Draft AESGP Submission to the Public Consultation on the proposed PFAS restriction by ECHA[1]

General Comments

AESGP, the Association of the European Self-Care Industry, represents manufacturers of non-prescription medicines, self-care medical devices and food supplements that together are also referred to as consumer healthcare products.

We support the efforts made to address and mitigate the risks associated with some PFAS as well as the unlimited exemption for active substances in pharmaceutical products (API, Active Pharmaceutical Ingredient) However, we would like to express our concerns about the fact that the term "PFAS" is a broad, general, non-specific term, which does not inform whether a compound is harmful or not" and therefore, without considering the loss of human health benefits due to the restriction and without applying a risk-based approach, the consequences for consumer healthcare products could be detrimental.

The following substances and applications would be subject to restrictions after the 18-month transition period with a significant impact on self-care patients and users in and outside the European Union.

- **Primary packaging materials** (e.g. tubes, sachets, blisters[2]) and sterile barrier systems, even if they are part of the market authorization of Medicinal Products and the certification of Medical Devices.
- **Active Pharmaceutical Ingredients (APIs)** without EU marketing authorization, such as APIs that belong to the PFAS family (as defined by ECHA) for global export.
- **APIs in development**. Beyond a production volume of 1 ton per year, the exemption for scientific research and development no longer applies and both production and further development would no longer be possible in the EU.
- Other "non-active" components in consumer healthcare products, such as **additives/excipients** and propellants, as well as substances and aids required for their production (e.g., solvents, hoses, filters, etc.).
- **Fluoropolymers in industrial settings** – both as equipment and consumables:

    - **Chemical raw materials**, synthesis **starting materials**, catalysts, as well as intermediate products and other substances and aids necessary for synthesis (e.g., solvents, hoses, filters, etc.) to produce active substances.
    - **PFAS-containing equipmen**t in production, such as seals, valves, hoses, filters, and membranes, are necessary for producing and analysing essential products.

[1] Link to ECHA Public Consultation and its format: https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

[2] Except the potential derogation for PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF

- **<u>Impact of the restriction proposal and recommendation in relation to transition timelines</u>**

The restriction proposal refers to the security of the supply of medicinal products for the population in the justification on page 72 for the exemption for active pharmaceutical ingredients (API): "Human MPs are important for the protection of humans from diseases". All the substances as well as processes in and during the manufacture of medicinal products and medical devices (such as chemical raw materials, catalysts as well as e.g., intermediates and other substances required for synthesis e.g., tubes, filters, films, etc.), for which an exemption is not foreseen, are affected by the restriction. This will have far-reaching effects, particularly in the field of medicinal products and medical devices which are likely to negatively impact healthcare systems protecting the health of the EU population.

In order to ensure the supply of medicinal products to the population and to achieve the goal that the production of medicinal products can remain or even be expanded in Europe, further specific exemptions (raw materials/intermediates, reagents, materials such as PVDF filters, PFAS-coated equipment parts for manufacturing) are necessary in addition to the exemption for active pharmaceutical ingredients in medicinal products, which is not limited in time.

Therefore, we call for a full exemption for finished consumer healthcare products, particularly non-prescription medicinal products, and self-care medical devices including manufacturing, covering:

1. **APIs without EU approval**.
2. **Chemical raw materials, synthesis starting substances, catalysts as well as e.g., intermediates and other substances and auxiliaries required for synthesis (e.g. solvents, tubes, filters, etc.) for production and manufacturing.**
3. **APIs and medical devices under development.**
4. **Other "non-active" ingredients, such as additives/excipients and propellants, as well as substances and auxiliaries required for their manufacture (e.g. solvents, tubes, filters, etc.).**
5. **Primary packaging materials and sterile barrier systems, even if they are part of the marketing authorisation.**
6. **Products containing PFAS, such as seals, valves, tubes, filters and membranes, which are required in production facilities for the manufacture and analysis of consumer health products.**

If a full exemption or a full exemption subject to conditions of the required points 1. - 6. is not possible, we request a minimum transition period of 13.5 years. The proposed transition periods are necessary, as not only technical development and substitution may be considered, but additional periods for requalification, revalidation, performance of stability studies, regulatory changes or re-authorisation are required.

Time-unlimited derogations, which will not be limited to the active substances in pharmaceutical products (API, Active Pharmaceutical Ingredient), would be indispensable to guarantee the uninterrupted supply of medicinal products to the population and to promote pharmaceutical manufacturing growth in Europe. This is especially relevant for raw materials, intermediates, reagents, and all kinds of primary packaging materials.

For instance, using primary packaging materials is crucial in preserving and protecting pharmaceutical and healthcare products, such as tablets, which are classified as medicinal products, substance-based medical devices, or food supplements. **Consequently, restricting PFAS packaging which is crucial to deliver the respective consumer healthcare product, as well as failing to allow sufficient timelines for replacing PFAS packaging, will lead to supply and availability issues of crucial medicine for EU citizens.**

- **Need for time-unlimited derogations for specific packaging used for consumer healthcare products without alternatives**

There is a need for time-unlimited derogations for specific primary packaging materials, notably with regard to thermoform blisters used for tablet packaging commonly utilize PCTFE (Polychlorotrifluoroethylene) due to its exceptional properties, including high moisture barrier, transparency, thermoformability, chemical stability, inertness, non-sticking characteristics, non-ageing properties, and sterilizability. Incorporating a layer of PCTFE offers technical advantages for medications requiring enhanced protection for the delivery of safe and sterile products to patients. The self-care industry supports the proper disposal of waste blisters through collection and incineration, ensuring the appropriate handling of medicinal products.

- **Need for longer transition periods for specific packaging used for consumer healthcare products with alternatives**

For packaging where alternatives could be found the transition periods must account for technological advancements and substitution possibilities as well as consideration of the time required for requalification, revalidation, stability studies, regulatory changes (variations), or new approvals (which can take up to 10 years). The high-level requirements to consider are the following:

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

Longer transition periods are necessary for two main reasons: the time needed for the development of alternative options and the qualification and registration process for primary packaging. When replacing a primary packaging material in the market, a thorough and typically lengthy requalification process is required. If the vitamin is used in a medicinal product, this process involves working closely with health regulators to ensure compliance and would fall under exemptions and longer transition periods of medicinal products. However, it is important to note that, within the EU, the classification of the same vitamin product can vary, with some markets considering it a food supplement while others classify it as a medicinal product. One example is prenatal vitamins which could in some countries be marketed as a food supplement and in other cases as medicinal products. Due to the importance of vitamins as well as to maintain consistency for the same product across the EU, we, therefore, recommend applying the same transition periods for primary packaging for both food supplements, ingested medical devices, and medicinal products.

Likewise, implementing a prohibition on fluoropolymers in industrial settings – both as equipment and consumables – might imply changing our manufacturing processes. For medicinal products, for instance, this could trigger the submission of several variations to update registered manufacturing processes, which would take considerable time and effort for assessment and approval from regulators. Furthermore, certain medicinal products lack substitutes for numerous applications where properties, e.g. chemical resistance are needed. This situation presents a potential risk of shortages if these modifications are not meticulously strategized, permitting exemptions are authorised where essential and ample transition periods are provided.

- **Conclusion**

We call for a general exemption for consumer healthcare products, particularly medicinal products, and self-care medical devices that undergo rigorous registration, market authorization or certification schemes, proving their beneficial health effects and safety of use.

Raw and starting materials, intermediates, auxiliaries, equipment, and consumables required for the manufacture and packaging of healthcare products should also be exempt, as these are handled under controlled conditions.

In general, if a full exemption or a full exemption subject is not possible, we request a minimum transition period of 13.5 years.

This is justified by the societal necessity of consumer healthcare products, the limited ability for substitution with non-PFAS chemicals, the fact that APIs used in medicines 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 (https://www.sciencedirect.com/science/article/pii/S0160412019309493). Any emission of industrial manufacturing into environments is controlled and regulated via other existing EU legislation and any risk posed by emissions of these substances can be further mitigated through waste management regulations. Fluoropolymers are not volatile or bioavailable. As the only common property is persistence, their emission should be restricted rather than the use of the substances. Moreover, the derogation for APIs as currently drafted would not allow continued manufacturing of many APIs in the EEA, which conflicts with recent EU strategies to reduce dependency on supply chains located mainly outside of the EEA.

- **Additional comments**

There are many complexities involved in fully investigating this proposed restriction with all the self-care industry suppliers and partners throughout the entire supply chain. We rely on information from our suppliers, who themselves might have to investigate with their (raw ingredient) suppliers. Time and resources will be required throughout many levels of the supply chain to fully assess the impact of this restriction. Therefore, we are not able to respond to the specific info requests as a Downstream User industry, however, we would like to emphasize the proposed restriction will have far-reaching consequences that are not fully realised yet including the unintentional elimination of critical uses/processes/products.

Answer to specific info request 1: Sectors and (sub-)uses: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

The AESGP submission refers to the use of PFAS in consumer healthcare products comprising non-prescription medicines, self-care medical devices and food supplements.

Answer to specific info request 2: Emissions in the end-of-life phase: The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

(a) Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.

(b) If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.

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Answer to specific info request 3: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

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Answer to specific info request 4: Impacts on the recycling industry: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:

- ***a. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).***
- ***b. The measures that recyclers would need to take to achieve the proposed concentration limits.***
- ***c. The costs associated with these measures.***

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Answer to specific info request 5: Proposed derogations – Tonnage and emissions: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations,

information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

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Answer to specific info request 6: Missing uses – Analysis of alternatives and socio-economic analysis: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

- *a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.*
- *b. The key functionalities provided by PFAS for the relevant use.*
- *c. The number of companies in the sector estimated to be affected by the restriction.*
- *d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.*
- *e. For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.*
- *f. For cases in which substitution is technically and economically feasible but more time is required to substitute:*
  - *i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);*
  - *ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);*
  - *iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);*
  - *iv. information on the benefits for alternative providers.*

- *g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.*

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Answer to specific info request 7: Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives

can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

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Answer to specific info request 8: Other identified uses – Analysis of alternatives and socio-economic analysis: Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

Answer to specific info request 9: Degradation potential of specific PFAS sub-groups: A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

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Answer to specific info request 10: Analytical methods: Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

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