CHIESI POSITION ON HYDROFLUOROCARBON (HFC) USAGE IN PHARMACEUTICAL PRODUCTS

2023

POSITION STATEMENT

Chiesi
air rare care

UK-CHI-2300188 June 2023

TRANSITIONING INHALED PHARMACEUTICALS THROUGH HYDROFLUOROCARBONS PHASE-DOWN STRATEGIES

High global warming potential (GWP) hydrofluorocarbons (HFCs) are a group of industrial chemicals widely used in daily life, including pharmaceutical products, such as pressurised metered dose inhalers (pMDIs).

HFCs are the target of a greenhouse gas emission phase-down strategy at international level as agreed by the Parties to the Montreal Protocol in the 2016 Kigali Amendment.[1] Phase-down strategies are now being implemented at a regional or national level through local legislation or policies.[2]

Regarding the phase-down of HFCs used by the pharmaceutical sector, the United Nations Environment Program's (UNEP) Technology and Economic Assessment Panel (TEAP) recognises that policies should ensure that healthcare providers continue to be able to prescribe treatment for respiratory conditions based on patient need.[3] Net Zero strategies should be developed preserving patient care and patient choice: carbon minimal pMDI alternatives are under development and will play a key role in helping decarbonising healthcare systems.

Chiesi Group (Chiesi) shares the authorities' concerns related to the environmental impact of HFC propellants used in pMDIs (hydrofluoroalkanes (HFA)-134a and HFA-227ea). Chiesi has committed €350 million in an investment plan to develop a carbon minimal pMDI from 2025,[4] replacing the current HFC propellant with the lower GWP propellant HFA-152a, thereby reducing the carbon footprint of its pMDI portfolio by up to 90%.[4,5]

While in full support of the HFC phasedown strategies, Chiesi calls on decision makers to ensure that these do not limit therapeutic options and hinder timely access and treatment availability. Patient quality of care and therapeutic choice should not be compromised.

Efforts to decarbonise health systems require an integrated vision for sustainability, ensuring that the quality of patient care is not compromised and that resources are used as efficiently as possible in any proposed strategy.

A comprehensive, collaborative and multi-stakeholder response is needed to guarantee the successful development and implementation of environmentally sustainable policy solutions by prioritising patient centricity in the interest of the most beneficial therapeutic outcome. Chiesi calls for collaboration between industry, governments, and stakeholders to achieve such ambitious environmental objectives and to develop future-oriented policies that reward investments in innovation. Chiesi is committed to producing shared value for its patients and communities as well as taking decisive action to lead the industry in our approach to innovating for sustainability.

CREATING SHARED VALUE FOR PATIENTS, THEIR COMMUNITIES AND THE ENVIRONMENT

Chiesi has taken active steps to formalise and apply its commitment to long-term sustainability, as defined in the United Nations 2030 Agenda for Sustainable Development.[6] As a pharmaceutical company this gives us a dual role: taking care of our patients whilst also taking care of the environment.

As a Benefit Corporation and certified B Corp, Chiesi is committed to creating shared value, an approach that aims to generate economic value in a way which also benefits society by addressing its needs and challenges. This means improving the outcomes of patients while also benefiting the communities where the company operates and the planet.

In 2019, Chiesi was the first pharmaceutical company to announce that we would lead the way to address the impact of the propellant in pMDIs. To preserve patients' choice whilst addressing serious environmental concerns, Chiesi is transitioning its inhaler portfolio by introducing alternative propellants in turn reducing the carbon footprint of its MDIs by up to 90%, similar to the level of dry powder inhalers (DPI).[3,4,7] This will play an important role in Chiesi's efforts to achieve Net Zero emissions by 2035.

The transition puts into action the principle of shared value. The project prioritises the needs and interests of patients; ensures that the whole range of therapeutic solutions remains accessible; minimises the environmental impact; and integrates sustainable practices into business operations.

AMBITIOUS ENVIRONMENTAL OBJECTIVES NEED INNOVATION AND INVESTMENT

Chiesi's commitment to creating shared value implies investment in research and development efforts to advance medical knowledge and develop innovative solutions. By pushing the boundaries of science and technology, they can contribute to improved and sustainable treatment options aimed at increasing patients' quality of care.

The carbon minimal pMDI will include the propellant HFA-152a which has a low GWP (GWP value is approximately ten times lower than HFA-134a, the propellant currently used).[5] 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.[1]

In May 2022, Chiesi completed pharmacokinetic (PK) studies on a product with positive results showing evidence of similar lung deposition, systemic exposure, safety and tolerability of the formulation when compared to the current one.[4] With these first PK studies completed, Chiesi is on track in the development of a platform of carbon minimal pMDIs, to enable a seamless transition for patients and to benefit the planet.

It is crucial to Chiesi that national health policies to reduce the environmental impact of inhalers are carefully and holistically considered, prioritising patient centricity in the interest of the most beneficial therapeutic outcome.

Chiesi understands that moving to lower carbon inhalers is a key element in delivering carbon reductions for many health systems on their path to reaching Net Zero for example, the NHS targets to achieve this by 2040.[8] The significance of greener alternatives such as low GWP propellants and inhaler disposal in helping to reach these targets can also not be underestimated. Chiesi will continue to share, learn and partner with health care systems and related stakeholders, with the purpose to enable environmentally conscious initiatives and co-create sustainable solutions in the interest of respiratory patients and future respiratory care.

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.[9,10,11,12,13] The choice of the most suitable inhaler is a complex decision taken between doctor and patient; pMDIs need to remain available so treatment options can remain personalised.[14] Chiesi strives to minimise the impact of those treatments on the environment and to continue investing in their DPI platform.

The European Respiratory Society's Position on Asthma and the Environment addressed this: *'Data show that inhaler devices should not be considered interchangeable with regard to their pharmaceutical performance. Each of the five classes of device has a different way in which the patient inhales from the device. Switching patients from one inhaler type to another is not a simple process. Decisions about the choice of the inhaler device should be made on an individual clinical basis between healthcare professionals and patients.'*[14]

Patient health and wellbeing are the final goal of Chiesi's current and future therapeutic solutions and globally, the company is committed to maintaining access to the range of treatment options that patients need.

COMMITMENT TO LONG-TERM, LIFECYCLE SUSTAINABILITY

Everyone has a role in the fight against climate change. Chiesi calls for decision makers, peers and partners across the value chain to take a holistic approach, preserving the interest of the patients while progressing and rewarding environmental sustainability. For example, encouraging the recycling of inhalers, educating patients in optimising inhaler technique and use, decreasing the reliance on short-acting beta agonist (SABA) pMDIs and promoting patient adherence to maintenance therapy[11,13] would benefit both patients and the planet. This requires a regulatory environment built on trust and ongoing dialogue.

In addition, Chiesi believes that HFC phase-down strategies, such as the EU F-Gas Regulation,[2] should, in the interest of patients' continuity of care, consider the unpredictable

timelines of pharmaceutical development and the uncertainties of the regulatory approval process.

Chiesi is proud to have taken decisive and ambitious action to ensure patients access to diversified treatment options that best suit their needs, whilst innovating to find the most environmentally conscious solution.

References

[1] Ozone Action Kigali Fact Sheet. The Kigali Amendment to the Montreal Protocol: HFC Phase-down 2017 Available at: https://multimedia.3m.com/mws/media/1365924O/unep-fact-sheet-kigali-amendment-to-mp.pdf Accessed June 2023

[2] European Commission. Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0150 Accessed June 2023

[3] United Nations Environment Programme. Report of the Technology and Economic Assessment Panel, September 2022. Available at: https://ozone.unep.org/system/files/documents/TEAP-Decision-XXVIII-2-HFC-%20Alternatives-report-sept2022.pdf Accessed June 2023

[4] Chiesi press release, 2022. Available at: https://www.chiesi.com/en/first-carbon-minimal-pmdi-is-on-track-with-the-goal-to-benefit-patients-and-planet/ Accessed June 2023

[5] On Drug Delivery. Panigone, Sandri, Nicolini. An environmentally sustainable, patient-centred solution for asthma and COPD. 16 April 2020. Available at: https://www.ondrugdelivery.com/an-environmentally-sustainable-patient-centred-solution-for-asthma-copd/ Accessed June 2023

[6] United Nations Sustainable Development. Available at: https://www.un.org/sustainabledevelopment/development-agenda Accessed June 2023

[7] National Academy of Medicine. Action Collaborative on Decarbonizing the U.S. Health Sector Climate Collaborative. Available at: https://nam.edu/programs/climate-change-and-human-health/action-collaborative-on-decarbonizing-the-u-s-health-sector/climate-network-organizations Accessed June 2023

[8] NHS England. Delivering a Net Zero NHS. September 2020. Available at: https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf Accessed June 2023

[9] Bonini, M., Usmani, O.S. The importance of inhaler devices in the treatment of COPD. COPD Res Pract 1, 9 (2015)..

[10] Dekhuijzen PN, Vincken W, Virchow JC, Roche N, Agusti A, Lavorini F, van Aalderen WM, Price D. Prescription of inhalers in asthma and COPD: towards a rational, rapid and effective approach. Respir Med. 2013 Dec;107(12):1817-21

[11] Lavorini F. Inhaled drug delivery in the hands of the patient. J Aerosol Med Pulm Drug Deliv. 2014 Dec;27(6):414-8

[12] Usmani O.S., Scullion J., Keeley Our planet or our patients – is the sky the limit for inhaler choice? The Lancet Respiratory Medicine. 2019 Jan;7(1):11-13

[13] Azzi E. A., et al. Understanding reliever overuse in patients purchasing over-the-counter short-acting beta2 agonists: an Australian community pharmacy-based survey. BMJ Open. 2019; 9(8):e028995.

[14] European Respiratory Society. Position statement on asthma and the environment, 05 May 2021. Available at: https://www.ersnet.org/wp-content/uploads/2021/04/ERS-position-statement-on-asthma-and-the-environment-5-May-2021.pdf Accessed June 2023