

From: [REDACTED] (SANTE)
Sent: 23 February 2021 16:35
To: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE)
Cc: [REDACTED] (SANTE)
Subject: BTO - virtual meeting with Efpia on revision of variation framework 23 February 2021

DG SANTE: [REDACTED] (B5)
Efpia: [REDACTED]

The virtual meeting was arranged at the request of Efpia.

Efpia asked, whether an external study will be commissioned, about timelines for the revision, if also the general pharmaceutical legislation will be revised concerning variations, about the outcome of the consultation of EMA on industry's proposal for changes to the variation system and if COM would like further information on new issues such as experience with COVID-19 pandemic and drug/device combination variations.

DG SANTE does not expect an external study to support the revision of the variation framework, has a wish to move this project forward in 2021 but currently is also managing priority files like COVID-vaccines, sees a justification to review and change the variation framework, including where necessary the general pharmaceutical legislation, and would appreciate to receive information about new issues relating to variations from Efpia.

END



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