List of questions for DG Environment following publication of UWWTD and EQS:

UWWD

1. It is the first time that a definition of "micropollutant" is introduced in the EU legal text. It focuses on the mere presence of a substance while not considering its concentration levels and environmental behaviour, nor the negative impact on health and/or environment. What was the rationale for this definition and why it is hazard based rather than risk based?

2. According to the definition, any substance classified under CLP is considered a micropollutant if found in water. Does it mean that any substance used in a formula of a medicine, given a reference in Annex III to pharmaceutical legislation, is potentially subject to EPR? Who and how will they determine a list of substances that will have to pay and inform concerned manufacturers? Would manufacturers pay per marketed product or per number of substances deemed to be micropollutants?

3. We understand that manufacturers of pharmaceutical and personal care products, which will be subject to EPR, will have to set up Producer Responsibility Organisations (PROs). Do we understand correctly that we will have to set up PROs together with cosmetics industry and other sectors under Annex III? What safeguards do you foresee ensuring that chosen system for quaternary treatment is cost-efficient and covers only necessary costs? In the text, it is stated that more than one PRO may exist at national level. Could you please elaborate on in which cases more than one PRO may exist and how it could work?

4. We would like to understand why those sectors targeted under the EPR system were not consulted during the drafting process? Engagement would have ensured transparency and provided accurate data.

5. We have several questions regarding feasibility study supporting the impact assessment for EPR.

    a. Is it possible to know what briefing was given to the contractor and if the sectors for Annex III were mentioned from the start?

    b. Why there was no targeted consultation (in the feasibility study and impact assessment) with those sectors selected?

    c. Why is it limited to 2 industries and focuses on selected number of ingredients?

    d. The 92% figure related to concentration of pharmaceuticals (and cosmetic products) as micropollutants – the data presented is not clear or transparent with no rationale where this number originated, however, it is the basis behind inclusion in the EPR system. Can the Commission disclose more information?

    e. It appears from the study that cost estimation is based on the submission of only one stakeholder/source. We have a reason to believe that costs will be significantly higher. How impactful do you see this margin of error to be, who will oversee the extra costs beyond Commission estimates and will the costs be capped at those identified in the impact assessment?

f. Is it correct to assume we are expected to pay for the system indefinitely (the same amount every year) even after quaternary treatment is in place? What is the rationale for it?

g. Who pays – MAH vs API supplier ?
h. who determines hazardousness and on which basis?

6. We have concerns with the timeline. As you might be aware in Switzerland a similar system is being put in place since 2018 funded by all taxpayers. It has the same deadline as UWWTD – 2040. However, at best-case-scenario, implementation of UWWTD will start only in 2026. Don't you think it is too short, knowing that first deadline is 2030 and given that a number of UWWT facilities do not even have tertiary treatment in place?

   What happens in countries where tertiary treatment not in place – will that be funded by the scheme too?

   What is the removal rate of contaminants from quaternary treatment?

7. We have number of questions regarding exemption for products below 2t:

   a. 2t is relative to the weight of final product or concerned substance?

   b. 2t is meant at EU/national/regional level? What happens with multi-country markets?

   c. 2t is of a particular product of a manufacturer or a combined sum of all products containing same substance?

EQS:

8. What are the reasons for changing legal process for the future addition of substances from co-decision to comitology?

9. EQS: Why is the responsibility for establishing EQS moving from JRC to ECHA? It is the first time we have pharmaceutical substances included in the list and ECHA, until now, has no competence in the assessment of pharmaceuticals.

10. EQS: Until now, only scientific evidence was considered in the assessment process. We are surprised to see that stakeholder views will become part of the assessment given that there are no guarantees that those views are based on science or any sound evidence. Could you please comment.

GWD:

11. A quality standard for pharmaceuticals (total) is given with 0.25 µg/L. Where does this number come from, what is the scientific rationale? What is the process to derive this limit?