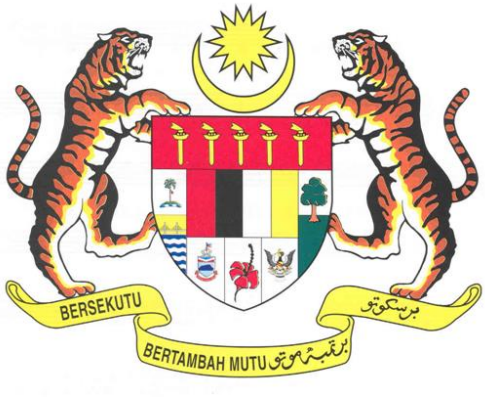

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

GUIDANCE DOCUMENT FOR PLASMA PRODUCT LOT RELEASE IN MALAYSIA

Second Edition – Revised in December 2016

GUIDELINE HISTORY

No.	Description of amendment	Effective date
1	Preparation of draft guidance	Feb - June 2015
2	Discussion/Dissemination of draft guidance	June 2015
3	Collation of feedback and comments	23 June – 3 July 2015
4	Final guidance	10 July 2015
5	Consideration for adoption and first publication	1 January 2016
6	Revision of Guidance Document for Plasma Product Lot Release in Malaysia	1 December 2016

GUIDANCE DOCUMENT FOR APPLICANTS:
INFORMATION AND SUBMISSION REQUIREMENTS FOR PLASMA PRODUCT LOT RELEASE

National Pharmaceutical Regulatory Agency
Ministry Of Health Malaysia
December 2016

NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)
MINISTRY OF HEALTH MALAYSIA

VISION:

TO BE A WORLD RENOWNED REGULATORY AUTHORITY FOR MEDICINAL PRODUCTS AND COSMETICS.

MISSION:

TO SAFEGUARD THE NATION'S HEALTH THROUGH SCIENTIFIC EXCELLENCE IN THE REGULATORY CONTROL OF MEDICINAL PRODUCTS AND COSMETICS.

OBJECTIVE:

TO ENSURE THAT THERAPEUTIC SUBSTANCES APPROVED FOR THE LOCAL MARKET ARE SAFE, EFFECTIVE AND OF QUALITY AND ALSO TO ENSURE THAT COSMETIC PRODUCTS APPROVED ARE SAFE AND OF QUALITY.

ACKNOWLEDGEMENTS

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ABBREVIATIONS AND ACRONYMS

CQC	Centre for Quality Control
CCL	Centre for Compliance and Licensing
DRGD	Drug Registration Guidance Documents
MVG	Malaysian Variation Guidelines
NCL	National Control Laboratory
NPRA	National Pharmaceutical Regulatory Agency
NRA	National Regulatory Authority
PRH(s)	Product Registration Holder(s)
Rh_0	Rhesus Positive
SOP	Standard Operation Procedure
TRS	Technical Report Series
VWF	Von Willebrand Factor
WHO	World Health Organisation

GLOSSARY

Applicant (product registration holder): The company or corporate or legal entity in the field of pharmaceuticals whose name the marketing authorization has been granted. This party is responsible to all aspects of the product, including quality and compliance with the conditions of marketing authorization. The authorized holder must be subjected to legislation in the country that issued the marketing authorization, which normally means being physically located in that country (1).

Blood Component: A constituent of blood (erythrocytes, leukocytes, platelets or plasma) that can be prepared under such conditionsthat it can be used either directly or after further processing for therapeutic applications(8).

Blood Product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma-derived medicinal products (4).

Fractionation: A (large scale) process by which plasma is separated into individual protein fractions that are further purified for medicinal use (variously referred to as plasma derivatives, fractionated plasma products or plasma-derived medicinal products). The term fractionation is used to describe a sequence of processes, including: plasma protein separation steps (typically precipitation and/or chromatography), purification steps (typically ion-exchange or affinity chromatography) and one or more steps for the inactivation or removal of blood-borne infectious agents (most specifically viruses and, possibly, prions) (8).

Inspection: Activity to conform the lot of plasma products are in compliance with the Good Distribution Practice (GDP) requirements. This includes conformance on cold chain (if required) and physical inspection.

Licensed importer: A person to whom an import license has been issued under Regulation 12, CDCR 1984(2).

Licensed wholesaler: A person to whom a wholesaler's license has been issued Regulation 12, CDCR 1984(2).

Lot: A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a lot into a number of sub- lots, which are later accumulatedto form a final homogeneous lot. In continuous manufacture, the lot must correspond to a defined fraction of the production, characterised by its intended homogeneity. The lot size can be defined either as a fixed quantity or as the amount produced in a fixed time interval (9).

Lot release: The process of NRA/ NCL evaluation of an individual lot of a licensed vaccine / other biological products before giving approval for its releasing onto the market.

Lot summary protocol: A document summarising all manufacturing steps and test results for a lot of vaccine / other biological products, certified and signed by the responsible person of the manufacturing company.

Non-compliance: Failure or refusal to comply with a standard or a set of limits (9).

NRA: National regulatory authorities (also called national medicines regulatory authorities) are legally-established bodies that promulgate medicines regulations and enforce them (4).

Plasma: The liquid portion remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure(8).

Plasma products: A range of medicinal products obtained by the process of fractionation of human plasma.Also called *plasma derivatives, fractionated plasma products* or *plasma-derived medicinal products* (8).

Recombinant products: Products which are produced by genetic modification in which DNA coding for the required product is introduced, usually by means of a plasmid or viral vector into a suitable microorganism or cell line, in which DNA is expressed and translated into protein. The desired product is then recovered by extraction and purification (1).

Reference country: The reference country for Malaysia is listed as per the latest version ofDrug Registration Guidance Document (DRGD) by National Pharmaceutical Control Bureau (1).

Viral inactivation: A process of enhancing viral safety in which the virus is intentionally “killed” (8).

Viral removal: A process of enhancing viral safety by removing or separating the virus from the protein(s) of interest (8).

1.0 INTRODUCTION

Plasma products are manufactured from human blood plasma (*plasma*). Plasma is the source of a wide range of medicinal therapeutic products that are used for the treatment and prevention of a variety of life threatening injuries and diseases often associated with protein deficiency states.

Improvements in protein purification and molecular separation technology over recent years have made available a wide variety of products, with medical applications covering a large and growing field, and the therapeutic value of these is unquestioned. However, the potential for viral transmission is well recognized, and because of the large number of donations which are pooled, a single contaminated batch of a plasma product, with the contamination possibly originating from a single donation, viral disease can be transmitted to a large number of recipients.

This guidance document is intended to facilitate local stakeholders to understand and meet the requirements for plasma products lot release in Malaysia.

1.1 General Overview of Plasma Product Lot Release

Plasma products are complex in nature and more variable either in the production process or in their nature than chemically synthesized drug.

Evaluation of starting materials, production processes and test methods are imperative to ensure the quality, safety and consistency of plasma products.

The quality and safety of these products rely on the source of materials and their origin as well as on the subsequent manufacturing procedures, including infectious marker testing, viral removal and virus inactivation. The complexity of the manufacturing process and the tendency of the occurrence of inconsistency need an independent review of manufacturing and quality control data.

In addition to the manufacturing complexity, proper storage condition and efficient supply chain management must be ensured to preserve the sensitivity and limited shelf life properties of plasma products.

Each plasma products lot is subjected to the lot release programme before it is released onto the market. The PRH or importer must submit relevant documents or samples to NRA for independent assessment. Manufacturers must ensure that every new lot of plasma product is identical in its specific characteristics as outlined in the approved marketing authorisation. Lot release programme will enable NRA to ascertain the safety and effectiveness of every lot of plasma products produced. Upon approval from the NRA, a formal release letter or certificate will be issued to allow release onto the market.

Independent assessment of plasma products can be based on:

a) review of manufacturers' summary protocols, which include manufacturing and testing data for each manufactured lot of the product
b) recognition/ acceptance of lot release certificate from responsible National Regulatory Authority
c) assessment of cold chain system monitoring, where applicable
d) independent testing.

These approaches are not mutually exclusive and may be product-specific. Where appropriate, strategy for each particular plasma products shall be established by taking into consideration such as the nature of plasma products, the post- market experience including production history and safety profile.

1.2 Guiding Principles

Our main intention is to safeguard public health and well-being. The lot release programme provides an additional monitoring on each newly manufactured lot of plasma products. The approach employed in this programme is based on the recommendations by World Health Organisation (WHO).

1.3 Scope

This guideline is focused on registered imported plasma products for human use.This document does not address those products manufactured by recombinant techniques. This document is intended to provide guidance to PRHs, importers and wholesalers of plasma products.

The content of this guideline will be reviewed and amended accordingly in the future for locally produced plasma products.

1.4 Scientific Guidelines Applicable to Plasma Products Lot Release

Assessment Criteria for National Blood Regulatory Systems and Technical Report Series (TRS) related to plasma products are available at WHO website: *http://www.who.int/*.

1.5 Implementation Timeline:

The plasma products lot release will be implemented prospectively according to a phased timeline established by National Pharmaceutical Regulatory Agency (NPRA). The implementation will be conducted in 2 phases as follow:

a) Pilot study phase – Factor VIII:VWF Complex, Human Albumin and Factor VIII-Effective on 1st January 2016

b) Full implementation – Other plasma products (either single ingredient or complex) that are not stated in pilot study phase such as Rh_0 (D) Immunoglobulin, Hepatitis B Immunoglobulin, Tetanus Immunoglobulin, Anti-Rh_0 (D) Immunoglobulin and others - Effective on 1st July 2016.

Under both phases, monitoring of cold chain system (if applicable) is mandatory before releasing the plasma products onto the market.

2.0 GUIDANCE FOR IMPLEMENTATION

2.1 General

This guideline is largely based on the recommendation outlined in the Assessment Criteria for National Blood Regulatory Systems (4). The lot release approaches for imported plasma products in Malaysia include:-

a) Review of manufacturer's summary protocol based on product dossier which has been approved by NPRA during product registration,

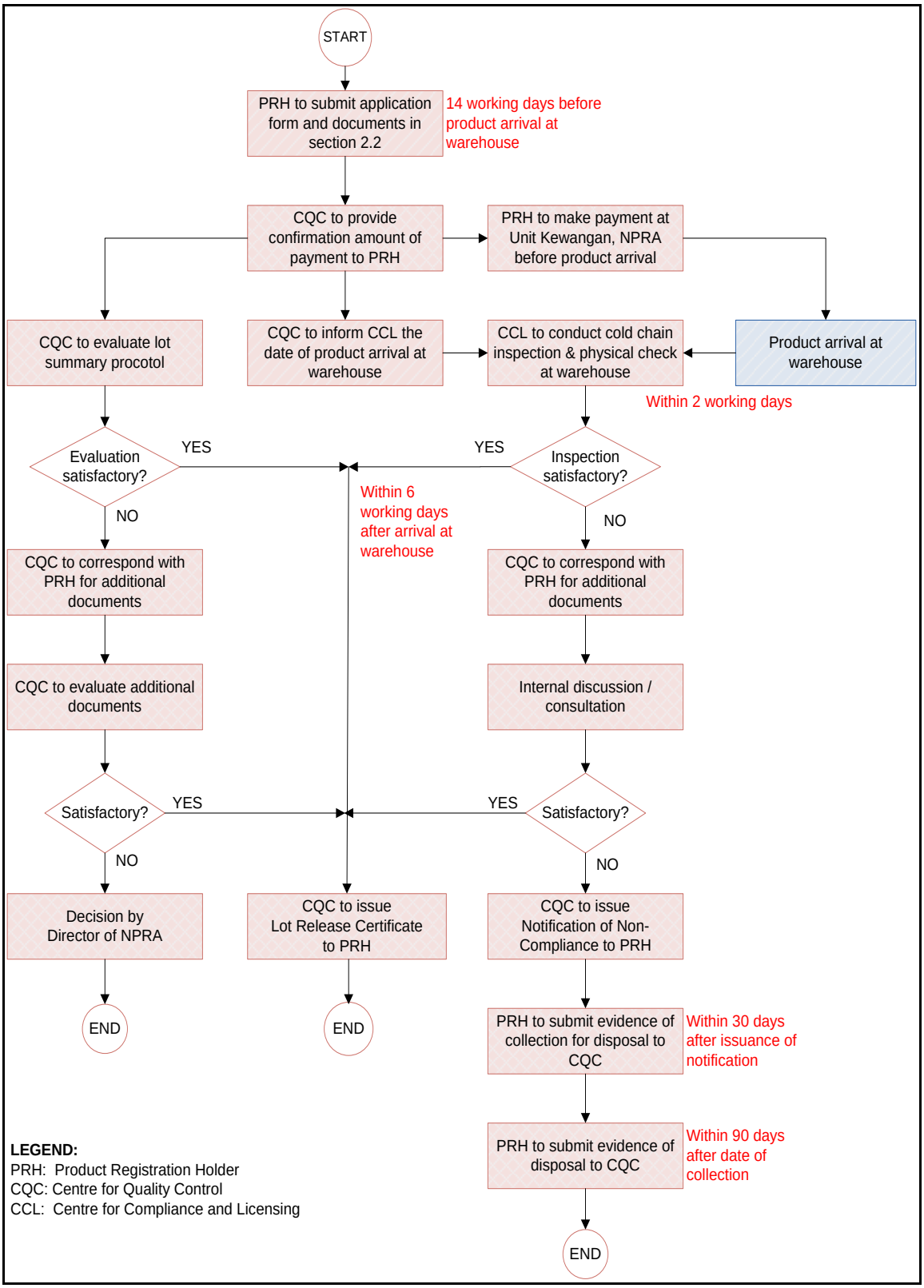
b) Inspection of plasma products lot upon arrival.

PRHs are fully responsible to ensure the plasma products comply to the product registration information. PRHs are sought to obtain approval for variation prior submission of documents if there are any changes on the plasma products.
Please refer to the Malaysian Variation Guideline for Pharmaceutical Products for further details.

The Process Flow 1 diagram (below) illustrates the processes in plasma products lot release. The process involves:

a) Applicants (PRH)
b) National Pharmaceutical Regulatory Agency (NPRA)
c) Importers and
d) Wholesalers

Process Flow 1: PLASMA PRODUCT LOT RELEASE PROCESS



General Procedure of Plasma Product Lot Release in Malaysia:

i. Applicant submits application form (refer to Appendix 2) and documents (refer to section 2.2) via email to CQC (pplr@npra.gov.my)
ii. NPRA will response to the email by providing confirmation on the amount of fee to be paid. Please refer to section 2.10.1 of the guideline for further details on fees.
iii. Before product arrival, applicant makes payment to NPRA.
iv. Evaluation of lot summary protocol is conducted.
v. Within 2 working days after the arrival of plasma products at warehouse, NPRA's officer will conduct inspection of the plasma products.
vi. NPRA will issue lot release certificates if all the requirements have been fulfilled, within 6 working days after product arrival at warehouse.
vii. If the requirements are not met, NPRA will issue notification of non-compliance to reject the plasma products.
viii. In the event of non-compliance, it is the sole responsibility of the PRH to ensure proper safe disposal of the plasma products. A copy of collection for disposal documentation shall be sent to NPRA within 30 days after issuance of rejection and a copy of disposal documentation shall be sent to NPRA within 90 days after the collection date.
ix. Lot summary protocol for the same lot number being imported into the country at different times will not be evaluated again. However, inspection will still be conducted.
x. For cases stated in (ix), PRH should only submit the application form, import packing list, airway bill and make payment for inspection.

2.2 Guidance on the Submission of Documents

This guidance outlines the general requirement for documents submission. All the documents shall be written in *Bahasa Malaysia* or English only. Each document must be clearly tagged (indexed and labelled). Documents to be submitted are:

a) Application Form
b) Lot Release Certificate
c) Plasma Pool Certificate
d) Lot Summary Protocol
e) Certificate of Analysis (COA) for Finished Products
f) Importing Packing List.
g) Airway Bill

Incomplete submission of documents may result in rejection of the application. Importing packing list and airway bill may be submitted two working days before product arrival.

2.2.1 Application Form

a) Application form is available in NPRA official website (refer to Appendix 2) and applicant shall use the same form without any amendment of the format
b) All sections shall be filled by applicant except section "For Office Use only"
c) Incomplete form will not be processed
d) The application form shall be submitted to CQC via email to pplr@npra.gov.my
e) The lot number (in final packaging) stated in the application form must be identical to the lot number on the lot summary protocol, lot release certificate and certificate of analysis.

2.2.2 Lot Release Certificate

Lot release certificate provided should be issued by the NRA from the country of origin.
In the event where the NRA does not provide a release certificate,lot release certificate from any of the NPRA's eight (8) reference countries (United Kingdom, Sweden, France, United States of America, Australia, Canada, Japan and Switzerland)will be accepted.

2.2.3 Plasma Pool Certificate

Plasma pool certificate provided should be issued by the NRA from the country of origin.
In the event where the NRA does not provide a plasma pool certificate, plasma pool certificate from any of the NPRA's eight (8) reference countries (United Kingdom, Sweden, France, United States of America, Australia, Canada, Japan and Switzerland) will be accepted.

2.2.4 Lot Summary Protocol

The evaluation of the summary lot protocol will be based on dossier (Chemistry, Manufacture and Controls) which has been approved by NPRA during product registration.

2.2.5 Certificate of Analysis (COA) for Finished Products

All release tests and its specification shall be the minimum requirement. Certificate of analysis for finished products shall contain the following information:

a) name of manufacturer,
b) product name, dosage form and strength,
c) lot number (must be parallel to the lot number in the application form),
d) date of expiry,
e) date of manufacture,

f) list of tests,
g) specification of tests,
h) result of tests,
i) approval from responsible person.

2.2.6 Importing Packing List

Applicant shall provide the details of importing packing such as:

a) date of shipment,
b) port of loading and discharge,
c) container numbers,
d) numbers and types of package,
e) gross weight (kg),
f) dimension Height x Width x Length (cm),
g) quantity,
h) description of goods and
i) other information related to the shipment.

The importing packing list must be submitted to CQC two (2) working days before the product arrival.

2.2.7 Airway bill (AWB)

For plasma products transported via air route, applicant shall provide the details of AWB such as:

a) Airway bill number
b) Airport of departure
c) Airport of destination
d) Flight number and date of arrival
e) Shipper's Name and Address
f) Consignee's Name and Address
g) Total number of packages
h) Description of goods

The airway bill must be submitted to CQC two (2) working days before the product arrival.

2.2.8 Criteria for requesting additional data

NPRA shall request additional data from PRH under conditions including but not limited to:

a) data provided are not reliable
b) insufficient information to support the evidence of the data (such as unavailability of raw data to support the results)
c) trending analysis data is out of normal trends (in this case, validation data for each parameter should be provided)
d) information of reference standard is not available (such as source of standard, procedure to produce standard and method used to standardize the standard)
e) authority from the country of origin does not issue lot release certificate.

Under condition (e), applicant shall provide all the testing raw data for the whole manufacturing process. Submission of requested data is mandatory for the first lot release application.

2.3 Guidance on Temperature Monitoring

Deviation of temperature or incorrect storage condition of plasma product may affect the quality, efficacy and subsequently the safety of plasma product. Hence, it is recommended that all plasma products should be stored in their respective recommended condition at all times with continuous monitoring. Failure to show the traceability of temperature monitoring and appropriate storage condition may result in rejection of the entire lot of plasma products.

To facilitate the Cold Chain Inspection on arrival of product, suitable electronic temperature monitoring devices should be included in all shipments to document whether temperature limits have been exceeded. These devices shall serve as a quick reference to determine whether the shipment has been exposed to temperature at which products could have been damaged.

As temperature deviation could happen during transportation or redressing, PRH must submit relevant data and supporting document such as thermal cycling studies and shipping validation to justify temperature excursion for each product. The data must be sufficient to prove that the plasma product products remain stable at those storage conditions. All data must be submitted and will be evaluated by CCL. If the supporting documents or data provided is not sufficient to show evidence of product stability, the plasma product lot shall be rejected.

Please refer to the Guidelines on Good Distribution Practice (GDP) and Supplementary Notes for Management of Cold Chain Products/Material for further details on plasma product temperature monitoring.

2.4 Guidance on Non- Compliant

2.4.1 Non-compliant plasma products

In the event of non-compliant plasma products, the PRH shall ensure that the supply of the plasma products for the local use will not be affected.

The PRH shall ensure that non-compliant plasma products are not released onto the market and will be disposed in Malaysia. PRH shall provide appropriate proof of collection for disposal within 30 days after issuance of non-compliance notification and proof of disposal within 90 days after the date of collection.

2.4.2 Non-compliant product importer or wholesaler

Failure of importer or wholesaler to meet the requirement of Good Distribution Practice may result in revocation of import or wholesale license. In such cases, the PRH shall have a contingency plan to ensure that the supply of the plasma products for the local use will not be jeopardised.

2.5 Guidance on Exceptional Case

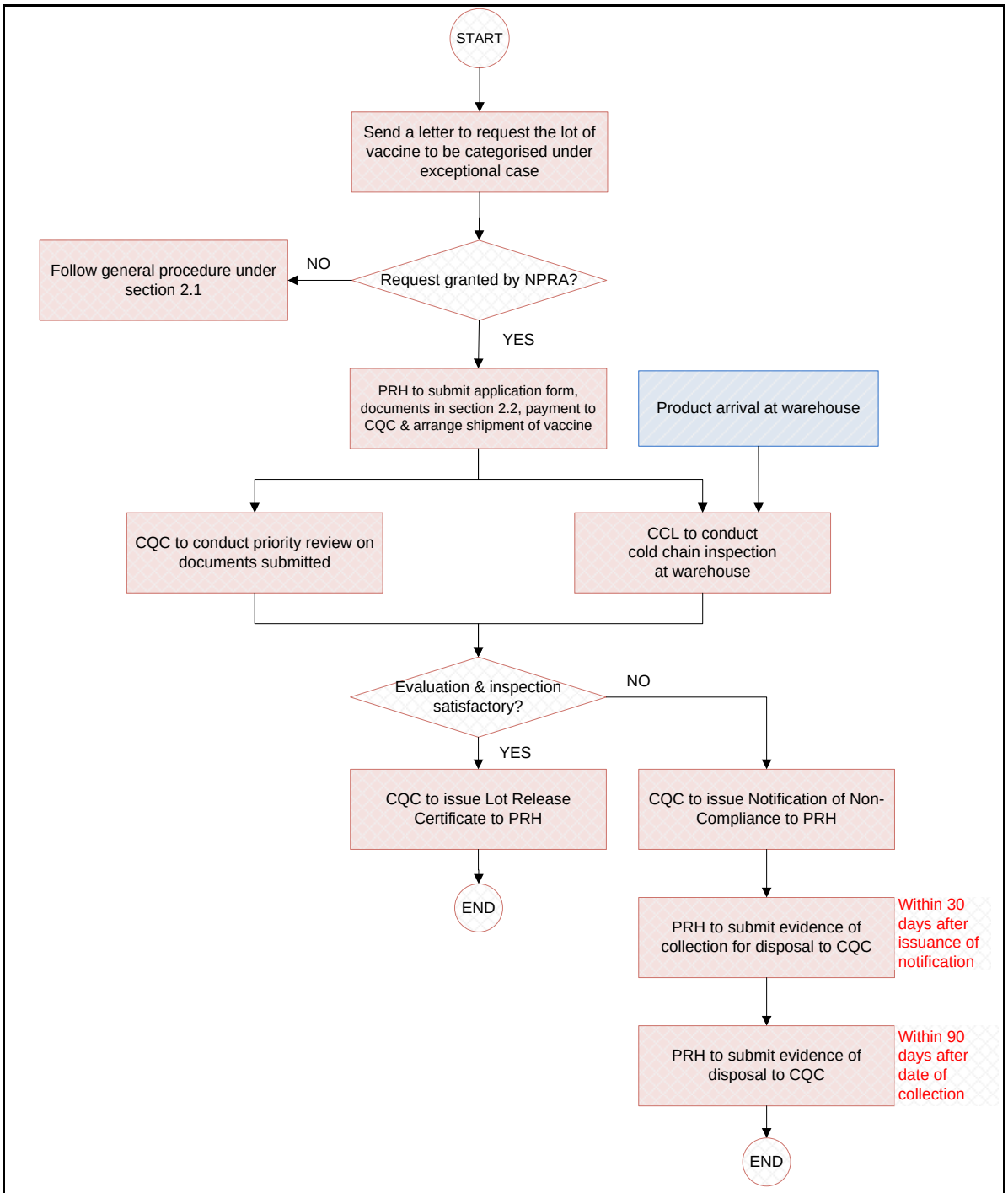
This guidance shall only apply to the emergence of crisis situation such as pandemic, epidemic, the shortage of product on the market or an urgent need due to changes in national health policy recommendation

Exceptional case application shall be supported by related documents. It is not applicable as an alternative plan to support improper supply planning and handling of stock by applicant.

The Process Flow 2 diagram (below) illustrates the process of plasma product lot release system under exceptional case.

For other situations in which releases of plasma product lot need to conducted immediately, it will be handled on case-to-case basis.

Process Flow 2: LOT RELEASE PROCESS FOR EXCEPTIONAL CASE



LEGEND:
PRH: Product Registration Holder
CQC: Centre for Quality Control
CCL: Centre for Compliance and Licensing
NPRA: National Pharmaceutical Regulatory Agency

General Procedure for Exceptional Case:

i. Applicant sends a requisition to Director of NPRA with accompanying justification for exemption case.
ii. If the request is accepted, applicant submits application form (refer to Appendix 2) and documents (refer to section 2.2) via email to CQC (pplr@npra.gov.my)
iii. NPRA will response to the email by providing confirmation on the amount of fee to be paid. Please refer to section 2.10.1 of the guidelines for further details on fees.
iv. Before product arrival, applicant makes payment to NPRA.
v. Priority review on all the documents submitted will be conducted.
vi. Upon the arrival of plasma products at warehouse, NPRA shall conduct inspection.
vii. If the evaluation and inspection are satisfactory, NPRA shall issue lot release certificate.
viii. In the event of unsatisfactory evaluation or inspection of the respective lot, NPRA shall issue a non-compliance notification (NNC). A copy of collection for disposal documentation shall be sent to NPRA within 30 days of issuance of rejection. A copy of disposal documentation shall be sent to NPRA within 90 days after collection date.
ix. Lot summary protocol for the same lot number being imported into the country at different times will not be evaluated again. However, inspection will still be conducted.
x. For cases stated in (ix), PRH should only submit the application form, make payment for inspection and submit importing packing list.

2.6 Rejection Criteria for Plasma Products Lot Release

Lot of plasma products shall be rejected under conditions including but not limited to:

a) decision from Director of NPRA based on the supporting document, comments from other NRA (if available) and summary from evaluator
b) failure to commit the requirement of cold chain management (if applicable) with no supporting data for temperature excursion
c) unseal of plasma products /quarantine plasma products without approval from NPRA
d) failure in physical appearance check during inspection with no supporting data
e) failure to provide additional data requested during evaluation or inspection
f) the product information leaflet and label are not updated accordingly or updated without NPRA's approval (approval for product variation by NPRA shall be received before the submission of lot release).

2.7 Guidance on Product Recall and Disposal

Please refer to the Guideline on Good Distribution Practice for further details on product recall and disposal.

2.8 Decision making

All the decisions made by NPRA are final and no appeal shall be allowed in any circumstances. The reason(s) of non- compliance will be clearly stated in the non- compliance certificate.

2.9 Timeline

Table 1 below shows the timeline for each activity in the lot release process.

Table 1:

Activity	Duration
Submission of application form and documents in section 2.2.1 - 2.2.5	14 working days before arrival of plasma products
Payment for plasma product lot release	Within 14 working days before arrival of plasma products
Submission of import packing list and airway bill (Section 2.2.6 and 2.2.7)	2 working days before arrival of plasma products
Conduct inspection	Within 2 working days after arrival of plasma products at warehouse
Issue of lot release certificate	Within 6 working days after arrival of plasma products at warehouse
Submission of evidence of collection for disposal in the event of non-compliance	Within 30 days after issuance of notification of non-compliance
Submission of evidence of disposal in the event of non-compliance	Within 90 days after date of collection for disposal

2.10 Fees

Every application for plasma product lot release shall be charged.

Payment made shall **NOT** be **REFUNDABLE** once the application has been submitted and payment confirmed.

Applications without the correct fees will not be processed.

2.10.1 Types of Fees

The fees imposed for plasma product lot release are shown in Table 2. The evaluation fee will be waived if the same lot of plasma products arrives at different times.

Table 2: Processing Fee

Type of Plasma Product (active ingredient)	**Inspection and Evaluation of Lot Summary Protocol**	**Inspection for Lot Summary Protocol has been evaluated**
Single	RM500/plasma product lot	RM200/plasma product lot
Complex	RM800/plasma product lot	

2.10.2 Mode of Payment

The processing fee and any other charges shall be paid in the form of cash/credit card/ bank draft/banker's cheque/ money order/ postal order made payable to **"Biro Pengawalan Farmaseutikal Kebangsaan"**.

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4.0 APPENDIX

4.1 Appendix 1: Plasma Products (8)

Products
Albumin
Human Serum Albumin
Blood Coagulation Factors
Factor VIII
Prothrombin Complex
Factor IX
Factor VII
Von Willebrand Factor
Factor XI
Fibrinogen
Factor XIII
Activated PCC
Protease Inhibitors
Antithrombin
Alpha 1 antitrypsin
C1-inhibitor
Anticoagulants
Protein C
Fibrin Sealants
Intravenous Immunoglobulins (IVIG)
Normal (polyvalent)
Cytomegalovirus
Hepatitis B
Rho(D)
Intramuscular Immunoglobulins (IMIG)
Normal (polyvalent)
Hepatitis B
Tetanus
Anti-Rho(D)
Rabies
Varicella/zoster

4.2 Appendix 2: Application Form for Plasma Products Lot Release

PP/001A
Version 2
Effective Date: 01 December 2016

Agensi Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia
Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor
No. Tel : 03-78835400
No. Faks: 03-79567075
Laman Web: http://npra.moh.gov.my
Emel Unit Kawalan Kualiti Produk Darah: pplr@npra.gov.my
Emel Pemeriksa Rangkaian Sejuk : cc@npra.gov.my

PLASMA PRODUCT LOT RELEASE APPLICATION FORM

1. APPLICANT INFORMATION	
1.1 Name & Address of Product Registration Holder	
1.2 Name & Address of Importer	
1.3 Name & Adress of Warehouse	
1.4 Contact Person	
1.5 Contact no.	

2. PLASMA PRODUCT INFORMATION	
2.1 Name of plasma product (as registered in Quest system)	
2.2 Ingredients & strength	
2.3 Name of manufacturer	
2.4 Name of other manufacturer (If any)	

2.5 MAL no.	2.6 Lot no. of plasma product
2.7 Date of manufacture	2.8 Expiry date
2.9 Storage condition	2.10 Types of final container plasma product ☐ Vial ☐ Prefilled syringe ☐ Ampoule ☐ Others; please specify _____

3. DILUENT INFORMATION (IF ANY)	
3.1 Name of diluent	3.2Lot no. of diluent
3.3 Date of manufacture	3.4 Expiry date
3.5 Storage condition	3.6 Types of final container for diluent ☐ Ampoule ☐ Prefilled syringe

4. QUANTITY OF PLASMA PRODUCT IMPORTED		
4.1 Quantity in primary packaging	4.2 Quantity in secondary packaging	4.3 Total no. of doses per shipment

PP/001A
Version 2
Effective Date: 01 December 2016

5. TRANSPORTATION OF PLASMA PRODUCT	
5.1 Arrival date	**5.2 Transit point (if any)**
5.3 Route of transportation ☐ Air ☐ Ocean	**5.4 Mode of transportation** ☐ Active system ☐ Passive system

6. DOCUMENTATION	
6.1 Documents submitted	☐ Lot Summary Protocol ☐ Lot Release Certificate ☐ Certificate of Analysis of Finished Product ☐ Importing Packing List ☐ Air Way Bill / Sea Way Bill

7. REDRESSING / REPACKING/RELABELLING INFORMATION (ONLY APPLICABLE FOR MAL NO. WITHOUT SUFFIX -R)	
7.1 Do these product require redressing/repacking/ relabelling? ☐ Yes. Refer to 7.2 ☐ No	**7.2 Have you submitted a request letter to conduct ANY redressing/repacking for these products to the Regulatory Coordination Section, Centre for Product Registration (SKR PPP)?** ☐ Yes. Submission date: _____ ☐ No

The Malaysian Drug Registration Guidance Document defines redressing, repacking and relabelling as a manufacturing activity. Manufacturing of products without a valid manufacturing license is an offense under Control of Drugs and Cosmetics Regulations 1984 [Regulation 12(1)]

8. APPLICANT DECLARATION		
I hereby certify that the above information given are true and correct as to the best of my knowledge. I understand that if any of the above information is found to be false or untrue or misleading or misrepresenting, I am aware that I may be held liable for it, this application will be rejected and any payments made will not be refunded.		
Remarks		
Name	**Signature**	**Date**

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PPLR Documents complete?	☐ YES ☐ NO. List of pending documents: ☐ LRC ☐ COA ☐ AWB/SWB ☐ Importing Packing List	**Received by, date & signature**
SAB Reference No.: Bil ( ) BPFK/PKK/16/04 **Date of issuance:**	**Amount:** ☐RM200 ☐RM500 ☐RM800	**Issued by, date & signature**
Date of payment received:	**Receipt no.:**	**Received by, date & signature**

5. LIST OF UPDATES

NO.	REVISON	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1	December 2016	Title	Change of title from "Guidance Document and Guidelines for Plasma Product Lot Release in Malaysia" to "Guidance Document for Plasma Product Lot Release in Malaysia"	Task Force Biological Lot Release Meeting No. 6/2016
2	December 2016	Whole document	Change of name from"National Pharmaceutical Control Bureau (NPCB)" to "National Pharmaceutical Regulatory Agency (NPRA)"	Task Force Biological Lot Release Meeting No. 6/2016
3	December 2016	2.3	Include the requirement to use electronic temperature monitoring devices	Task Force Biological Lot Release Meeting No. 6/2016
4	December 2016	2.5	Include additional requirement for Exceptional case application	Task Force Biological Lot Release Meeting No. 6/2016
5	December 2016	2.10.1	Change of amount of fee imposed for plasma product lot release	Task Force Biological Lot Release Meeting No. 6/2016
6	December 2016	Appendix 2	Change of application form for Plasma Product Lot Release to version 2 (Effective date 1 December 2016)	Task Force Biological Lot Release Meeting No. 6/2016