

**From:** [REDACTED] (SANTE)  
**Sent:** 11 September 2020 15:23  
**To:** [REDACTED]; [REDACTED] (SANTE)  
**Cc:** [REDACTED]; [REDACTED] (SANTE); [REDACTED]  
[REDACTED] (SANTE)  
**Subject:** RE: Request for a meeting- regulatory issues regarding COVID-19 vaccines

Dear [REDACTED]

Thank you for your email I hope you are well too.

Since May the Commission has taken a lot of actions together with EMA and the Member States to address the issues that your industry raised and to facilitate the speedy development and distribution of vaccines.

We will certainly make time to discuss with you any outstanding issues, but it would be very useful if you could specify which of the issues on your list are not yet resolved and what difficulties you encounter. This will help us organise the meeting efficiently and have around the table the right colleagues.

[REDACTED] will send you some available timeslots.

With kind regards,  
[REDACTED]

**From:** [REDACTED] <[REDACTED]@vaccineseuropa.eu>  
**Sent:** Friday, September 11, 2020 1:13 PM  
**To:** [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE)  
<[REDACTED]@ec.europa.eu>  
**Cc:** [REDACTED] <[REDACTED]@gsk.com>; [REDACTED] <[REDACTED]@vaccineseuropa.eu>  
**Subject:** Request for a meeting- regulatory issues regarding COVID-19 vaccines

Dear [REDACTED],

Dear [REDACTED],

I hope this email finds you well.

I am contacting you to follow up on some regulatory issues that we highlighted in the Vaccines Europe assessment of barriers and bottlenecks to the rapid development and authorisation of COVID-19 vaccines, which was shared with you mid-May and I attach to this email. In the document, we made some proposals for the Commission consideration.

It is now becoming an urgency for the manufacturers to have some clarity on some of the issues raised in the document, such as the implementation of the ICHQ12, labelling and packaging, testing importation and serialisation, among others. Companies cannot plan the production of the COVID-19 vaccines based on assumptions and would like to understand whether and how the Commission is going to address these issues and when a decision will be taken. This is why we would like you to consider organising a call next week. It will also give an opportunity to further explain the impact it will have in speeding up production and facilitate the distribution of the so much needed COVID-19 vaccines.

Thank you for considering my request.

Looking forward to hearing from you.

Best regards,

[Redacted]

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[Redacted]

Vaccines Europe

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