From: @pfizer.com>
Sent: 19 October 2020 12:28
To: (SG-RECOVER) (SJ); GALLINA Sandra (SANTE); (SJ); (SANTE);
Cc: 
Subject: RE: [EXTERNAL] RE: Draft Advance Purchase Agreement - Comments and Suggestions
Attachments: Mark-up APA - second draft (19 October)- Pfizer_BNT(105957364.1).docx

Dear [Redacted]

Please find attached a further mark-up of the APA, having first accepted your changes. We have answered your comments and added explanations (including on the [Redacted] we discussed on our call last week) and also re-drafted based on the concerns/questions you raised in your mark-up and on our call.

You will see that we have accepted most of your suggested amendments and dealt with the majority of your comments. We have also attached the Specification (which, of course, is provisional at this point and could change up until the grant of the MA) and various other logistics-related attachments.

Finally, we can confirm that our experts can be available for a logistics call with you and the Member States on Friday at 16:00.

Best regards.

[Redacted]

From: @ec.europa.eu @ec.europa.eu>
Sent: 16 October 2020 16:59
To: @pfizer.com>
@ec.europa.eu; @ec.europa.eu; Sandra.Gallina@ec.europa.eu; @ec.europa.eu; @ec.europa.eu
Subject: RE: [EXTERNAL] RE: Draft Advance Purchase Agreement - Comments and Suggestions

Thanks for the message, [Redacted]

If you are able to send us the new revised draft of the contract Monday morning, we would propose to have a discussion on Tuesday 16:00.

For the discussions on logistics, we have foreseen a slot next week Friday at 16:00 for a discussion with all the Member States. From the side of the Member States, their logistics expert will participate. Since we will still have to make some arrangements for the call and for the participation of the logistics experts, please let us know as soon as possible whether this time slot is convenient for you.

Best,
From: @pfizer.com
Sent: Thursday, October 15, 2020 7:51 PM
To: (COMP) @ec.europa.eu
Cc: @ec.europa.eu; GALLINA Sandra (SANTE) <Sandra.Gallina@ec.europa.eu>; (SANTE) @ec.europa.eu; (SJ) @ec.europa.eu; (SJ) @ec.europa.eu
Subject: Re: [EXTERNAL] RE: Draft Advance Purchase Agreement - Comments and Suggestions

Thanks We have a drafting call tomorrow morning after which I’ll be able to get you a best estimate of timing. I think it will most likely be over the weekend but I’ll confirm tomorrow.

Sent from my iPhone

On 15 Oct 2020, at 18:13, @ec.europa.eu wrote:

Hi

Thanks for your message. When would you envisage to send us the revised version and the further explanations as discussed today?

We will then propose a slot for the drafting call early next week. We’ll come back to you on the logistics call.

From: @pfizer.com
Sent: Thursday, October 15, 2020 5:19 PM
To: (COMP) @ec.europa.eu
Cc: (SJ) @ec.europa.eu; (SJ) @ec.europa.eu; GALLINA Sandra (SANTE) <Sandra.Gallina@ec.europa.eu>; (SANTE) @ec.europa.eu; (SJ) @ec.europa.eu; (SJ) @ec.europa.eu
Subject: RE: Draft Advance Purchase Agreement - Comments and Suggestions

Hi & Team
We will get to work immediately on the issues we discussed today. In the meantime, we would be happy to hold time now for a logistics call next week. Please could you let us know what your availability would be for that?

Can we also hold time now for a further drafting call early next week? We can make ourselves available to suit your schedule.

Thanks very much.

Best,

From: @pfizer.com>
Sent: Wednesday, October 14, 2020 7:09 PM
To: (COMP) @ec.europa.eu>
Cc: biontech.de>; @ec.europa.eu; @ec.europa.eu;

Subject: [EXTERNAL] RE: Draft Advance Purchase Agreement - Comments and Suggestions

Dear,

We could split the meeting. Do you think it will be possible for your clinical and regulatory colleagues to give an overview where you stand in the development trials within, say, 20 minutes?

Then we could move over to a discussion of the APA. While the time will probably not be sufficient to go into all the details of the comments, we will be able to discuss a number of topics and organise the next steps in an efficient way.

Would this be convenient for you?

Best,
Subject: RE: Draft Advance Purchase Agreement - Comments and Suggestions

Hi

Good to hear from you and thank you for the document.

We just wanted to check if the call tomorrow will be a drafting meeting? We have clinical and regulatory colleagues on standby to join but perhaps they won’t be needed if we will be focussing solely on the provisions of the APA?

Thanks in advance for the clarity.

Best,

From: @ec.europa.eu

Sent: 14 October 2020 16:49

To: @pfizer.com

Cc: @biontech.de;
    @ec.europa.eu;
    @ec.europa.eu;
    @ec.europa.eu;
    @ec.europa.eu;
    @pfizer.com;

Subject: [EXTERNAL] Draft Advance Purchase Agreement - Comments and Suggestions

Dear

Thank you to Pfizer and BioNTech for submitting the tender documents.

In advance of tomorrow’s meeting of the Evaluation Committee, please find attached a version including our preliminary comments and some changes already set out in the text.
Looking forward to the discussion tomorrow.

Kind regards,