Apply to release a vaccine or a blood product to market

Information for people who wish to apply to release a vaccine or a blood product to market in the UK.

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Medicines and Healthcare products Regulatory Agency

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Marketing Information Form

When a Marketing Authorisation Holder (MAH) wants to release a batch of a vaccine or a blood product to market, they must get the batch testing by an Official Medicines Control Laboratory (OMCL). Once the OMCL has issued a batch release certificate, the MAH can release the batch in all member states.

To place a batch on the market of a member state you must follow the “EC Administrative Procedure for the Official Batch Release” (OCABR). You must inform the Competent Authority (CA) in each member state, using the “Marketing Information Form” (MIF).

In the UK, the CA is the Medicines and Healthcare products Regulatory Agency (MHRA) and the OMCL is the National Institute for Biological Standards and Control (NIBSC).

A model of Marketing Information Form can be found on the EDQM website.

Procedure

Send the MIF and associated documents to the following contacts at MHRA:

Prime contact: Marketing Information Form: MIF@mhra.gov.uk
Second Prime Contact: Stephen.Young@mhra.gov.uk
Secondary contact: Aleksandra.Korzeniowska@mhra.gov.uk

Every MIF must be sent to MHRA Inspection, Enforcement and Standards Division for response.

Sending a Marketing Information Form

Check if your documentation is complete - a MIF and batch release certificate must be attached to the email.

Check the lot number matches on the MIF and batch release certificate. Note batch numbers may include extra suffixes (e.g. 86759-A) – this is acceptable as long as the main number is the same.

Check the number of containers to be marketed (on the MIF) is less than or equal to the total number of containers in the batch. Note the number on the batch release certificate refers to the total size of the batch – it may be supplied to the UK and also to other countries.

Check the expiry date on the MIF is not later than that on the batch release certificate.

What you can expect from us

We will normally acknowledge receipt of your MIF, within 2 days. You will only hear further from is if there is a question about the MIF.

If MHRA does not object within 7 working days after sending the documents (MIF), you can place the batch on the market.

It remains the responsibility of the MAH to formally release the batch to market.

Expedited release notifications

A “7-day waiver” or expedited release can be granted if waiting for 7 days would mean that patients would not receive medicines.

In those cases, mark your email appropriately and provide a reason (i.e. stock shortages; need to meet DHSC immunisation schedule; competitor dropped out of market and need to ramp up production) for the 7-day waiver and we will review as a matter of urgency and acknowledge the receipt of this special request.

What you can expect from us

Where expedited release is justified, we will review the documents within 2 working days and, if the documents are in order, provide a confirmation that we will not object to the MAH releasing the batch.

Guidance for the OCABR Release and Marketing Information Form processes in a no-deal Brexit

If there is a no-deal Brexit, the UK will no longer be subject to EU Directive 2001/83/EC (Article 114(1)) which allows for mutual recognition of batch certificate and release from another OMCL.

NIBSC will remain a full member of the OMCL network and is committed to maintaining its ISO (International Organization for Standardisation) 17025 accreditation and use of the OCABR guidelines after the UK leaves the EU.

If there is a no-deal Brexit, NIBSC will be a stand-alone National Control Laboratory and the UK will require national certification by NIBSC before batches of biological medicines can be placed onto the market. If a batch has an EU OCABR certificate issued on or before the day the UK leaves the EU, or a certificate manufactured in and issued by a country with whom the UK has a mutual recognition agreement (MRA) in place, then it can be placed on the market without national certification from NIBSC.

OCABR certificates issued before the UK leaves the EU would be accepted by the UK, whether they have been issued by the UK or another OCABRlaboratory.

The regime for UK certification in the event of no deal would be:

- After the UK leaves the EU, the UK will carry out its own batch release of biological medicines at NIBSC and will take a risk-based approach to laboratory testing. NIBSC will decide whether to rely on a paper assessment to issue the UK certificate or whether to carry out laboratory testing of the batch. NIBSC will take into consideration all available data, including any release certificate issued by a laboratory in an approved list* (where available) as well as potential risks to public health.
- If no such certificate is available, NIBSC will carry out a full laboratory assessment in line with current OCABR guidelines, except where NIBSCindicates differently.
- For batches marketed exclusively in the UK, NIBSC will test and certify batches as the UK National Control Laboratory. New statutory fees will apply under the new UK certification scheme.
- There would be new statutory fees to enable NIBSC as the UK National Control Laboratory to charge for certification and testing in the UK, broadly the same as the current fees charged by NIBSC in its role as an OCABR laboratory. These fees will be published in due course.

Approved list

If the UK leaves the EU with no deal, for a fixed period NIBSC will review OCABR certificates issued by EU/EEA OCABR laboratories when deciding whether to rely on a paper assessment or to carry out laboratory testing of batches. After this period, the list of countries whose release certificates we will consider will appear on the NIBSC website.

Actions to follow for marketing a batch in the UK in a no deal Brexit:

- If the batch has been certified on or before the day the UK leaves the EU, or special MRA arrangements have been made, the relevant certificate and the new UK Marketing Information Form (MIF) should be sent to the MHRA as the Competent Authority. The MHRA will continue to follow the MIF procedure from before the UK leaves the EU.
- If the batch has not been certified on or before the day the UK leaves the EU, or has no special MRA arrangements, Marketing Authorisation Holders (MAH) will need to send samples, documentation and protocols for all batches to be marketed in the UK. This is regardless of whether NIBSCcarries out full independent control authority testing and release, including for any product currently released by NIBSC. No UK MIF will be required.

For European batch release, NIBSC can continue to offer batch release testing in liaison with a European OMCL via a subcontract arrangement, by prior agreement.

Further guidance can be found on the NIBSC website. Alternatively, you can contact marketinginformationform@mhra.gov.uk for further information.