Sanquin
Plasma Products

Sanquin Plasma Products BV
Plesmanlaan 125
NL-1066 CX Amsterdam
P.O. Box 9091
NL-1006 AD Amsterdam
The Netherlands
www.sanquin.org

Memo

To	5.1.2e	Of	Mw 5.1.2e
Date	April 2 2020	Telephone	+ 5.1.2e
Our reference	2004-0021 v1.0	E-mail	5.1.2e @sanquin.nl
Subject	Production of anti-COV immunoglobulin		

Dear 5.1.2e

Please find enclosed a high level list of actions to be addressed for the collection, processing, marketing and distribution of anti-COVID19 immunoglobulin.

At this moment Sanquin Blood Bank has started the collection of anti-Covid-19 plasma for the production of FFP for direct transfusion to COVID-19 patients. The trial treatment is based on the assumption that recovered patients have neutralizing antibodies against the virus. If this treatment is successful, a change to anti-Covid-19 immunoglobulin is preferred, as the product:

- will be more constant (donor to donor variation will disappear in a large batch)
- will be better characterized
- will have undergone several pathogen reduction steps, mandatory for the safety of plasma for patients;
- has a higher concentration of immunoglobulin, therefore less volume is needed for same dose
- will have a controlled anti-SARS-CoV-2 titer
- can be used for prevention therapy

The process to manufacture such a product is in place and can be used without modifications. The only QC issue is the determination of the anti-Covid-19 antibody titer of the product.

However, when plasma is collected in other blood establishments than currently registered in SPPs Plasma Master File, several regulatory steps have to be taken very quickly (or waivers must be available). These steps usually take a long time (several months) and may become an obstacle for the availability of anti-Covid-19 immunoglobulin.
The steps include, but are not limited to:
- Including the plasma supplier in the Plasma Master File of SPP
- Including the plasma in the regulatory files of the product.

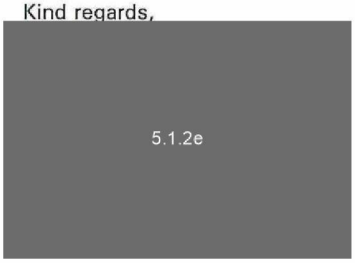
As for every plasma supplier, independent of the amount of plasma to be delivered, the necessary regulatory activities are equal, the process can proceed quicker when the number of blood establishments (i.e. countries) involved in the collection and delivery remains limited.

5.1.2e

In addition, the transport of plasma to SPP premises is less at risk when only a limited number of countries are involved, due to the lock-down and transport regulations in the countries.

It is essential to have alignment with all competent authorities in all countries involved, to ensure that any mandatory approval is obtained quickly.

Kind regards,



Annex: issues to be addressed for manufacturing and distribution of the anti-COVID19 IgG

Plasma

1. Determination of the titer immunoglobulin in the plasma
2. Donor selection criteria (important for donor, blood establishment, patient)
3. Increased collection of plasma from selected donors
4. Mandatory assessment of plasma not in regulatory file of SPP (within EU / outside EU)
5. Mandatory assessment of blood establishment not in regulatory file of SPP (within EU / outside EU)
6. Registration in Plasma Master File
7. Registration in product file

Trial product

8. Determination of the titer immunoglobulin in the product
9. Trial (protocol, target group, etc)
10. OMCL release
11. Product information
12. Dosing and administration
13. Packaging and labeling
14. Monitoring and pharmacovigilance