Contribution ID: 9f70070a-7572-41f9-a495-b0456e4bb43c

Date: 21/05/2026 22:40:40

General survey

Fields marked with * are mandatory.

1 Respondent background information

Before responding to the survey, please read the following documents (see links in the sidebar):

1. **Guidance Document**
2. **Use Mapping**
3. **Privacy Statement**

☑

- I have read and understood the information in the **Guidance Document** and **Use Mapping**.
- I agree to the privacy policy as set out in the **Privacy Statement**.

---

* 1.1 **[Q2.0]** Select the EU language in which you will respond to the questions (the questions themselves will be in English only).

English

* 1.2 **[Q2.1]** Which of the following best describes you or your affiliation?

Select Citizen/individual if you are responding in a personal capacity.

Select Organisation if you represent an organisation (e.g. company) or other official role.

- ○ Citizen/Individual
- ◉ Organisation

* 1.3 **[Q2.2]** What type of organisation are you responding for?

- ( ) Government organisation
- ( ) Non-governmental organisation
- ( ) Academic institution
- (•) Industry association
- ( ) Company

* 1.4 **[Q2.3]** What is the name of the organisation you are reporting for?

Text of 1 to 300 characters will be accepted

International Pharmaceutical Aerosol Consortium and International Pharmaceutical Aerosol Consortium on Regulation and Science

* 1.5 **[Q2.4]** Please name a point of contact ECHA can contact if needed.

Text of 1 to 100 characters will be accepted

A point of contact is needed for seeking clarification or justification for the consultation responses if considered necessary by SEAC.

For individual respondents, the contact's name is always kept confidential.

.

Maureen Hardwick

* 1.6 **[Q2.5]** What is the email address for that contact point?

maureen.hardwick@faegredrinker.com

1.7 **[Q2.6]** If you submitted comments in the previous consultation on the Annex XV restriction proposal (Mar-Sep 2023), please list the comment numbers (e.g. #1234, #5678).

300 character(s) maximum

#4063, #4064, #4065, #4066, #8070

* 1.8 **[Q2.7]** Is your organisation national or international?

Organisations having activities in several countries (in EEA or globally) should choose "international".

- ( ) National
- (•) International

* 1.9 **[Q2.8]** What country are you (or your organisation) based in?

Individuals should choose the country where they permanently reside.

Respondents representing organisations, such as companies, should select the country where the largest share of their PFAS related activities occur.

Respondents representing other organisations may choose the country where the organisation is based in.

United States of America (US)

1.10 **[Q2.9]** How many members does your association have?

Provide the number of member organisations (e.g. for industry associations), or individuals (e.g. for trade unions).

24

2 General survey questions

Instructions

Please do not include links to particular websites or source literature in the response fields. For security reasons, links to external sources will not be opened.
If you wish to cite a third-party source (e.g. research paper), you can reference it in the response field. This allows SEAC to note the source and request it from you if necessary.

For more information, please see the Guidance document.

---

* 2.1 **[Q2.17]** Choose all sectors that are relevant or covered by your responses in this general survey.

Minimum 1 selection(s)

Select the sector(s) for which you will provide information. You can choose PFAS manufacturing and 22 sectors (14 sectors covered by SEAC sector-specific evaluation and additional eight sectors identified in the Background Document).

You can select as many sectors as you see fit. Information provided will apply to all selected sectors unless you specify otherwise in your answers. If you prefer to do it so, you can submit one survey for each specific sector of use your answers apply to.

If your use is not covered by any of the identified sectors, choose “other” and specify it in the next question.

- [ ] **[01] PFAS manufacturing**
- [ ] **[02] Textiles, upholstery, leather, apparel and carpets (TULAC)**
- [ ] **[03] Food contact materials (FCM) and packaging**
- [ ] **[04] Metal plating and manufacture of metal products**
- [ ] **[05] Consumer mixtures and miscellaneous consumer articles**
- [ ] **[06] Cosmetics**
- [ ] **[07] Ski wax**
- [ ] **[08] Applications of fluorinated gases**

- [ ] **[09] Medical devices**
- [ ] **[10] Transport**
- [ ] **[11] Electronics and semiconductors**
- [ ] **[12] Energy**
- [ ] **[13] Construction products**
- [ ] **[14] Lubricants**
- [ ] **[15] Petroleum and mining**
- [ ] ***[16] Printing applications***
- [ ] ***[17] Sealing applications***
- [ ] ***[18] Machinery applications***
- [x] ***[19] Other medical applications***
- [ ] ***[20] Military applications***
- [ ] ***[21] Explosives***
- [ ] ***[22] Technical Textiles***
- [ ] ***[23] Broader industrial uses***
- [ ] **[24] Other sector**

---

* 2.2 **[Q2.18]** Please provide a general description of the use(s) of PFAS (or alternatives) you are providing comments on

Text of 1 to 2000 characters will be accepted

Briefly describe the use(s) of PFAS (or alternatives) in this sector(s).

Medical Propellants and Coatings are Essential for Life Saving Therapies and a Range of Therapeutic Options are Essential for Patients
IPAC represents an industry that is committed to transitioning all pressurised metered-dose inhalers (pMDIs) to novel medical propellants ensuring the delivery of inhaled medicines is significantly more sustainable and maintaining the range of medicines for patients. IPAC members are individually committed to innovation, in line with the evolution of scientific understanding, to ensure patients access to device options and a full range of medicines. IPAC supports the critical uses of fluorinated propellants and coatings in pMDIs and advocates for a careful approach that protects patient access and avoids supply issues for medicines and negative impacts to national health care systems. A full assessment of the sector and consultation with key stakeholders, including health authorities, clinicians and patient groups, prior to adopting broad restrictions is necessary to avoid negative impacts to patients. The European Commission adopted this careful approach in the prior CFC MDI transition.
Based on available technical, regulatory and patient safety evidence and considerations, IPAC recommends the following approach for critical pMDI uses:
-12-year derogation for HFC-134a and HFC-227ea as medical propellants
-time-unlimited derogation for HFO-1234ze as a medical propellant
-time-unlimited derogation for fluorinated coatings (PTFE and FEP) used in pMDI
A propellant in a pMDI to treat asthma and COPD must be safe, non-toxic, compatible with APIs, excipients and components, inactive, stable, acceptable for patient use and achieve the desired aerosol formation. pMDIs fulfil a unique and essential clinical function for patients unable to effectively use other inhalers. Inhaler choice and options are important to promote personalised approaches for patients and achieve optimal control of respiratory diseases.

2.3 **[Q2.19]** Please provide your comments on section 1.2. SEAC opinion

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Critical Role of Fluorinated Materials in Ensuring pMDI Efficacy and Patient Safety
Restriction of medical propellants and coatings would result in significant negative impacts on patient health and mortality, imposing enormous socio-economic costs on the 500 million people globally who suffer from chronic respiratory diseases, and on health systems and society overall. IPAC recommends:
-12-year derogation for HFC-134 and HFC-227ea as medical propellants
-time-unlimited derogation for HFO-1234ze as a medical propellant
-time-unlimited derogation for fluorinated coatings (PTFE and FEP) used in pMDIs
Due to different physiochemical properties, the suitability of a medical propellant for a medicine varies depending on the specific API and formulation of a pMDI medicine. A pMDI is a drug-device combination, and elements of it are not readily interchangeable. Additionally, practical aspects (e.g. significant investment for specialized facilities) and supply chain resilience must be considered. Reliance on a single propellant, which could also mean a single supplier in the short-term, increases risks of supply disruption and drug shortages (Buttini 2023; Dohmeier 2025; Wang 2024).
The new propellants (HFC-152a and HFO-1234ze) are not directly interchangeable with each other; they are both equally important to ensure the transition away from the legacy propellants which supports the aims of both PFAS and F-Gas regulations.
Restrictions on HFO-1234ze would risk the availability of approved inhaled medicines, it is important that at least two propellants remain on the market. There is relevant historical precedent from the CFC to HFC MDI transition that illustrates that at least two options for propellants supports reformulation and key medicines are likely to be lost if only one propellant is available (Pritchard 2020). Supply chain realities must also be considered, including the risk of a single (or limited) source of medical propellant (TEAP 2025 Progress Report). HFO-1234ze is already approved by the EMA, MHRA, TGA and MedSafe in a pMDI (Chandel 2019).

For non-stick coatings, finding a material that matches PTFE's and FEP's unique combination of extreme chemical inertness, ultra-low friction, hydrophobicity, and biocompatibility, and a dense barrier to minimise drug-container interactions, while also being cost-effective and manufacturable for mass production, is extraordinarily technically challenging.
Many alternative polymers might excel in one area but fail in others. Some materials offer reduced surface energy and low friction but lack the necessary chemical inertness or barrier performance required to withstand F-gas propellants or interact negatively with APIs. Others might be chemically stable but have surface properties that lead to unacceptable drug adhesion or absorption, negatively impacting dose consistency, chemical stability and shelf life.
Fluorinated coatings and linings are critical for ensuring the efficacy, safety, and stability of life-saving medications. PTFE and FEP perform complementary but distinct roles, each of which is essential to pMDI performance and patient safety across both suspension and solution formulations, directly contributing to optimal drug stability, shelf life, the accurate delivery of drug in every dose, and patient outcomes.
Scientific evidence supporting the critical use of PTFE and FEP in pMDIs include:
-PTFE's exceptionally low friction prevents drug particles from adhering to internal components (canister and metering valve) ensuring the API can be readily dispersed in the propellent to achieve precise, consistent dosing —critical for the effective treatment of asthma and COPD.
-PTFE and FEP are highly resistant to medical propellants and APIs. This inertness prevents chemical reactions and ensures the compatibility of valve elastomers, which is vital for overall MDI performance.
-FEP provides a robust, uniform mechanical barrier on aluminum canisters to prevent API interaction and degradation preventing the drug from interacting with the canister wall which might promote chemical reactions (acting as a catalytic surface).
-PTFE's non-stick surface minimizes drug deposition on internal walls, which would otherwise reduce the delivered dose and shorten shelf life. This ensures patients receive the full intended dose, particularly in solution-based MDIs.
-Both materials are biocompatible and well-tolerated by the respiratory system. This is a fundamental safety requirement for devices delivering medication directly to the lungs.
-PTFE is essential for the smooth, precise operation of the metering valve. This functionality is integral to device efficacy, as it allows for the dispensing of an exact metered quantity of the drug formulation.
Replacing fluorinated coating materials in direct contact with the drug is likely to require full complex future life cycle management programs of work with high regulatory burden and long timelines.

2.4 **[Q2.20]** Please provide your comments on section 2.2. Summary of the opinion and 2.2.2. SEAC opinion summary

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

pMDIs Deliver Life-Saving Medicines for a Range of Serious Respiratory Illnesses. Any potential restrictions to propellants or coatings need to reflect the views of relevant experts, including health authorities, clinicians, and patients.

PFAS used in the manufacture and delivery of inhaled medicines via pMDIs are essential, as non-pMDI alternatives are not adequate in all medical settings. Based on available technical, regulatory and patient safety evidence and considerations, IPAC recommends the following approach for critical pMDI uses
-12-year derogation for HFC-134 and HFC-227ea as medical propellants.
-time-unlimited derogation for HFO-1234ze as a medical propellant.
-time-unlimited derogation for fluorinated coatings (PTFE and FEP) used in pMDIs.

PFAS used in the manufacture and delivery of inhaled medicines via pMDIs are essential and non-pMDI

alternatives are not adequate in all medical settings.

The two legacy propellants (HFC-134a & HFC-227ea) will be phased down and ultimately phased out no later than 2050 due to their high Global Warming Potential (GWP) by the European F-Gas Regulation (2024/573). They will be replaced with two new propellants with significantly lower GWP, HFO-1234ze & HFC-152a. The two new propellants (HFC-152a and HFO-1234ze) are not interchangeable with each other, and therefore both are equally important to ensure the smooth, seamless transition away from the two legacy propellants supporting the aims of both PFAS and F-Gas regulations. Individual IPAC members are firmly committed to transitioning away from HFC-134a and HFC-227ea and have made significant investments to innovate to lower GWP MDIs. Globally, there are divergent definitions of PFAS and the definitions are evolving. HFO-1234ze falls under the OECD definitions of PFAS which is used in the restriction proposal, but not other definitions (e.g., at the Federal level in the United States (US EPA) while some individual states align with the OECD definition). HFC-152a is not classified as a PFAS under the OECD definition of PFAS used in the restriction proposal.

pMDIs are complex devices and each medicine has unique requirements in terms of interaction with the propellant. The selection of propellant is an individualised, product-specific decision dependent on a number of factors.

Most pMDIs require a non-stick coating in the can and valve (e.g., FEP or PTFE) to ensure that an accurate dose of the API is administered at each actuation. Without these coatings, a portion of the API would adhere to the can and valve, thereby risking each dose being out of specification. The ultra-low surface energy and non-stick properties of PTFE and FEP dramatically reduce this risk. These coatings ensure the precise and efficacious dose of the API throughout the pMDI's shelf life. Because less API is lost to the canister wall, there is no need to add an overage of API to the canister to ensure on-target dose delivery. Currently, there are no alternatives to FEP and PTFE as non-stick coatings for pMDIs.

Inhaled medicines are the cornerstone of respiratory therapies. Uncertainty around the permissibility and therefore availability of medical propellants would jeopardize patient care.

There is no 'one size fits all' with respect to the inhaler type utilized. The type of inhaler treatment used depends on the patient's specific needs, including clinical status, age, and physical ability. For many patients with insufficient inspiratory capacity, a pMDI-delivered medicine may be the only therapeutic option. Therefore, having more than one respiratory drug delivery system and associated respiratory medicine on the market is vital.

In addition to ensuring access, efficient treatment, and choice for patients, preserving different treatment options (pMDIs, dry powder inhalers (DPIs) and soft mist inhalers (SMIs)) is crucial for various reasons. Options should not be confused with alternatives. For example, switching from pMDIs to DPIs for environmental reasons without medical justification could result in adverse consequences for patients, such as impacting their quality of life, compromising symptom control, as well as potentially increasing use of healthcare resources, resulting in growing costs (Albanna, 2023; Roche, 2025; Adachi 2006, Quinet 2010, Usmani 2024).

The choice of medicine and device is one for the health care provider and/or prescriber, and decisions related to the care for patients suffering from chronic lung diseases must not be driven by non-clinical factors.
A failure to carefully assess all relevant factors noted above will likely lead to negative outcomes and unintended consequences for patients and health care systems.

2.5 **[Q2.21]** Please provide your comments on section 3.2. Justification that action is required on a Union-wide level

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.6 **[Q2.22]** Please provide your comments on section 3.3.1 Availability and technical and economic feasibility of alternatives

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

pMDIs Are Complex Devices and the Selection of Propellant is Complex and Specific to Each Medicine and MDI Formulation.

pMDIs rely on aerosol propellants and coatings to operate and deliver life-saving medicines. Viable options for both coating and propellants are extremely limited given technical and performance characteristics, including safety. Any changes require careful consideration, lengthy timeframes, and substantial resource investment. There are important physicochemical differences between the two low GWP propellant options which impact how and whether a medicinal formulation can be developed and device compatibility. A propellant change requires reformulation, extensive testing to meet global requirements of quality (performance) and safety, and compatibility with materials and components. A propellant change might require different concentrations of co-solvents (e.g. addition/removal/change in ethanol), and surfactants, to ensure that the new formulation with specific API(s) will remain a suspension or solution, will continue to deliver appropriate particle size distribution and have consistent dose uniformity (key performance characteristics). If through these modifications appropriate properties cannot be achieved, a pMDI with an alternative propellant cannot be developed. Having two options available greatly increases the chances of success. The more changes made, the more complex from a regulatory review and approval perspective. It can also negatively impact the ease of transitioning patients to a new pMDI.

The suitability of a propellant varies depending on the specific APIs and/or excipients in pMDIs due to the different physicochemical properties of legacy propellants (e.g. solubility, density, vapor pressure) versus HFO-1234ze and HFC-152a. Practical aspects (e.g. significant investment for specialized facilities) and supply chain resilience (reliance on a single propellant – which in this case could also means a single supplier in the short-term – increasing risks of supply disruption and consequent drug shortages) must be considered (Buttini, 2023; Dohmeier, 2025; Wang, 2024).

The new propellants (HFC-152a and HFO-1234ze) are not interchangeable, they are both equally important to ensuring the transition away from the existing propellants which supports the aims of both PFAS and F-Gas regulations.

HFO-1234ze is approved in Europe for a pMDI medicine (combination therapy) and is widely used by a large number of patients to treat COPD. Further inhaled medicines delivered via pMDIs using HFO-1234ze are also in last-stage development to replace the legacy propellants HFC-134a and HFC-227ea. Investigation into the feasibility of using HFC-152a for the aforementioned approved therapy indicated significant challenges, such as unfavorable stability for the APIs and inconsistent aerodynamic particle size distribution. Modeling suggested that HFC-152a could not consistently achieve the regional lung deposition required to maintain therapeutic intent for this specific combination therapy (Lachacz, 2026).

Even if reformulation were theoretically possible for a sub-set of medicines, the prohibitive cost of maintaining alternative products and supply chains for different markets (potentially tens of millions of Euros) would mean,

in most cases, needing to submit to all markets, not just the EU. The time for global approvals is variable, unpredictable and lengthy. Major changes like this can take 3-5 years for global regulatory approval, although global approval timelines of up to 8 years have been noted for significant changes (Deavin, 2024). Additional required steps to transition technical and manufacturing processes will require additional time and complexity.

The number of changes submitted to regulators concurrently, which is likely in a scenario of a wide-ranging restriction impacting pMDIs, will likely impact the capacity of regulators to review them and lead to even longer timelines. If development activities cannot demonstrate that products formulated with either of the two new propellants (HFC-152a and HFO-1234ze) are therapeutically equivalent to the ones containing the legacy propellant through limited in-vitro and in-vivo testing equivalent to the legacy propellant, this may require a company to undertake more extensive clinical trials to show the safety and efficacy of the reformulated pMDI with significant risk of negative outcomes and loss of therapeutic options for patients.

The properties of HFC-152a require specific manufacturing equipment and safety controls requiring reconfiguration or construction of all new production facilities, and procurement of new specialist manufacturing equipment with long lead times. The transition to low-GWP propellants can take many years in relation to upgrading manufacturing capacity with considerations specific to each propellant.

2.7 **[Q2.23]** Please provide your comments on section 3.4.1. Regulatory risk management options other than restriction

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Existing Regulatory Risk Management Practices Mitigate Emissions from pMDIs

Key takeaway: Restriction is not the most appropriate tool as pharmaceutical companies already practice emission controls and individual take-back programs, and each must comply with a range of EU regulations and directives supporting the control of emissions. Furthermore, an approach that unduly restricts medical propellants and coatings would contradict the European Commission's "Better Regulation" principles regarding predictability and proportionality.

• Pharmaceutical companies represented by IPAC already practice emission controls at their respective manufacturing sites and some have individually conducted take-back program pilots for proper recycling or destruction of propellant from returned inhalers at end of life, including controlled disposition and storage of waste products. These pilots demonstrated feasibility of preventing further emission of unused propellant and provide a foundation for potential scaling up those programs in the future. The manufacture of medicinal products including pMDIs, is already subject to a range of stringent regulations controlling site emissions and other aspects, including the Industrial Emissions Directive, the Medicinal Products Directive, and the Persistent Organic Pollutants Regulation (2019/1021). Therefore, restriction is not the only and not the most appropriate tool. Maintaining access to both suitable low GWP propellants is itself a key risk management option to protect patient health while supporting climate change objectives. A restriction of HFO-1234ze would negatively impact these goals.

• The use of pMDIs takes place within the EU medicinal product framework, under which the EU-wide approval of medicines is subject to stringent product-specific authorisation and ongoing regulatory oversight.

• There has already been approval of a pMDI in HFO-1234ze in the EU and UK, with further pMDIs in HFO-1234ze planned. Banning HFO-1234ze for use in pMDIs would contradict the European Commission's "Better Regulation" principles, which aim to ensure regulatory predictability, proportionality and evidence-based policymaking.

2.8 **[Q2.24]** Please provide your comments on section 3.4.2.2.1. Socio-economic analysis: Approach

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.9 **[Q2.25]** Please provide your comments on section 3.4.2.2.2. Socio-economic analysis: Costs

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Negative Economic Consequences of Restricting Low-GWP Propellants, Forcing Double Transitions, and Increased Health Care Costs

Elements of pMDIs, including propellants and coatings, are not readily interchangeable. The suitability of a medical propellant varies depending on the specific API and formulation of a pMDI. In the absence of suitable alternatives, a ban of approved pMDI propellants would jeopardise the availability of inhaled medicines, causing harm to patients and increased healthcare costs through preventable hospitalizations, as well as socio-economic costs due to the cessation of pMDI manufacturing in Europe.

Moving stable patients from pMDIs to other delivery systems (e.g., dry powder inhalers (DPIs)) for non-clinical reasons is repeatedly linked to worse disease control and higher emergency use. In a large recent real-world transition (>250,000 veterans), a formulary driven switch was followed by increases in emergency department visits (+5%), hospitalisations (+8%), respiratory related hospitalisations (+10%) and pneumonia related hospitalisations (+24%) (Rabin 2025). A targeted review found most unconsented/unsupervised inhaler switches were associated with worsened symptoms, treatment changes and increased acute medication use (Albanna 2023). These events are high cost and accelerate disease progression, amplifying long term resource use (Parsekar 2026, Pernigotti, 2021).

Elderly patients, young children, and people with cognitive or dexterity limitations often cannot reliably use DPIs /SMIs (GINA, 2023; GOLD, 2024; Laube, 2011). Forced switching in these groups risks disproportionate harm and higher utilisation, with resulting economic and social costs (carer time, transport, long term disability).

Expert consensus indicates a median ~35 minutes of clinician time per patient for education, technique training and follow up, well beyond typical European primary care slots and diverting scarce respiratory specialist and nursing time. At population scale this equates to hundreds of thousands of extra visits and substantial opportunity costs (Usmani, 2024).

Increased exacerbations drive absenteeism and earlier workforce exit, compounding the already large economic burden of COPD and asthma in Europe (WHO, 2025, Chronic Respiratory Diseases Programme; WHO, 2025, Chronic Respiratory Diseases: More Than 80 Million Affected). In severe COPD and asthma, productivity impairment and workplace losses are substantial and correlate with exacerbation frequency and disease severity (Løkke, 2021). Any policy induced rise in exacerbations or hospitalisations therefore imposes outsized societal costs.

The updated restriction dossier states that the overall costs incurred by a transition of pMDIs to HFC-152a would be 3 to 5 billion Euros and states that a significant share of these costs would – due to the requirements in the F-gas regulation – affect the sector eventually regardless of a PFAS restriction. These statements neglect that the first transition of a pMDI medicine to HFO-1234ze has already been completed in 2025, and that companies have - in light of the requirements of the EU F-Gas Regulation – individually committed to a transition of further inhaled medicines delivered by pMDIs to HFO-1234ze and HFC-152a. It must be assumed that inhaled medicines using HFO-1234ze would effectively be banned, as HFC-152a cannot be assumed as a substitute for all products/formulations.

Banning essential medical propellants and coatings could mean that the use of respiratory manufacturing facilities based in the EU, which supply many countries across the entire world, may no longer be viable. Bans could remove their core products, therefore risking closures, with losses of high skill direct jobs, indirect and induced employment, gross value added, exports and fiscal revenue.

Rapid removal of pMDIs without technically feasible substitutes would concentrate demand on fewer platforms. Manufacturing capacity cannot be scaled quickly; acute shortages trigger crisis driven care (ER/ambulance /nebulisation), increasing costs, and may prompt stockpiling that further destabilises supply. For LMICs importing EU made pMDIs, reduced exports could impair access and affordability, with global public health and economic repercussions.

Economic analyses show transitions from pMDIs to alternative devices (e.g., DPIs) can increase inhaler acquisition costs, with documented out of pocket increases (Pritchard 2020).

2.10 **[Q2.26]** Please provide your comments on section 3.4.2.2.3. Socio-economic analysis: Benefits

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.11 **[Q2.27]** Please provide your comments on section 3.4.2.2.4. Socio-economic analysis: Other relevant impacts

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Negative Implications to Patient Health Must be Avoided.

Key takeaway: The health burden of respiratory illnesses is enormous. The intersection between the goals of the EU F-Gas Regulation and a potential REACH PFAS Restriction must be carefully assessed to avoid regulatory uncertainty that risks harm to patients. Switching a patient's inhaler regime must be driven by clinical considerations to avoid poor health outcomes and increased costs to healthcare systems. Based on available technical, regulatory and patient safety evidence and considerations, the IPAC recommends the following approach for critical pMDI uses

- 12-year derogation for HFC-134 and HFC-227ea as medical propellants
- time-unlimited derogation for HFO-1234ze as a medical propellant
- time-unlimited derogation for fluorinated coatings (PTFE and FEP) used in pMDIs

- Asthma and COPD are serious, life-threatening illnesses with substantial costs to individuals and healthcare systems. COPD has a high mortality rate and is estimated to account for 6% of total healthcare spending in the European Union (equivalent to €38.6 billion per year) and 56% of the total cost of treating respiratory diseases (EFA, 2023, The Cost of COPD in Europe).

- The intersection between the goals of the EU F-Gas Regulation and a potential REACH PFAS Restriction need to be carefully assessed and considered. Both new propellants (HFC-152a and HFO-1234ze) are equally important to ensuring the transition away from the existing propellants which supports the aims of both PFAS and F-Gas regulations. Regulatory uncertainty for either new propellant is counterproductive and risks harm to patients. Individual IPAC members are committed to transitioning away from high GWP HFC-134a and HFC-227ea as soon as possible, likely by 2030, depending on individual timelines.

- Patients needing inhaled medications would be negatively impacted because of possible pMDI shortages and even unavailability of certain medications if medical propellants are not exempted with a significant impact to national health care systems.

- Switching a patient's inhaler regime is not a trivial matter and must be driven by clinical considerations. Switching inhalers should occur to improve patient care and outcomes, rather than being driven by non-clinical factors.

- Patients whose inhalers are switched without proper guidance can experience poorer asthma symptom management; patient consent and informed decision-making are essential for proper inhaler switching (A+LUK, 2026, All Puffed Out: How Poor Inhaler Care is Failing People with Asthma).
- Patients and clinicians must have the autonomy to choose the inhaled therapy that best suits medical needs. Abrupt, ill-managed inhaler switching yields poor health outcomes which negatively impact patient health and exacerbates environmental outcomes through unintended hospitalizations (Rabin, 2025, Rethinking Inhalers in the Era of Climate Change, JAMA; Zain, 2025, Clinical Effectiveness and Implementation Outcomes of PMDI-to-DPI Switch in Children Between 5 and 12 Years of Age: A Scoping Review Protocol, BMJ). The optimal inhaler is the one that is safest for both the patient and the planet. Inhaler choice must firstly depend on clinical considerations rather than being driven by environmental impact (GINA, 2025, Summary Guide for Asthma Management and Prevention: For Adults, Adolescents and Children 6 – 11 Years). Switching patients' inhalers for non-clinical reasons leads to negative outcomes, including higher costs, for both patients and healthcare systems (Morales, 2025, An Estimation of the Economic and Environmental Impact of Inhaled Devices Switch for Non-Clinical Reasons in COPD and Asthma: The Case for Spain, Journal of Market Access).
- Training for clinicians and patients adds further direct costs (Pernigotti, 2021, Reducing Carbon Footprint of Inhalers: Analysis of Climate and Clinical Implications of Different Scenarios in Five European Countries, BMJ).

2.12 **[Q2.28]** Please provide your comments on section 3.4.2.2.5 Socio-economic analysis: Proportionality

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Proportionality and the Health Impacts of Restricting Medical Propellants, and Disproportionate Concentration Limits

Key takeaway: A restriction impacting medical propellants is not proportionate, due to high negative impact on patients suffering from serious diseases which include a leading cause of hospitalisations and death. Without the availability of two propellants for pMDIs, patients' respiratory conditions could deteriorate and furthermore could lead to increased medical costs and concomitant negative environmental impacts elsewhere in the healthcare chain (Rabin, 2025, Rethinking Inhalers in the Era of Climate Change, JAMA; Zain, 2025, Clinical Effectiveness and Implementation Outcomes of PMDI-to-DPI Switch in Children Between 5 and 12 Years of Age: A Scoping Review Protocol, BMJ).

Additionally, concentration limits are critical to the effectiveness and practical implementation of the proposed restriction, but they need to be achievable and quantifiable.

- ppb levels of impurities as proposed in the consultation are at or beyond the reliable detection limits of current pharmacopeial approved methods, redevelopment of methods to quantify down to ppb levels could result in high uncertainty and poor reproducibility. Gaseous systems introduce variability that will make consistent ppb measurement difficult when compared to that of solid and liquid medium.
- Achieving consistent ppb impurity control is beyond current purification technology capability and would require substantial changes to manufacturing parameters, leading to higher batch rejection rates and significant increases in waste generation even if found to be engineeringly feasible. There is a potential for contamination from equipment, environment, and handling to occur at or above ppb levels post processing distorting results. These combined factors make ppb limits impractical to verify and apply consistently, whereas current low ppm levels remain robust and achievable thus ensuring availability of medical propellants.

2.13 **[Q2.29]** Please provide your comments on section 3.4.2.3. Practicality, including enforceability

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.14 **[Q2.30]** Please provide your comments on section 3.4.2.4. Monitorability

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.15 **[Q2.31]** Please provide your comments on section 3.4.3.2.1. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (i) PFAS definition

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.16 **[Q2.32]** Please provide your comments on section 3.4.3.2.1 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: (ii) Exclusion of PFAS from the scope

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.17 **[Q2.33]** Please provide your comments on section 3.4.3.2.2 Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Scope of the proposed restriction

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.18 **[Q2.34]** Please provide your comments on section 3.4.3.2.3. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Concentration limits

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.19 **[Q2.35]** Please provide your comments on section 3.4.3.2.4. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: General 18-month transition period

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.20 **[Q2.36]** Please provide your comments on section 3.4.3.2.5. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Derogations

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

Medical Propellants and Coatings Must be Available to Meet Patient Need.

Key takeaway: pMDIs fall under “Other medical applications”. IPAC emphasises the need to fully assess the patient implications of restrictions of HFO-1234ze and coatings because of possible pMDI shortages and unavailability of certain medications, with a significant impact to national health care systems.

2.21 **[Q2.37]** Please provide your comments on section 3.4.3.2.6.1. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Reporting requirements

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.22 **[Q2.38]** Please give an indication of the costs related to the reporting requirements.

Consult the SEAC draft opinion section 3.4.3.2.6.1. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Reporting requirements.

Provide an estimate of the magnitude of the costs for the implementation of the reporting requirements, from very low when the impacts are estimated to be insignificant to very high when they may result in a decision to discontinue your business activities.

- Very low or none
- Low
- Moderate
- High
- Very high
- I do not know

2.23 **[Q2.39]** Please provide your comments on section 3.4.3.2.6.2. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.24 **[Q2.40]** Please give an indication of the costs related to the implementation of a site-specific PFAS management plan

Consult the SEAC draft opinion, section 3.4.3.2.6.2. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan.

Provide an estimate of the costs for monitoring of emissions at industrial sites. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

- Very low or none
- Low
- Moderate
- High
- Very high
- I do not know

2.25 **[Q2.41]** Please give an indication of the costs related to monitoring of PFAS emissions at industrial sites

Consult the SEAC draft opinion, section 3.4.3.2.6.2. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Site-specific PFAS management plan.

Provide an estimate of the costs for monitoring of emissions at industrial sites. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

- ○ Very low or none
- ○ Low
- ○ Moderate
- ○ High
- ○ Very high
- ○ I do not know

2.26 **[Q2.42]** Please provide your comments on section 3.4.3.2.6.3. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

2.27 **[Q2.43]** Please give an indication of the costs related to the additional conditions considered by RAC

Consult the SEAC draft opinion, section 3.4.3.2.6.3. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Additional conditions considered by RAC.

Provide an estimate of the costs for implementing these conditions. Use the scale from very low (minimal impact) to very high (may result in a decision to discontinue business activities).

- ○ Very low or none
- ○ Low
- ○ Moderate
- ○ High
- ○ Very high
- ◉ I do not know

2.28 **[Q2.44]** Please provide your comments on section 3.4.3.2.7. Conclusion whether the suggested restriction is the most appropriate EU-wide measure: Interaction with other relevant legislation

Text of 1 to 1000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

F-Gas Regulations Interactions

Key takeaway: The intersection between the goals of the EU F-Gas Regulation and a potential REACH PFAS Restriction need to be carefully assessed and considered. Both HFC-152a and HFO-1234ze are equally important to ensuring the transition away from the existing propellants which supports the aims of both PFAS and F-Gas regulations. Regulatory uncertainty for either new propellant is counterproductive and risks harm to patients in terms of lack of availability.

2.29 **[Q2.45]** Please provide your comments on section 3.5.2. Uncertainties evaluated by SEAC

Text of 1 to 5000 characters will be accepted

Consult the SEAC draft opinion and provide your comments relevant to this specific section of the opinion.

3 Confidentiality and submission

3.1 **[Q2.46]** Indicate each section for which your response contains confidential information.

Select all the questions for which you consider your responses confidential. The options below include all questions in the survey.

- ☐ Respondent background information
- ☐ General survey questions

Useful links

Guidance Document (https://echa.europa.eu/documents/10162/17091/upfas-seac-do_consultation_guidance-for-respondents_en.pdf/68d5b13b-d7d6-f14b-2c3e-9b3c07c98113?t=1765956675386)

Use Mapping (https://echa.europa.eu/documents/10162/17091/pfas_use-mapping_annex_to_guidance_for_respondents_en.pdf/e242dcf0-0aab-2619-234e-09445bb181c5?t=1765893415372)

Background Documents

Privacy Statement

Contact

https://comments.echa.europa.eu/comments_cms/Contact_REACH.aspx