**MARKETING INFORMATION FORM FOR THE UNITED KINGDOM**

Notification of the intention to market a batch of an immunological medicinal product or medicinal product derived from human blood or plasma which has a marketing authorisation in the **United Kingdom.**

Please specify for which market(s) this batch is destined1: GB [ ]  NI [ ]

|  |  |
| --- | --- |
|  Addressee:  | Medicines & Healthcare Products Regulatory Agency, 10 S Colonnade, Canary Wharf, London E14 4PUe: marketinginformationform@mhra.gov.uk   |
| Trade name:  | ‘*Trade name of the product in the UK’*  |
| Product type: | *‘Vaccine or Blood Product’* |
| Batch number(s) on the market package:  | *‘Batch number of the product in the UK’*  |
| Other batch identification numbers associated with this batch:2 | *‘Filling bulk number, final lot number and packaging lot number’*  |
| Name & address of marketing authorisation holder:  |  |
| Date of start of period of validity:  |  |
| Date of expiry:  |  |
| Intended date of marketing (dd/mm/yyyy):  |  |
|  **PRODUCTS FOR GB** |  |
| Number of containers to be marketed in GB:  |  |
| Marketing authorisation number:  |  |
| NIBSC or MRA certificate number:3 |  |
| EU OCABR certificate dated before 01 Jan 2021:4 | *'Certificate number and issue date'* |
|  |  |
| **PRODUCTS FOR NI** |  |
| Number of containers to be marketed in NI: |  |
| Marketing authorisation number:  |  |
| Certificate number:3 |  |
| Name of Control Authority:5 |  |

I hereby declare that:

-this batch is in compliance with the above marketing authorisation(s) and the relevant European Pharmacopoeia monograph(s);

 -this batch is the batch referred to in the accompanying batch release certificate(s).

A copy/copies of the batch release certificate(s) is/are attached.

|  |  |
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| Signature of authorised6 person:  |   |
| Name of authorised6 person:  |   |
| Date of issue: |   |

Notes:

1) GB - Great Britain (England, Scotland, Wales); NI - Northern Ireland

2) Sufficient detail should be given to allow clear traceability back to the level of the final bulk

3) Products with release certificates from authorities with mutual recognition agreement with UK do not require NIBSC certification or EU OCABR certificates

4) Products with EU OCABR certificates dated before 01 January 2021 do not require NIBSC certification

5) Name of releasing OMCL, e.g. EU OMCL or authority with mutual recognition agreement with UK

6) MIF should be signed by a representative of the company authorised for this purpose