EU Official Control Authority Release, Official Batch Protocol Review

Immunological Veterinary Medicinal Products

EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6

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EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in application of Article 128 of Regulation (EU) 2019/6

List of Abbreviations

EDQM: European Directorate for the Quality of Medicines and HealthCare (Council of Europe)

EEA: European Economic Area

EU: European Union

IVMP: Immunological Veterinary Medicinal Product

MAH: Marketing Authorisation Holder

MS: Member State

CA: Competent Authority

OBPR: Official Batch Protocol Review

OCABR: Official Control Authority Batch Release

OMCL: Official Medicines Control Laboratory

Ph. Eur.: Pharmacopée Européenne/European Pharmacopoeia

Notes:

The terms Competent Authority (CA) and Official Medicines Control Laboratory (OMCL) are used in conjunction throughout the text to accommodate the different organisational structure in the different Member States. In some Member States the CA and OMCL are completely separate bodies with only administrative ties while in other Member States the two bodies are combined in one service. In some places in the text where reference is specifically to the testing performed only the OMCL is mentioned.

For the purpose of this guideline, all reference to Member States and to the European Union (EU) shall be taken as the European Union Member States and the States that have signed the European Economic Area (EEA) agreement, namely Norway, Iceland and Liechtenstein. These Member States, together with the European Commission, the European Directorate for the Quality of Medicines and HealthCare (EDQM), acting as secretariat, and the Agency as observer, are, in the context of the activities described herein, referred to as the Veterinary Batch Release Network (VBRN). Non-EU/EEA countries with formal arrangements at the level of the EU for mutual recognition of OCABR e.g. Mutual Recognition Agreement (MRA) are also members of the VBRN.

INTRODUCTION

Article 128 of Regulation (EU) 2019/6 of the European Parliament and of the Council of December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC is entitled ‘Proof of the product quality specific for immunological veterinary medicinal products’. It provides mechanisms for CAs to monitor the quality of IVMPs.

Paragraph 3 of Article 128 allows a competent authority to require samples to be submitted for testing by an OMCL for reasons of human or animal health. This is referred to as Official Control Authority Batch Release (OCABR). In line with paragraph 6 of Article 128 a 'shortlist' of IVMPs for which a restricted list of justified tests has been developed based on risk assessment analysis and will be reviewed regularly and updated when appropriate. The list of concerned IVMPs can be found in Annex I of this document. In line with paragraph 7 of Article 128 the competent authorities shall recognise the results of the tests carried out. This is referred to as mutual recognition.

When paragraph 3 of Article 128 is not applied some Member States may choose to control individual batches of a given IVMP as foreseen in paragraph 1 of Article 128. This is referred to as Official Batch Protocol Review (OBPR) and includes a review of the results and associated data in the manufacturer's batch release protocol, as provided by the marketing authorisation holder (MAH), before the batch is released on to the market. By agreement of the Member States mutual recognition of OBPR is also encouraged to avoid unnecessary duplication of effort.

This Administrative Procedure has been developed to apply the framework of the legislation in a codified way and to combine and simplify the previously separate procedures for OBRP and OCABR. The procedure described below aims at providing a harmonised approach to OCABR and OBPR and should be used in combination with the relevant product specific guidelines available separately on the EDQM website and model protocol templates, as outlined in the subsequent sections.

LEGAL BACKGROUND

This document combines and replaces the 'EU Administrative Procedure for a Harmonised Application of Article 81 for Official Batch Protocol Review of Immunological Veterinary Medicinal Products' and the 'EU Administrative Procedure for Application of Article 82 for Official Control Authority Batch Release of Immunological Veterinary Medicinal Products' which was adopted in April 2007 to supersede the previous procedure from the Committee on Veterinary Medicinal Products (ref - III/5372/93 – July 1993) after use in a pilot phase. It is for use in the implementation of the optional provisions of the so-called 'OCABR' or the so-called 'OBPR' as laid down in Article 128 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

"1. For the purpose of application of Article 127 (1) competent authorities may require the holder of a marketing authorisation for immunological veterinary medicinal product to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article 97.

2. The holder of a marketing authorisation for immunological veterinary medicinal products shall ensure that an adequate number of representative samples of each batch of veterinary medicinal product is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities on request.

3. *Where necessary for reasons of human or animal health, a competent authority may require the holder of a marketing authorisation for an immunological veterinary medicinal product to submit samples of batches of the bulk product or of the immunological veterinary medicinal product for control by an Official Medicines Control Laboratory before the product is placed on the market.*

4. *On request of a competent authority, the marketing authorisation holder shall promptly supply the samples referred to in paragraph 2, together with the control reports referred to in paragraph 1, for control testing. The competent authority shall inform the competent authorities in other Member States in which the immunological veterinary medicinal product is authorised, as well as the EDQM and the Agency in case the immunological veterinary medicinal product is authorised under the centralised procedure of its intention to control batches of the immunological veterinary medicinal product.*

5. *On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished immunological veterinary medicinal product, in accordance with the relevant specifications in its dossier for marketing authorisation.*

6. *The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all competent authorities in the relevant Member States, and if appropriate, the, EDQM agree to such a restriction.*

   For immunological veterinary medicinal products authorised under the centralised procedure, the list of tests to be repeated by the control laboratory may be reduced only upon agreement of the Agency.

7. *The competent authorities shall recognise the results of the tests referred to in paragraph 5.*

8. *Unless the Commission is informed that a longer period is necessary to conduct tests, the competent authorities shall ensure that the control is completed within 60 days of receipt of the samples and control reports.*

9. *The competent authority shall notify the competent authority of other relevant Member States, the EDQM, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.*

10. *The competent authority shall verify that the manufacturing processes used in the manufacture of immunological veterinary medicinal product are validated and that batch-to-batch consistency is ensured. "*

Article 127 is referred to in paragraph 1 of Article 128 and states:

1. *The marketing authorisation holder shall have at its disposal the results of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in the marketing authorisation.*

2. *If a competent authority concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures in relation to the marketing authorisation holder and the manufacturer, and shall inform accordingly the competent authorities of other Member States in which the veterinary medicinal product is authorised, and also the Agency in case the veterinary medicinal product is authorised under the centralised procedure.*

PURPOSE AND SCOPE

This document provides specific guidance for the application of Article 128 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC for the control of batches of IVMPs.

The present document is for use by Member States' CAs and OMCLs when implementing the option of OCABR or OBPR in the territories and for the MAHs and manufacturers of IVMPs who will apply to the Member States with batches intended for their markets.

It outlines the steps for CAs, OMCLs and MAHs/manufacturers of IVMPs for OCABR and OBPR and provides relevant templates for communication.

Use of the procedure should facilitate mutual recognition of the results of OCABR and OBPR between Member States thus preventing unnecessary duplication of effort and promoting the free movement of IVMPs throughout the EU/EEA.

PRINCIPLES

Application of paragraph 1 (OBPR) or paragraph 3 (OCABR) of Article 128 is an option, not an obligation and individual Member States shall decide the requirements for their own territory.

The individual Member State shall communicate their requirements to the concerned MAHs and to the CAs in other Member States in which the IVMP is authorised, as well as the EDQM and the Agency in case the immunological veterinary medicinal product is authorised under the centralised procedure.

OBPR is an evaluation based on document review by a CA/OMCL. OCABR is an evaluation based on document review and testing by a CA/OMCL.

A shortlist of IVMPs for which paragraph 3 and 6 of Article 128 may be applied, such that OCABR is carried out using a reduced list of justified tests for the OMCLs, has been agreed upon by the Member States and is presented in Annex 1 of this document.

Both OCABR and OBPR operate on the principle of mutual recognition. For OCABR, results for a given batch from one Member State are recognised by the CAs by obligation as foreseen in paragraph 7 of Article 128. For OBPR this recognition is based on common agreement of the involved Member States. To foster mutual recognition in the case of OCABR and to allow the possibility for mutual recognition for OBPR a harmonised application of the procedure described below is applied.

Any Member State requiring OBPR according to paragraph 1 of Article 128 or OCABR according to paragraph 3 of Article 128 before releasing of all individual batches of a given IVMP onto its national market shall use the relevant harmonised certificate of compliance or the form notifying of non-compliance, hereafter attached in annex, to communicate the notification to the concerned MAH for any given batch.

In accordance with the provisions of Article 128 paragraph 7, any Member State implementing the said provisions for OCABR shall recognise the results of the tests performed by another Member State having already applied OCABR on the given batch of IVMP. The results shall be readable to any Member State and therefore harmonised OCABR certificates have been agreed upon and are provided in annex to this procedure. This certificate, if available, should also be accepted by Member States choosing to apply paragraph 1 of Article 128 (OBPR) for a given IVMP as it covers both document review and re-testing. For the harmonised application of OBPR a harmonised OBPR certificate has also been agreed upon. An OBPR certificate cannot be accepted if application of paragraph 3 of Article 128 (OCABR) is requested.

PROCEDURE

I. Simplified Flowchart

OBPR

Member State notifies MAH of need for OBPR (see 1)

↓

MAH submits batch documentation (protocol) to a CA/OMCL for evaluation (see 2.B and 2.C.i)

↓

CA/OMCL evaluates documentation (see 3.A)

↓

CA/OMCL provides MAH with certificate (compliant or non-compliant) within 15 working days and informs VBRN if non-compliant (see 4.A and 4.C.i)

↓

Compliant certificate can be used in other Member States requiring OBPR (see 5.A)

↓

The recognition process is completed within 7 working days (see 5.C)

OCABR

Member State notifies MAH of need for OCABR (see 1)

↓

MAH arranges with an OMCL for OCABR of a given IVMP (see 2.A)

↓

MAH submits batch documentation (protocol) and samples to a CA/OMCL for evaluation (see step 2.B and 2.C.ii)

↓

CA/OMCL evaluates documentation and carries out testing of samples (see 3.B)

↓

CA/OMCL provides MAH with certificate (compliant or non-compliant) within 60 days) and informs VBRN if non-compliant (see 4.B and 4.C.ii)

↓

Compliant certificate can be used in other Member States requiring OCABR or OBPR (see 5.B)

↓

The recognition process is completed within 7 working days (see 5.C)

CA/OMCLs inform intentions for application of OBPR and OCABR and report on activity in Annual Reports

II. Details

1. Notification of the MAH by the CA of the requirement for application of official-batch release by OCABR or OBPR

Where the CA in a Member State 'A' requires official batch release for a given IVMP by:

- **OBPR**

or

- **OCABR**

It informs the MAH that its particular authorised IVMP is subject to this official batch release before being placed onto their national market.

Templates for model letters have been developed to collate the information requested by the given CA of the Member State to the concerned MAH (**Annex IIA** (OBPR) **and Annex IIB** (OCABR)).

The model letter allows also the MAH to identify the contact person in the Member State 'A' to whom all matters related to the official batch release should be addressed.

Member States requiring OCABR or OBPR for a given product should also notify all other Member States and the EDQM of their intention to require OCABR for that product in their annual report.

2. MAH's Responsibilities

Once notified that official batch release is required in Member State 'A' for a given product the MAH should prepare for the application of the requested procedure for each batch to be submitted to that Member State.

A) Arrangement with OMCL(s) for OCABR testing

When OCABR is required by a Member State for a given IVMP, the MAH should make arrangements with at least one competent CA/OMCL within the EU/EEA to carry out the required evaluation. The chosen OMCL should operate under an externally audited quality assurance system based on the international standard ISO/IEC 17025 and should have access to the relevant quality sections of an up-to-date, valid, marketing authorisation dossier for the IVMP in question. In principle the IVMP should have a marketing authorisation in the Member State of the OMCL carrying out the evaluation.

The necessary arrangements for technical transfer, including exchange of samples and reagents and standard operating procedures where relevant should be foreseen sufficiently in advance of the intended release.

It is recommended that the MAH identifies more than one OMCL for this activity for a given IVMP.

The concerned MAH shall inform the CA of Member State 'A' to which CA/OMCL within the EU, he intends to submit the batches of the given authorised IVMP, for Official Control Authority Batch Release.

B) Control Documentation for OBPR and OCABR

Model protocols for different product types are provided separately and are available on the EDQM website (www.edqm.eu). They are meant to encourage a harmonised presentation of documentation by the MAH and should be used when preparing the documentation for review.

The batch control documentation provided should be signed by the responsible qualified person of the MAH before submission to the CA or officially designated OMCL.

C) Submission of batches for evaluation

i) For OBPR

The MAH shall provide **the control documentation** of the batch in question to a CA with which he has an agreement for batch protocol review or to the OMCL officially designated by that CA. The Member State that reviews the protocol should have the product licensed on their own market.

The MAH should apply to only one CA for an OBPR certificate for any given batch such that only one OBPR certificate is issued per batch in the EU/EEA.

ii) For OCABR

The MAH shall submit **samples, other relevant materials for the required testing and control documentation** for the batches of the given authorised IVMP to a CA/OMCL with which he has an arrangement for OCABR as outline in step 2.A.

The MAH should apply to only one CA/OMCL for an OCABR certificate for any given batch such that only one OCABR certificate is issued per batch in the EU/EEA

To reduce release times the MAH is encouraged to submit samples of the batch at the same time they begin their own control testing and in advance of finalisation and submission of the manufacturer's batch documentation. This is referred to as parallel testing.

3. Evaluation of batches by the CA/OMCL

A) OBPR by a CA/OMCL

OBPR consists of the **examination of the IVMP's control reports** and associated data in the protocol from the manufacturer as submitted by the MAH for the concerned batch in close comparison with the required specifications laid down in the authorised marketing authorisation for the given IVMP used for the evaluation.

B) OCABR by a CA/OMCL

OCABR consists of the **examination of the IVMP's control reports as described in section 4.A and performance of a restricted list of justified tests for a given authorised IVMP**. These tests are agreed upon by all the Member States choosing to apply the batch release procedure for the given authorised product and also by the Agency for any IVMP having been granted a centralised marketing authorisation. The EDQM might be consulted to agree on

such a restricted list of justified tests.[1]

The tests have nevertheless to be part of the batch release tests performed by the manufacturer as outlined in the relevant marketing authorisation for the given IVMP.

The list of products for which a restricted test list has been agreed is found in **Annex 1**.

Product specific guidelines that outline the agreed tests to be performed for those IVMPs have been developed and codified by the network. They are provided separately and are available on the EDQM website (www.edqm.eu).

Member States shall ensure that OCABR of IVMPs is performed under a quality assurance system based on the international standard ISO/IEC 17025.

4. Notification of results

Certificates may be prepared in the official language of the CA however it must be accompanied by an EU certificate written in English.

A) Compliance

If a batch has been shown to comply with all of the specifications of the marketing authorisation and is thus satisfactory for approval, the CA or the officially designated OMCL will prepare a Certificate indicating compliance following the model formats presented in annex and provide it to the MAH.

The certificate of compliance shall attest that the batch of the given IVMP has been examined and **complies** with the approved specifications for that given IVMP as laid down in the relevant marketing authorisation dossier and that the procedure described in this document has been applied.

Certificate for OBPR (annex IIIA) notes the examination has been carried out based on paragraph 1 of Article 128 and is thus based on protocol review.

Certificate for OCABR (annex IIIB) notes the examination has been carried out based on paragraph 3 of Article 128 and is thus based on protocol review and testing by an OMCL on the request of a CA.

B) Non-Compliance

Should a batch not comply with the specifications in the relevant marketing authorisation dossier, this information, together with the reason for the non-compliance, should be provided to the MAH and to all the VBRN, by a rapid information exchange mechanism to specified contact persons (refer to **Annex VI**) using the model formats.

The form for notice of non-compliance shall attest that the batch of given IVMP has been examined and **does not comply** with the approved specifications for the given IVMP as laid down in the relevant marketing authorisation dossier and that the procedure described in this document has been applied and therefore the batch cannot be released on to the market via the normal OBPR/OCABR procedure. Technical details of the non-compliance shall be included

[1] In the case where there is no agreement among the concerned Member States on a reduced testing scheme for an IVMP such that paragraph 6 of Article 128 is not applicable, the OMCL performing OCABR repeats of all tests carried out by the manufacturer on the finished product, in accordance with the relevant marketing authorisation as stipulated in paragraph 5 of Article 128.

in the notice of non-compliance.

Notice of non-compliance for OBPR (annex IVA) notes the examination has been carried out based on paragraph 1 of Article 128 and is thus based on protocol review.

Notice of non-compliance for OCABR (annex IV B) notes the examination has been carried out based on paragraph 3 of Article 128 and is thus based on protocol review and testing by an OMCL on the request of a CA.

In the particular case, where an arrangement for batch release testing in parallel has been agreed by the MAH and CA/OMCL, any batch failing tests and subsequently withdrawn by the manufacturer before completion of the batch release procedure shall not be formally considered as non-compliance. Nevertheless, information of the withdrawal, including the reasons, shall be circulated to all CA/OMCLs within the network whenever this occurs (using the rapid information form (**annex V**)) in order to avoid the possibility of the batch being submitted inappropriately for release at another CA/OMCL.

C) Timing

i) OBPR

Notification of the outcome shall occur within 15 working days of receipt of the completed signed protocol.

ii) OCABR

Unless the Commission is informed that a longer period is necessary to conduct tests, the competent authorities shall ensure that the control is completed within 60 days of receipt of the samples and control reports and the notifications are sent accordingly.

5. Use of Certificates

A) OBPR

Provided the batch in question is compliant, the MAH should receive an EU/EEA certificate of approval from the CA or designated OMCL of the Member State 'X' where the batch was submitted for evaluation (see 4.A). Upon the receipt of this certificate, the MAH may consider that it has permission to place the given batch on the market in that Member State 'X' where there is a valid marketing authorisation.

In the eventuality, that the MAH wishes to place the given batch on the market in another Member State 'Y' where the given IVMP is authorised, if that Member State has also indicated the requirement for OBPR for that product (see 1), the MAH shall provide a copy of the Certificate to the designated contact in Member State 'Y'. Documented information necessary to ensure the traceability of the batch of final product, destined for Member State 'Y', to the certificate, especially if there has been re-packaging or creation of sub-lots, should also be provided.

On the rare occasion that a given batch has undergone the procedure for OCABR under paragraph 3 of Article 128 in a Member State other than that requesting application of paragraph 1 of Article 128, the Member State requiring application of paragraph 1 of Article

128 shall accept the OCABR certificate in lieu of the OBPR Certificate of Approval.

B) OCABR

Provided the batch in question is acceptable, the MAH should receive an EU/EEA OCABR certificate from the CA or designated OMCL of the Member State 'X' that performed OCABR (see 4.B). Upon the receipt of this certificate, the MAH may consider that it has permission to place the given batch on the market in Member State 'X', where there is a valid marketing authorisation. In the eventuality, that the MAH wishes to place the given batch on the market in another Member State 'Y' where the given IVMP is authorised, if that Member State 'Y' has also indicated the requirement for OCABR of that product (see 1), the MAH shall provide the designated contact in Member State 'Y' with a copy of the given OCABR Certificate. Documented information necessary to ensure the traceability of the batch of final product, destined for Member State 'Y' to the certificate, especially if there has been re-packaging or creation of sub-lots, should also be provided.

C) Timing for recognition of OBPR and OCABR

The contact in Member State 'Y' shall inform the MAH of the procedure for recognition of the certificate in their Member State. The procedure should be completed in a maximum of 7 working days.

Use of the certificates does not preclude the right of a Member State to ask for batch documentation or samples at any time.

ANNUAL REPORTS

The CA/OMCLs should provide annual reports using the agreed template available from EDQM. Annual reports are for confidential use within the VBRN and associated regulatory authorities. They will include a statement of intention for application of paragraph 1(OBPR) or paragraph 3 (OCABR) of Article 128 on particular product groups for the coming year. They will also provide an accounting of the batches reviewed under both paragraph 1 and paragraph 3 of Article 128 during the reporting period, including an indication of their status e.g. compliant or non-compliant with details of the non-compliance where relevant. The annual reports should include trend analysis of the testing performed at both the OMCL and the manufacturer for a given product and/or group of products under paragraph 3 of Article 128. This data should be used to evaluate the testing schemes. Particular attention should be given to the use of *in vitro* alternatives.

ANNEX I

Short list of IVMPs for which a restricted test list for OMCLs has been agreed and list of associated guidelines for OMCLs

IVMPs listed alphabetically

Short list of IVMPs for which a restricted test list for OMCLs has been agreed	Exempted Categories (e.g. live, inactivated, recombinant etc.)	Relevant guideline(s)
IVMP's against Aujeszky's Disease	none	PA/PH/OMCL (03) 7 DEF 2CORR PA/PH/OMCL (03) 8 DEF 2CORR
IVMPs against Brucello sis	none	PA/PH/OMCL (03) 23 DEF 2CORR
IVMPs against Equine Influenza	none	PA/PH/OMCL (04) 4 DEF 2CORR PA/PH/OMCL (14) 81 R
IVMPs against Infectious Bovine Rhinotracheitis	none	PA/PH/OMCL (03) 9 DEF 2CORR PA/PH/OMCL (03) 6 DEF 2CORR
IVMPs against Newcastle Disease	none	PA/PH/OMCL (02) 3 DEF 2CORR PA/PH/OMCL (02) 4 DEF 2CORR
IVMPs against Rabies	none	PA/PH/OMCL (11) 209 DEF 2CORR PA/PH/OMCL (04) 05 DEF 2CORR
IVMPs against Swine Erysipelas	Swine erysipelas vaccine (inactivated)	PA/PH/OMCL (03) 10 DEF 2CORR
Brucellin Preparations	none	PA/PH/OMCL (04) 119 DEF 2CORR
Tuberculin PPD, Avian	none	PA/PH/OMCL (14) 126 DEF
Tuberculin PPD, Bovine	none	PA/PH/OMCL (14) 125 DEF

ANNEX II A

MODEL LETTER OBPR

From a Competent Authority of a Member State to the Marketing Authorisation Holder as regards the requirement of Official Batch Protocol Review of Immunological Veterinary Medicinal Products

Subject: Official notification of OBPR to be applied to

BRAND NAME of the concerned authorised IVMP:

MARKETING AUTHORISATION NUMBER of the concerned authorised IVMP:

Before releasing onto the [Member State name] market.

Dear Madam, Dear Sir,

1. In accordance with [cite appropriate national legislation reference] implementing the provisions of paragraph 1 of Article 128 of Regulation (EU) 2019/6 of the European Parliament and of the Council of December 2018 on veterinary medicinal products and repealing Directive 2001/82/, we [Name of the competent authority of Member State A] require that your immunological veterinary medicinal product [name of IVMP] be submitted for Official Batch Protocol Review before being released onto our national market.

2. The MAH should apply to only one CA within the EU/EEA for an OBPR certificate for any given batch. The Member State performing the review should have a marketing authorisation for the given product on their own market.

   The completed batch control documentation should be signed by the responsible qualified person(s) from the manufacturer(s) and/or the MAH as fixed in the marketing authorisation.

   Model protocols for the different product types are provided separately, and are available on the EDQM website (www.edqm.eu). They are meant to encourage a harmonised presentation of documentation and should be used when preparing the documentation for review.

3. In case you intend to submit the batch documentation of above mentioned IVMP for OBPR to our national CA [name of the CA from MS "A"], you shall submit the signed batch protocol for the given batch of IVMP directly to [name of the CA or officially designated OMCL from MS "A"].

[name of the CA or officially designated OMCL from MS "A"] will notify you of the results of the OBPR within 15 working days (unless otherwise justified) of receipt of the completed and signed batch protocol and the appropriate fees as noted _____.

If the batch is in compliance with the concerned Marketing Authorisation's specifications notified by [name of the CA from MS "A"], you will be authorised to release the concerned batch of IVMP on the market.

4. In the eventuality, that a given batch has already received an OBPR Certificate of Approval by a CA in any other Member State where the IVMP is authorised, you shall provide a copy of the given OBPR Certificate of Approval and a copy of the final product label for our market and submit it to [appropriate contact point (CA)].
5. [Description of the procedure for recognition of the OBPR certificate within the Member State in question, which should take no longer than 7 working days.]

Yours faithfully,

Copy: EDQM – contact point details of the person responsible for OBPR of IVMPs.

ANNEX II B

MODEL LETTER OCABR

From a Competent Authority of a Member State to the Marketing Authorisation Holder as regards Official Control Authority Batch Release of Immunological Veterinary Medicinal Products

Subject: Official notification of OCABR to be applied to

BRAND NAME of the concerned authorised IVMP:

MARKETING AUTHORISATION NUMBER of the concerned authorised IVMP:

Before releasing onto the [Member State name] market.

Dear Madam, Dear Sir,

1. In accordance with [cite appropriate national legislation reference] implementing the provisions of paragraph 3 of Article 128 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

   we [Name of the competent authority of Member State A] require that your veterinary medicinal product [name of IVMP] be submitted for Official Control Authority Batch Release before being released onto our national market.

2. Consequently, in return of receipt of this notification, you [MAH name] shall inform us [Competent Authority of Member State "A"] which CA within the EU/EEA you intend to interact with for the submission the samples and control documentation of the batches of the above named IVMP for Official Control Authority Batch Release testing.

   Samples of a given batch of IVMP shall not be submitted to more than one CA/OMCL within the EU/EEA for the purpose of repeated testing for Official Control Authority Batch Release.

   The completed batch control documentation should be signed by the responsible qualified person(s) from the manufacturer(s) and/or from the MAH as fixed in the marketing authorisation. Model protocols for the different product types are provided separately and are available on the EDQM website www.edqm.eu. They are meant to encourage a harmonised presentation of documentation and should be used when preparing the documentation for review.

3. In case you intend to submit a given batch of above mentioned IVMP for OCABR to our national CA [name of the CA from MS "A"], you shall submit the requested samples of the given batch of IVMP together with the signed batch protocol directly to [name of the CA or officially designated OMCL from MS "A"].

   [name of the CA or officially designated OMCL from MS "A"] will notify you and communicate accordingly the results of the OCABR tests within **60 days** (unless otherwise justified) of receipt of the samples together with the completed and signed batch protocol and appropriate fees as noted_____.

   If the batch is in compliance with the concerned Marketing Authorisation's specifications notified by our [name of the CA from MS "A"], you will be authorised to release the concerned batch of IVMP on the market.

   6. In the eventuality, that a given batch has already received an OCABR certificate by a CA in any other Member State where the IVMP is authorised, you shall provide a copy of the given OCABR Certificate to [appropriate contact point (Competent Authority/OMCL)].

   7. [Description of the procedure for recognition of the OCABR certificate within the Member State in question, which should take no longer than 7 working days.]

Yours faithfully,

Copy: EDQM – contact point details of the person responsible for OCABR of IVMPs.

ANNEX III A

EU/EEA OFFICIAL BATCH PROTOCOL REVIEW CERTIFICATE OF APPROVAL FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Name and address of the control authority performing the document review

_____

Examined under paragraph 1 of Article 128 of Regulation (EU) 2019/6 repealing Directive 2001/82/EC in accordance with the current EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

Trade name:	
International non-proprietary Name / Ph. Eur. name / common name	
Name and address of marketing authorisation holder	
Name and address of manufacturer, if different:	
Marketing authorisation number (Member State /EU) issued by:	
Manufacturer's identification numbers associated with the batch (as relevant):-	
Final bulk number	
Final batch number	
Packaging lot number(s)	
Batch number of diluent (where appropriate)[2]	
Type of container:	
Total number of containers in this batch[3]:	
Number of doses/volume per container:	
Date of start of period of validity:	

The signed manufacturer's release protocol for this batch has been examined in conformity with the current EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

This batch **IS in compliance** with the all of the approved specifications laid down in the above noted marketing authorisation.

Signed:	
Name and function of signatory:	
Date of issue:	

Certificate Number:

[2] Provision of different batch numbers of authorised diluent to different Member States should not impair mutual recognition of OPBR for the batch of active component covered by the certificate, however if a diluent batch different from that on the certificate is provided, protocol documentation on the new diluent batch may be requested in addition to the certificate.

[3] If different fillings exist, please indicate

ANNEX III B

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Name and address of the Competent Authority for release

Examined under the paragraph 3 according of Article 128 of Regulation (EU) 2019/6 repealing Directive 2001/82/EC and in accordance with the current EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

Trade name:	
International non-proprietary Name / Ph.Eur. name /common name	
Name and address of marketing authorisation holder	
Name and address of manufacturer, if different:	
Marketing authorisation number (Member State/ EU) issued by:	
Manufacturer's identification numbers associated with the batch (as relevant):-	
Final bulk number	
Final batch number	
Packaging lot number(s)	
(where appropriate) **Batch number of authorised diluent:**[4]	
Type of container:	
Total number of containers in this batch[5]**:**	
Number of doses/volume per container:	
Date of start of period of validity:	

This batch has been examined in conformity with the above-mentioned procedure. This examination is based on review of the manufacturer's protocol and repetition of the appropriate control laboratory tests. The testing has been carried out under a quality system which is in accordance with ISO/IEC 17025.

This batch **IS in compliance** with the approved specifications laid down in the above-mentioned marketing authorisation. Technical details of these compliance results are annexed to this form.

Signed:	
Name and function of signatory:	
Date of issue:	

Certificate Number:

[4] Provision of different batch numbers of authorised diluent to different Member States should not impair mutual recognition of OCABR for the batch of active component covered by the certificate, however if a diluent batch different from that on the certificate is provided, protocol documentation on the new diluent batch may be requested in addition to the certificate.

[5] If different fillings exist, please indicate

ANNEX IV A

EU/EEA OFFICIAL BATCH PROTOCOL REVIEW FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

FORM FOR NOTICE OF FAILURE/ NON-COMPLIANCE

Name and address of the control authority performing the document review

_____

_____

Examined under paragraph 1 of Article 128 of Regulation (EU) 2019/6 repealing Directive 2001/82/EC in accordance with the current EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

Trade name:	
International non-proprietary name / Ph. Eur. name/ common name	
Name and address of marketing authorisation holder	
Name and address of manufacturer, if different:	
Manufacturer's identification numbers associated with the batch (as relevant):	
Final bulk number	
Final batch number	
Packaging lot number(s)	
Type of container:	
Total number of containers in this batch[6]:	
Number of doses/volume per container:	
Marketing authorisation number (Member State / EU) issued by:	

The signed manufacturer's release protocol for this batch has been examined in conformity with the EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

This batch is **NOT in compliance** with all the specifications laid down in the above noted marketing authorisation.

Technical details of these non-compliance results are noted below.

This batch is not compliant for the following reasons;	
Signed:	
Name and function of signatory:	
Date of issue:	

Document Number:

6 If different fillings exist please indicate

ANNEX IV B

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

FORM FOR NOTICE OF FAILURE/ NON-COMPLIANCE

Name and address of the Competent Authority for release

_____

Examined under paragraph 3 of Article 128 of the Regulation (EU) 2019/6 repealing Directive 2001/82/EC and in accordance with the current EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6.

Trade name:	
International non-proprietary name / Ph. Eur. name / common name	
Name and address of marketing authorisation holder:	
Name and address of manufacturer, if different:	
Manufacturer's identification numbers associated with the batch (as relevant):	
Final bulk number	
Final batch number	
Packaging lot number(s)	
Type of container:	
Total number of containers in this batch[7]:	
Number of doses/volume per container:	
Marketing authorisation number (Member State / EU) issued by:	

This batch has been examined in conformity with the above-mentioned procedure. This examination is based on review of the manufacturer's protocol and the repetition of the appropriate control laboratory tests. The testing has been carried out under a quality system which is in accordance with ISO/IEC 17025.

This batch is **NOT in compliance** with the specifications laid down in the above-mentioned marketing authorisation.

Technical details of these non-compliance results are annexed to this form.

This batch was rejected for the following reasons;	
Signed:	
Name and function of signatory:	
Date of issue:	

Document Number:

[7] If different fillings exist please indicate

ANNEX V

MODEL LETTER

For Important Information exchange between the official contacts points of the EU Veterinary Batch Release Network (VBRN) (refer to Annex VI)

CONFIDENTIAL

To the
EU Veterinary Batch Release Network (VBRN)

IMPORTANT INFORMATION

Issue identified during: OCABR*/OBPR*/OTHER (specify)* (*select as appropriate)

Name and address of Marketing Authorisation Holder:

Name and address of the Manufacturer, if different:

Brand Name of the IVMP:

Marketing Authorisation Number:

Manufacturer's Batch Number(s):

Nature of the Important Information:

Action/Decision already taken:

Action Required (if any):

Notifying CA/OMCL contact details:

Date:

Signed by:

ANNEX VI

THE CURRENT LIST OF OFFICIAL CONTACT POINTS FOR THE EU VETERINARY BATCH RELEASE NETWORK (VBRN) CAN BE FOUND ON THE EDQM WEBSITE.

WWW.EDQM.EU

FOLLOW: MEDICINES>OMCL NETWORK > VETERINARY BIOLOGICALS (OCABR/OBPR)

HTTPS://WWW.EDQM.EU/EN/VETERINARY-BIOLOGICALS-OCABR/OBPR-

THE CONTACT LIST WILL BE UPDATED AS NECESSARY. USERS ARE ENCOURAGED TO CHECK THE SITE REGULARLY TO ENSURE THEY ARE USING THE MOST UP TO DATE INFORMATION.