CHIESI POSITION ON F-GASES USAGE IN PHARMACEUTICAL PRODUCTS

2021

POSITION STATEMENT

Chiesi
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F-GASES AND PHARMACEUTICALS: OVERVIEW

High global warming potential (GWP) hydrofluorocarbons (HFCs) are the object of a phase-down strategy as agreed by EU regulation No 517/2014 (2nd F-Gases Regulation)[1] and the Parties to the Montreal Protocol in the 2016 Kigali Amendment[2]. Currently, EU regulation recognizes an exemption for HFC propellants for pharmaceutical use, which is specifically relevant for pressurized metered dose inhalers (pMDIs) otherwise known as spray inhalers. As recognized by UNEP's Technology and Economic Assessment Panel (TEAP) report, this exemption is important as it ensures healthcare providers continue to be able to prescribe treatment for respiratory conditions based on patient need[3].

Chiesi shares authorities' concerns related to the environmental impact of hydrofluorocarbon (HFC) propellants used in pMDIs – hydrofluoroalkanes (HFA) 134a and 227ea – and have committed €350 million in an investment plan to introduce the first carbon minimal pMDI by 2025[4], replacing the current HFC propellant and thereby reducing the carbon footprint of our inhaled drugs by nearly 90%[5,6].

While it is important to keep in mind that the proportion of greenhouse gas emissions from pharmaceutical uses of HFAs is less than 0.1% of the total[2,6], we believe it needs to be addressed. Restrictive and short-term approaches to addressing the GWP of propellants risks jeopardizing the investments in innovation needed to achieve such ambitious environmental objectives. It is only through collaboration between industry, governments and stakeholders that real solutions can be found. As a company committed to ensuring their work produces shared value for society and the business in equal measure, Chiesi is committed to leading the industry in their approach to innovating for sustainability.

CREATING SHARED VALUE FOR SOCIETY AND THE ECONOMY

Chiesi Group has taken active steps to formalize and apply its commitment to long-term sustainability, as defined in the United Nations 2030 Agenda for Sustainable Development. As a pharmaceutical company this gives us a dual role: taking care of our patients while we also take care of the environment.

Chiesi announced in 2019 that we would lead the way as the first pharmaceutical company to address the impact of the propellant in pMDIs[4], in line with our goal to become Carbon Neutral by 2035, achieving scope 1 & 2 emission neutrality by 2030. We are developing a new solution that will preserve patients' choice and wellbeing whilst addressing pressing environmental concerns by replacing HFA 134a propellant in inhalers in 2025.

This directly reflects the principle of shared value which guides us: the creation of economic value that also creates value for society, considering its needs and challenges. This new business model is intrinsic to our business and has been officially recognized since 2018 when we registered as a Benefit Corporation, more recently becoming the largest global biopharmaceutical group to be awarded B Corp™ Certification in June 2019.

AMBITIOUS ENVIRONMENTAL OBJECTIVES NEED INNOVATION AND INVESTMENT

As a B Corp, we support continuous research, investing in innovation to create more effective and environmentally friendly products while enhancing and preserving patient health.

Reducing the environmental impact of inhalers by limiting the use of pMDIs risks not only undermining the innovation ecosystem around carbon minimal pMDIs but also impeding patient access to the innovative solutions that they need. To bring our new generation of pMDIs to market, we announced a 5-year plan, with investments worth € 350 million in 2019. It will reduce the carbon footprint of our pMDIs by close to 90%, down to the level of dry powder inhalers (DPIs)[4,5].

The new carbon minimal pMDI will include HFA 152a (1, 1-difluoroethane) which is classified as a low GWP propellant (GWP value is ten times lower than HFA 134a, the propellant currently used[6]). This is in line with the Kigali Amendment objective to encourage use of low GWP alternatives and to reduce consumption and emissions of high GWP HFCs[2].

PATIENT HEALTH AT THE CENTRE OF HEALTHCARE

A proportion of asthma and chronic obstructive pulmonary disease (COPD) patients rely on treatments delivered through a pMDI, as a solution they trust or as the only suitable option to manage their condition[7-11]. As the optimal choice of the most suitable inhaler is a complex decision taken between doctor and patient, products delivered though a pMDI need to remain accessible, while we as a company strive to minimise the impact of those treatments on our environment and continue investing in our DPI platform.

The most recent update of the UNEP's report of the Technology and Economic Assessment Panel (TEAP) recognized this: "No single delivery system is considered universally acceptable for all patients. Not all active ingredients are universally available as either an MDI or DPI. Healthcare professionals continue to consider that a range of therapeutic options is important, which is also necessary for ensuring patient choice"[3].

Patient health is at the heart of Chiesi's current and future therapeutic solutions and we are committed to maintaining access to the range of treatment options that patients need globally.

COMMITMENT TO LONG-TERM, LIFECYCLE SUSTAINABILITY

We are not in competition to address climate change and we will not reach the ambitious targets alone. A well-managed and stable patient requires fewer resources[11]. Taking a holistic approach, we can improve disease management hand in hand with environmental impact. For example, the overuse of short-acting beta agonist (SABA) pMDIs is a clear indicator of uncontrolled asthma[12] which if addressed would benefit both patient and planet. This requires a regulatory environment built on mutual trust and ongoing dialogue.

As a Benefit Corporation and certified B Corp, we are taking steps to minimize the environmental impact of our pMDI and DPI products, including assessing options for better management throughout their lifecycle.

We are proud to have taken decisive and ambitious action to ensure patients can continue to access the inhaled treatment options that best suit their needs, whilst innovating to find the most environmentally conscious solution available and we can only encourage other industry players to join us.

Sources

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