

**From:** SANTE PHARMACEUTICALS B5  
**Sent:** 11 December 2020 14:47  
**To:** [REDACTED]  
**Cc:** SANTE PHARMACEUTICALS B5; Leadership-team; [REDACTED]  
**Subject:** RE: Request for an exchange of views - Pharmaceutical Strategy and Orphans/Paediatrics IIA

Dear [REDACTED],

Thank you very much for your email.

The orphan and paediatric team will be happy to schedule a 30 min. meeting next week. Would you be available to organise the meeting on 15/12 at 16:00?

[REDACTED] in copy of this email, will follow up with all the technical details.

Kind regards,

Unit "Medicines: policy, authorisation and monitoring"



European Commission  
DG Health and Food Safety

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**From:** [REDACTED]  
**Sent:** Wednesday, December 9, 2020 12:24 PM  
**To:** [REDACTED]  
**Cc:** SANTE PHARMACEUTICALS B5 <[SANTE-PHARMACEUTICALS-B5@ec.europa.eu](mailto:SANTE-PHARMACEUTICALS-B5@ec.europa.eu)>; Leadership-[REDACTED]  
**Subject:** Request for an exchange of views - Pharmaceutical Strategy and Orphans/Paediatrics IIA

Dear [REDACTED],

I hope you are doing well.

As you can imagine, we noted with great interest the recent publications of the Communication on the Pharmaceutical Strategy as well as the Inception Impact Assessment on the Orphan and Paediatric Regulations. As we are coming closer to year-end, and in view of upcoming deadlines early next year, we would very much welcome the opportunity for an exchange of views with you and your services.

We would be particularly interested to better understand the next steps in the ongoing review of the Orphan and Paediatric Regulations. In addition, we would welcome an exchange of views on the overarching approach you intend to take on the topic of unmet need. EFPIA is currently finalising a report which explores how unmet need is currently understood, defined, and applied and proposes a conceptual framework by which unmet need can be more effectively addressed. A peer-reviewed publication is in development which may be relevant, inter alia in view of the upcoming discussion scheduled to take place in the Pharmaceutical Committee later this week.

We remain at your service to find a suitable date for an exchange of views.

Thank you very much in advance for your attention.

With best regards

[REDACTED] on behalf of EFPIA

[REDACTED]

EFPIA - European Federation of Pharmaceutical Industries and Associations

[REDACTED]

[www.efpia.eu](http://www.efpia.eu)

