ANNEX I

Template for a model letter from a Competent Authority to the Marketing Authorisation Holder as regards Official Control Authority Batch Release within EU

Dear Madam, Dear Sir,

PRODUCT NAME:
MARKETING AUTHORISATION NUMBER:
OFFICIAL CONTROL AUTHORITY BATCH RELEASE within EU

1. In accordance with Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC the competent authority of ..... requires that samples from each batch of this product be submitted for examination by the Official Medicines Control Laboratory (OMCL) before release on the market. The OMCL must declare that the batch in question conforms with the approved specifications, i.e. those set out in the above marketing authorisation and in the relevant monographs of the European Pharmacopoeia.

   Consequently, samples of the same batch must not be submitted to another OMCL within the EU/EEA for the purpose of the examination for batch release.

2. 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.

i. The samples submitted should have been collected so as to be truly representative of the relevant batch.

ii. 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, dosage and the name of the marketing authorisation holder.

iii. 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.

iv. Samples and protocols should be submitted to one of the OMCLs of the EU/EEA Member States (addresses available from the Council of Europe, EDQM, DBO, Batch Release Section www.edqm.eu - annex III list).

3. The marketing authorisation holder should inform this competent authority which OMCL(s) they intend to use within EU for the purpose of official control authority batch release. Any change in this arrangement should also be notified.

4. The marketing authorisation holder has the responsibility to ensure that the OMCL is provided with all the necessary documentation to allow the Official Control Authority Batch Release within EU to be undertaken i.e.:
   - copy of the marketing authorisation documents, providing details of in-process testing, finished product testing and specifications,
   - test methods including details of reference standards,
   - labels,
   - example of the protocol.

   In addition, the OMCL 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 OMCL immediately.

5. Prior to placing the batch on the market a copy of the Official Control Authority Batch Release certificate should be provided to the Member States where the batch of the product concerned will be marketed. The copy of the certificate should be complemented by a marketing information form addressed by the marketing authorisation holder to the competent authority of the Member State(s) where the batch of the product is to be marketed. A model marketing information form is given in Annex IV of the administrative procedure for the official control authority batch release.

Yours faithfully,

ANNEX IIa

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS

Name and address of the releasing authority

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE - Finished Product

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Medicinal Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	
International non-proprietary Name / Ph. Eur. name / common name:	
Batch numbers appearing on package and other identification numbers associated with this batch[3]:	
Type of container:	
Total number of containers in this batch:	
Number of doses per container:	
Date of start of period of validity:	
Date of expiry:	
Marketing authorisation number (member state / EU) issued by :	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard This examination is based on either[4]:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation application

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

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

Certificate Number:

---

[3]Such as batch number of final bulk.
[4]Delete as appropriate.

ANNEX IIb

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA

Name and address of the releasing authority

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	
International non-proprietary name / Ph. Eur. name / common name:	
Batch numbers appearing on package and other identification numbers associated with this batch [5]:	
Type of container:	
Total number of containers in this batch:	
Nominal dose per container:	
Date of start of period of validity:	
Expiry date:	
Marketing authorisation number (member state / EU) issued by :	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on either[6]:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation application.

All the constituent plasma pools have been tested by the OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

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

Certificate Number:

---

[5]Such as batch number of final bulk

[6]Delete as appropriate

ANNEX IIc

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE OF APPROVAL FOR MONOVALENT BULK OF POLIOMYELITIS VACCINE (ORAL)

Name and address of the releasing authority

EU/EEA CERTIFICATE OF APPROVAL FOR - Monovalent Bulk of Poliomyelitis Vaccine (Oral)

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name of final product for which it is intended:	
Poliomyelitis virus[7]:	
Batch number (final bulk):	
Virus titre of bulk:	
Volume of bulk:	
Marketing authorisation number (member state) issued by :	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant EU OCABR guideline for this product.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is approved.

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

Certificate Number:

[7]Please indicate serotype of virus (Type I, II or III).

ANNEX IId

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE

CERTIFICATE OF APPROVAL FOR PLASMA POOL

Name and address of the testing authority

_____

_____

EU/EEA CERTIFICATE OF APPROVAL FOR - Plasma pool for use in the manufacture of medicinal products

Examined in the context of Official Control Authority Batch Release of medicinal products derived from human blood or plasma in application of Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC.

Plasma Master File reference (+ certification):	
Code number of plasma pool:	
Date of manufacture:	
Country of origin of donations:	
Volume of pool:	
Name and address of manufacturer of plasma pool:	
Name and address of marketing authorisation holder (if applicable):	

This plasma pool has been examined using documented procedures, which form part of a quality system which is in accordance with the ISO/IEC 17025 standard.

This examination is based on the current EU OCABR guideline 'Official Control Authority Protocol for Approval of Plasma Pools': review of the plasma pool protocol and the following testing:

The samples of this plasma pool have been tested and found within the specifications for the following virological markers[8]: anti-HIV (1 and 2), HBsAg, HCV RNA and HAV RNA as determined by NAT and B19 DNA as determined by NAT.

This plasma pool is in compliance with the approved specifications laid down in the European Pharmacopoeia monograph 'Human plasma for fractionation' (0853) and the above Plasma Master File and is approved.

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

Certificate Number:

[8] Delete as appropriate

ANNEX IIe

EU Administrative Procedure for Official Control Authority Batch Release
GENERAL MODEL FOR NON-COMPLIANCE/FAILURE[9]

Name and address of the releasing authority

NOTICE OF **NON-COMPLIANCE** - Finished Product

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	
International non-proprietary name / Ph. Eur. name / common name:	
Batch numbers appearing on package and other identification numbers associated with this batch[10]:	
Type of container:	
Total number of containers in this batch:	
Number of doses per container:	
Date of expiry:	
Marketing authorisation number (member state / EU) issued by :	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on either[11]:

- the relevant EU OCABR guideline for this product, or, in the absence of the latter,
- the review of the manufacturer's protocol and the appropriate control laboratory tests as indicated in the marketing authorisation.

This batch is **NOT** in compliance with the specifications laid down in the above marketing authorisation/ the relevant European Pharmacopoeia monographs and cannot be released. Technical details of this non-compliance are available on request.

Reason for failure (specify non-compliance):

Comments (briefly if relevant):

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

Notice Number:

[9] To be sent to the relevant marketing authorisation holder and circulated to annex III contacts

[10] Such as batch number of final bulk.

[11] Delete as appropriate

ANNEX IIf

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE OF APPROVAL FOR ANCILLARY MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA IN A MEDICAL DEVICE

Name and address of the releasing authority

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE – Ancillary Medicinal Product
Examined under Article 1 of Directive 2000/70/EC (amending Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Ancillary medicinal product name: International non-proprietary name / Ph. Eur. name / common name:	
Name and address of manufacturer of ancillary medicinal product:	
Batch numbers appearing on package and other identification numbers associated with this batch[12]:	
Type of container:	
Total number of containers in this batch:	
Expiry date:	
Trade name of medical device in which the above product is to be used:	
EMA Consultation procedure number:	
CE number of medical device and member state / EU issued by:	
Name and address of CE holder of medical device if different from address above:	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant EU OCABR guideline for this product[13]_____, with the exception of the following tests[14]_____

All the constituent plasma pools have been tested by the OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monograph(s) (_____) [15] with the exception of the following[16];_____ and is released for its intended use as indicated above.

This product is not intended to be used for injection in humans or incorporation in pharmaceutical/medicinal products

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

Certificate Number:

[12] Such as batch number of final bulk
[13] please specify EU OCABR guideline used
[14] List test(s) which have not been completed OR delete this section as appropriate.
[15] insert monograph number
[16] list test(s) which have not been completed or do not comply with the monograph specifications and indicate the specification applied in practice (where applicable) OR delete this section as appropriate

ANNEX IIg

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE

CERTIFICATE OF APPROVAL
for
MONOVALENT PNEUMOCOCCAL POLYSACCHARIDE BULK CONJUGATES

Name and address of the releasing authority

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name of final product for which it is intended:	
Serotype of monovalent pneumococcal polysaccharide bulk conjugate:	
Batch number monovalent pneumococcal polysaccharide bulk conjugate:	
Date of end of shelf life:	
Marketing authorisation number of final product for which the bulk conjugate is intended to be used: (member state) issued by:	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

This monovalent pneumococcal polysaccharide bulk conjugate has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant EU OCABR guideline Multivalent Pneumococcal Polysaccharide Conjugate Vaccine (concerning section 3.2.1, 3.2.2.1 to 3.2.2.5 as relevant for the bulk in question).

This batch of monovalent polysaccharide bulk conjugate IS COMPLIANT with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation.

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

Certificate Number:

ANNEX III

Contact persons for results and questions concerning EU/EEA Official Control Authority Batch Release

A current list containing all the names and contact details of the representatives of the 27 EU Member States, EEA Member States and mutually recognised partners responsible for OCABR of human blood and plasma derivatives and vaccines for human use can be downloaded from the EDQM website:

www.edqm.eu

(see 'Annex III: Human OCABR contact list' under 'Control of Medicines' ⇒ 'OMCL' ⇒ 'Human Biologicals (OCABR)' or directly via 'Download').

OCABR contact's details for EDQM, the EMA and the European Commission can also be found on the list.

The Annex III list is kept as up to date as possible with the latest contact information. Users are encouraged to check periodically to ensure they are using the most recent details.

OCABR contacts should notify EDQM as soon as possible should there be any change in their information.

ANNEX IV

Model for manufacturers of a MARKETING INFORMATION FORM

Notification of the intention to market a batch of an immunological medicinal product, which has a marketing authorisation, or medicinal product derived from human blood or plasma, which has a marketing authorisation, in the following EU/EEA member state .....

Addressee:	*'Name and address of specified contact person(s) in the member state/EU where the batch of product is to be marketed'*

Trade name:	*'Trade name of the product in the member state/EU where the batch of product is to be marketed'*
Batch number(s) appearing on the market package:	*'Batch number of the product as in the member state/EU where the batch of product is to be marketed '*
Other batch identification numbers associated with this batch[17]:	*' Filling bulk number, final lot number and packaging lot number'*
Number of containers to be marketed in the member state:	
Market authorisation number:	*'MA number in the member state/EU where the batch of product is to be marketed'*
Name and address of marketing authorisation holder :	*'MA holder in the member state/EU where the batch of product is to be marketed'*
Date of start of period of validity:	
Expiry date in the member state where the batch is to be marketed:	
Intended date of marketing:	

OMCL performing batch release:	
Official batch release certificate number:	

I hereby declare that:

- this batch is in compliance with the above marketing authorisation and the relevant European Pharmacopoeia monographs ;
- this batch is the batch referred to in the accompanying batch release certificate.

A copy of the batch release certificate is attached.

Signature of qualified person:	
Name of qualified person:	
Date of issue:	

[17] Sufficient detail should be given to allow clear traceability back to the level of the final bulk

ANNEX V

MODEL FORMAT AND CONTENT OF ANNUAL REPORTS FOR THE NETWORK FOR OCABR OF HUMAN BIOLOGICAL MEDICINAL PRODUCTS

Each Competent Authority (CA)/Official Medicines Control Laboratory (OMCL) requiring Official Control Authority Batch Release (OCABR) for any product on their market must complete an annual report.

Member States in the network choosing not to apply OCABR should complete at least Part 1 and Part 2 Section A and Section B.3.2 if possible. All Member States are also encouraged to report any relevant related activity (Market Surveillance study, spot-testing, release for other markets where relevant (eg. WHO), limited national release etc.) in Part 2, section G.

Depending on the specific activity for the Member State the CA/OMCL should complete the relevant sections of the annual report below.

All EU OCABR activity should be covered, irrespective of the destination of the product. The report should be as succinct as possible but it is important that information required to promote transparency and confidence within the network be presented thus fostering the mutual recognition prescribed by the legislation for Article 114 of Directive 2001/83/EC as amended by 2004/27/EC. Trend analysis of data generated by manufacturer and the OMCL is particularly useful.

Reports should be circulated by the Member State to all relevant contacts (ie. blood or vaccine) on the Annex III contact list plus EDQM, the European Commission and EMA contacts. Normally reports should be sent at least 2 weeks in advance of the annual meeting unless a common decision is taken otherwise and the network informed. The use of hyperlinks for the electronic submissions is strongly encouraged to facilitate ease of use.

These annual reports are not intended for publication and remain strictly restricted to the EU/EEA OCABR network for human biological medicinal products and its secretariat.

STRUCTURE OF THE REPORT

CONTENTS

A table of contents should be included.

PART 1: GENERAL SECTION - *relevant to all CA/OMCLs regardless of framework of activity*

Introduction – Gives the name and address of the organisation(s) (if CA and OMCL are separate) and defines the reporting period covered in the report.

Section A: Organisation of the CA/OMCL

A.1 General Structure (Relation of the CA to the OMCL, organisation of each if separate)

A.2 Personnel Matters (indicating the name of responsible persons for the different relevant activities)

Section B: Quality Assurance System (systems in place, status of external audits/visits)

Progress in developing a quality assurance system, which (for OMCLs) meets the International Standard ISO 17025

PART 2: TECHNICAL SECTION – *specific to OCABR for human biological medicinal products*

Section A: Status of application of Article 114

A clear statement on whether article 114 is applied for blood and plasma derivatives and/or vaccines with the relevant national legal provisions noted.

Section B: Summary of batches tested for OCABR and batch traceability

This section should contain the total number of each product released for the European market during the reporting period together with the total number of batches rejected or withdrawn and the reason for doing so.

B.1 Summary Tables

Example for plasma pools

Source (manufacturer)	Number of pools tested	Number of pools tested for B19	Number of pools tested for HAV	Number of pools released
Octapharma				
Octapharma				

Total pools tested: Total pools released:

Example for blood and plasma derivatives

Product Type	Trade name	Manufacturer	Number of batches tested	Number of batches released
Human Albumin	Albumina humana 20%	Grifols		
Human Albumin	Albumina humana 5%	Grifols		
Fibrin sealant kit	Tissucol duo S	Baxter		

Total batches tested:
Total batches released:

Example for Vaccines

Vaccine Type	Trade name	Manufacturer	Number of batches tested	Number of batches released
dT	Diftavax			
dT IPV	Revaxis			
dT ap IPV	Repevax			
DT aP	Infanrix			
DTaP IPV	Infanrix IPV			
DTP/Hib	Infanrix IPV Hib			
DTaP-IPV-Hib	*Pediacel*			

Total batches tested:
Total batches released:

B2 Details on rejected/withdrawn batches

Common name	Manufacturer	Trade Name	Batch number	Nominal potency (blood products) or number of doses (vaccines)	Total number of containers in the batch	Expiry date	Date of notice of non-compliance or withdrawal	Reason

Additional details as required: Example; any follow up action (may also refer to details in section D).

B3 Batch traceability

This section may be included as an annex.

B3.1 Detailed list of batches tested at the OMCL

Common name	Manufacturer	Trade Name	Batch number	Nominal potency (blood products) or number of doses (vaccines)	Total number of containers in the batch	Expiry date	OMCL certificate date	MA number used for release

B3.2 Detailed list of imported batches released by another Member State

Common name	Manufacturer	Trade Name	Batch number	Nominal potency (blood products) or number of doses (vaccines)	Number of containers marketed in the Member State	Expiry date	Release date	Releasing OMCL

Section C: Technical Details of tests methods applied for OCABR

Indicate which laboratory test methods were performed by the OMCL for the tests listed in the OCABR product specific guidelines (e.g whether the test is described in a European Pharmacopoeia monograph, in the manufacturer's MA, in a WHO requirement or is a validated 'in-house' method).

Also indicate any relevant details such as the sharing of test sera from the manufacturer.

Example tables

Eg. Plasma pools

Viral Marker	**Test Kit**	**Other relevant details** (eg: sensitivity/specificity of test kit)	**Specification** (indicate origin e.g. Ph Eur, MA or other, please specify)
HCV RNA			
HAV RNA			
HBsAg			

Eg Blood products

Product	**Release test(s)**	**Brief description; indicate if it is Ph Eur/WHO/MA or in house*[18]**
Eg Albumin	Appearance	
	Distribution of molecular size	
	Pre-kallikrein activator	
Other relevant details (as necessary)	*Eg; any reference material used, source and identity*	
Factor VIII	Solubility and appearance	
	Potency	
Other relevant details (as necessary)		

Eg Vaccines (and vaccine components)

Vaccine component(s)	**Release test(s)**	**Brief description; indicate if it is Ph Eur/WHO/MA or in house***
Eg Diphtheria containing vaccines including combinations	Potency Identity	
Other relevant details (as necessary)		

[1] *If more than 1 method is used (for different products/combinations) list them all

Hepatitis A vaccines including combinations	Potency Identity Antigen content	
Other relevant details (as necessary)		
Hepatitis B vaccines including combinations	Potency & identity In vitro HBsAg content Purity& identity	
Other relevant details (as necessary)		

Section D: Summary of test results

For each product (as listed in the table(s) in section B1), the specifications used for the OCABR tests for the particular product should be stated. Results should be given, preferably as graphs or figures demonstrating trend analysis (particularly for potency test data) with appropriate and clear indication of the values obtained on the axis. It is helpful where possible to indicate the specification limits also on the graphs. Tables of results for every test on every batch are not necessary where graphs are provided. OMCL data should be compared to manufacturer's data (preferably incorporated into the trend analysis graphs).

A brief interpretation of the data by the OMCL should be included.

It is not sufficient to indicate that testing is compliant with the MA or Ph Eur, the specification for each test should be given.

In conjunction with the summary figures on product data, data collected on reference preparations should be included and reference material should be clearly identified.

Further data from the OMCL or manufacturer's protocol should also be included where relevant.

It is important to provide information on batches failing the requirements; all failing batches should be reported in section B2. Additional details concerning the batches not released and the reasons for non-compliance and any follow up action may be provided here (a reference to any information provided in section D on failing batches should be indicated in section B2).

Example trend data:

dT – Diftavax Sanofi Pasteur

Specifications Applied (indicate origin ie MA or Ph Eur)

Final bulk	
Test	Actual Specification Applied
Assay Diphtheria	
Assay Tetanus	
Final lot	
Test	Actual Specification Applied
Appearance	
Identity Diphtheria	
Identity Tetanus	

D Potency assay

Insert graph comparing OMCL and manufacturer's results

Additional comments as necessary

T potency

Insert graph comparing OMCL and manufacturer's results

Additional comments as necessary

Appearance and identity

Summary of results
Additional comments as necessary

Data on reference preparations used

Section E: Developmental Work, Technical Difficulties

Any problems with assays and technical developmental work and suggestions for improvements/amendments of relevant guidelines and European Pharmacopoeia monographs

Section F: Network Activity

Participation in EDQM collaborative studies or PTS studies or any other collaborative studies or performance measuring studies external to the network.

Declaration of any subcontracting arrangements for OCABR testing and identification of partners.

Section G: Other Related Activity

OMCLs are encouraged to report any relevant related activity (Market Surveillance study, spot-testing, release for other markets where relevant (eg. WHO), limited national release etc.)

ANNEX VI

MODEL LETTER

For Distribution of Important Information to the Contacts for the Official Control Authorities responsible for Human Vaccines*/Human Blood and Plasma Derivatives* in annex III

CONFIDENTIAL

Network of Official Medicines Control Authorities responsible for Human Vaccines*/ Human Blood and Plasma Derivatives*

IMPORTANT INFORMATION

(To be used for information on need for phase 2 testing, specific product or method related problems of interest to the network etc..: For notification of non-compliance of batches use annex IIe. For notification on batches withdrawn during parallel testing use annex VII)

Name of Company:

Trade Name of Product:

Nature of Problem:

Decision:

Batch Numbers (if appropriate): (include filling bulk number, final lot number and packaging lot number in addition to the batch number appearing on the product as in the member state /EU where the batch of product is to be marketed)

Comments:

Action Required (if any):

Notifying Member State/OMCL/OMCA:

Contact (include phone number and e-mail):

Date:

Signed:

* delete as appropriate

ANNEX VII

MODEL LETTER
BATCH RELEASE PROCEDURAL INFORMATION

For Distribution to the Contacts for the Official Control Authorities responsible for Human Vaccines*/Human Blood and Plasma Derivatives* in annex III

CONFIDENTIAL; FOR INFORMATION ONLY

Network of Official Medicines Control Authorities responsible for Human Vaccines*/ Human Blood and Plasma Derivatives*

INFORMATION ON OCABR PROCEDURE INTERRUPTION DURING PARALLEL TESTING

Involved Member State/OMCL/OMCA:

Contact (include phone number and e-mail):

The following batch(es) were withdrawn from the OCABR procedure by the manufacturer during parallel testing:

Name of Company:

Trade Name of Product:

Batch Numbers: (include filling bulk number, final lot number and packaging lot number)

Nature of Reason for interruption:

Comments:

THIS BULLETIN IS FOR INFORMATION ONLY

ALL APPROPRIATE FOLLOW UP HAS BEEN TAKEN

NO FURTHER ACTION IS REQUIRED

Please contact the notifying OMCL for any further information

Date:

Signed:.

*delete as appropriate

ANNEX VIII

EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE NOTIFICATION OF NULLIFICATION OF CERTIFICATE

For circulation to the involved marketing authorisation holder and Annex III contacts

This is official notification that

Name and address of the releasing authority

_____

has found it necessary to consider null and void the EU Release Certificate number _____

that was issued for:

Trade name:	
International non-proprietary Name / Ph. Eur. name / common name:	
Batch numbers appearing on package and other identification numbers associated with this batch[19]:	
Type of container:	
Total number of containers in this batch:	
Number of doses per container:	
Date of start of period of validity:	
Date of expiry:	
Marketing authorisation number (member state / EU) issued by :	
Name and address of manufacturer:	
Name and address of marketing authorisation holder if different:	

For the following reason(s):
(e.g. Withdrawal of the batch from the market due to quality or safety concerns – details should be provided)

The above noted certificate is no longer valid for the purpose of releasing the batch in question on to the market.

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

Notification Number:

[19]Such as batch number of final bulk.