**From:** [redacted]
**To:** [redacted] (GROW); [redacted] (ENV); [redacted] (GROW); [redacted] (ENV)
**Cc:** [redacted]
**Subject:** Essential uses - Follow up from EFPIA
**Date:** vendredi 17 décembre 2021 08:21:30

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Dear [redacted], [redacted], [redacted] and [redacted],

We would like to thank you once again on behalf of EFPIA and AESGP for the opportunity to meet with you on December 2nd, this was a very beneficial and informative discussion on the EUC (Essential Use Concept). We would like to take this opportunity to re-iterate certain key points made during the meeting.

**Development of an EUC – Work by Commission Appointed Consultant, Wood**

We have reviewed the Woods presentation from the CARACAL meeting of 17 November 2021, on the Essential Use study, and would like to reiterate the following:

- Screening of legislation and stakeholders

  It was noted during the meeting that the mapping of relevant legislation and key stakeholders is not complete yet. The proposed EUC goes beyond REACH and the impact on other regulatory fora e.g. Medicinal Products Directive and associated regulations needs due consideration by the Commission.

- Testing the application of EUC – case studies

  We agree it is not appropriate to conduct a case study on the use of PFAS or OPE in any sector at this point, due to "*ongoing regulatory processes*". Previous pharmaceutical manufacturing sector experience with the authorisation application process, involving the use of Bis(2-methoxyethyl) ether (Diglyme) and 1,2-dichloroethane is very relevant and should be considered as a suitable case study.

During the meeting we expressed our keen interest to be part of the consultation process. Please confirm our contact details have been shared with the consultant Wood? (EFPIA: [redacted]@efpia.eu and AESGP: [redacted]@aesgp.eu).

**EFPIA Position on Essential Use**

In addition to the position as stated in the attached paper, we would like to reiterate the following key points made on the proposed PFAS restriction during the meeting.

The EUC has been raised in the context of a proposed PFAS Restriction. We note unsubstantiated commentary included in background documentation published by the member states preparing the Annex XV Restriction dossier, "*For medicinal products non-PFAS alternatives are available*". To apply such a blanket statement to all fluorinated medicines is inappropriate, in our opinion, for two

reasons:

- Today in drug discovery and development, fluorine is introduced into APIs (active pharmaceutical ingredients) when required to achieve stability/clearance, potency, pharmacokinetics and/or bioavailability of the drug candidate when these cannot be achieved by other means.
- It is incorrect to assume that fluorinated & non-fluorinated drugs in the same therapeutic class are interchangeable. Due to the pharmacology and distinct activity/side effect profiles, a medical professional will select between them based on the unique circumstances of the patient e.g. health status, complications with other prescribed medication or individual response etc. Limiting the treatment options in a therapeutic class because some have fluorinated groups would have a profound impact on the ability to treat patients with the most safe and efficacious medicine.

As recommended during the meeting we intend to provide additional information on the impact of the proposed PFAS Restriction to the relevant member states, preparing the Annex XV dossier.

As a key stakeholder we are open to continued dialogue on the reform of the REACH regulation and the application of the EUC. Please do not hesitate to contact us if we can help with any additional clarification on any of the information provided above.

With kind regards and best wishes for the festive season.

[redacted]

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