uk/government/collections/mhra-windsor-framework.

From 1 January 2025, the PLGB number will cover these UK-wide advertisements because that number represents a UK-wide licence for these products from this date.

From **1 January 2025 until 31 December 2025**, the PMCPA is providing a grace period. During this period, the PMCPA will not consider it a breach of the ABPI Code if the MA number and/or MA holder's name and address, as required by Clause 12.2(vii), is incorrect for NI. However, this grace period is subject to the company also satisfying all of the following criteria:

- the rest of the PI is otherwise consistent with the summary of product characteristics ("SPC") in place from 1 January 2025;
- other changes to the PI have not been needed (in which case the MA number and MA holder's name and address should be updated at that point);
- the PI has an MA number that was accurate as of 31 December 2024; and
- from 1 January 2025, the MA holder can still be contacted via the address given in the PI.

For the avoidance of doubt, this grace period only applies to the MA number and MA holder's name and address, and only if all the criteria above have been met. It is nonetheless important that the MA number and MA holder's name and address is updated at the earliest available opportunity to avoid any potential confusion.

If all the criteria above cannot be met, then the company should withdraw/amend the promotional material promptly, and at the very latest by 15 January 2025. This date has been selected for the purposes of considering complaints under the Code and takes account of the holiday period, the unique circumstances of the Windsor Framework and the large volume of material that may be impacted. However, the company has an obligation under UK law to keep all promotional information up-to-date at all times, and therefore the company is responsible for any continued use of its material from 1 January 2025 onwards.

4. Advertising territories

Following changes made by the Windsor Framework, the vast majority of MAs will be UK-wide and therefore these medicines can be advertised UK-wide. However, there may be exceptional cases where a medicine is only licensed in part of the UK (e.g. GB or NI). In these cases, the medicine may only be advertised in the part of the UK where it is licensed, and UK-wide advertising is prohibited. Where the licence is not UK-wide, companies should continue to make it clear as to which part of the UK the material relates e.g., "For NI health professionals only" or "For GB health professionals only".

Q&As

Question: Section 3 above refers to the PI. What about the rest of the promotional material content?

Answer: Companies should be making preparations to update their materials so that the information is up-to-date as soon as possible from 1 January 2025. If the content of the promotional material is not consistent with the SPC in place from 1 January 2025 then the promotional material should be withdrawn/amended promptly, and at the very latest by 15

January 2025. This date has been selected for the purposes of considering complaints under the Code and takes account of the holiday period, the unique circumstances of the Windsor Framework and the large volume of material that may be impacted. However, the company has an obligation under UK law to keep all promotional information up-to-date at all times, and therefore the company is responsible for any continued use of its material from 1 January 2025 onwards.

Question: If promotional material is currently labelled as "For GB health professionals only", however, the material will be applicable to all UK health professionals from 1 January 2025, will companies be in breach of the Code if this wording is not updated on 1 January 2025?

Answer: Companies should be making preparations to update their materials so that the information is up-to-date as soon as possible from 1 January 2025. Promotional material that is labelled as being for a narrower health professional audience than the licence permits may not in itself be a breach of the Code. However, companies should look to update this as soon as possible and at the earliest available opportunity to avoid any potential confusion, bearing in mind the user experience for GB and NI health professionals trying to navigate through the material.

Question: If promotional digital materials have links to separate GB and NI SPCs, will they be in breach of the Code on 1 January 2025 if the licence has become UK-wide?

Answer: Companies should be making preparations to update their materials so that the information is up-to-date as soon as possible from 1 January 2025. If the SPC is being provided as part of the PI (Clause 12.2 i-viii) then the guidance in Section 3 above should be followed. If the promotional material has links to SPCs *in addition* to the provision of PI, the company needs to ensure that the material is not misleading and should use the principles at Section 3 above.

If promotional material links to SPCs or PI hosted on a third party site (e.g. eMC/datapharm), companies need to ensure that they bear in mind the operational timelines and plans of the third party site.

Question: How should NI health professionals be informed in scenarios where the SPC effective from 1 January 2025 is different in terms of safety information/clinical practice to that which was in effect on 31 December 2024?

Answer: Companies should contact the MHRA for guidance in relation to proactive communications to NI health professionals.

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