From: @sanofi.com
Sent: 11 September 2020 11:57
To: (SG-RECOVER) (SJ); GALLINA Sandra (SANTE); SAUTE; @gsk.com; @gsk.com; (SJ); FR;
Cc: @sanofi.com; @sanofi.com; @sanofi.com; (SJ); @ec.europa.eu; @ec.europa.eu; @sanofi.com; @ec.europa.eu; @sanofi.com;
Subject: RE: EU APA SP GSK revised version 10092020
Attachments: APARedlineSP_GSK_11092020.docx

Dear [Name],

Thank you for your feedback on the revised version sent.

- We are in agreement with all the proposed changes that we have included in the attached version (dated 10092020).
- In such attached version we have renumbered the Appendices (in track changes) and have added in reference to [missing text] in the Vaccine Order Form when we are referring to [missing text] as it was missing. (changes highlighted in yellow)
- Regarding the contact details related to [missing text], we will provide you the elements at the earliest.

We would be grateful if you could confirm your agreement on this final version of the APA.

Kind regards
[Your Name] on behalf of GSK and Sanofi Pasteur teams

De: @ec.europa.eu @ec.europa.eu @ec.europa.eu
Envoyé : vendredi 11 septembre 2020 09:58
À : @sanofi.com
Cc: @ec.europa.eu; @ec.europa.eu; @ec.europa.eu; @sanofi.com; @ec.europa.eu; @sanofi.com; @ec.europa.eu; @sanofi.com
Objet : [EXTERNAL] RE: EU APA SP GSK revised version 10092020

EXTERNAL : Real sender is [Name] @ec.europa.eu

Dear [Name],
Thanks for the revised version. Attached you will find a version with a few track changes on top of the tracks you sent yesterday.

Our changes relate to:

The appendices still have to be renumbered; correspondingly the references in the text.

We still have to discuss with the Member States the designation of a contact point for each of them. We will send to you the corresponding list once it is available. It would be good if you could also send to use some information.

I would be grateful if you could confirm that these changes – and the overall version – are acceptable to you in the course of the morning, i.e. before 12:00. In this case, there would be no need for an additional call.

Kind regards,
Dear [Name],

Thank you for your answer on the FM clause.

We will find attached a revised version of the APA which includes:

- The agreed version of the article
- The revised version of the Vaccine Order Form’s annex
- An update of the Appendix H
- Rewording of the article
- Few wording adjustments and typos

We understand that your agreement on the clause would lift our discussions on the.

Looking forward to get your feedback on this last version of the APA.

Kind regards

on behalf of GSK and Sanofi Pasteur teams

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De : @ec.europa.eu @ec.europa.eu>
Envoyé : jeudi 10 septembre 2020 12:05
À : @sanofi.com>
Cc @sanofi.com; @sanofi.com; @sanofi.com; @sanofi.com; @sanofi.com; @sanofi.com; @sanofi.com; @sanofi.com>
Objet : [EXTERNAL] RE: EU APA: Proposed draft of for your review

EXTERNAL : Real sender is @ec.europa.eu

Dear [Name],

Many thanks for the clarification with regard to the clause and the.

We understand your points. On that basis, we would, while this does not require a change of the draft contract.

Kind regards,
From: @sanofi.com
Sent: Thursday, September 10, 2020 9:51 AM
To: (COMP) @ec.europa.eu;
Cc: (SJ) @ec.europa.eu;
     @ec.europa.eu;
     @ec.europa.eu;
     @sanofi.com;
     @gsk.com;
     @sanofi.com;
     GALLINA Sandra (SANTE) @ec.europa.eu;
     (SJ) @ec.europa.eu;
     @ec.europa.eu;
     @sanofi.com;
Subject: RE: EU APA: Proposed draft of ___ for your review

Dear ___

Thank you for your feedback on clause ___ and for the clarifications which are agreeable to us. We will send you a revised version of the APA by lunch time today which will include the revised version of the Vaccine Order Form’s annex.

Kind regards
___ on behalf of Sanofi Pasteur and GSK teams
Dear [Name],

This is fine for us with a few small clarifications, see below. Could you please send to us a revised draft of the whole text so that we can see how the clause fits in? If you had the time to revise the latest annex, it would be good if you could include it.

If you could send the revised text of the full contract by tomorrow lunch time, we would aim at organising a session of the Evaluation committee on Friday.

Kind regards,
From: @sanofi.com
Sent: Wednesday, September 9, 2020 4:55 PM
To: (COMP) @ec.europa.eu
Cc: (SJ) @ec.europa.eu; @sanofi.com; @gsk.com; @sanofi.com; GALLINA
(SJ) @ec.europa.eu; @ec.europa.eu; @ec.europa.eu
Sandra (SANTE) @ec.europa.eu; @ec.europa.eu; (SANTE) @ec.europa.eu
Subject: RE: EU APA: Proposed draft of for your review
Dear [Name],

Further to the principles agreed yesterday during our call on [Date], please find hereunder the proposed mechanism to implement such agreed principles.
As discussed, this is subject to the approval by the Commission of [Clause].
Thank you in advance for your feedback.

Kind regards,

[Name] on behalf of Sanofi Pasteur and GSK teams
Dear [Redacted]

Further to the constructive discussion this morning, please find attached a revised version of the contract, reflecting the issues which we have discussed in the call. The version includes our changes in track while having accepted all your changes before. We have taken out also most of your comments insofar as they were no longer operational. The revised annexes sent by you on Saturday have not yet been included.

For the sake of clarity, please note that the revision does not deal with (i) the issue of the [Redacted] and (ii) the [Redacted]. Please also note that we will still have to more thoroughly review the new annex.

Best regards,
Dear [Name],

Thank you for email.

As discussed yesterday, please find attached our last version (subject to proof reading/formatting and adjustments and discussions of the still open points).

This attached version includes:

1. The modifications we agree upon during our last calls
2. GSK and Sanofi Pasteur suggested changes (track changes) further to our yesterday discussions

Looking forward to get your feedback on the working draft clause sent yesterday after our call and to our joint review Monday morning.

Best regards

on behalf of GSK and Sanofi Pasteur teams
Also thanks for the constructive discussions from our side.

We will have to check the draft with our [redacted]. We will probably only be able to come back to you on this by cob tomorrow.

However, why don’t you already send the remaining text to us by the envisaged time tomorrow?

Best regards,

From: [redacted]@sanofi.com>
Sent: Thursday, September 3, 2020 7:16 PM
To: [redacted]@ec.europa.eu> (COMP)
Cc: [redacted]@ec.europa.eu>; [redacted]@sanofi.com>; [redacted]@gsk.com>; [redacted]@sanofi.com>
Subject: EU APA: Proposed draft of [redacted] for your review

Dear [redacted]

As agreed, please find attached the proposed working draft version of [redacted].

Our objective is you to have our final complete working draft before tomorrow 2pm so that, as the case may be, the Commission has it in hands for its Steer Co.

We are looking forward for your prompt return on the article hereto (do you have any timelines?)

Thank you again for our constructive discussion today.

Best regards

[redacted] on behalf of SP and GSK teams