SUPPLY CHAIN MAPS FOR LICENSED PLASMA PRODUCTS SUPPLIED TO SNBTS AND THE PROCESS FOR ADDITION OF NEW LICENSED PLASMA PRODUCTS USED FOR PATIENT CARE AT SCOTTISH HOSPITAL PHARMACIES

EFFECTIVE DATE	14 SEPT 2021

Standard Operating Procedure NATS PCF 025 07

1. INTRODUCTION

SNBTS holds a wholesale dealers licence which authorises them to hold and distribute Plasma Products to Scottish Hospital Pharmacies. This SOP describes what to do in the event that any new products or different dose sizes of currently held products are to be added to the portfolio of Plasma Products stored and issued by SNBTS.

Key Changes from Previous Revision
Addition of Supply Chain Maps

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This SOP includes references to the following documents:

Reference in text
NATF 635
NATF 2044, NATF2045, NATF2046, NATF2047,NATF 2048, NATF 2050

Relevant other references	
Regulations:	
Standards:	
Guidelines:	
Other:	

2. SAFETY

Observe health and safety instructions regarding:

- Electrical equipment
- VDUs

3. MATERIALS

N/A

4. STAFF

4.1 Only authorised and fully trained staff may carry out these procedures.

5. Supply Chain Maps

Supply Chain Maps should be drawn up for each supplier of plasma Products to the Scottish National Blood Transfusion service.

These forms should be updated when any new products are supplied or a new supplier is added.

A separate form for each supplier should be completed and referenced in this Document.

These forms should contain the following.

1. Supplier Name
2. Current Products Supplied
3. Manufacturing sites

4. Import Site
5. WDAs (storage and shipping organisations in the supply chain and associated licensure)

Current Forms/ Suppliers

NATF 2044 Bio Products Limited
NATF 2045 Biotest
NATF 2046 CSL Behring
NATF 2047 Grifols
NATF 2048 Shire/Takeda
NATF 2050 Octopharma

6. Responsibilities for new products added

6.1.1 SNBTS Procurement Staff
It is the responsibility of procurement staff to:

- Obtain Summary of Product Characteristics (SPC) from supplier
- Make sure SPC is current version before distributing
- Distribute SPC to all relevant pharmacy staff
- Complete change control for new or newly named products

6.1.2 *Responsible person*

- Deal with any medical information and/or regulatory issues arising

6.1.3 *Pharmacy staff*

- Ensure third party customers are aware of switch in product
- Supply SPC to all customers

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7. PROCEDURE

7.1 To ensure the integrity of the distribution chain with regard to falsified medicines. When a new/or newly named product due to processing change, or a change of dose or strength of a current licensed Plasma Product is going to be introduced into Scottish Hospital Pharmacies the following instructions should be carried out.

The SPC should be requested from the supplier if possible at least one month prior to delivery of the product to the Jack Copland Centre (JCC). These should then be forwarded by E-mail to the Pharmacy purchasing leads at the Bonafide Scottish Hospital Pharmacies. The content of the E-mail should also make clear when the new product will start to be issued and which product it will be replacing if any. A copy of these E-mails should be attached to the worksheet NATF 635 (Record of Supply of New Plasma Products for Patient care at NHS pharmacies), which will be used in conjunction with this SOP.

Plasma Products added to the SNBTS Portfolio such as new products, newly named products or a new dose size of a currently stocked product should be covered by a change control. This should include the storage conditions, copy of the SPC sent to Scottish Hospital Pharmacies, updating of the electronic stock control system and SNBTS order form. SNBTS trained Procurement staff should also be made aware of new products including a physical look when it arrives on site for familiarity. National Procurement set up the contracts for these products and ensure they are from authorised suppliers.

8. NOTES

8.1 A list of contacts will be kept by the Procurement department at the JCC. The list will be updated annually. This will be kept in the plasma workbook spreadsheet