From: [redacted] (SANTE) on behalf [redacted] (SANTE)
Sent: 15 December 2020 14:30
To: [redacted]
Cc: [redacted]; [redacted] (SANTE); [redacted] (SANTE)
Subject: RE: VE position on a revision of the Annex to the EC guideline on "Excipients in the labelling and package leaflet of medicinal products for human use"

Dear Ms [redacted]

Thank you very much for your email and we are sorry for our late reply on the matter.

Thank you for sharing with us the VE position on a proposal to revise the Annex of the EC's guideline on ***"Excipients in the labelling and package leaflet of medicinal products for human use"*** (SANTE-2017-11668). We have looked at the document and feel we would need to reflect further on the scientific merits of the proposal also with EMA colleagues, prior to a meeting.

Given the on-going developments and expedited pace of the COVID-19 vaccine assessment and authorisations both the EC and EMA vaccine teams are currently fully tied up, thus we would prefer to organise the meeting at an appropriate time after the holidays.

We would therefore encourage you that you get in contact with us again after the Christmas holidays to arrange a meeting then.

With best wishes for the festive season,

Kind regards,

[redacted] on behalf [redacted]
[redacted]

European Commission
Health and Food Safety Directorate General (SANTE)
Unit B5 Medicines-policy, authorisation and monitoring
B232-[redacted]
B-1049 Brussels, Belgium

From: [redacted] <[redacted]@efpia.eu>
Sent: Thursday, November 5, 2020 10:58 PM
To: [redacted] (SANTE) <[redacted]@ec.europa.eu>
Cc: [redacted] <[redacted]@vaccineseurope.eu>; [redacted] (SANTE) <[redacted]@ec.europa.eu>

Subject: VE position on a revision of the Annex to the EC guideline on "Excipients in the labelling and package leaflet of medicinal products for human use"

Dear [redacted]

On behalf of Vaccines Europe (VE) members I would like to share with you the VE position paper on a ***proposal for a revision*** of the Annex to the European Commission guideline on ***"Excipients in the labelling and package leaflet of medicinal products for human use"*** (SANTE-2017-11668), which cover the following section:

1. Background and objective
2. Vaccine Europe assessment
    - 2.1 Para-aminobenzoic Acid (PABA)
    - 2.2 Phenylalanine
    - 2.3 Sodium and potassium
    - 2.4 Ethanol
3. Discussion and recommendation
4. Literature references

We would like to propose to set up a virtual meeting (TC) to explain the issue described in the VE position paper and to discuss the possible solution. I would like to inform you that the attached documents (word, pdf) have also been submitted to EMA.

Looking forward to hearing from you,

kind regards

[redacted]

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