

**From:** [REDACTED]@efpia.eu>  
**Sent:** 05 November 2020 22:58  
**To:** [REDACTED] (SANTE)  
**Cc:** [REDACTED] (SANTE)  
**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"  
**Attachments:** Position paper VE\_30 October 2020\_final.docx; Position paper VE\_30 October 2020\_final.pdf  
**Categories:** Orange Category

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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