The Global Initiative for Chronic Obstructive Lung Disease (GOLD) is an international organization that works with health care professionals (HCPs), health officials and the general public to raise awareness for Chronic Obstructive Pulmonary Disease (COPD) and to improve prevention and treatment for this lung disease. In general, we welcome the proposed regulation of per- and polyfluoroalkyl substances (PFAS) chemicals by the European Union which is being evaluated by the European Chemicals Agency (ECHA).

COPD represents an important public health challenge that is both preventable and treatable. COPD is a major cause of chronic morbidity and mortality throughout the world: many people suffer from this disease for years and die prematurely from it or its complications. Globally, the COPD burden is projected to increase in coming decades because of the continued exposure to COPD risk factors and aging of the population.

Medicines delivered to the lungs via metered dose inhaler (MDI) devices remain crucial treatment options for asthma and COPD patients globally, since for many of them alternative types of delivery devices for inhaled therapy are not appropriate or accessible. Due to increased regulations on F-gases, due to their global warming potential (GWP), many pharmaceutical companies are in the process of developing next generation inhaler devices using lower or negligible GWP propellants. Such metered dose inhaler devices will be transitioning to next-generation hydrofluorocarbon (HFC) or hydrofluoroolefins (HFO) propellants and transitioning away from current hydrofluorocarbons.

There are, currently, two alternative propellants in development for medical use in pMDIs – HFC-152a (which is subject to phase down under the Kigali Amendment and EU F-Gas Regulation), and HFO-1234ze(E) (which falls within the scope of this restriction proposal, but is not subject to phase down under the Kigali Amendment and EU F-Gas Regulation). Other alternatives have been investigated by the industry but are considered unsuitable for use in pressurized metered dose inhalers.

Pharmacological therapy for COPD is used to reduce symptoms, reduce the frequency and severity of exacerbations, and improve exercise tolerance and health status. There is also evidence that supports a reduction in mortality. Metered dose inhalers remain an important treatment option for medication delivery for the everyday management of many patients around the world. Moreover, salbutamol, also known as albuterol, is the most commonly prescribed rescue inhaler given to chronic respiratory disease patients around the world. It is among the cheapest inhalers available and listed on the World Health Organization's Essential Medicines List for all countries. Currently, this medication has little current availability outside of metered dose inhalers.

Europe is a global manufacturer of inhalers. We are concerned that a restriction on propellants for inhalers as an outcome of the ECHA PFAS proposal, will result in the inability for millions of patients to access essential medicines.

GOLD calls on the EU legislators and all those involved in regulations relevant to inhalers to:

i) Ensure that medical supplies of current propellants remain available until inhaled medications with low global warming potential become available in sufficient quantities for all patients everywhere.

ii) Ensure sufficient time is allowed for new inhaler devices with low global warming potential to be developed and prescribed for vulnerable people such as, those with limited manual dexterity and people with COPD in poorer nations.