Ad-Hoc open BCR Meeting – PFAS Restriction - 28/03/2023 in FPS premises

1. Please fill in this questionnaire if you want to present a topic during the Ad-Hoc PFAS meeting :

The document should be send back before 13th March 2023 to: [redacted]@health.fgov.be and Cc: @health.fgov.be

It will help us to frame the agenda and organize the discussion on this large restriction.

2. Your presentation should be shared with the Authorities ( [redacted]@health.fgov.be and Cc: @health.fgov.be ) no later than the 20th March 2023 . The presentation should be maximum 5 slides ( the time allowed to each stakeholders will be 10 min max ).

3. The final agenda will follow before the meeting including a Teams link to follow the discussion remotely. Registration is mandatory, not registered stakeholders will not be admitted in the room or online.

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Questionnaire to send back to the BCR secretariat before the 13 March 2023

- Do you have remarks on the scope (definition of the PFAS ?)

The term “PFAS” is used indifferently for various substance groups. Originally coined to include all short and long chain fluorosurfactants and film forming fluids, the current much wider definition also includes fluoropolymers and molecules with low fluorine content. The definition should, if possible, be aligned beyond the EU (e.g. with U.S. EPA), to facilitate a later global implementation.

- Please indicate your sector and describe briefly the Restriction impact/influence on your sector .

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical (innovative) industry operating in Europe.

The biopharmaceutical industry is dedicated to providing safe and sustainable medication in the best available quality to benefit patients.

Under the current restriction proposal, active pharmaceutical substances are derogated in one scenario, but any materials/chemicals required for manufacture, as well as development products are in scope. We are concerned that even in this scenario pharmaceutical manufacturing in the EU is not possible. In addition, restriction of primary packaging materials restricts sales of medicines in Europe that are under a valid market authorisations, creating regulatory conflicts that cannot be resolved by the industry.

- Do you have specific remarks on the restriction text and its exemptions.
  ➔ Are you concerned by an exemption?
  ➔ If yes, is the timing foreseen reasonable for your sector?
  ➔ Have you conducted an alternative assessment that indicates that the proposed timing is reasonable or not?

The drug development and commercial portfolio of medicinal products and starting materials used in manufacture has been investigated, and several substances meeting PFAS criteria are currently used by EFPIA members. These substances can be categorised in the following groups:

- Active Pharmaceutical Ingredients (APIs),
- Starting Materials and Chemical Intermediates,
- Auxiliaries and Production Materials,
- Synthetic and Analytical Reagents,
- Primary Packaging Materials, and
- Medical Devices.

Currently, a derogation is foreseen for Active pharmaceutical ingredients but not for the starting materials and chemicals intermediates nor auxiliaires and Production materials which would make not possible to manufacture such API in the EU.

For use in primary packaging, a derogation of 13.5 years is foreseen envisaged for PCTFE only. No derogation exists for other fluoropolymers, such as ETFE coated

parts. Such applications of PFAS are in direct contact with the drug product. As such, they are part of the drug product qualification and registration. As far as our industry is aware, there are no feasible alternatives though we continue to engage with our Supply network to identify any alternatives available in the required volume. Any replacement of a primary packaging material of medicine in the market triggers a full requalification with the relevant Health Regulators. This process would take at least five years depending upon which global market the products are sold into and would entail the following activities:

- Compatibility / Stability study – shelf-life qualification
- Extractables / Leachable assessment
- Functionality qualification
- Processability qualification
- Re-submission to health authorities

For use in medical devices, a derogation of 13.5 years is foreseen. On contact with pharmaceuticals and marketing authorization, the points made about primary packaging apply here as well.

Further details available at: https://www.efpia.eu/media/636866/pfas-position-_-efpia-and-animalhealtheurope-january-2022.pdf

- Other

EFPIA members propose that authorized products such as API or excipients, finished pharmaceuticals including approved packaging and medical devices be exempted from the proposed PFAS restriction. As described above, this proposal is based on the societal necessity of medicines, the limited ability for substitution with non-PFAS chemicals, the fact that APIs are already subjected to environmental risk assessment, and the low risk that these materials have for impact on the environment due to both limited volume and minimal hazard. The chemical substances approved under pharmaceutical regulations (API) should be exempted generally rather than individually, to reflect the API exemption in REACH Authorization procedures and avoid regulatory conflicts.

In addition, the raw materials, intermediates and auxiliaries required for manufacture of these pharmaceuticals and medical devices should also be exempted, on the basis that any emission in industrial manufacturing environments

is well controlled and regulated. Manufacturing should remain in EU countries to reduce dependency on supply chains located mainly outside of the EU.