**ΠΑΡΑΤΗΜΑ Ι - ANNEX I**

**Brexit Derogation Request Form**

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 supply the following medicinal product(s) to the Cypriot market:

**Product specific details**

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

*\*NB: In case of an exceptional MA (based on article 126a or 126c of the Directive) the exceptional MA authorisation holder should be stated.*

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

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| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
| **B.1** | The medicinal product will be imported into Cyprus from parts of the United Kingdom other than Northern Ireland by holders of a Wholesale Distribution Authorisation and not a Manufacturer’s/Importer’s Authorisation (MIA) holders provided that the conditions of Article 2(5) of Directive 2022/642/EC are fulfilled. *(If ‘yes’, complete section B.1 below.)* | [ ]  | [ ]  |
| **B.2** | The investigational medicinal product will be imported into Cyprus from parts of the United Kingdom other than Northern Ireland without 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.)* | [ ]  | [ ]  |
| **B.3** | 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.*)  | [ ]  | [ ]  |
| **B.4** | Medicinal products will be exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Cyprus provided that the conditions of Article 2(5)(b) are fulfilled. *(If ‘yes’, complete section B.4 below.)* | [ ]  | [ ]  |
| **B.5** | Marketing authorisation holder is established in parts of the United Kingdom other than Northern Ireland (article 126 c (2)) | [ ]  | [ ]  |

Please provide the reasons and justifications for the request(s) and detail any previous correspondence with the Pharmaceutical Services on this issue.

**Section B: Notification of request**

**B****.1 Importation of Medicinal Products without a MIA**

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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 Cyprus 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 Cyprus 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 Cypriot 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 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):*      **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 Drugs Council 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 Cyprus and are not subsequently distributed from Cyprus 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 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 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 2022/642/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 Cyprus (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 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 Cyprus and are not subsequently distributed from Cyprus 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 Cyprus:      **Conditions B.4***(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.[ ]  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 Cyprus and are not subsequently distributed from Cyprus to other EU Member States.[ ]  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. |

**B.5: Marketing authorisation holder established in parts of the United Kingdom other than Northern Ireland**

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| Name and address of the Marketing Authorisation Holder established in parts of the United Kingdom other than Northern Ireland:      Registration number of the Marketing Authorisation Holder established in parts of the United Kingdom other than Northern Ireland:      **Conditions B.5***(Please tick each of the conditions to confirm compliance with Directive 2022/642/EC.)*[ ]  It is acknowledged that this derogation will cease to apply from 31 December 2026. |

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| **DECLARATION**I hereby confirm that the information provided is correct and request the Drugs Council to grant a time limited derogation(s) as requested above.I hereby confirm that the derogations shall not affect the obligations of the Marketing Authorization Holder/ Sponsor to ensure the quality, safety and efficacy of the medicinal product placed on the market of Cyprus. On behalf of the marketing authorisation holder/ Sponsor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Signature of the authorised contact person* Printed name of the authorised contact person:      Date:       |