To: 5.1.2e , 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 1.2. (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e .(5.1.2e)[5.1.2e @minvws.nl]
Cc: 5.1.2e , 1.2. 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 1.2. (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]
From: 5.1.2e , 5.1.2e . 5.1.2e (5.1.2e)
Sent: Fri 2/5/2021 11:08:17 AM
Subject: RE: Nanogam - opzet nota voor minister - graag je reactie
Received: Fri 2/5/2021 11:08:18 AM
Nanogam 5.1.2e docx

Hierbij mijn suggesties om de nota op te bouwen

Van: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
Verzonden: vrijdag 5 februari 2021 10:55
Aan: 5.1.2e , 5.1.2e . 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 1.2. (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
CC: 5.1.2e , 1.2. 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 1.2. (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: Nanogam - opzet nota voor minister - graag je reactie

Allen,

Ik ben bezig met een opzet voor een nota, maar ik wil eerst checken of ik alle feitelijke informatie juist op een rij heb gezet. Graag ontvang ik jullie aanvullingen/correcties zo snel mogelijk.
(5.1.2e ik zie dat 5.1.2e afwezig is, kun jij vanuit jullie expertise en ervaring aanvullen?

Met vriendelijke groet,
5.1.2e

Van: 5.1.2e , 5.1.2e . 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>
Verzonden: donderdag 4 februari 2021 21:55
Aan: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
CC: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 1.2. 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 1.2. (5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: RE: COVIg-product SPP - clarification meeting - further information requested - case 858779

Allen,

Zojuist 5.1.2e aan de lijn gehad vanuit CBG. Zij hebben over de status van het COVig gesproken, ook met hun juristen. Zij komen tot de volgende conclusie:

- Als dit plasma gewoon wordt gebruikt voor het Nanogam product dan kan het off-label worden ingezet maar dan zijn de immuoglobulines natuurlijk verdund aanwezig.
- Gebruik maken van alleen een subset van donoren maakt het juridisch gezien een ander product, en kan het dus niet off-label worden toegepast.

CBG ziet dan een 'named patient' (per keer langs de IGJ) of een Research Clinical Trial als optie.
Zij zetten eea op papier en sturen dit naar Sanquin en VWS.

5.1.2e gaf wel aan hier ook best wel moeite mee te hebben omdat het zo juridisch wordt uitgelegd, immers er geen enkel bezwaar tegen gebruik van het plasma voor het originele product en als de we een tijdje verder zijn en een groot deel van de bevolking is in aanraking geweest met COVID dan komen deze anitstoffen sowieso in het Nanogam product terecht.

Ik heb 5.1.2e voorgehouden dat wij - ook vanwege de snelheid – mogelijk kiezen voor een emergency use (ontheffing) op basis van het advies van de werkgroep van medisch specialisten. Met begeleiding van een ZonMW groep. Daar kon hij wel begrip voor opbrengen en zou niet iets zijn waar hij tegen is. Heb ook gedeeld dat het raar zou zijn om een Sanquin product nu op de plank te laten liggen en wel inkoop te gaan doen van externe farmaceuten die antilichamen op de markt willen brengen.

Kortom, we volgen de lijn die we vanmiddag afspraken. Ik zie geen andere optie.
Groet
5.1.2e

Van: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
Verzonden: donderdag 4 februari 2021 15:32

Aan: 5.1.2e , 5.1.2e , 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
CC: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: FW: COVIg-product SPP - clarification meeting - further information requested - case 858779

Ter info, voor ons overleg straks. Argumentatie van Sanquin.

Van: 5.1.2e , 5.1.2e < 5.1.2e @sanquin.nl>
Verzonden: donderdag 4 februari 2021 10:08
Aan: 5.1.2e , 5.1.2e . (5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: FW: COVIg-product SPP - clarification meeting - further information requested - case 858779

FYI - 5.1.2e

Van: 5.1.2e
Verzonden: woensdag 3 februari 2021 17:09
Aan: 5.1.2e 5.1.2e @cbg-meb.nl>
CC: 5.1.5 < 5.1.2e @cbg-meb.nl>; 5.1.5 5.1.2e @sanquin.nl>
Onderwerp: RE: COVIg-product SPP - clarification meeting - further information requested - case 858779

Dear Mr. 5.1.2e

Please see attached for SPP's response to the request for clarification from CBG on 01 February 2021.

Kind regards,

5.1.2e
Sanquin Plasma Products, Unit Medical and Regulatory Affairs
Plesmanlaan 125, 1066 CX Amsterdam
The Netherlands
Mobile: +31 5.1.2e
5.1.2e @sanquin.nl

From: 5.1.2e [5.1.2e @cbg-meb.nl]
Sent: maandag 1 februari 2021 13:09
To: 5.1.2e
Cc: Case Intern ; Regulatory Affairs
Subject: COVIg-product SPP - clarification meeting - further information requested - case 858779

Dewar dr. 5.1.2e

Thank you for sharing your concern with the MEB. The MEB is very much aware of the urgency in this matter.
Further clarification is needed however, as the situation is not fully elucidated at this moment:

5.1.1c

In your email dated 28JAN21 (below) you indicate that *'the batch which has been released is a batch of normal Nanogam 10%. So, for clarity, we will refer to this as Nanogam 10% with a known amount of aCOV19 antibodies. It is NOT an investigational product. … This batch Nanogam 10% that was produced, was produced from plasma from normal, healthy plasma donors, using the normal production process and the normal release criteria of Nanogam 10%. So it is a normal Nanogam 10% batch. This batch Nanogam 10% was manufactured from plasma, collected in the period March 2020-May 2020. That is the period from which it is known (from investigations of the RIVM) that up to 10% of the donors had anti-COV19 antibodies…'.*

5.1.1c

(Note: This is comparable -except for the route of administration-, to the former Quin-products, more specific: the manufacturing of VariQuin, for which a separate registration exists, for which the Nanogam manufacturing process is used, and for which donors are selected who recovered from VZV-infection and who can donate plasma for a certain amount of time).

Would you please further clarify?

The information provided will be taken into account by the MEB.

Kind regards,

5.1.2e

Van: 5.1.2e < 5.1.2e @sanquin.nl>
Verzonden: donderdag 28 januari 2021 19:48
Aan: 5.1.2e < 5.1.2e @cbg-meb.nl>
CC: 5.1.5 < 5.1.2e @cbg-meb.nl>; 5.1.5 < 5.1.2e @sanquin.nl>; 5.1.2e , 5.1.2e < 5.1.2e @sanquin.nl>
Onderwerp: RE: COVIg-product SPP - clarification meeting - case 858779

Dear Mr. 5.1.2e

We would like to provide information to the CBG upfront to avoid any misunderstandings further down the line. There is a concern on SPP's side on the timing proposed in your e-mail below, as the letter of the CBG has raised concerns in the field of the medical professionals.

SPP would like to stress that the batch which has been released is a batch of normal Nanogam 10%. So, for clarity, we will refer to this as Nanogam 10% with a known amount of aCOV19 antibodies. It is NOT an investigational product. As you will know, Nanogam always contains antibodies against a large number of different agents, depending on the antibodies that are present in the donor population.
Immediately after the start of the COVID-19 pandemic, SPP suspected that from a certain moment in time the donor plasma (obtained from routinely selected healthy donors) was going to contain an amount of antibodies against the SARS-CoV-2 virus. As this donor plasma is used routinely for the Nanogam production, it was expected that – again from a certain point in time - Nanogam would also contain variable levels of these antibodies, just because these antibodies occur in the donor plasma.

This can be compared with seasonal antibodies, like anti-flu antibodies. It can be expected that plasma that is collected in the winter period contains a certain amount of antibodies against the flu-virus. In plasma, collected in the summer period, this level will be less. But as we do not measure these specificities, we do not know.

Every Nanogam batch is produced from plasma that is collected during a number of weeks or even a number of months. This batch Nanogam 10% that was produced, was produced from plasma from normal, healthy plasma donors, using the normal production process and the normal release criteria of Nanogam 10%. So it is a normal Nanogam 10% batch.
This batch Nanogam 10% was manufactured from plasma, collected in the period March 2020-May 2020. That is the period from which it is known (from investigations of the RIVM) that up to 10% of the donors had aCOV19 antibodies.

At the donor selection, the medical history of the donor was asked. In some cases the donor stated that he / she had a reactive aCOV19 test in the past. Such donors are expected to have a certain level of aCOV19 antibodies. Of course at the moment of the donation, all donors were in good health.
This meant that SPP knew that donations in which a certain amount of aCOV19 antibodies could be expected, existed. Using amongst others, these donations and due to the concentration effect of the manufacturing process of Nanogam, we obtained a batch Nanogam 10% with a detectable level of aCOV19 antibodies. As we measured the level of these specific antibodies, we know the level. In fact, it is very likely that in the future, all Nanogam (and other IVIg product) batches will contain a certain level of aCOV19 antibodies, depending on the plasma used (origin and collection date).

aCOV19 antibodies can protect patients in an early stage of the COVID-19 infection and is especially beneficial for patients who cannot make such antibodies themselves. This mechanism and opportunity was recognized by several medical professionals and endorsed by the Ministry of Health, who ordered us to produce Nanogam with aCOV19 antibodies.

From a pharmacovigilance point of view, this batch is a normal Nanogam 10% batch with a known and approved safety profile. Nanogam is often used off label to prevent or mitigate emerging infections in susceptible patients; in fact this is the mechanism of the on-label indication: Replacement therapy in primary immunodeficiency syndromes (PID) with impaired antibody production.

At this moment patients who have an impaired antibody production and are at risk of an infection with the SARS-CoV-2 virus, are in need of these antibodies, as they cannot make them themselves.
As this indication is off-label, such use will be registered in the SPP safety database as off label use. It is possible that specific monitoring reports are sent to the CBG.
But this Nanogam batch is not an investigational product. It is normal Nanogam 10% - with a known level of aCOV19 antibodies.

Please confirm that this information is taken into account by the CBG.

Kind regards,

5.1.2e
Sanquin Plasma Products, Unit Medical and Regulatory Affairs
Plesmanlaan 125, 1066 CX Amsterdam
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Mobile: +31 (0) 5.1.2e
5.1.2e @sanquin.nl

From: 5.1.2e 5.1.2e @cbg-meb.nl]
Sent: donderdag 28 januari 2021 14:07
To: 5.1.2e
Cc: Case Intern
Subject: RE: COVIg-product SPP - clarification meeting - case 858779

Dear dr. 5.1.2e
An internal MEB meeting regarding the COVIg-product of SPP is scheduled for Feb 4th, 2021.
The available information on this topic will be discussed. Asap after the meeting I will inform you accordingly.
It is not yet decided if this will be done in writing or at a separate meeting with SPP.
Kind regards,

Drs
Sr. 5.1.2e

Van: 5.1.2e 5.1.2e @sanquin.nl>
Verzonden: donderdag 28 januari 2021 13:38
Aan 5.1.2e 5.1.2e @cbg-meb.nl>
CC: 5.1.5 < 5.1.2e @cbg-meb.nl>; 5.1.2e 5.1.2e @cbg-meb.nl>; 5.1.2e
< 5.1.2e @cbg-meb.nl>; 5.1.2e , 5.1.2e . . < 5.1.2e @cbg-meb.nl>; 5.1.2e , 5.1.2e . 5.1.2e . . . < 5.1.2e @cbg-meb.nl>;
5.1.2e , 5.1.2e . 5.1.2e . 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.5 < 5.1.2e @sanquin.nl>; 5.1.2e , 5.1.2e
< 5.1.2e @sanquin.nl>
Onderwerp: RE: COVIg-product SPP - clarification meeting - case 858779

Dear Mr. 5.1.2e

During our conversation on 21 Jan. 2021, you informed me that the clarification meeting would not be possible last Friday (22 Jan. 2021), and that you would schedule the meeting early this week instead. You also mentioned you would forward the information the CBG provided the Ministry of Health on the topic.

As I have not heard back yet, could you please inform me what the current status is and when the meeting will be possible? It is urgent we have this meeting as soon as possible.

Kind regards,

5.1.2e
Sanquin Plasma Products, Unit Medical and Regulatory Affairs
Plesmanlaan 125, 1066 CX Amsterdam
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Mobile: +31 (0 5.1.2e
5.1.2e @sanquin.nl

From: 5.1.2e
Sent: 21 January 2021 12:41
To: 5.1.2e < 5.1.2e @cbg-meb.nl>
Cc: 5.1.5 < 5.1.2e @cbg-meb.nl>; 5.1.2e < 5.1.2e @cbg-meb.nl>; 5.1.2e
< 5.1.2e @cbg-meb.nl>; 5.1.2e , 5.1.2e . . < 5.1.2e @cbg-meb.nl>; 5.1.2e , 5.1.2e . 5.1.2e . . . < 5.1.2e @cbg-meb.nl>;
5.1.2e , 5.1.2e . 5.1.2e . 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.5 s < 5.1.2e @sanquin.nl>; 5.1.2e , 5.1.2e
< 5.1.2e @sanquin.nl>
Subject: RE: COVIg-product SPP - clarification meeting - case 858779

Dear Mr. 5.1.2e

Indeed this is the topic we wish to discuss, as we have a different understanding and would like to align with the CBG.

I await your confirmation on the time of the meeting.

Pagina's zijn verwijderd 1121937

6 - 7

buiten verzoek

Van: 5.1.2e <5.1.2e@sanquin.nl>
Verzonden: woensdag 25 november 2020 17:12
Aan: 5.1.5 <5.1.2e@cbg-meb.nl>; 5.1.2e <5.1.2e@cbg-meb.nl>
CC: 5.1.5 <5.1.2e@sanquin.nl>; 5.1.2e, 5.1.2e <5.1.2e@sanquin.nl>
Onderwerp: RE: Minutes Monthly Call SPP-CBG November 2020

Dear 5.1.2e

As agreed on our monthly call on 10 Nov. 2020, SPP would like to update you on the outcome of the combined meeting between SPP, IGJ, and the CBG held on 13 Nov. 2020. The meeting was held to discuss SPP's proposal to continue to supply the existing Quins alternative products, via what is known as the 'Staatscourant' routing, until the end of 2021. The IGJ did not approve this proposal to extend the permission until end of 2021, and only grants permission until the end of 2020. This decision was based on the grounds that there must be a temporary shortage to grant the 'Staatscourant' permission, and once SPP announced the decision to discontinue the Quins products, there is no longer a temporary shortage but a permanent shortage. The IGJ's decision means that the routing as of 1 Jan. 2021 must go back to the individual doctors' certificate. Following this feedback, SPP Management has decided to temporarily continue with the alternative products until the current supply of alternatives lasts (for the first Quin product this will be April 2021, Beriglobin).

Also as agreed on the monthly call on 10 Nov. 2020, please see attached for SPP's statement regarding submission of the HepBQuin PSUR for further internal assessment at the CBG.

Attached you will also find the Quins slides requested by the CBG on 17 Nov. 2020, with updated information on the donor-pools, sales per product per year, and numbers of patients treated per product per year. New slides were prepared with the information that was of special interest (instead of updating the old slides), as most of the information in the slides is now outdated.

If you have any further questions, please feel free to ask.

Kind regards,

5.1.2e
5.1.2e
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