**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**.**

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| Addressee: | Medicines & Healthcare Products Regulatory Agency, 10 S Colonnade, Canary Wharf, London E14 4PU 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:21 | *‘Filling bulk number, final lot number and packaging lot number’* |
| Name & address of marketing authorisation holder: |  |
| UK Marketing authorisation number: |  |
| Date of start of period of validity: |  |
| Date of expiry: |  |
| Intended date of marketing (dd/mm/yyyy): |  |
| Number of containers to be marketed |  |
| NIBSC certificate number |  |
|  |  |
| **Additional information for products for NI Only2 or products form countries with Mutual Recognition Agreement**3 |
| Marketing authorisation number:4 |  |
| Country of Manufacture:5 |  |
| Country of Certificate issue:6 |  |
| Certificate number: |  |

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 authorised7 person: |   |
| Name of authorised7 person: |   |
| Date of issue: |   |

Notes:

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

2) Products only for submission to NI with category 2 licence (MRDCP) and EU OCABR certificate

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

4) PL number issued by MHRA or MA number for country with mutual recognition agreement

5) As described on the certificate

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

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