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### **ECPA view on UK role in managing future regulatory dossier evaluations - Brexit**

Dear Dr Berend

Following the recent publication on the DG SANTE web site of the Note to economic operators on Brexit, ECPA would like to take this opportunity to provide some input on ECPA view on the UK role in managing future regulatory dossier evaluations.

In carrying out the work as rapporteur, we believe that the UK still has an important role to play and continues to be an important resource provider. They should remain a part of the process as long as it is practically feasible. Consideration needs to be given to ensure a smooth transition in the evaluation process.

For active substance evaluations, we believe that the UK should maintain their role as RMS and there should be no need to re-allocate pending AIR dossiers; this should however be in close liaison with the Co-RMS, so that the Co-RMS would be able to take over the later stages of the evaluation if necessary (e.g. peer review). Thus the RMS/Co-RMS system would allow a smooth transition at the stage that the UK is no longer part of the process. This would clearly need some additional cooperation between the joint-rapporteurs and the notifier. We therefore ask that the UK should not at present be replaced as the RMS of AIR substances, there is however a need to ensure the proper involvement of the co-RMS for all dossiers where the UK is the RMS.

For product evaluations, we would support a system whereby the UK could continue to accept the role as zRMS until the final stages of Brexit, and where they could complete the EU evaluation, even when they are no longer part of the EU.

For future evaluations post Brexit, we would also support a role for the UK CRD as an evaluator in the EU process. We do however appreciate that this requires formal discussions and agreement within the Brexit framework.

We understand that there will be a meeting on 4<sup>th</sup> October to discuss RMS allocations for active substance reviews. I hope these comments can be shared with Member States via CIRCABC, and will be taken into consideration in your discussions. Please do not hesitate to contact me if you require further clarification of our views.

Yours sincerely



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