GSK Public policy positions

Respiratory Products and Global Warming

The Issue

Metered Dose Inhalers (MDIs) are one of the main treatments for asthma and chronic obstructive pulmonary disease (COPD). MDIs use a hydrofluorocarbon (HFC) propellant to deliver the medicine from the inhaler to the patient, which is then released into the atmosphere. Whilst HFCs do not deplete the ozone layer, they are greenhouse gases with a relatively high Global Warming Potential (GWP) and can remain in the atmosphere for many years.

GSK is a leader in the treatment of respiratory disease, producing MDIs which use a propellant to deliver the medicine, and Dry Powder Inhalers (DPIs) which are propellant free. This paper details the evolving legislative environment regarding gases with a high GWP and GSK's views on, and support for, medical exemptions within this legislation.

GSK's Position

- Climate change is one of the world's most pressing issues, and as a healthcare company we recognise we can contribute to tackling both the causes and effects of climate change. We have ambitious targets in place to reduce our environmental impact by 2030.

- The Montreal Protocol on Substances that Deplete the Ozone Layer entered into force in 1989 to manage the global elimination of chlorofluorocarbon (CFC) gases and other ozone-depleting substances (ODS). The Kigali amendment, which entered into force in 2019, extends the targets to include HFCs. It seeks to phase down the use of HFCs by 85% by 2047.

- The Kigali Amendment is primarily focused on the largest sources of HFC emissions, widely acknowledged to be air conditioning units and refrigeration units[1].Recognition of the vital role HFC-driven MDIs can have on patients' lives is reflected in related legislation via exemptions when the gas is used for medical applications.

- GSK is committed to reducing our environmental impact and we continue to invest in new generation dry powder technologies, like the Ellipta device, which are dry powder inhalers (DPIs) and do not release greenhouse gas emissions. In 2017, a certified assessment of our respiratory inhaler portfolio by the Carbon Trust showed that the lifecycle carbon footprint of our DPIs is around 24 times lower than a propellant-based inhaler[2] for one month's treatment. By producing propellent free DPIs in place of MDIs, GSK has avoided approximately 2 million tonnes CO2e emissions per year.

- GSK acknowledges the high Global Warming Potential of HFCs, the propellant used in our MDIs. However, there are situations when an MDI may be the most appropriate inhaler device for the patient. We therefore support the exemptions for medical applications within some global and national legislation.

Background

Legislative environment

There are numerous global and national regulations regarding HFC emissions.

Kigali Amendment to the Montreal Protocol

For decades, chlorofluorocarbons (CFC) were the most suitable propellant for use in MDIs until the negative impact CFCs have on the ozone layer was identified.

[1] Source: European Commission website "Fluorinated greenhouse gases" Accessed on 27.06.18 and available here: https://ec.europa.eu/clima/policies/f-gas_en

[2] For one month's treatment, a 120-dose propellant inhaler has a carbon footprint of 19kg CO2e per pack compared with a 30 dose once-daily Ellipta DPI which has a carbon footprint of 0.8kg CO2e per pack.

The Montreal Protocol came into force in 1989 to address this challenge and has successfully phased out 98% of ozone depleting substances. As a result, the ozone layer is showing signs of recovery[3].

GSK played our part in this global effort by reformulating all our MDIs; manufacture of GSK CFC-based MDIs has now ceased. This was a lengthy and costly process, with total costs estimated at $1billion.

CFCs were replaced by HFCs in many types of industrial use. Although HFCs do not deplete the ozone layer, some HFCs have a high global warming potential, which is a measure of the potential impact substances can have on climate change.

EU F-gas regulation

The 2014 EU F-Gas Regulation seeks to minimise the global warming caused by emissions of the three groups of F-gases - hydrofluorocarbons (HFCs), perfluorocarbons (PFCs) and sulphur hexafluoride (SF6). HFCs are by far the most relevant F-gases from a climate perspective. The Regulation uses a quota system that will phase down the quantity of F-gas placed on the EU market. By 2030 it aims to cut the EU's F-gas emissions by two thirds compared to 2014 levels. Suppliers of HFCs are working to develop a lower GWP propellant. In the meantime, HFCs for use in MDIs are exempt from the quota requirements under the regulation.

US Environment Protection Agency Significant New Alternatives Policy (SNAP)

The US Environment Protection Agency (EPA) continues to update their list of alternatives to ozone depleting dubstances; this list includes the acceptable use of HFCs as medical propellants. In 2015, the EPA confirmed that the continued use of the medical propellant used by GSK is acceptable in FDA-approved MDIs. We expect this exemption to last for the foreseeable future.

GSK's portfolio

GSK has a broad respiratory portfolio, comprising both MDIs and DPIs. GSK's new generation of inhaler products, including our Ellipta device, were developed and launched as DPIs and have an acknowledged lower carbon footprint than MDIs. The UK Government supports the prescribing of DPIs over MDIs where medically appropriate for this reason. In addition, the British Thoracic Society encourages all prescribers and patients to consider switching MDIs to nonpropellant devices whenever they are likely to be equally effective.

There are times when patient use of an MDI over a DPI may be appropriate. For example, due to patient preference, or as a 'reliever' medication for exacerbations of asthma[4]. It is this need to maintain a range of options for patients that has prompted the medical exemptions agreed in legislation.

May 2019

[3] Source: European Commission website "Ozone layer". Accessed on 13.07.18 and available here: https://ec.europa.eu/clima/policies/ozone_en

[4] Current British Thoracic Society and Scottish Intercollegiate Guidelines Network guidance recommends an MDI (and spacer) for exacerbations. Available at www.brit-thoracic.org.uk and www.sign.ac.uk.