From: [redacted]
To: EC PRESIDENT VDL; SEIBERT Bjoern (CAB-VON DER LEYEN)
Cc: [redacted]
Subject: Sharing the EFPIA response to the ECHA consultation on PFAS
Date: vendredi 29 septembre 2023 09:14:38
Attachments: image001.png
EFPIA report in response the Annex XV PFAS restriction proposal.pdf
Annex 3_Industrial Use of Fluoropolymers in Pharma Manufacturing_Final.pdf
Annex 1 EFPIA_SEA_PFAS_FINAL.pdf
Annex 2 Patient Impact Survey_Human health associations.pdf

Dear President von der Leyen, dear Mr Seibert,

We met in Copenhagen on 14 September where I and others mentioned the potential significant impact of the ongoing PFAS REACh Restriction.

I currently serve as President of EFPIA, the European Federation of Pharmaceutical Industries and Associations. EFPIA submitted its response to the European Chemical Agency (ECHA)'s public consultation on this restriction on 25 September. **The response includes external assessments that conclude, if "the proposed restriction is implemented, a large number of important medicines will no longer be available."**

Attached you will find EFPIA's response to the ECHA consultation, incorporating detailed input from member companies. By sharing it with you, I wish to equip your services with the information they may need when assessing the fitness of ECHA's eventual proposal, when you receive it in the first quarter of 2024. I understand that, typically, the Commission adopts ECHA's proposed REACh restrictions with little change.

As things stand, the grave concern I shared with you on 14 September, that "we will be forced to cease pharmaceutical production operations in Europe," still applies. I would very much welcome learning that this will not be the case.

Should you wish to meet to discuss this issue, I would welcome the opportunity to do so.

Yours sincerely,

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Attachments:

- **Report:** Detailed document on the EFPIA response and positioning to the 10 questions as proposed in the consultation of the ECHA .

- **Annex 1: EFPIA Socio-economic analysis report prepared by EPPA**

  This analysis looks at the potential impacts of the restriction of the PFAS used in the production, packaging and delivery of human medicinal products. The report has the intention of providing regulators with strong evidence-based findings on social and economic impacts that are expected to occur should PFAS be restricted under REACH. The socio-economic analysis (SEA) gathers technical and economic information to describe ex-ante in both qualitative and, where feasible, quantitative terms, the (orders of magnitude of) socio-economic impacts the pharmaceutical industry as well as the relevant EEA supply chain and society are expected to face as a result of a ban on PFAS. In particular, this SEA covers the function of PFAS APIs in human medicines as well as the crucial importance of PFAS at the different stages of the manufacturing process of medicinal products, and for immediate packaging and drug delivery devices. It will also describe the lack of available technologically suitable and economically viable alternatives, the technical difficulties associated with the substitution of PFAS via alternatives, the social and economic impacts from their restriction, and the broader impacts on society.

- **Annex 2: Human Health Medicinal Products Sector Survey - Impact of Proposed PFAS Restriction on Patient Access to Medicines and EU Strategic Autonomy**

  European-based human pharmaceutical trade associations carried out a survey across their memberships to outline how the proposed PFAS Restriction could impact patient access to medicines and hinder the utilisation of pharmaceutical manufacturing capacity in the EU. The objective of this work was to gather evidence to justify derogations, to prevent medicine shortages, and to inform ECHA and the Commission of the potential impact of the PFAS Restriction on medicinal product supply chains.

- **Annex 3: Industrial Use of Fluoropolymers & Fluoro-Elastomers in Pharmaceutical Manufacturing Facilities (in collaboration with ISPE)**

  EFPIA worked in coordination with the International Society of Pharmaceutical Engineers (ISPE) to compile a report on the industrial use of fluoropolymers & fluoro-elastomers in pharmaceutical manufacturing facilities. This included information gathered in a survey (August 2023) where the objective was to identify the impact of the proposed restriction on PFAS on various sectors of the pharmaceutical industry during the production and packaging stages. Responses were received from 130 companies of varying sizes with a very wide spread of activity such as supply of materials and manufacture of drug substance (small molecule and biologics), supply of materials and manufacture and package drug product (sterile and non-sterile), provision of analytical and manufacturing materials and equipment. The report also includes case studies/infographics identifying the various uses of fluoropolymers & fluoro-elastomers across medicinal product manufacturing facilities.