Official Control Authority Batch Release (OCABR) Procedure

Information for Marketing Authorization Holders on the Official Control Authority Batch Release Procedure in the Netherlands

1. In accordance with Article 114 of Directive 2001/83/EC, the Dutch legislation (Regeling Geneesmiddelenwet) requires that each batch of human vaccines and each batch of medicinal product derived from human blood or human plasma is examined by an Official Control Authority Laboratory (OMCL) in the EU/EEA prior to placing it on the market. The OMCL must declare that the batch in question is in compliance with the approved specifications laid down in the Marketing Authorisation and in the relevant monographs of the European Pharmacopoeia.
   Batches originating from a final lot that has already been tested and released within the EU/EEA in accordance with the EC official control authority batch release must not be submitted to another OMCL for the purpose of the examination for batch release.
2. In the Netherlands the National Institute of Public Health and the Environment (RIVM) is the Competent Authority for official control authority batch release. Within the RIVM, the batch release activities are performed by the Centre for Health Protection (GZB).
   a. For batches to be released by RIVM, samples and summary protocols should be submitted in accordance with the administrative procedure for the official control authority batch release and the product specific relevant guidelines. A batch release application should be accompanied with a completed “marketing information form/request for official control authority batch release form ” (available on the RIVM website). The batch release application should be sent to:
      Coordinator Europese Vrijgifte
      RIVM-GZB
      Antonie van Leeuwenhoeklaan 9 / P.O. Box 1
      3721 MA Bilthoven / 3720 BA Bilthoven
      The Netherlands
      e-mail: OCABR@RIVM.nl
   b. The samples submitted should have been collected so as to be truly representative of the relevant batch.
   c. Each dosage container submitted should be labelled with the final labelling, unless there are valid reasons stated for not doing so, in which case a specimen of the final label should be provided and every dosage container labelled with the name of the product, batch number and, if applicable, dosage.
   d. The applicant is responsible for the delivery of the samples to the RIVM. Damaged samples and samples that were obviously not transported under the correct conditions will not be accepted and will be destroyed. In that case, the applicant is notified and new samples have to be submitted.
   e. Samples from stages other than the final lot stage should be labelled to clearly indicate the stage in the manufacturing process and the date on which the samples were secured, the name of the product, the batch number (or other appropriate identification) and the name of the marketing authorisation holder; in case of blood derivatives plasma pool samples should be submitted prior to product samples or at latest at that stage.
   f. Further information may be requested via e-mail: OCABR@rivm.nl
3. As legally established in Article 7.13 of the Regeling Geneesmiddelenwet, a fee of € 5720,-- per batch has to be paid for an application for batch release. The RIVM will issue an invoice

within 2 months after a decision on the application for batch release (released/not released/withdrawn) has been taken. The invoice will be sent to the billing address indicated by the applicant.

4. For the examination a maximal statutory term of 60 days is applied. For products requiring long testing periods, it is advised to submit samples to the RIVM as soon as they have been filled in the final container. The "marketing information form/request for official control authority batch release form" together with the manufacturer's production and control protocol and a copy of the label should be submitted at a later stage. Such a procedure will reduce the time between the protocol submission and the release by the RIVM. However, in case a batch is withdrawn from the batch release procedure, details on the reason for withdrawal should be provided to the RIVM.
5. The marketing authorisation holder should inform the licensing authority which OMCL(s) they intend to use within EC for the purpose of official control authority batch release. For (new) products to be released by the RIVM, it is advised to inform the RIVM contact person well in advance of the marketing authorisation application.
6. The marketing authorisation holder has the responsibility to ensure that the RIVM is provided with all the necessary documentation to allow the EU official control authority batch release to be undertaken i.e.:
    a. copy of the marketing authorisation documents, providing details of in-process testing, holding times, reference standards, finished product testing and specifications
    b. test methods including details of reference standards
    c. labels
    d. example of the protocol
    e. specific test reagents that cannot be easily commercially obtained, such as manufacturer's reference standards, antisera, monoclonal antibodies.

    In addition, the RIVM may request further information to facilitate the official control authority batch release procedure and this should be provided.
    Changes to the above must be approved by the competent authority and these should be notified to the RIVM immediately.
7. For lots to be marketed in the Netherlands which have been released by an OMCL in another EU/EEA country, a copy of the official control authority batch release certificate should be submitted to the RIVM prior to placing the lot on the market. The copy of the certificate should be complemented by a marketing information form (available on the RIVM website) undersigned by the responsible Qualified Person of the marketing authorisation holder in the Netherlands. Documentation is preferably sent to OCABR@rivm.nl.