International Pharmaceutical Aerosol Consortium

A Multi-Stakeholder Approach to Minimizing the Environmental Impact of Inhaled Therapies and Improving Patient Care

A Proposal for Discussion

Purpose

This paper sets out initial thoughts from members of the International Pharmaceutical Aerosol Consortium (IPAC) on a proposed patient outcome-based approach to reduce the carbon footprint of patients using inhaler treatments, and therefore simultaneously supporting improvements in patient care **together with** reducing the environmental impact of inhaler devices.

This paper was prepared in response to the ambition set out in the NHS England Long Term Plan to halve emissions from inhalers by 2030 and in support of the action plan being developed by the NHS England and NHS Improvement Inhaler Working Group led by the Sustainable Development Unit (SDU). The core elements of this proposal, to undertake focused interventions to improve inhaler use, also align with the work being undertaken by the national Taskforce for Lung Health[1].

The overarching vision of this proposal is to introduce a fully integrated model of inhaler management and disposal that can become embedded into 'business as usual' for pharmacists, whilst in parallel, industry and the NHS undertake efforts to inspire and prepare for transition to low carbon inhalers. Low carbon inhalers include DPIs, SMIs, and pMDIs with lower global warming potential propellants (under development). It is important to note that some SMIs and DPIs are reusable which lowers the impact of plastic waste. Taking active measures along the patient journey has the potential to reduce the overall environmental impact of the component parts of inhalers, whilst supporting improvement in patient outcomes of their condition. It is also important to encourage and support innovation for new technologies, including pMDIs using novel, low carbon medical propellants.

The paper proposes a multi-stakeholder, co-creation approach, focused on improving specific elements of the patient journey. Each element has the potential for improving patient outcomes as well as minimizing environmental impact. Combining all elements together into a fully integrated programme provides the opportunity for focused activities at each touchpoint of the patient journey, including supporting correct diagnosis, effective prescribing, inhaler device choice, device training, waste management and the effective disposal of inhaler components.

[1] https://www.blf.org.uk/taskforce/plan

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM (IPAC)

IPAC is a group of companies that manufacture medicines, including pressurised metered dose inhalers (pMDIs), reusable soft mist inhalers (SMIs), and dry powder inhalers (DPIs) for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). IPAC's members are AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, GlaxoSmithKline and 3M.

IPAC was formed in the early 1990s in response to the mandates of the Montreal Protocol and fully supported a timely and effective transition away from chlorofluorocarbons (CFCs) under the Montreal Protocol that balanced patient health and environmental concerns. HFC MDIs played a critical role to the transition as one of the key ozone-friendly alternatives developed to replace CFC MDIs. IPAC members and others invested significant resources to research and develop HFC MDIs, DPIs, and SMIs as therapeutic options for patients. A core lesson from the transition under the Montreal Protocol is the importance of undertaking a holistic view of the environmental impact of inhaled therapies, *not solely focusing on the propellant*.

IPAC would be pleased to collaborate with NHS, the UK government and other key stakeholders to co-create policies and initiatives for inhaler devices.

OVERVIEW

Inhalers are the mainstay of treatment for many patients with lung conditions in the UK. However, there is an impact on our environment from the current manufacturing, use and disposal of inhaler devices because of the propellant gas used in pMDIs and the plastic associated with all devices. Lower carbon inhalers, such as DPIs and SMIs (reusable), are currently available for patients and can be prescribed in many cases. There are, however, patients who will continue to require a pMDI for optimal disease management. A critical objective is to preserve the range of therapeutic options for patients. Innovative low carbon inhalers that will use a new, low global warming potential (GWP) propellant are also under development and should ensure preserving therapeutic options for patients. In the near term, reducing the environmental impact of the current propellant gas and plastics needs to be tackled as a matter of urgency.

Manufacturers of inhalers are one of a number of stakeholders that have a responsibility to take action. All contributors to the patient and inhaler journey such as manufacturers, prescribers, healthcare professionals, dispensers, patients and waste management agencies have a role to play.

The UK Parliament Environmental Audit Committee Report 2018 focuses on the propellant gases (HFC 134a and HFC 227); however, the propellant is only part of the carbon footprint of pMDIs and subsequent environmental impact of inhaler treatment. Whilst it is important that we continue to reduce the environmental impact of inhaled therapies, there are a number of interdependencies associated with the treatment pathways for patients using inhaler treatments that compound the scale and complexity of the issue, including treatment adherence and ensuring appropriate inhaler technique. It should be noted that the European Fluorinated Gas (F-gas) Regulation exempted HFC MDIs as of 2018. In adopting the Kigali Amendment to the Montreal Protocol, the EU and other Parties recognized that HFCs would remain critical for MDIs and some other applications and, therefore, adopted a phase-down, rather than phase-out, approach.

There are four discrete touchpoints, listed below, across the journey for every patient using inhaler treatments, with Pharmacists (either practice- or community-based) being at the interface of all points:

- Supporting the selection of the most appropriate drug and device;
- optimising the use of the device;
- the ongoing supply; and
- the waste disposal.

It is assumed that a patient who experiences poor symptom control as a result of possible inappropriate device choice, poor adherence to maintenance treatment, or deterioration of condition, is likely to be a higher user of healthcare resources, thereby contributing to the collective carbon footprint associated with inhaler devices.

This proposal suggests we should go beyond simply addressing the environmental impact of inhalers, but rather to approach the solution from the patient journey perspective and consider opportunities at each point with healthcare professionals (in the case of this proposal – pharmacists) to optimise care and the use of inhalers.

TARGET AUDIENCE

This paper is for all relevant stakeholders involved in the manufacture, prescribing, commissioning, supply, dispensing and waste collection of inhalers, primarily in England but may also be applicable for devolved authorities in the UK.

Key audiences initially will be:

- Inhaler manufacturers
- NHS England Chief Pharmaceutical Officer/National Clinical Director for Respiratory
- NHS England Practice Based Pharmacist Programme Lead
- NHS England (NHSE) Pharmacy Waste Contract Manager
- NHS Improvement GIRFT*/RightCare Programme Leads

- Pharmaceutical Services Negotiating Committee (PSNC)
- Local Pharmaceutical Committee (LPC)
- Primary Care Respiratory Society (PCRS)
- British Thoracic Society (BTS)
- MHRA
- NICE
- UKIG
- Patient Groups (including Asthma UK and British Lung Foundation)

BACKGROUND

Since the start of the *Montreal Protocol on Substances that Deplete the Ozone Layer (1987)*, pMDIs have been a focus of attention from national and international agencies. Whilst the transition from CFC-based pMDIs achieved the intended effect of reducing the impact on the Ozone layer, the replacement propellants, Hydrofluorocarbons (HFCs), have a high GWP. HFCs are used predominantly in refrigeration and air-conditioning systems; however, they are also used as the propellant in pMDIs. After extensive research and safety testing, HFCs were identified as the optimal replacement for CFCs and also have a significantly lower global warming potential than CFCs. HFCs remain in the atmosphere for 14-34 years[2] and therefore the GWP is compounded by this longevity.

The UK Government is currently reviewing the *UK Progress on Reducing F Gas Emissions*. The report from the Environmental Audit Committee (EAC) shines a spotlight on the level of emissions from inhalers, the types of inhalers used in the NHS, and the volume of propellant in pMDIs that are disposed of in domestic waste and consequently finding their way to landfill sites. The release of residual HFCs into the atmosphere from domestic waste management activities cannot be controlled. Efforts should therefore be made to divert inhaler waste from the domestic system to more environmentally sustainable solutions.

The EAC report recommends that the UK Government should work with medical professionals, pharmacists, the pharmaceutical industry and patients to move towards a lower carbon impact for inhaled therapies, including higher use of DPIs and significantly improving recycling rates for inhalers. The NHS Long Term Plan and the Report published by the Taskforce for Lung Health (2018) highlight the need for patients, supported by pharmacists, to choose the best inhaler for their treatment and to have regular reviews to

[2] https://unfccc.int/process/transparency-and-reporting/greenhouse-gas-data/greenhouse-gas-data-unfccc/global-warming-potentials

support adherence. The Long Term Plan acknowledges the need for patients to be supported for the correct use of inhalers and to reduce the use of short acting bronchodilator inhalers (which currently represent approximately 60% of prescribed pMDIs in the UK). Interventions to support patients with their inhalers can link where appropriate to supporting efforts to reduce the environmental impact of inhalers at various stages of the patient journey.

VISION - IMPROVING PATIENT OUTCOMES AND MINIMIZING ENVIRONMENTAL IMPACT
A PROPOSED APPROACH

By taking a patient and inhaler journey approach, the vision of the programme is to improve patient outcomes as well as reducing the carbon footprint associated with managing respiratory illnesses. ***A patient-centric approach will maximize potential carbon savings while improving patient care.***

The proposed programme utilises the opportunities and touchpoints of direct patient contact with their health care team, including pharmacy staff to address some of the challenges associated with treatment and management of respiratory conditions, as set out in the recently published NHS Long Term Plan, in combination with focused efforts on reducing inhaler emissions through more effective prescribing, waste management, disposal and recycling of the component parts of inhaler devices. The integration of all elements of the programme across primary care and community pharmacy touchpoints will be the critical success factor for the programme. No one element of the programme should operate in isolation and robust evidence to support assumptions should be available.

Operating in tandem with the pharmacy-led interventions will be review and analysis of options for disposal of the propellant gas and device plastics. There is some data on the carbon reduction effects of different methods of disposal as well as some awareness of the value of recovered propellant and an assumption that recovery and resale into non-medicinal markets will achieve a greater carbon reduction than existing incineration methods. However, such assumptions and analysis will need to be validated.

The programme centres on establishing a patient engagement and support programme combining medicines optimisation and waste management interventions. The interventions will encourage patients to take active steps, supported by practice-based and community pharmacists, to contribute to helping reduce the carbon footprint of inhalers. The programme will be structured around four components:

- **Patient-focused education, choice and support**: Health care providers and pharmacists will support patients with inhaler device choice, educate patients on their prescribed treatments' aims, and encourage adherence to prescribed maintenance

treatment, to ensure good control and thereby reduce reliance on reliever medications, and to seek healthcare advice should demand for their reliever medication increase. In some instances (e.g., online purchases), solutions such as interactive messages may need to be deployed. Published inhaler choice guidelines should be deployed: https://www.guidelines.co.uk/respiratory/inhaler-choice-guideline/252870.article.

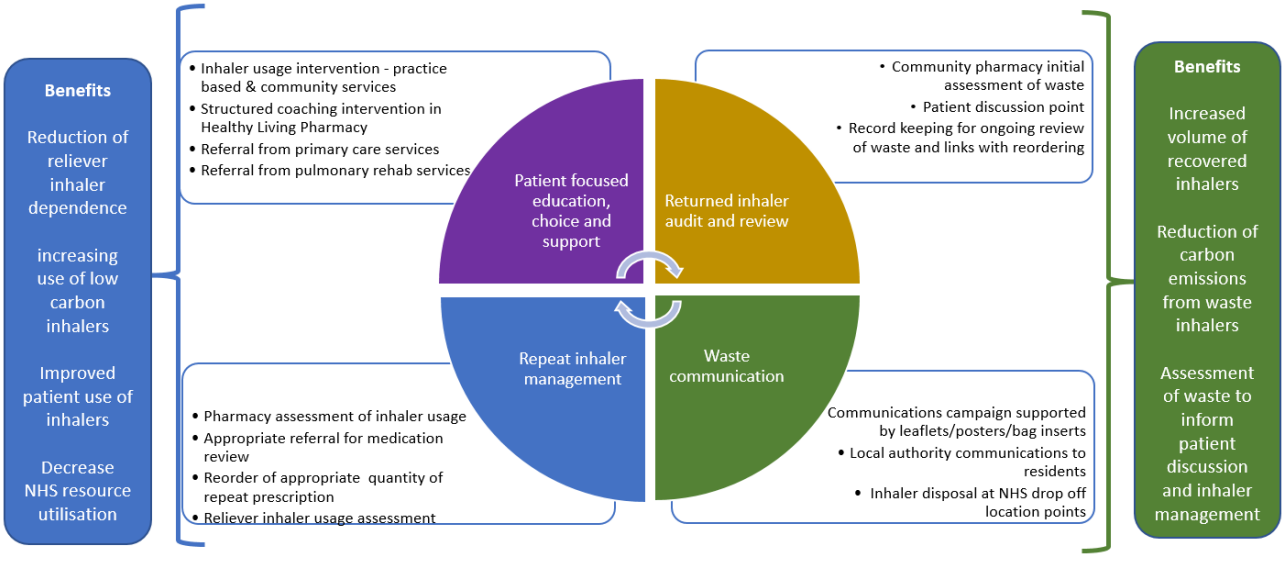
- **Repeat inhaler management**: Prescription guidance for pharmacies and patients to ensure ongoing supply is appropriate for patient's need. Where appropriate, refer for support.

- **Returned medicine audit and review**: An initial assessment can be undertaken at the pharmacy with a review of returned waste inhalers to identify adherence issues, help tackle over-prescribing and/or reliever over-reliance. Where appropriate, refer for support. Longer term audits should be undertaken at the waste collection point with a waste analysis reporting function built into the disposal/recovery contract.

- **Waste Communication**: Provision of information to patients and the public of inhaler disposal options and locations.

By combining all four programme components, and associated activities (see fig 1), and integrating into existing community pharmacy and primary care services, the efforts to reduce the carbon footprint and other environmental impacts across the patient and inhaler journey has the potential to achieve a greater impact on treatment and environmental outcomes than each component in isolation.

Fig 1: Programme components - Reducing the carbon footprint of the patient and inhaler journey



Role of Industry

Manufacturers of inhalers have an important role to play in supporting the reduction of the carbon footprint of inhalers. We will do this in several ways: helping ensure patient access to low carbon devices (e.g., DPIs and SMIs), through innovation and development of new low global warming potential propellant gases, developing inhaler devices with lower environmental impacts, developing reusable inhaler components, providing appropriate environmental information to healthcare professionals and patients, and supporting the development and implementation of NHS-led programmes. Technology innovation is also aimed at increasing adherence and minimising waste.

For this proposal, we will help to mobilise stakeholders and provide support and resources to scope the programme. Ongoing industry participation will be determined as the work progresses. The MHRA also has a central role to play and, where possible, expedited review of new innovative technologies should be considered.

Getting Started

Translating this proposal (or any other options) into a feasible proposition will require a multi-stakeholder, phased approach. The following suggested phases allow for stakeholders to co-create and shape the detail of the model, to ensure it is practical and scalable and will deliver the expected benefits of improving patient care and reducing the overall carbon footprint of the patient and inhaler journey. The timescales shown below are estimates and most likely some aspects of each phase will mature faster than others. An important element of the programme will be to identify 'quick wins' and prioritise these within the plan.

Phase 1 (3 – 6 months)

a) Refining the vision
b) Identify 'quick win' activities and prioritise these within the planning
c) Securing buy-in from stakeholders
d) Understanding industry contribution (short, medium & longer term)
e) Budgetary considerations and funding models, including incentives, for all parties
f) Understanding timescales for programme development

Phase 2 (6 months)

a) Development and user testing of communications material
b) Detailing the component activities and supporting resources
c) Refine financial and carbon footprint modelling

Phase 3 (6 months)

a) Launch communications
b) Testing and refining initiatives within 'pilot' locations

Phase 4 (12-24 months)

a) Track progress on recovery and disposal
b) Engage MHRA on innovative technologies
c) Track progress and feedback from patient and clinical communities
d) Progress development and investment in low carbon propellants and other technologies – updates will be provided as allowed within commercial sensitivities

SUMMARY & CALL TO ACTION

Inhalers are the mainstay of treatment for many patients with lung conditions in the UK. Availability of DPIs, SMIs, and innovation of the pMDI platform, with the introduction of low carbon propellants will, over time, significantly reduce the environmental impact of the devices. In the meantime, we must ensure that efforts to reduce the carbon footprint of inhalers do not undermine patient care and choice and patients receive the inhalers they need. Seeking to improve the outcomes for patients while reducing the environmental impact of current inhaler devices needs to be tackled from a multi-stakeholder approach and should include all contributors to the patient and inhaler journey.

This paper sets out one proposed approach in which all contributors can take part. This approach goes beyond simply addressing the environmental impact of inhalers but focuses on the wider challenge of the carbon footprint of the sub-optimally controlled respiratory patient by considering all touchpoints along the patient journey, ending with effective waste management of inhalers through pharmacies and future options for optimised end of life specialist disposal of the component parts of all inhalers.

IPAC calls on all stakeholders to work together to shape a new approach to the challenge and to co-create a comprehensive programme to improved patient outcomes whilst reducing the overall carbon footprint of the patient journey and the environmental impact of inhalers.