Request for a derogation under Directive 2022/642

Request to the HPRA for a derogation under Directive 2022/642, and/or Regulation (EU) 2022/641, as regards derogations from certain obligations concerning certain medicinal products for human use made available in Ireland, to facilitate the supply of medicinal products to markets with historical links to the UK; ‘Brexit derogation’.

* [Directive (EU) 2022/642 of the European Parliament and of the Council of 12April 2022 was published in the Official Journal on 20th April 2022 and amends Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta.](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2022.118.01.0004.01.ENG)
* [Regulation (EU) 2022/641 was published in the Official Journal on 20 April 2022 and amends the clinical trials regulation (Regulation (EU) 536/2014).](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0641&qid=1653484990312)

introduction

Due to the historical dependence of Ireland (IE), Malta, Cyprus and Northern Ireland on medicines supplied from or through parts of the United Kingdom, other than Northern Ireland, and with the aim of preventing shortages of medicines and ensuring a high level of public health protection with regard to medicinal products for human use, the Commission adopted legislative proposals amending Directive 2001/83/EC, Directive 2001/20/EC and Regulation (EU) 536/2014 by way of Directive 2022/642/EC and Regulation (EU) 2022/641. This permits the HPRA to apply certain derogations to facilitate supply of medicinal product to the Irish market. The permitted derogations applicable to Ireland are outlined in Directive 2022/642/EC and Regulation (EU) 2022/641, and are subject to certain conditions.

**Request to the HPRA for a derogation as per Directive 2022/642/EC and Regulation (EU) 2022/641**

Approval of derogation requests will be primarily based on the information provided and the conditions agreed to by the applicant in this form, which should be carefully completed. Applicants should ensure the information provided here is in line with the information provided in the ‘Directive 2022/642: Justifiable case template for inclusion of UK(GB) sites in regulatory submissions for Ireland‘ form (hereafter the ‘justifiable case template’) submitted at the time of validation of an MR/DCP variation or a new application; however, the granting of this derogation will be based on the information provided in this request. Derogations may be refused, notwithstanding a previous acceptance of a justifiable case template for the purposes of validation by the HPRA or other Member States.

Acceptance by the HPRA of any requests for derogations applies only to medicinal products supplied to the Irish market or to investigational medicinal products provided in clinical trials approved in Ireland. The derogations are limited in time and will maximally apply as stipulated in Directive 2022/642/EC and Regulation (EU) 2022/641.

**Section A** must be completed for all requests and **Section B (including subsections and associated condition sections)** for the specific derogations that are requested. All derogation requests relating to a product should be contained within the same form. Please send the completed form to [brexit@hpra.ie](mailto:brexit@hpra.ie)

Section A: Administrative details

With reference to a request for a derogation under Directive 2022/642/EC and/or Regulation (EU) 2022/641, we hereby request a time-limited derogation to continue to supply the following medicinal product(s) or investigational medicinal product(s) to the Irish market:

**Product specific details**

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

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|  | **Yes** | **No** |
| The medicinal product will be imported into Ireland from parts of the United Kingdom other than Northern Ireland by holders of a Wholesale Distribution Authorisation rather than a Manufacturer’s/Importer’s Authorisation (MIA) provided that the conditions of Article 2(5) of Directive 2022/642/EC are fulfilled. *(If ‘yes’, complete section B.1 below.)* |  |  |
| The investigational medicinal product will be imported into Ireland from parts of the United Kingdom other than Northern Ireland by holders of a Wholesale Distribution Authorisation rather than a Manufacturer’s/Importer’s Authorisation (MIA) provided that the conditions of Article 1 of Directive 2022/642/EC or Article 1 of Regulation (EU) 2022/641 are fulfilled. *(If ‘yes’, complete section B.2 below.)* |  |  |
| Quality control testing will be conducted in part of the United Kingdom other than Northern Ireland provided that the conditions of Article 2(4) of Directive 2022/642/EC are fulfilled. (*If ‘yes’,* *complete section B.3 below.*) |  |  |
| Medicinal products will be exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Ireland provided that the conditions of Article 2(5)(b) are fulfilled. *(If ‘yes’, complete section B.4 below.)* |  |  |

Please detail any previous correspondence with the HPRA on this issue, e.g. agreed justifiable case template, etc:

**Section B: Notification of request**

**B.1 Medicinal Products**

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| **Please clearly indicate if B.1.1 or B.1.2. applies.**  **B.1.1:** To import a medicine from part of United Kingdom other than Northern Ireland into Ireland under a Wholesale Distribution Authorisation (WDA) where batch release takes place in the EU.  Yes  No  or  **B.1.2:** To import a medicine from part of United Kingdom other than Northern Ireland into Ireland under a WDA where batch release takes place in part of United Kingdom other than Northern Ireland.  Yes  No  Name, address and WDA number of the current Irish wholesaler importing product from part of United Kingdom other than Northern Ireland:  Timeline for obtaining/using a manufacturer’s/importer’s authorisation (MIA) for the proposed EU site of importation:  Name and address of the **currently registered** batch release site(s) in either the EU and/or in the United Kingdom other than Northern Ireland:  Name and address of the batch release site intended for use:  If site is based in the United Kingdom other than Northern Ireland please specify the following:   1. EudraGMDP reference or MHRA/VMD reference number of MIA for current site: 2. Name and address of the **proposed** EU site of batch release: 3. 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 derogation above):*  Where an EU batch release site is registered but not being used, please provide a full justification why this site is not at the MAH’s disposal:  **Conditions B.1**  *(Please tick each of the conditions to confirm compliance with Directive 2022/642/EC.)*  **For Marketing Authorisations**  The medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20 of Directive 2001/83/EC, in an establishment designated by the third party conducting the quality control testing, supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks.  The medicinal products have been subject to batch release by a qualified person in the Union, in accordance with Article 51(1) of Directive 2001/83/EC or, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1) of Directive 2001/83/EC.  The marketing authorisation of the medicinal product concerned is issued by the HPRA or by the Commission.  The medicinal products supplied from or through the United Kingdom other than Northern Ireland are made available to the end consumer in Ireland and are not subsequently distributed from Ireland to other EU Member States.  The operator importing medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta or Northern Ireland holds a distribution authorisation (WDA) issued in accordance with Article 77(1) of Directive 2001/83/EC for human medicinal products.  The medicinal products bear the safety features referred to in Article 54, point (o) of Directive 2001/83/EC.  It is acknowledged that this derogation will cease to apply from 31 December 2024. |

**B.2 Investigational Medicinal Products**

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| **Complete this section to import an investigational medicinal product from other parts of the United Kingdom other than Northern Ireland without holding a manufacturing and import authorisation for investigational medicinal products.**  Name and address of the **registered** batch release site(s) in the United Kingdom other than Northern Ireland to be used:  Name and address of the proposed EU site of batch release:  Timeline for registration of the proposed EU site of batch release (*should be no later than the end date of the requested derogation above)*:  **Conditions B.2**  *(Please tick each of the conditions to confirm compliance with Directive 2022/641/EC or Regulation (EU) 2022/641.)*  The investigational medicinal products have undergone certification of batch release in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in either Article 13(3) of Directive 2001/20 or Article 63(1) of Regulation (EU) No 536/2014, as appropriate.  The investigational medicinal products imported from part of United Kingdom other than Northern Ireland are made available to clinical trial subjects in Ireland (and are not subsequently made available in other EU Member States).  It is acknowledged that this derogation will cease to apply from 31 December 2024. |

**B.3: Notification of request to permit continued QC testing in part of United Kingdom other than Northern Ireland**

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| Name and address of the **currently registered** QC testing site in part of United Kingdom other than Northern Ireland intended for use as part of this derogation:  EudraGMDP or MHRA/VMD reference number of QC testing site in part of United Kingdom other than Northern Ireland:  Name and address of the **proposed** EU site of QC testing:  Timeline for transfer and registration of the proposed EU site of QC testing:  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 (or UK GMP cert):  **Conditions B.3**  *(Please tick each of the conditions to confirm compliance with Directive 2022/642/EC.)*  Each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51 of Directive 2001/83/EC.  The establishment conducting the quality control testing is supervised by the competent authority of the United Kingdom, including on-the-spot checks.  Where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.  The medicinal products supplied from or through the United Kingdom other than Northern Ireland are made available to the end consumer in Ireland and are not subsequently distributed from Ireland to other EU Member States.  It is acknowledged that this derogation will cease to apply from 31 December 2024. |

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

**B.4: Notification of request to import batches of medicinal product from parts of the United Kingdom other than Northern Ireland which have undergone quality control testing and batch release in the EU**

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| Name and address of the sites in the EU where quality control testing has taken place:  Name and address of the sites in the EU where batch release has taken place:  Name and address of the site in the United Kingdom other than Northern Ireland where the batches of medicinal product have been stored prior to importation into Ireland:  **Conditions B.4**  *(Please tick each of the conditions to confirm compliance with Directive 2022/642/EC.)*  All batches of medicinal products have undergone the controls upon importation referred to Article 51(1) of Directive 2001/83/EC, first and second subparagraphs, in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and are accompanied by the control reports referred to in Article 51(1), third subparagraph of Directive 2001/83/EC.  It is acknowledged that this derogation will cease to apply from 31 December 2024. |

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| **DECLARATION**  I hereby confirm that the information provided is correct and request the HPRA to grant a time limited derogation as requested above.  On behalf of the marketing authorisation holder:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Signature of the authorised contact person*  Printed name of the authorised contact person:  Date: |