

From: [REDACTED]@sanofi.com>

Sent: 14 September 2020 22:33

To: [REDACTED] (SG-RECOVER)

Cc: [REDACTED] (SJ); [REDACTED] (SJ); [REDACTED]
[REDACTED]@gsk.com; [REDACTED]@gsk.com; [REDACTED]
GALLINA Sandra (SANTE); [REDACTED] (SJ); [REDACTED]
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED]

Subject: RE: EU APA SP GSK_final version14092020

Attachments: APARedlineSP_GSK_14092020_FINAL.docx

Dear [REDACTED]

Thank you very much for this revised version. We are pleased to confirm you that we are in agreement with it as final version.

In the attached version (14092020Final), we have integrated the cross reference changes you made and have added few small formatting changes (as the numbering of paragraph "I.5.1" was not necessary anymore, we have deleted it and anywhere it was cross-referenced. We have also fixed the subheadings of I.6 and all their cross-references). We have left this couple of changes in track changes.

May we kindly ask you to let us know what are the next steps for the signature.

Thank you.

Kind regards

[REDACTED] on behalf of GSK and Sanofi Pasteur teams

De [REDACTED]@ec.europa.eu [REDACTED]@ec.europa.eu>

Envoyé : lundi 14 septembre 2020 10:45

À : [REDACTED]@sanofi.com>

Cc : [REDACTED]@ec.europa.eu; [REDACTED]@ec.europa.eu; [REDACTED]
[REDACTED]@sanofi.com>; [REDACTED]@gsk.com; [REDACTED]@gsk.com; [REDACTED]
[REDACTED]@sanofi.com>; [REDACTED]@ec.europa.eu;
[REDACTED]@ec.europa.eu; [REDACTED]n@ec.europa.eu;
[REDACTED]@ec.europa.eu; [REDACTED]@sanofi.com>; [REDACTED]
[REDACTED]@sanofi.com>

Objet : [EXTERNAL] RE: EU APA SP GSK revised version 10092020

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

Dear [REDACTED]

Attached you will find attached the very slightly revised version of the APA, compared to the version which you sent last week.

As already indicated, the most important changes relate to the correction of cross-references, so in Article 17. Apart from these corrections, no substantive changes have been done.

Please let us know if we can consider this the final version from your side.

Kind regards,

[Redacted]

From: [Redacted] (COMP)
Sent: Friday, September 11, 2020 7:15 PM
To: [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>
Cc: [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; [Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>; [Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; GALLINA Sandra (SANTE) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SANTE) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SANTE) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>
Subject: RE: EU APA SP GSK revised version 10092020

Dear [Redacted]

Thank you for the revised version.

The draft APA sent by you is generally fine for us. However, we have still spotted a few mistakes in the cross-references and, more generally, we will need to re-read it. We will come back to you on Monday.

Thank you for all the efforts in the last week.

Kind regards,

[Redacted]

From: [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>
Sent: Friday, September 11, 2020 11:57 AM
To: [Redacted] (COMP) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>
Cc: [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; [Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>; [Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; GALLINA Sandra (SANTE) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>

[redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>; [redacted] (SANTE)
[redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>; [redacted] (SANTE)
[redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>;
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>; [redacted]
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>

Subject: RE: EU APA SP GSK revised version 10092020

Dear [redacted]

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 11092020).
- In such attached version we have renumbered the Appendices (in track changes) and have added in reference to VAT in the Vaccine Order Form when we are [redacted] it was missing. (changes highlighted in yellow)
- Regarding the contact details related to Product technical complaints, we will [redacted].

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

Kind regards

[redacted] on behalf of GSK and Sanofi Pasteur teams

De : [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)> [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>

Envoyé : vendredi 11 septembre 2020 09:58

À : [redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>

Cc : [M](#) <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>; [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>;
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>; [redacted] <[\[redacted\]@gsk.com](mailto:[redacted]@gsk.com)>; [redacted] <[\[redacted\]@gsk.com](mailto:[redacted]@gsk.com)>;
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>;
xxxxxx.xxxxxxx@xx.xxxxpa.eu; [redacted] <A@ec.europa.eu>;
[redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>; [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>;
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>; [redacted]
[redacted] <[\[redacted\]@sanofi.com](mailto:[redacted]@sanofi.com)>

Objet : [EXTERNAL] RE: EU APA SP GSK revised version 10092020

EXTERNAL : Real sender is [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>

Dear [redacted]

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 on the "report

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,

From: [REDACTED] <[REDACTED]@sanofi.com>

Sent: Thursday, September 10, 2020 12:58 PM

To: [REDACTED] (COMP) <[REDACTED]@ec.europa.eu>

Cc: [REDACTED] (SJ) <[REDACTED]@ec.europa.eu>; [REDACTED] <[REDACTED]@ec.europa.eu>; [REDACTED] <[REDACTED]@sanofi.com>; [REDACTED] <[REDACTED]@gsk.com>; [REDACTED] <[REDACTED]a@gsk.com>; [REDACTED] <[REDACTED]@sanofi.com>; GALLINA

Sandra (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SJ)

[REDACTED] <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE)

[REDACTED] <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE)

[REDACTED] <[REDACTED]@ec.europa.eu>;

[REDACTED] <[REDACTED]@sanofi.com>;

[REDACTED] <[REDACTED]@sanofi.com>

Subject: RE: EU APA SP GSK revised version 10092020

Dear [REDACTED]

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 [REDACTED] For sake of clarity
- [REDACTED]
- Few wording adjustments and typos

We understand that your agreement on the [REDACTED] clause would lift our [REDACTED] clause.

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

Kind regards

[REDACTED] on behalf of GSK and Sanofi Pasteur teams

De : [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)> [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>

Envoyé : jeudi 10 septembre 2020 12:05

À : [REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>

Cc : [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)> [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)> [REDACTED]

[REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>; [REDACTED] <[\[REDACTED\]@gsk.com](mailto:[REDACTED]@gsk.com)>;

[REDACTED] <[\[REDACTED\]@gsk.com](mailto:[REDACTED]@gsk.com)>;

[REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>

[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;

[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;

[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;

[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;

[REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>;

[REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>

Objet : [EXTERNAL] RE: EU APA: Proposed draft of [REDACTED] for your review

EXTERNAL : Real sender is [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>

Dear [REDACTED]

Many thanks for the clarification with regard to the [REDACTED] and the [REDACTED] agreement.

We understand your points. On that basis, we would [REDACTED]

[REDACTED] while this does not

require a change of the draft contract.

Kind regards,

[REDACTED]

From: [REDACTED] <[REDACTED]@sanofi.com>
Sent: Thursday, September 10, 2020 9:51 AM
To: [REDACTED] (COMP) <[REDACTED]@ec.europa.eu>
Cc: [REDACTED] (SJ) <[REDACTED]@ec.europa.eu>;
[REDACTED] (SJ) <[REDACTED]@ec.europa.eu>; [REDACTED]
<[REDACTED]@sanofi.com>; [REDACTED] <[REDACTED]@gsk.com>;
[REDACTED] <[REDACTED]@gsk.com>; [REDACTED]
<[REDACTED]@sanofi.com>; GALLINA Sandra (SANTE)
<[REDACTED]@ec.europa.eu>; [REDACTED] (SJ)
<[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE)
<[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE)
<[REDACTED]@ec.europa.eu>; [REDACTED]
<[REDACTED]@sanofi.com>;
[REDACTED] <[REDACTED]@sanofi.com>

Subject: RE: EU APA: Proposed draft of [REDACTED] for your review

Dear [REDACTED]

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

[REDACTED]

[REDACTED]

Kind regards

[REDACTED] on behalf of Sanofi Pasteur and GSK teams

De : [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
Envoyé : mercredi 9 septembre 2020 18:35
À : W [REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>
Cc : M [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>; [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;
Co [REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>; [REDACTED] <[\[REDACTED\]@gsk.com](mailto:[REDACTED]@gsk.com)>;
[REDACTED] <[\[REDACTED\]@gsk.com](mailto:[REDACTED]@gsk.com)>; [REDACTED] <[\[REDACTED\]@sanofi.com](mailto:[REDACTED]@sanofi.com)>; [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;
[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>; [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>;
[REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
Objet : [EXTERNAL] RE: EU APA: Proposed draft of [REDACTED] for your review

EXTERNAL : Real sender is [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>

Dear [REDACTED]

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.

[REDACTED]

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,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]

[Redacted]

From: [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>
Sent: Wednesday, September 9, 2020 4:55 PM
To: [Redacted] (COMP) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>
Cc: [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>;
H [Redacted] (SJ) <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted]
<[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; [Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>;
[Redacted] <[\[Redacted\]@gsk.com](mailto:[Redacted]@gsk.com)>; [Redacted] <[\[Redacted\]@sanofi.com](mailto:[Redacted]@sanofi.com)>; GALLINA Sandra (SANTE)
<[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] (SJ)
[Redacted] <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] ina (SANTE)
[Redacted] <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>; [Redacted] na (SANTE)
[Redacted] <[\[Redacted\]@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>
Subject: RE: EU APA: Proposed draft of [Redacted] for your review

Dear [Redacted]

Further to the principles agreed yesterday during our call on [Redacted]
[Redacted], please find hereunder the proposed mechanism
to implement such agreed principles.

As discussed, this is subject to the approval by the Commission of [Redacted]
[Redacted]

Thank you in advance for your feedback.

Kind regards.

[Redacted] on behalf of Sanofi Pasteur and GSK teams

[Redacted]

[Redacted]

[Redacted]

- [Redacted]

- [Redacted]

[Redacted]

De : [Redacted] [@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)

[Redacted] [@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)>

Envoyé : lundi 7 septembre 2020 19:55

À : [Redacted] ley@sanofi.com>

Cc : [Redacted] [@ec.europa.eu](mailto:[Redacted]@ec.europa.eu); [Redacted] [@ec.europa.eu](mailto:[Redacted]@ec.europa.eu);

[REDACTED]@sanofi.com>; [REDACTED]@gsk.com;
[REDACTED]@gsk.com; [REDACTED]
[REDACTED]sanofi.com>; Sandra.Gallinx@xx.xxxopa.eu ;
[REDACTED]@ec.europa.eu; [REDACTED]@ec.europa.eu;
[REDACTED]@ec.europa.eu

Objet : [EXTERNAL] RE: EU APA: Proposed draft of [REDACTED] for your review

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

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 [REDACTED] lause. Please also note that we will still have to more thoroughly review the new annex.

Best regards,
[REDACTED]

From: [REDACTED]@sanofi.com>
Sent: Friday, September 4, 2020 1:10 PM
To: [REDACTED] (COMP) [REDACTED]@ec.europa.eu>
Cc: [REDACTED] (SJ) [REDACTED]@ec.europa.eu>;
[REDACTED] (SJ) [REDACTED]@ec.europa.eu>; [REDACTED]
[REDACTED]@sanofi.com>; [REDACTED]@gsk.com;
[REDACTED]@gsk.com; [REDACTED]
[REDACTED]sanofi.com>

Subject: RE: EU APA: Proposed draft of [REDACTED] for your review

Dear [REDACTED]

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

De : ██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)

██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)>

Envoyé : jeudi 3 septembre 2020 19:25

À : ██████████ [@sanofi.com](mailto:██████████@sanofi.com)>

Cc : ██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu); ██████████ K@ec.europa.eu;

██████████ [@sanofi.com](mailto:██████████@sanofi.com)>; ██████████ [@gsk.com](mailto:██████████@gsk.com);

██████████ [@gsk.com](mailto:██████████@gsk.com);

██████████ [@sanofi.com](mailto:██████████@sanofi.com)>

Objet : [EXTERNAL] RE: EU APA: Proposed draft of ██████████ for your review

EXTERNAL : Real sender is

██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)

Dear ██████████

Also thanks for the constructive discussions from our side.

We will have to check the draft with our ██████████. 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: ██████████ [@sanofi.com](mailto:██████████@sanofi.com)>

Sent: Thursday, September 3, 2020 7:16 PM

To: ██████████ (COMP) ██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)>

Cc: ██████████ (SJ) ██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)>;

██████████ (SJ) ██████████ [@ec.europa.eu](mailto:██████████@ec.europa.eu)>;

██████████ [@sanofi.com](mailto:██████████@sanofi.com)>; ██████████ [@gsk.com](mailto:██████████@gsk.com)>;

██████████ [@gsk.com](mailto:██████████@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