Request for time-limited conditional exemption in relation to Human and Veterinary medicinal product supply to Ireland, as outlined in ‘Commission Notice 22.12.2020 C(2020) 9264: Application of the Union’s pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period.’

The European Commission has published a Notice outlining an approach, which may be permitted by the competent authorities of Ireland, Cyprus, Malta and UK (NI) in relation to certain challenges arising in the transition by operators towards full compliance with the Union Pharmaceutical acquis. The link to the Commission notice is included below:

<https://ec.europa.eu/health/sites/health/files/human-use/docs/c_2020_9264_en.pdf>

**Introduction**

Due to the historical dependence of Ireland (IE), Malta, Cyprus and Northern Ireland (UK (NI)) on medicines supplied from Great Britain, in the exceptional cases where additional time is required to transfer certain functions to EU/EEA, and in the exceptional circumstance of a global pandemic, an additional period of up to one year (Jan 2021 to 31st Dec 2021) to comply with aspects of the Union’s acquis, has been agreed. These exemptions are as follows, and are subject to certain conditions:

1. Medicinal products or investigational medicinal products can be imported from Great Britain into one of the above markets by wholesalers/importers which do not hold the relevant Manufacturer’s/Importer’s Authorisation to act as the site of physical importation and/ or to act as the site of batch release for those markets. This means that medicines and investigational medicinal products can be imported from Great Britain (GB) into one of the above markets and placed on the market in accordance with Union law, having been subject to batch release by a Qualified Person (QP) in Great Britain applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human and animal health.
2. Medicines can be imported from Great Britain into one of the above markets and placed on the market in accordance with Union law having undergone quality control testing in Great Britain, in line with Article 20 (b) of Directive 2001/83/EC for human medicinal products or Art 24(b) of Directive 2001/82/EC for veterinary medicines.
3. Article 22 of the Commission Delegated Regulation (EU) 2016/161 on safety features obliges wholesalers to decommission unique identifiers (UIs) on products they intend to distribute outside of the Union. The conditional exemptions include a provision that allows a 12 month exemption from decommissioning the UIs on joint EU/UK packs that are intended for export to Great Britain.

The presence of UIs on the medicinal products imported into, Ireland, Northern Ireland Cyprus and Malta through Great Britain is an essential requirement as regards ensuring a high level of public health protection. The presence of UIs can only be achieved at present, if wholesale distributors, located in the Union, do not decommission the UIs on medicinal products in joint packs.

**Applying to the HPRA for a conditional exemption to permit continued supply to Ireland**

In order for the MAH (**which must be established in the Union**) or EU based sponsor/legal representative for a clinical trial, to apply for this **time limited conditional exemption**, please provide the following information to HPRA for the evaluation of your request (*no later than 30th Jan 2021 where it relates to quality control (QC) testing*). Approval of this request will be primarily based on the information provided and the conditions agreed to by the applicant in this form, which should be carefully completed.

The exemptions relating to batch release and QC testing are intended to allow these activities to continue for a short period of time at currently registered sites in Great Britain to facilitate continued supply of medicines while these functions are being transferred to sites in the Union or Northern Ireland. Please note that these exemptions may not generally be availed of where the specific functions have already been transferred to EU/EEA sites.

Acceptance, by the HPRA, of any requests for exemptions applies only to medicinal products/ investigational medicinal products supplied to the Irish market/clinical trials being carried out in Ireland. The exemptions are limited in time and will expire no later than 31st December 2021.

**Section A** must be completed for all requests, then **Section B (including subsections and associated condition sections)** completed for the specific exemptions that are requested. One application form is required for each product. Where possible, all exemption requests relating to a product should be contained within the same form. Please note that there is a requirement on the part of the applicant to provide, to the HPRA, regular updates on progress towards compliance and, where requests are accepted, an Excel template for this reporting will be provided. This Excel template should be completed for the initial request (one sheet per product) and updated and returned to the HPRA by the 20th of the month if there is any change to the date and pathway to regulatory compliance ([Brexit@hpra.ie](mailto:Brexit@hpra.ie) for human medicines and [vetinfo@hpra.ie](mailto:vetinfo@hpra.ie) for veterinary medicines). Regardless of proposed changes, an update must be provided to the HPRA at the end of each quarter. Any proposed changes to the date and pathway to regulatory compliance must be justified.

**Section A: Administrative details**

With reference to the published communication from the EU Commission dated 22nd December 2020, we hereby request a time-limited exemption to continue to supply the following medicinal product or investigational medicinal product to the Irish market:

**Product specific details**

|  |  |  |  |
| --- | --- | --- | --- |
| Invented name of medicinal product and its INN(s), or name of Investigational medicinal product\*: | PA /VPA Number or Clinical Trial authorisation number, in Ireland: | DCP/MRP procedure number, if applicable: | Marketing authorisation (PA/VPA) holder\*\* name and address or EU Sponsor/legal representative for clinical trial: |
|  |  |  |  |

*\*NB: In case of an MRP/DCP product, only the product name in Ireland should be included*

*\*\*NB: In case of an MRP/DCP product, only the MAH in Ireland should be included here (see also declaration below)*

The following situation applies for the above product: *(tick ‘yes’ or ‘no’ to indicate which case applies)*:

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| It will be imported into Ireland under a Wholesale Distribution Authorisation rather than a Manufacturer’s/Importer’s Authorisation (MIA) and / or Batch release will take place in GB (if ‘yes’, *complete section B.1 of form*) |  |  |
| Quality control tests will be conducted in GB (*if yes,* *complete section B.2 of form*) |  |  |
| An exemption from decommissioning the unique identifier (UI) on packs exported to GB (and an exemption from re-affixing the UI when the product comes back into the EU (i.e. Ireland in this case)) (*if yes,* *complete section B.3 of form*) |  |  |

End date of the requested exemption: \_\_\_\_Date/Month/2021

Please detail previous correspondence with HPRA on this issue:

**Section B: Notification of request:**

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| **B.1.1: To import a medicine/IMP from Great Britain into Ireland under a Wholesale Distribution Authorisation (WDA) where batch release takes place in the EU**  **and / or**  **B.1.2: To import a medicine/IMP from Great Britain into Ireland under a WDA where batch release takes place in GB**  Name, address and WDA number of the current Irish wholesaler importing product from GB:  Timeline for obtaining/ using a manufacturer’s /importer’s authorisation (MIA) for the proposed EU site of importation <*should be no later than the end date of the requested exemption above*>:  Name and address of the **currently registered** batch release site in GB and intended for use as part of this exemption:  EudraGMDP reference or MHRA/VMD reference number of MIA for current site:  Name and address of the **proposed** EU site of batch release:  EudraGMDP reference number of MIA or GMP certificate, if available:  Timeline for registration of the proposed EU site of batch release: <*should be no later than the end date of the requested exemption above*>.  Concise justification of the timeline required:  **Conditions B.1 (Please tick each of the conditions to confirm compliance):**  **For Marketing Authorisations**  ☐ The medicinal products supplied from or through Great Britain and placed on the market in accordance with Union law (i.e. imported into Ireland) have undergone quality control testing (‘batch testing’) either in the Union, as provided for in Article 51(3) of Directive 2001/83/EC for human medicinal products and in Article 44(3) of Directive 2001/82/EC for veterinary medicinal products, or in Great Britain in compliance with Article 20 (b) of Directive 2001/83/EC for human medicinal products and with Article 24b of Directive 2001/82/EC for veterinary medicinal products (see Section 2 of the Commission Notice);  ☐ The medicinal products supplied from or through Great Britain and placed on the market in accordance with Union law (i.e. imported into Ireland) have been subject to batch release by a Qualified Person (QP) in the Union or by a QP in the UK (UK NI or UK GB) applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human or animal health;  ☐ The marketing authorisation of the medicinal product concerned has been issued by the HPRA or by the Commission, before the end of the transition period and in accordance with Union law;  ☐ The medicinal products supplied from or through Great Britain are made available to the end consumer in Ireland and are not subsequently distributed from Ireland to other EU Member States;  We will provide a minimum of a quarterly update of plans to achieve EU regulatory compliance. Any changes or updates will be reported as they arise, by the 20th of each month.  ☐ **For Investigational medicinal products**  ☐ The investigational medicinal products (including comparators) supplied from or through Great Britain and approved for use in the clinical trial in accordance with Irish law (i.e. imported into Ireland) have undergone batch release either in the Union, as provided for in Article 13(3) of Directive 2001/20, or in Great Britain in compliance with Article 13(3) of Directive 2001/20/EC;  ☐ The clinical trials authorisation of the medicinal product concerned has been issued by the HPRA before the end of the transition period and in accordance with Union law;  ☐ The investigational medicinal products imported from Great Britain are made available to the end consumer (trial subject) in Ireland and are not subsequently made available in other EU Member States;  ☐ We will provide a minimum of a quarterly update of plans to achieve EU regulatory compliance. Any changes or updates will be reported by the 20th of the month they arise. |

**B.2: Notification of request to permit continued QC testing in Great Britain**

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| Name and address of the **currently registered** QC testing site in Great Britain intended for use as part of this exemption:  EudraGMDP or MHRA/VMD reference number of QC testing site in Great Britain:  Name and address of the **proposed** EU site of QC testing:  Timeline for transfer and registration of the proposed EU site of QC testing<*should be no later than the end date of the requested exemption above*>:  EudraGMDP reference number of EU QC testing site if available:  Name and address of the currently registered batch release site to be used:  EudraGMDP reference number of MIA of the batch release site:  **Conditions B.2: Please tick each of the conditions to confirm compliance**  ☐ The Qualified Person(s) of the batch release site(s) indicated above in EU/EEA, UK NI or UK Great Britain is/are responsible for ensuring that the quality control testing at the site(s) in Great Britain is conducted in accordance with EU GMP and the requirements of the Marketing Authorisation;  ☐ The establishment conducting the quality control testing is supervised by a competent authority, including on-the-spot checks;  ☐ The medicinal products imported from Great Britain are made available to the end consumer in Ireland only, and they are not subsequently distributed from Ireland to other EU Member States;  ☐ We have taken necessary steps to prepare for transfer of the quality control testing and the transfer will be complete by the end of Dec 2021 at the latest;  ☐ We will provide a minimum of a quarterly update of plans to achieve EU regulatory compliance. Any changes or updates will be reported by the 20th of the month they arise. |

*Note: Please copy the above table in case of multiple QC testing sites*

**B.3: Notification of request for exemption from decommissioning the safety feature unique identifiers for joint IE/UK packs:**

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| --- |
| **B3.1:** An exemption to the requirement to decommission product going to the UK is required for joint IE/UK packs being distributed to Ireland from an EU member state or directly from the UK  **YES 󠄀󠄀 NO 󠄀󠄀** *(tick ’yes’ or ‘no’ as applicable)*  **Conditions for B3.1 (Please tick each of the conditions to confirm compliance):**  ☐ We confirm that the manufacturer or wholesaler responsible for the export of the medicinal product has systems to verify that a unique identifier has been attached and uploaded to the EU repository;  ☐ We confirm that the unique identifier of the product placed on the Irish market complies with Directive 2001/83/EC and Commission Delegated Regulation (EU)2016/161;  ☐ We will provide a minimum of a quarterly update of plans to address the issue of decommissioning product going to the UK. Any changes or updates will be reported the 20th of the month they arise.  **B3.2:** An exemption is required for joint IE/UK packs that will be exported to Great Britain from an EU member state, and will subsequently be re-imported into the EU, in this case the Irish market. Please note, in this situation, in addition to not decommissioning the UI of product going to Great Britain, you are also seeking an exemption from re-affixing the UI when the product comes into Ireland.  **YES 󠄀󠄀 NO 󠄀󠄀** *(tick ’yes’ or ‘no’ as applicable)*  **Conditions for B3.2 (Please tick each of the conditions to confirm compliance):**  ☐ We confirm that the manufacturer or wholesaler responsible for the export of the medicinal product to Great Britain has systems to verify that a UI has been attached and uploaded to the EU repository;  ☐ We confirm that the UI of product placed on the Irish market complies with Directive 2001/83/EC and Commission Delegated Regulation (EU)2016/161;  ☐ We confirm that, when the product is imported to Ireland, the MIA holder (or WDA holder if an exemption has been sought under B.1.1 above) will check the UI for a minimum of one pack per batch to confirm that the UI has been attached and uploaded to the EU repository;  ☐ We will provide a minimum of quarterly update of plans to address the issue of decommissioning product going to the UK and reaffixing the UI for product imported to Ireland. Any changes or updates will be reported on the 20th of the month they arise. |

I hereby apply for the time-limited exemption(s) listed above.

**On behalf of the marketing authorisation holder:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and printed name of the authorised contact person*

Date: …