Directive 2022/642: Justifiable case template for inclusion of UK(GB) sites in regulatory submissions for Ireland

To newly register a UK(GB) site in Ireland for either an existing marketing authorisation or a new application for a marketing authorisation a justifiable case must be presented to the HPRA.

To present this justifiable case, please complete the following information and Section A and/or Section B as required, and send the completed form to brexit@hpra.ie.

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| Product name/proposed product name in Ireland |       |
| PA number |       |
| EU procedure no., where applicable |       |
| Rationale for the justifiable case  |       |

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| **Section A**To propose addition of a **QC site in UK(GB)**,<state name and address>, to the above referenced application the following three points must be confirmed according to Directive 2001/83 Article 20, as amended by Directive 2022/642:

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| (a) | 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. | [ ]  Yes |
| (b) | The establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks.  | [ ]  Yes |
| (c) | 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. | [ ]  Yes |

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| **Section B**To propose addition of a **Batch release site in UK**(**GB)**,<state name and address>,to the above referenced application please confirm the requirements of Article 2 (5)(a) of Directive 2022/642 are met: [ ]  Yes |

Please include this template in Module 1 of your regulatory submission to the RMS.

Furthermore, please note that after approval of the above EU procedure and at the time of marketing in IE, applicants **must also apply to the HPRA to request a derogation** to allow supply of the product to the market and to confirm the details for the Commission list according to Directive 2022/642. Please see the HPRA website for further details [www.hpra.ie](http://www.hpra.ie).

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| **For HPRA use only:** Reviewed - digital signature and date: |