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Subject: CMC Rapporteurs/Applicant/EMA TC  
26/11/20 - Post-meeting note - Priority OCs in  
quality LoQ

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Sent: Mon, 30 Nov 2020 17:51:42 +0100

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**Message:**

Dear Rosmarie and Ornella,

Following up on the CMC  
Rapporteurs/Applicant/EMA teleconference held  
on Thursday 26th November 2020, please find  
attached, as a post-meeting note, a supportive  
document entitled "Priority OCs in quality LoQ".

All questions raised in the quality LoQ should be  
satisfactorily responded to. During the  
teleconference held on Thursday 26th November  
2020, the applicant explained the difficulties faced  
in preparing a single consolidated response to the  
full LoQ, and indicated that their response to LoQ  
may be submitted in two parts; an earlier and later  
response submission. As requested by the  
Applicant, the Rapporteurs/CMC assessment teams  
have highlighted the questions raised as other  
concerns which could be prioritised by the  
applicant for the earlier response submission. The  
questions marked in the attached document relates  
to the control strategy of both DS and DP including

specifications and critical analytical methods. These issues are considered critical especially in the context of the novelty of this product type and the limited experience, therefore, a more stringent control strategy is expected.

To assist the planning of the Rapporteurs/assessment teams, the applicant is asked to confirm as soon as possible, in advance of the first response submission, which questions will be addressed in each submission and on which dates.

Kind regards  
Agnese

Filename	Type	Size
Priority OCs in quality LoQ - Delete COVID-19 mRNA Vaccine BioNTech.docx	MS Word Document	754kb

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