

To: 5.1.2e @minbuza.nl 5.1.2e @minbuza.nl
Cc: 5.1.2e @minvws.nl 5.1.2e @minvws.nl 5.1.2e 5.1.2e @modernatx.com
From: 5.1.2e
Sent: Wed 7/28/2021 1:00:23 PM
Subject: FW: Donation by The Netherlands to Surinam
Received: Wed 7/28/2021 1:00:34 PM

Dear Madam,

In the absence of 5.1.2e would you be available to set up the call with our respective legal teams ?

Many thanks ahead and regards,



From: 5.1.2e
Sent: Wednesday, July 28, 2021 3:56 PM
To: 5.1.2e . <5.1.2e @minvws.nl>
Cc: 5.1.2e 5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com>; 5.1.2e (x)
 <5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com>
Subject: RE: Donation by The Netherlands to Surinam

Dear 5.1.2e

Thank you for your response.

5.1.2e and we agree with your proposal of meeting with our legal teams to meet asap.

Would any of these slots work for you :

- Tomorrow Thursday 4 to 4:30PM your time
- Friday 30st between 1:45PM and 3PM or 10:30 to 11:30AM.

5.1.2e will be joining the call.
 Upon your response, I will send up the invite.

Best regards,

5.1.2e



From: 5.1.2e . <5.1.2e @minvws.nl>
Sent: Tuesday, July 27, 2021 12:51 PM

To: 5.1.2l Functionele emailadressen <5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 5.1.2e <5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 <5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com>
 Cc: 5.1.2e <5.1.2e @minvws.nl>; 5.1.2e <5.1.2e @minvws.nl>
 Subject: RE: Donation by The Netherlands to Surinam

EXTERNAL

Dear 5.1.2e

Thank you for the draft tripartite agreement.

We have studied it and much of it has also been included in the donation agreement between The Netherlands and Surinam.

At the same time looking from a more legal perspective, we have the opinion that the draft agreement you have sent us is not fully in accordance with the APA and therefor in its current form not suited for donation agreements.

According to art. 1.4.6 sub 6 of the APA for example, the participating member state enters into an agreement in writing with the respective donation country. This means in our opinion that Moderna is not part of the donation agreement as suggested by your legal team.

What we should do is safeguarding your legal interests, and that is exactly what we have done with the draft donation agreement we have send you.

What we would like to suggest is that our legal advisors discuss this matter with your legal advisors. Could you please indicate to whom we could reach out to make this happen?

As we have announced to you in our e-mail of July 11th, our Minister and the Minister of Suriname have signed a bilateral donation agreement on July 12th for the donation of 10.000 doses of the Moderna vaccine. These have been very much welcomed in Surinam and will be used to vaccinate pregnant women.

In the coming months more donations are to be foreseen as vaccination rates rise in Europe, whilst needs are still great in other parts of the world.

We need to find a way which is working for both Moderna and the donating and recipient countries.

Therefore we very much welcome a discussion a suggested above.

Best regards,

5.1.2e

Verzonden met BlackBerry Work
www.blackberry.com

Van: 5.1.2l Functionele emailadressen <5.1.2e @modernatx.com<5.1.2e @modernatx.com>>
 Datum: donderdag 15 jul. 2021 8:08 AM
 Aan: 5.1.2e <5.1.2e @minvws.nl<5.1.2e @minvws.nl>>, 5.1.2e <5.1.2e @minvws.nl>>
 <5.1.2e @modernatx.com<5.1.2e @modernatx.com>> 5.1.2e <5.1.2e @modernatx.com>>
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 Kopie: 5.1.2e <5.1.2e @minvws.nl<5.1.2e @minvws.nl>>, 5.1.2e <5.1.2e @minvws.nl>>
 <5.1.2e @minvws.nl<5.1.2e @minvws.nl>>
 Onderwerp: Re: Donation by The Netherlands to Surinam

Dear 5.1.2e

Following my previous email, could you please use the version attached. Thank you.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

5.1.2e @modernatx.com

From: 5.1.2i Functionele emailadressen 5.1.2e @modernatx.com>

Sent: Wednesday, 14 July 2021 08:16

To: 5.1.2e . <5.1.2e @minvws.nl>, 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 <5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 <5.1.2e @modernatx.com> 5.1.2e <5.1.2e @modernatx.com>
 Cc: 5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e) <5.1.2e @minvws.nl>

Subject: Re: Donation by The Netherlands to Surinam

Dear 5.1.2e

Our legal team is finalizing the tripartite letter agreement (NL - Surinam - Moderna) and will send it to you asap today.

We apologize for the long process; we understand the emergency of the situation. We will stay in close contact with you to get everything finalized rapidly, as the agreement must be finalized.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

5.1.2e @modernatx.com

From: 5.1.2e . <5.1.2e @minvws.nl>

Sent: Sunday, 11 July 2021 23:37

To: 5.1.2i Functionele emailadressen 5.1.2e @modernatx.com> 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 5.1.2e ; 5.1.2e @modernatx.com>; 5.1.2e <5.1.2e @modernatx.com> 5.1.2e
 <5.1.2e @modernatx.com> 5.1.2e <5.1.2e @modernatx.com>
 Cc: 5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e) <5.1.2e @minvws.nl>

Subject: Donation by The Netherlands to Surinam

EXTERNAL

Dear 5.1.2e

Please find the answers to your questions in your email below (in bold).

We hereby send you the latest version of the donation agreement and the informal translation of this agreement. We believe that this donation of 5.1.1c doses of the Moderna vaccines to Surinam, can be best based on a bilateral agreement between two sovereign states. It is an agreement based on Dutch law, drafted in accordance with all the relevant articles from the APA and respecting the interests of all parties involved.

In case of any doubt, we kindly suggest to consult with a qualified Dutch lawyer, as he will confirm that this is a balanced agreement. The donation agreement will be signed by our Minister of Health, Welfare and Sport and the Minister of Health of the Republic of Suriname this Monday July 12th. Any further delay will be politically unexplainable and negligent.

We have contacted you several times and we have sent you this agreement upfront to inform you about the donation. We have had so far no reaction on this draft.

In your last email of last Friday, you mentioned that Moderna is now drafting a legal (three party?) agreements for this donation as well. However, as indicated in my previous e-mail, we are running out of time. This donation is meant specifically for pregnant women and their unborn babies, who risk dying from the grave COVID-19-pandemic in Suriname. In our view this medical emergency justifies that we proceed with this donation on the basis of the included agreement, in which we safeguard all the relevant legal aspects of the APA.

Most concerns that seem to be arising from your e-mail from last Friday will be taken away by the arrangements in the bilateral agreement.

Furthermore, we have send you a side letter that assures Moderna that the terms and conditions of the EU APA continue to apply with respect to the donated doses.

Also, the side letter provides Moderna with information about the donated doses such as batch numbers. We are willing to sign this side letter for your reassurance so please let us know if you would appreciate this.

Best regards,

5.1.2e

5.1.2e

Ministry of Health, Welfare and Sports

The Netherlands

Van: 5.1.2i Functionele emailadressen <5.1.2e @modernatx.com<5.1.2e @modernatx.com>>

Datum: vrijdag 09 jul. 2021 10:21 PM

Aan: 5.1.2e . <5.1.2e @minvws.nl<5.1.2e @minvws.nl>>, 5.1.2e)
<5.1.2e @minvws.nl<5.1.2e @minvws.nl>>, 5.1.2e) <5.1.2e
5.1.2e @minvws.nl<5.1.2e @minvws.nl>>

Kopie: 5.1.2e <5.1.2e @modernatx.com<5.1.2e @modernatx.com>> 5.1.2e
<5.1.2e @modernatx.com<5.1.2e @modernatx.com>>, 5.1.2e
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< 5.1.2e @modernatx.com< 5.1.2e @modernatx.com>>

Onderwerp: Re: Donation by The Netherlands to Surinam

Dear 5.1.2e

Following my previous email, we wanted to confirm that we have received your request to donate product to Suriname. In accordance with the APA, we are working through the logistical and operational components, including drawing up the relevant legal agreements to oversee the management key terms (for example those related to safety, supply chain, regulatory responsibilities) required for us to consent to the donation. While we are working on these efforts internally, it would be very helpful if you could provide insight as to the following logistical and operational elements and whether the countries are prepared to assume the outlined responsibilities:

- Will there be any transfer of funds related to the donation between the Netherlands and Surinam? (aka is this a true donation or are these doses being "resold") No
-
- Who will be responsible for the import permits, export permits, and transportation of product? No import / export permits required
-
- Is Suriname prepared to do the following:
- Indemnify Moderna to terms equivalent to those in the APA Yes, as stated in the donation agreement
- Agree to comply with applicable laws and Moderna's security and destruction directives Applicable law is Dutch law
- Confirm that the doses will solely be used in the territory for vaccinating residents and in a manner consistent with the product label
Yes, results from donation agreement
- Ensure a pathway for pharmacovigilance reporting exists to an existing database to which Moderna has access and/or to Moderna and cooperate with any requests from Moderna for information relating to any AEs or PQC inquiries from Moderna
Suriname has agreed in the Donation Agreement to be responsible for reporting adverse reactions to Moderna in accordance with pharmacovigilance regulations using the instructions accessible by following the QR code printed on the relevant Vials (results from side letter)
- Has/will obtain all necessary authorizations to accept the donation No authorizations needed
- Obtain all relevant regulatory approvals for exporting/importing unlicensed product from the EU and (if Netherlands is importing) importing unlicensed product into Suriname. The Republic of Suriname has send us an approval letter that states that the Donated Doses can be stored, distributed, used and administered within Suriname without Moderna having to obtain a market authorisation or any other public law approval like a license or otherwise
- Confirm what regulatory approvals/authorizations (or waivers) are required and which have been obtained and in whose name they have been obtained (where applicable)

- Provide a copy of the approval / confirm whether the issued approvals/authorizations/waivers place any expectations or requirements on Moderna.

- Confirm that the necessary regulatory authorizations are in place in Suriname for the distribution and administration of the vaccine (e.g., emergency use authorization)

The Republic of Suriname has stated that the Donated Doses can be stored, distributed, used and administered within Suriname without Moderna having to obtain a market authorisation or any other public law approval like a license or otherwise

- Confirm that Suriname will not require any documentation from Moderna/will work directly with the Netherlands to obtain any and all required documentation (batch release/qualifications/regulatory approvals, etc.) related to the product This will go through The Netherlands

- Jointly with Netherlands have the responsibility for maintaining cold chain ensure that the product remains within the recommended temperature ranges during shipping and storage (please clarify which country is responsible throughout the supply chain for donated product) Yes

- Is Netherlands prepared do the following (where applicable):

- Ensure compliance with the terms above occur prior to the product being shipped

The terms and conditions of the EU APA continue to apply with respect to the Donated Doses before and after shipment (results from side letter)

- Take responsibility for transportation (and maintenance of cold chain) of product to Suriname
Yes

- Obtain all relevant regulatory approvals for exporting/importing unlicensed product from the EU and (if Netherlands is importing) importing unlicensed product into Suriname No license needed

- Deliver the product in a timely manner to ensure adequate shelf life Yes, results from donation agreement

- Provide all documentation related to the product required by Suriname (PILs, labels, batch release, etc.) Yes, results from donation agreement

- Jointly with Suriname have the responsibility for maintaining cold chain ensure that the product remains within the recommended temperature ranges during shipping and storage (please clarify which country is responsible throughout the supply chain for donated product). Yes

Please come back to us with relevant answers to the points above mentioned. I propose we organize a meeting with you next week to closely follow-up.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

5.1.2e @modernatx.com< 5.1.2e @modernatx.com>

From: 5.1.2i Functionele emalladressen < 5.1.2e @modernatx.com< 5.1.2e @modernatx.com>>

Sent: Thursday, 8 July 2021 19:17

To: 5.1.2e . < 5.1.2e @minvws.nl< 5.1.2e @minvws.nl>>; 5.1.2e)
< 5.1.2e @minvws.nl< 5.1.2e @minvws.nl>>; 5.1.2e) < 5.1.2e
5.1.2e @minvws.nl< 5.1.2e @minvws.nl>>

Subject: Re: Donation by The Netherlands to Surinam

Dear 5.1.2e

We now have a positive decision to move forward and work with you on an agreement to be able to do the donation from NL to Surinam. Our legal team is working on it based on the documents you provided.

I will keep you informed and put you in the loop with the team to move forward.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

5.1.2e @modernatx.com< 5.1.2e @modernatx.com>

From: 5.1.2e . <5.1.2e @minvws.nl> 5.1.2e @minvws.nl>>

Sent: Thursday, 8 July 2021 09:30

To: 5.1.2f Functionele emailadressen <5.1.2e @modernatx.com> 5.1.2e @modernatx.com>>; 5.1.2e .
(5.1.2e) <5.1.2e @minvws.nl> 5.1.2e @minvws.nl>>; 5.1.2e) <5.1.2e @minvws.nl> 5.1.2e @minvws.nl>>

Subject: RE: Donation by The Netherlands to Surinam

EXTERNAL

Thank you 5.1.2e

But to be frank, this is not ok!

We are now waiting for more than a month for your consent, for a small donation of 5.1.1c doses Moderna, for pregnant women, in a country where people are simply dying from Covid.

I think bureaucracy is unacceptable in this situation. Our main program with Surinam is done with AstraZeneca vaccines, which we have been able to donate in large numbers.

So I would suggest that we get a go from you this week, or we will proceed anyway.

Best regards,

5.1.2e

Verzonden met BlackBerry Work

(www.blackberry.com<<http://www.blackberry.com>>)

Van: 5.1.2f Functionele emailadressen

<5.1.2e @modernatx.com> 5.1.2e @modernatx.com> 5.1.2e @ 5.1.2e
<5.1.2e @modernatx.com>>>

Datum: donderdag 08 jul. 2021 8:37 AM

Aan: 5.1.2e .

<5.1.2e @minvws.nl> 5.1.2e @minvws.nl> 5.1.2e @ 5.1.2e @minvws.nl>>>, 5.1.2e ,
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Onderwerp: Re: Donation by The Netherlands to Surinam

Dear 5.1.2e

Thank you for your message. We are currently working on having this decision taken by all relevant stakeholders. We apologize for the delay toward this decision.

Once we have taken a decision, if positive, we shall perform some diligence and then sign a three-way donation agreement.

We will keep you informed as soon as possible.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

5.1.2e <[REDACTED]@modernatx.com> 5.1.2e <[REDACTED]@modernatx.com>

From: 5.1.2e <[REDACTED]@minvws.nl> 5.1.2e <[REDACTED]@minvws.nl>>

Sent: Friday, 2 July 2021 14:48

To: 5.1.2e (x) <[REDACTED]@modernatx.com> 5.1.2e <[REDACTED]@modernatx.com>>; 5.1.2e (x)
 <[REDACTED]@modernatx.com> 5.1.2e <[REDACTED]@modernatx.com>>; 5.1.2e Functionele emailadressen
 <[REDACTED]@modernatx.com> 5.1.2e <[REDACTED]@modernatx.com>>; 5.1.2e)
 <[REDACTED]@minvws.nl> 5.1.2e <[REDACTED]@minvws.nl>>

Subject: RE: Donation by The Netherlands to Surinam

EXTERNAL

Dear 5.1.2e

We are now another week down the line since our last contact and it has been a month since we first approached you on a small donation to Surinam.

Can you tell us why this is taking so long?

I would suggest that we wait till Monday morning and if by then Moderna will not have reacted, we take it as if you have no objections to this donation and the legal contract that we will close with Surinam on this matter.

Best regards,

5.1.2e

[Description: Description: Description: Description: Description: Description: 5.1.2e <[REDACTED]@01CCDB7A.06F319F0>]

5.1.2e

5.1.2e

Directorate for International Cooperation
 Ministry of Health, Welfare and Sports
 Parnassusplein 5 | The Hague | The Netherlands

Tel: +31 5.1.2e

Email: 5.1.2e <[REDACTED]@minvws.nl> 5.1.2e <[REDACTED]@minvws.nl> 5.1.2e <[REDACTED]@minvws.nl>>

Van: 5.1.2e (x) <5.1.2e@modernatx.com<5.1.2e@modernatx.com>>

Verzonden: maandag 28 juni 2021 18:29

Aan: 5.1.2e <5.1.2e@minvws.nl> 5.1.2e @minvws.nl>; 5.1.2e (x)
 <5.1.2e@modernatx.com<5.1.2e@modernatx.com>> 5.1.2l Functionele emailadressen
 <5.1.2e@modernatx.com<5.1.2e@modernatx.com>>; 5.1.2e)
 <5.1.2e@minvws.nl<5.1.2e@minvws.nl>>

Onderwerp: RE: Donation by The Netherlands to Surinam

Dear 5.1.2e

Indeed we are currently working on it. The documents you sent are under review by our legal team, and we are working on the impacts your donation project may have.

We will get back to you as soon as possible.

Best regards,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

5.1.2e

M: 5.1.2e @:
 5.1.2e @modernatx.com<5.1.2e@modernatx.com<5.1.2e@> 5.1.2e
 5.1.2e @modernatx.com>>

De: 5.1.2e
 <5.1.2e@minvws.nl<5.1.2e@minvws.nl<5.1.2e@> 5.1.2e @minvws.nl>>>

Envoyé : lundi 28 juin 2021 17:57

À: 5.1.2e (x)
 <5.1.2e@modernatx.com<5.1.2e@modernatx.com<5.1.2e@> 5.1.2e
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Objet : RE: Donation by The Netherlands to Surinam

EXTERNAL

Dear 5.1.2e

May I request your attention for our communication on the donation of a small number of Moderna-doses, to the Republic of Surinam (5.1.1c doses).

I trust you are working on it, but for us it is a bit unclear whether you have received our request and are processing it.

We would like to finish this donation this week,

Therefor it would be appreciated if you could indicate whether you approve with the agreement with Surinam, we have send you.

Best regards,

5.1.2e

5.1.2e

Ministry of Health, Welfare and Sports

Verzonden met BlackBerry Work

(www.blackberry.com<<http://www.blackberry.com>><<http://www.blackberry.com>>)

Van: 5.1.2e (x)

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Datum: dinsdag 01 jun. 2021 9:59 AM

Aan 5.1.2e Functionele emailadressen

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 5.1.2e @ 5.1.2e @modernatx.com>>>>

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 5.1.2e @ 5.1.2e @ 5.1.2e @ 5.1.2e @minvws.nl>>>>

Onderwerp: Donation by The Netherlands to Surinam

Dear 5.1.2e

I was contacted by 5.1.2e (CC) of the Ministry of Health of The Netherlands. They request our approval to donate a part of the vaccine purchased from us to the independent nation of Suriname in South America. Please start the process to grant this approval internally and inform 5.1.2e to who he should address the official request.

5.1.2e Please write to

5.1.2e @modernatx.com< 5.1.2e @modernatx.com< 5.1.2e @ 5.1.2e

5.1.2e @modernatx.com>> to get an update on the process. Given pharmacovigilance and other requirements, it is not a completely straight forward process, which requires the cooperation of several departments within Moderna. However, we will be doing our best to give you a positive reply as early as possible.

Many thanks,

5.1.2e

5.1.2e 5.1.2e

5.1.2e

M: 5.1.2e E:
5.1.2e @modernatx.com< 5.1.2e @modernatx.com< 5.1.2e @
5.1.2e @modernatx.com>>

P Please consider the environment before printing this email

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