PILOT STUDY INTERIM REPORT FOR PLASMA PRODUCTS LOT RELEASE IN MALAYSIA

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OVERVIEW

Definition of plasma product :

- Plasma product is a medicinal product obtained by the process of fractionation of human plasma.
- It is also called plasma derivatives , fractionated plasma products or plasma-derived medicinal products.

  (WHO TRS , No.941, Annex 4 : Recommendations for the production, control and regulation of human plasma for fractionation)
- Used for the treatment and prevention of a variety of life threatening injuries and diseases often associated with protein deficiency states

PLASMA PRODUCTS REGISTERED IN MALAYSIA

- Human Albumin
- Factor VIII
- Factor VIII Inhibitor Bypassing Fraction
- Factor IX
- IV Immunoglobulin
- Fibrin Sealant
- Hepatitis B Immunoglobulin
- Rho(D) Immunoglobulin
- Tetanus Immunoglobulin
- Anti-Rho (D) Immunoglobulin
- Complex : Factor VIII ; Von Willebrand Factor (VWF)
- Complex : Factor II, Factor IX, Factor X
- Complex : Factor II, Factor IX, Factor VII, Factor X

86 products

* As of 1st June 2016

PLASMA PRODUCT LOT RELEASE

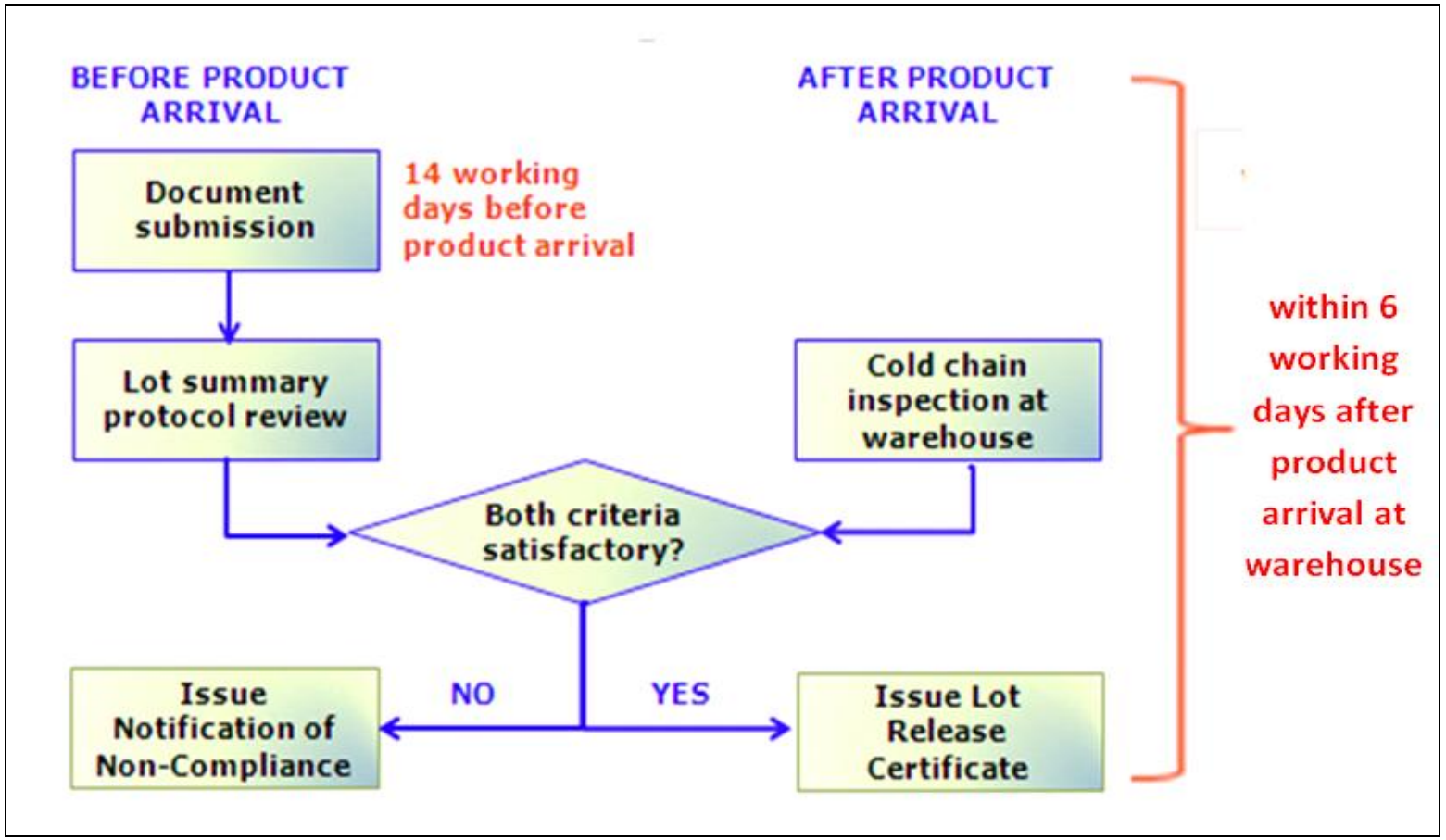
Review of manufacturer's lot summary protocol (LSP) against product registration dossier which has been approved by NPCB during product registration

OBJECTIVE :

- To ensure the consistency and quality of each plasma products lot in the market
- To enable the regulatory authority to ascertain the safety and effectiveness of every lot of plasma products produced

Cold chain inspection (CCI) upon plasma product arrival at warehouse

PROCESS FLOW OF PLASMA PRODUCTS LOT RELEASE



PROPOSAL TO DCA (293rd , 26 OCTOBER 2015)

- Plasma Product Lot Release implemented to registered imported / locally manufactured (if any) plasma products for human use
- NOT applicable to those products manufactured by recombinant techniques

Phase	Products involved
Pilot study 1 January 2016 – 30 June 2016 Total : 48	• Factor VIII 10 • Factor VIII: VWF Complex 9 • Human Albumin 29
Full implementation 1 July 2016 Total : 86	All registered plasma product in Malaysia

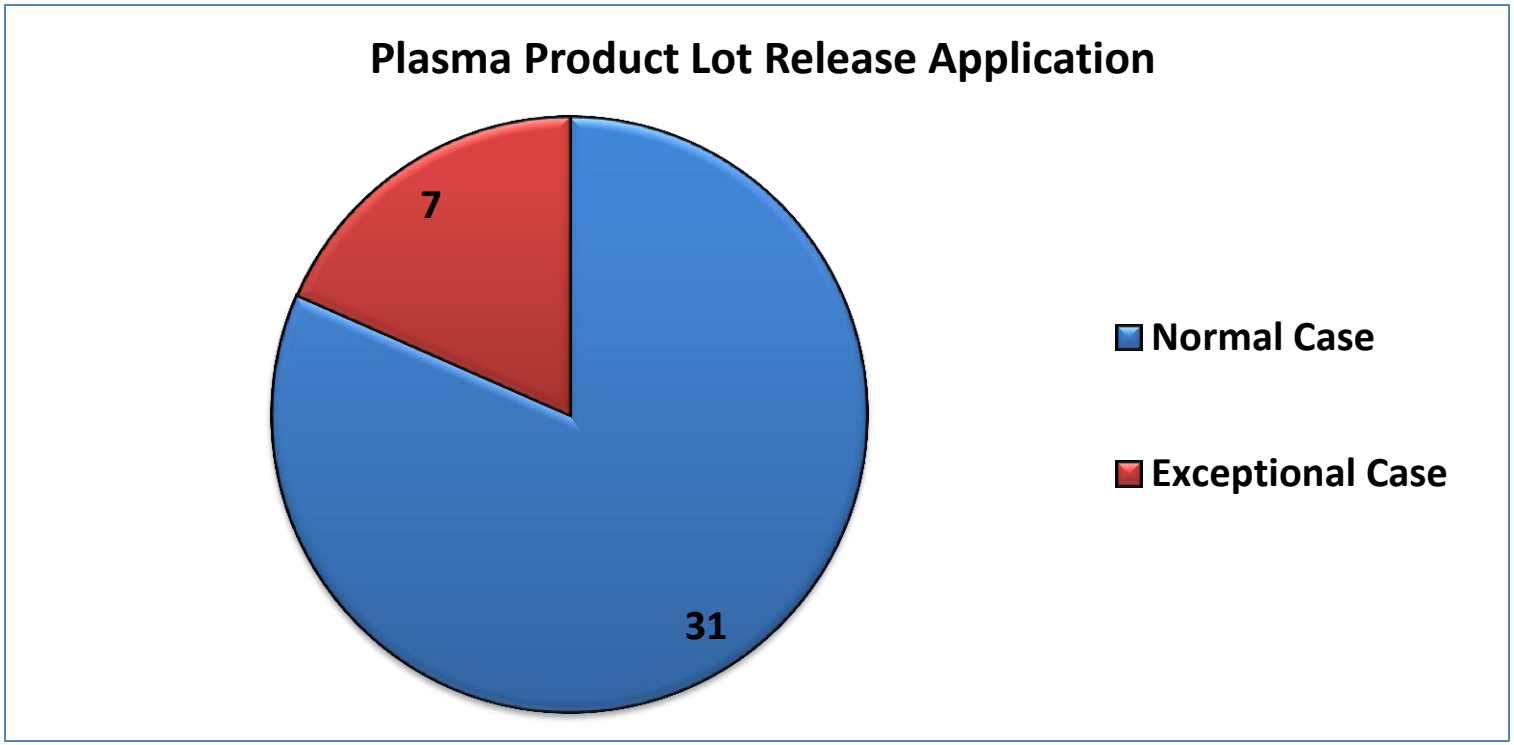
LOT SUMMARY PROTOCOL REVIEW

FINDINGS	RECOMMENDATION/ ACTION BY NPCB
Information on testing methods , certificate of analysis and testing specifications were not updated accordingly	Request for information to be updated by product registration holder through variation submission

COLD CHAIN INSPECTION

FINDINGS	RECOMMENDATION / ACTION BY NPCB
Unseal of consignment without the presence of cold chain inspector	Remind the industry on the requirements of Plasma Product Lot Release & Good Distribution Practices (GDP)
Power supply was not connected to the active temperature-controlled containers (Envirotainer) used for transportation causing raised of temperature	
Inappropriate choice of data logger (temperature reading could not be obtained during cold chain inspection)	

PILOT STUDY: STATISTICS (1)

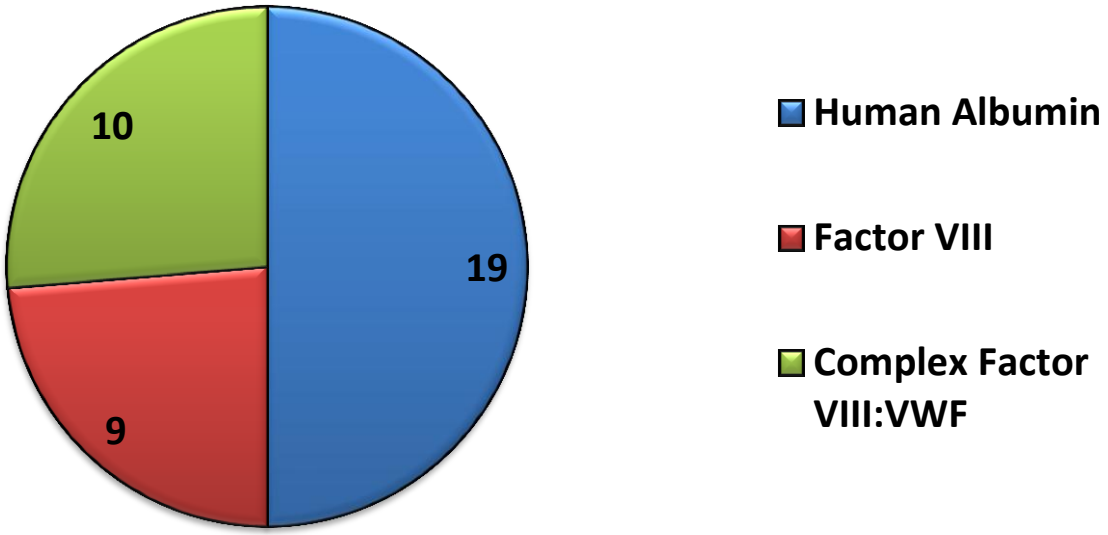


* As of 1st June 2016

Total number of 38 PPLR applications were received

PILOT STUDY: STATISTICS (2)

Plasma Product Category



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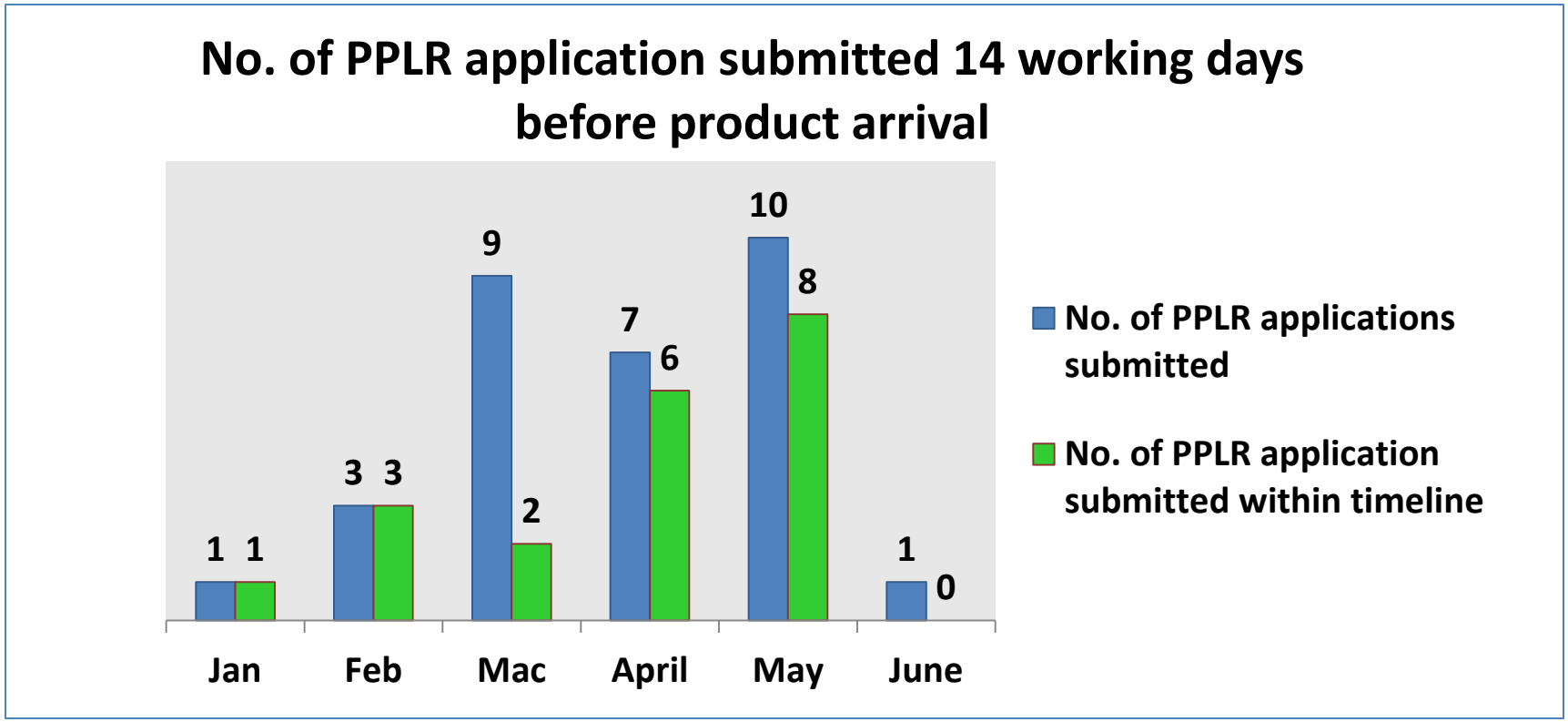
Plasma products involved in Pilot Study are Human Albumin, Factor VIII and Complex (Factor VIII: VWF)

PILOT STUDY: STATISTICS (3)

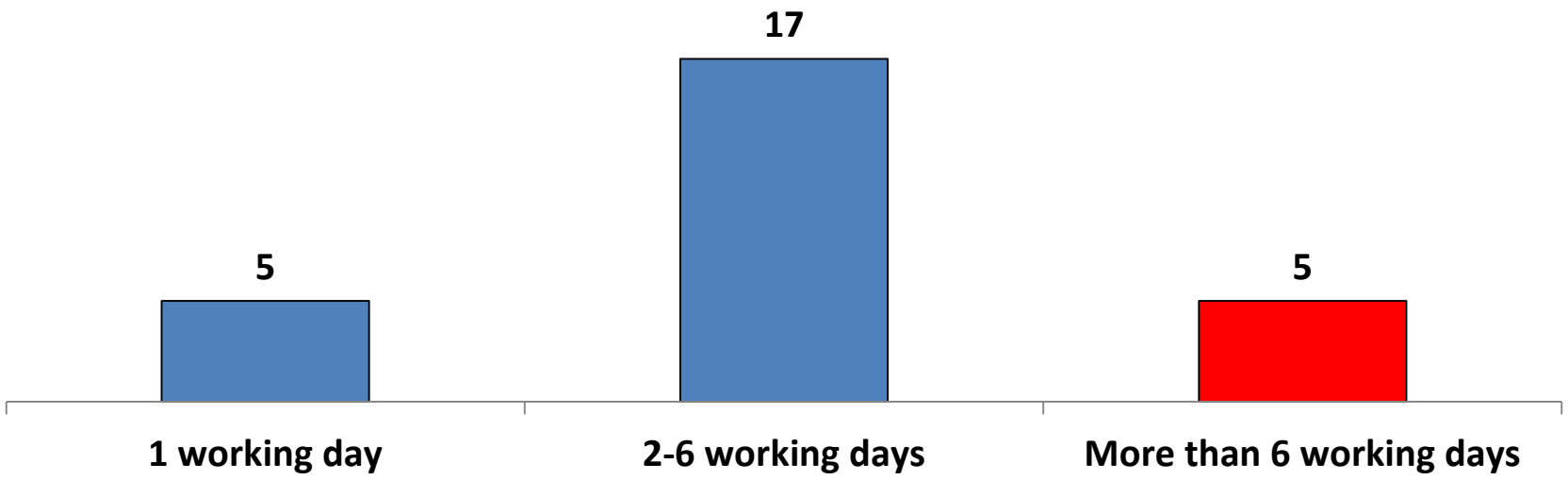


* As of 1st June 2016

From 1st Jan 2016 to 01st June 2016, total number of 11 PPLR applications (~29%) were not submitted 14 working days before product arrival

PILOT STUDY: STATISTICS (4)

No. of days taken to issue Lot Release Certificate after product arrival at warehouse



* As of 1st June 2016

Total number of 27 LRCs were issued. Five LRCs were issued after 6 working days of products arrival. The delay was due to unavailability of data logger reports during CCI

PILOT STUDY: STATISTICS (5)

Total number of Lot Summary Protocol (LSP) evaluation versus total number of Cold Chain Inspection (CCI) conducted for all released plasma products

Parameter	Total
Lot Summary Protocol (LSP) evaluation	25
Cold Chain Inspection conducted	27

As of 1st June 2016, total number of 27 LRCs were issued.

CONCLUSION FROM PILOT STUDY

- With the full implementation of Plasma Product Lot Release , the safety and effectiveness of every lot of registered plasma products being imported to Malaysia can be ascertained
- In addition, NPCB complies to WHO requirements where NRA should establish a lot release system for plasma products.

GUIDANCE ON NON-COMPLIANCE

NON-COMPLIANT PLASMA PRODUCTS

- ☑ In the event of non-compliance, the PRH shall ensure that the supply of the plasma product for the local use will **NOT** be affected.
- ☑ The PRH shall ensure that the plasma products are **NOT** released onto the market.
- ☑ Non-compliant plasma products will be disposed in Malaysia
- ☑ The PRH shall provide appropriate proof of collection for disposal **WITHIN 30 DAYS** after issuance of non-compliance notification
- ☑ The PRH shall provide appropriate proof of disposal **WITHIN 90 DAYS** after the date of collection.

NON-COMPLIANT PRODUCT IMPORTER/ WHOLESALER

- ☑ Failure of importer or wholesaler to meet the requirements of Good Distribution Practice (GDP) may result in revocation of import or wholesale license.

FEES

FEE FOR WEST MALAYSIA

Type of Plasma Product	Inspection and Evaluation of Lot Summary Protocol	Inspection for Lot Summary Protocol has been evaluated
Single active ingredient	RM 300 / plasma product lot	RM 200 / plasma product lot
Complex	RM 500 / plasma product lot	

FEE FOR EAST MALAYSIA

Type of Plasma Product	Inspection and Evaluation of Lot Summary Protocol	Inspection for Lot Summary Protocol has been evaluated
Single active ingredient	RM 600 / plasma product lot	RM 500/ plasma product lot
Complex	RM 800 / plasma product lot	


THANK
YOU!