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European Respiratory Society input to the European Chemicals Agency consultation on PFAS

The European Respiratory Society agrees with the proposed restriction on per- or poly-fluoroalkyl substances (PFAS) brought forward by several EU Member States and the European Chemicals Agency.¹ A wide-scale restriction is necessary to mitigate and reverse the implications that PFAS have on human health and the environment. Yet such a restriction should not endanger the availability and functionality of essential medical devices where in certain cases no alternatives are yet available (e.g., inhalers for children).

PFAS contribute to climate change as some are potent greenhouse gases. Because climate change is a serious threat to planetary and human health, restrictions on such substances must be taken. In the case of PFAS, there is a double burden. In addition to its environmental impact, PFAS has implications for human health. Although these are not fully understood to date, the European Environment Agency states that the substances may lead to health problems such as liver damage, thyroid disease, obesity, fertility issues and cancer.^{2,3}

Regarding the respiratory devices affected by this proposed restriction, metered dose inhalers (MDI) use PFAS in their manufacturing and aid in the stabilisation of medication. MDIs were estimated to contribute approximately 0.03 per cent of annual global greenhouse gas emissions in 2014.⁴ However, MDIs have a carbon footprint of

¹ ECHA. ANNEX XV RESTRICTION REPORT. <https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>. Date last updated March 22 2023. Date last accessed September 20 2023.

² EEA. What are PFAS and how are they dangerous for my health? <https://www.eea.europa.eu/help/faq/what-are-pfas-and-how#:~:text=They%20are%20known%20as%20'forever,obesity%2C%20fertility%20issues%20and%20cancer>. Date last accessed September 20 2023.

³ UNEP. Per- and Polyfluoroalkyl Substances (PFASs). <https://www.unep.org/explore-topics/chemicals-waste/what-we-do/persistent-organic-pollutants/and-polyfluoroalkyl>. Date last accessed September 20 2023.

⁴ UNEP. Montreal Protocol on Substances that Deplete the Ozone Layer. <https://ozone.unep.org/sites/default/files/2019-08/MTOC-Assessment-Report-2014.pdf>. Date last updated 2015. Date last accessed September 20 2023. ISBN: 978-9966-076-07-6.

approximately 10 to 37 times higher than other treatment alternatives such as dry-powder inhalers and soft mist inhalers.^{5,6}

Despite this, it is essential to safeguard the availability of MDIs as a treatment. MDIs are essential medications for children (especially pre-school age), elderly populations, emergency care and in many low- and middle-income countries MDIs may be the only medication available. Patients must have access to a variety of treatment options suited to their individual characteristics and needs.⁷ As such, it is crucial to find alternative substances to use in MDIs to ensure their availability for patients who require them, while also phasing out the harmful PFAS substances used in their manufacturing. There needs to be adequate time for the clinical research and implementation of alternative substances used in MDIs and we must ensure essential devices are always available to those in need.

⁵ Wilkinson AJK, Braggins R, Steinbach I, et al. Costs of switching to low global warming potential inhalers. An economic and carbon footprint analysis of NHS prescription data in England. *BMJ Open* 2019;9:e028763.

⁶ Wilkinson A and Woodcock A. The environmental impact of inhalers for asthma: A green challenge and a golden opportunity. *Br J Clin Pharmacol.*2022;88:3016–3022.

⁷ Keeley D, Scullion JE, Usmani OS. Minimising the environmental impact of inhaled therapies: problems with policy on low carbon inhalers. *Eur Respir J* 2020 55: 2000048