

To: [redacted] [redacted] [redacted]@rivm.nl]
From: [redacted] [redacted] [redacted]
Sent: Fri 3/19/2021 9:17:03 AM
Subject: FW: MTA negotiation
Received: Fri 3/19/2021 9:17:04 AM
[commercial MTA EVAg Valneva i.docx](#)

Ter info

From: [redacted] [redacted] <[redacted]@rivm.nl>
Sent: donderdag 18 maart 2021 14:36
To: [redacted] [redacted] <[redacted]@rivm.nl>
Cc: [redacted] [redacted] [redacted] <[redacted]@rivm.nl>; [redacted] <[redacted]@rivm.nl>; [redacted] [redacted]
<[redacted]@rivm.nl>
Subject: MTA negotiation

Beste collega's,

Wij maken deel uit van een Europees consortium project genaamd EVAglobal. Voor dit project delen we biologisch materiaal met andere laboratoria. Voor de meeste bestellingen wordt een standaard MTA gebruikt, waarmee [redacted] heeft ingestemd.

We hebben nu een bestellend laboratorium dat wil onderhandelen over een individuele MTA. Wij hebben hen meegedeeld dat dit proces verschillende maanden in beslag kan nemen, en zij willen toch doorgaan met de onderhandelingen.

Hieronder vinden jullie de vragen die hun juridische afdeling met jullie zou willen bespreken (geel gemarkeerd). Bijgevoegd is de standaard MTA die wij hen hebben aangeboden.

Hierbij verzoek ik jullie dit verzoek te behandelen en ons verder op de hoogte te houden. Gebruik graag dit tijdschrijfnummer voor dit werk: V/190002/01/PR.

Mogen jullie nog andere informatie van mij nodig hebben, dan hoor ik dat graag.

Beste wensen,

[redacted]

Contact:
Werkplek [redacted]
T: [redacted]
M: [redacted]
e-mail: [redacted]@rivm.nl

From: [redacted] <[redacted]@valneva.com>
Sent: donderdag 18 maart 2021 11:50
To: [redacted] [redacted] <[redacted]@rivm.nl>
Subject: RE: EVAg order 6401


Dear [redacted]

Please go ahead, if we are lucky your legal team might come back earlier than expected.

Kind regards,

[redacted]

[redacted]

 valneva

E [redacted]@valneva.com

T [redacted]

M [redacted]

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—
VALNEVA AUSTRIA GMBH
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 1030 Vienna, Austria
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 —

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From: [REDACTED] 5.1.5 <[REDACTED] 5.1.2e @rivm.nl>
Sent: Mittwoch, 17. März 2021 18:44
To: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @valneva.com>
Subject: RE: EVAg order 6401

Dear [REDACTED] 5.1.2e

Thank you very much for sending your questions. I can forward these questions to our legal department, but it looks like this would require a significant negotiation of the MTA. Please note that the current processing period will be several months in the legal department.

I understand that you would like to receive the material in a timely manner, but unfortunately this will not be possible at the moment.

Please let me know, how you would like to proceed?

Best wishes,

[REDACTED] 5.1.2e

[REDACTED] 5.1.2e [REDACTED] 5.1.2e [REDACTED] 5.1.2e
 National Institute for Public Health and the Environment
 A. van Leeuwenhoeklaan 9, 3721 MA Bilthoven, The Netherlands

Contact:

T: [REDACTED] 5.1.2e
 M: [REDACTED] 5.1.2e
 e-mail: [REDACTED] 5.1.2e @rivm.nl

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From: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @valneva.com>
Sent: maandag 15 maart 2021 15:05
To: [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>
Cc: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>; [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>; [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>; [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>
Subject: RE: EVAg order 6401

Dear [REDACTED] 5.1.2e

Below you find the questions that our IP department have regarding the MTA:

1. Transfer of the Material to different affiliates. As we work very closely with different affiliates in the development of our covid vaccines we would need to transfer the Material to other affiliates. Can we include a provision to that respect?
2. We are unclear about the definition/ownership rules of Modification and substances created through the use of the Material or Modification. We use the Material as a starting material and then inactivate the Material to obtain an inactivated substance that is then purified and further combined with adjuvant(s) and other excipient = vaccine. We understand from the draft MTA that said vaccine is a "substance created through the use of the Material or Modification". Can you confirm this? Please understand that we invest millions and a big amount of intellectual effort to create the vaccine and thus sharing ownership to the vaccine or its results, inventions, discoveries or know how is clearly a big problem for us. Please note that we clarified this questions also with our other providers of isolates. We are of course committed to negotiate a commercial

license for the starting Material or Modification to it (e.g. viral seed bank).

3. Commercial terms: as we would like to move very fast in order to create a vaccine to the newly emerging COVID variants we are very keen to understand your commercial demands. Also we need to invest a lot of money and effort upfront (i.e. work at risk) to evaluate such an approach. Thus a clear monetary path forward would help us very much in our planning. Could you give us an indication of your commercial terms of a commercial agreement or could we agree to start these discussions very promptly?

How long time do you estimate that would take your legal department to come back with a response to the questions?

Many thanks,

5.1.2e

5.1.2e

5.1.2e



E 5.1.2e @valneva.com

T 5.1.2e

M 5.1.2e

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From: 5.1.2e

Sent: Sonntag, 14. März 2021 17:28

To: 5.1.2e 5.1.2e

Cc: 5.1.2e ; 5.1.2e 5.1.2e ; 5.1.2e | 5.1.2e ; 5.1.2e 5.1.2e

Subject: Re: EVAg order 6401

Dear 5.1.2e

I will check with our legal/ip tomorrow, come back to you.

Thanks and have nice Sunday evening,

Urban

Sent from my iPhone

On 14.03.2021, at 17:17, 5.1.2e 5.1.2e <5.1.2e @rivm.nl> wrote:

Dear 5.1.2e

Thank you for your email. Since I don't have a legal background and our legal department is very busy at the moment, could you please send us the questions/parts that need clarifications in writing? Then I can forward this to my colleagues.

Thank you and best wishes,

5.1.2e

5.1.2e 5.1.2e 5.1.2e

National Institute for Public Health and the Environment
A. van Leeuwenhoeklaan 9, 3721 MA Bilthoven, The Netherlands

Contact:

T: 5.1.2e

M: 5.1.2e

e-mail: 5.1.2e @rivm.nl

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From: 5.1.2e <5.1.2e@valneva.com>

Sent: vrijdag 12 maart 2021 11:19

To: 5.1.2e 5.1.2e <5.1.2e@rivm.nl>

Cc: 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e 5.1.2e <5.1.2e@rivm.nl>

Subject: RE: EVAg order 6401

Dear 5.1.2e

It was not the intention from our IP department to request any changes to the MTA. They just want to have some clarification from your side regarding some point, that we have the same interpretation/understanding. As I wrote they are fine with the MTA, but they would like to have some clarifications what is from your side meant with some wordings. Therefore, a short call would suffice.

Kind regards,

5.1.2e

5.1.2e

E 5.1.2e @valneva.com

T 5.1.2e

M 5.1.2e

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From: [REDACTED] <[REDACTED]@rivm.nl>
Sent: Freitag, 12. März 2021 11:12
To: [REDACTED] <[REDACTED]@valneva.com>
Cc: [REDACTED] <[REDACTED]@rivm.nl>; [REDACTED] <[REDACTED]@rivm.nl>; [REDACTED] <[REDACTED]@rivm.nl>
Subject: RE: EVAg order 6401

Dear [REDACTED]

Thank you for your email. As I mentioned in my previous email it is not possible for us to accept changes to the MTA at the moment, because we are processing too many orders. It is not possible for our legal department to adapt every individual MTA. Therefore, at the moment I can only offer you the current version of the MTA or to cancel the offer.

Best wishes,

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]
National Institute for Public Health and the Environment
A. van Leeuwenhoeklaan 9, 3721 MA Bilthoven, The Netherlands

Contact:

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From: [REDACTED] <[REDACTED]@valneva.com>
Sent: donderdag 11 maart 2021 15:42
To: [REDACTED] <[REDACTED]@rivm.nl>
Cc: [REDACTED] <[REDACTED]@rivm.nl>; [REDACTED] <[REDACTED]@rivm.nl>
Subject: RE: EVAg order 6401
Importance: High

Dear [REDACTED]

Our IP department has already had a look at the MTA, in general they are fine with the MTA. However, they would like to have a short call with your lawyer to have a few things clarified. A short call would speed up the process instead of writing back and forth.

It would be very much appreciated from our side when possible.

Kind regards,

[REDACTED]

From: [REDACTED] <[REDACTED]@rivm.nl>
Sent: Donnerstag, 11. März 2021 11:37
To: [REDACTED] <[REDACTED]@valneva.com>
Cc: [REDACTED] <[REDACTED]@rivm.nl>; [REDACTED] <[REDACTED]@rivm.nl>
Subject: EVAg order 6401

Dear [REDACTED]

Thank you for your EVAg order with us.

Please find attached the MTA for your review. Please add the missing information in the lines that are highlighted in yellow. Please note that due to the very high number of demands we are currently facing, we cannot accept any substantial changes to the MTA at the moment.

Once you reviewed the MTA, we can send you the final file for signature. After you receive the final file, please print and sign **2 copies** of the MTA and send them both via regular mail to (please note that the **last page requires 2 signatures in blue ink**):

National Institute for Public Health and the Environment (RIVM)

5.1.2e 5.1.2e

A. van Leeuwenhoeklaan 9, 3721 MA Bilthoven
The Netherlands

In order to speed up the process, we can prepare the shipping in the meantime, if you send us a scanned version of the file.

Please note that **no parts** of the material that you ordered from RIVM can be integrated **into a (new) endproduct**. The material can only be used for evaluation/validation/or similar purposes.

If you have any questions, please let us know.

Best wishes,

5.1.2e 5.1.2e

5.1.2e 5.1.2e 5.1.2e

National Institute for Public Health and the Environment
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