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RESEARCH

# Estimation of carbon emissions from inhaled respiratory medicines in Ireland: a cross-sectional study from a national pharmacy claims database from 2020 to 2022

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## Abstract

**Introduction** Inhaled therapies are essential for managing asthma and chronic obstructive pulmonary disease (COPD), but device choice carries environmental consequences. Inhaler devices influence climate impact; propellant-based metered-dose inhalers (MDIs) have substantially higher carbon footprints than non-propellant inhalers (NPIs). Ireland has committed to net-zero greenhouse gas emissions by 2050, making prescribing practices a relevant focus for mitigation.

**Aim** To describe national dispensing patterns of inhaled respiratory medicines and estimate associated $CO_2$-equivalent ($CO_2e$) emissions in Irish primary care, 2020–2022.

**Method** We analysed Health Service Executive–Primary Care Reimbursement Service (HSE-PCRS) dispensing data for inhaled respiratory medicines (ATC R03) products. Items were classified as MDIs or NPIs. Trends of inhalers use were expressed as year-on-year inhalers dispensed. We conducted scenario analysis in which 10%, 25%, and 50% of 2022 MDIs use were replaced with NPIs to calculate the reduction in carbon emissions. Notably, PCRS schemes cover ~ 43% of the Irish population (predominantly older adults and a lower income group).

**Results** Between 2020 and 2022, a total of 9.94 million inhalers were dispensed under HSE-PCRS schemes, with annual volumes rising from 3.04 million (2020) to 3.60 million (2022)**.** MDIs increased from 1.50 million (2020) to 1.79 million (2021) and 1.95 million (2022), while NPIs declined − 15.7% in 2021 and then rebounded + 26.8% in 2022. The MDIs share of all inhalers changed from 49.2% (2020) to 57.9% (2021) to 54.2% (2022) for which estimated MDIs carbon emissions were 28.6, 34.6, and 37.6 kt $CO_2e$, respectively. This emission was accounted for 95–96% of inhaler-related emissions annually. In scenario analyses, replacing 10%, 25%, and 50% of 2022 MDIs use with NPIs resulted in estimated emission reduction of ~ 3.6, 8.9, and 17.9 kt $CO_2e$, respectively.

**Conclusion** The results show how MDIs influence the carbon footprint of the health sector and they encourage healthcare providers to support sustainable alternatives. When clinically appropriate, choosing sustainable devices provides significant, short-term CO2 savings without sacrificing treatment.

**Keywords** Asthma · Carbon footprint · Chronic obstructive · Dose inhalers · Drug prescriptions · Dry powder inhalers · Inhalation therapy · Metered · Pulmonary disease

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## Impact statements

- When non-propellant inhaler is clinically appropriate, choosing it over a metered-dose inhalers can reduce the treatment's carbon footprint without sacrificing efficacy.
- Device reviews and counselling for using technique and suitability can help in low global warming potential choices and reduce avoidable short acting β agonist containing metered-dose inhalers' use.

- Even a 10% metered-dose inhalers to non-propellant inhaler switch in 2022 would have saved ~ 3.6 kt $CO_2$e; scaled policies could yield larger and immediate gains.
- At the national level, formularies and purchasing mechanisms can mandate standards for environmental sustainability, therapeutic efficacy, and cost-effectiveness.

## Introduction

Asthma and chronic obstructive pulmonary disease (COPD) are major global health challenges, causing significant morbidity, mortality, and healthcare costs. Inhaled therapies are the central to disease management for COPD, but the inhaler device selection has environmental implications [1, 2]. Metered-dose inhalers (MDIs) use hydrofluoroalkane (HFA) propellants, which, while safe for the ozone layer compared to the previously used chlorofluorocarbons, remain potent to release greenhouse gases (GHG). Hydrofluoroalkane-134a has a global warming potential (GWP) of ~ 1,300, and HFA-227ea exceeds 3,000, meaning that each actuation of an MDI contributes significantly to GHG emissions [2]. In contrast, non-propellant inhalers (NPIs), such as dry-powder inhalers (DPIs) and soft-mist inhalers (SMIs), have a substantially smaller life cycle carbon footprints, often < 20 g $CO_2$e per device compared with > 10 kg $CO_2$e for MDIs [3–5]. At a global level, greenhouse gas emissions reached 59.1 gigatonnes $CO_2$e in 2019, and healthcare accounts for between 5 and 15% of national emissions depending on the country [8]. Within this healthcare portion, data from United Kingdom (UK) shows that, the inhalers contribute an estimated 3–4% of the entire National Health Service (NHS) carbon footprint, with MDIs accounting for the vast majority of inhaler-related emissions [6, 7]. This emphasizes that healthcare interventions, including inhalers can have a meaningful climate impact. Studies have demonstrated that replacing even a modest proportion of MDIs with NPIs could save hundreds of kilotonnes of $CO_2$e annually without compromising clinical care [8–12]. Healthcare guidelines demonstrate the need to reduce the $CO_2$e related to inhalers.

For example, The European Respiratory Society has explicitly called for prescribers to consider the environmental footprint of inhaler devices where clinically appropriate [13]. Internationally, the Paris Agreement commits nations to achieving net-zero carbon emissions by 2050 [14, 15], and Ireland has aligned with this target in its Climate Action Plan, pledging a 51% reduction in national emissions by 2030 and net-zero by 2050 [16]. Clinician-led device selection can significantly reduce inhaler related emission, but achieving national targets in any health system needs systematic management including formulary design, reimbursement incentives, procurement standards, recycling programmes, and public education [17].

This study, based on Irish prescription-dispensing claims, quantifies inhaler-related $CO_2$e and applies a reproducible calculation (dispensed items multiplied by published per-inhaler factors). We also illustrate a substitution scenario for 2022 to show the potential emission reductions if some metered-dose inhaler use were replaced with clinically appropriate non-propellant devices. The workflow is transferable: payers and clinicians can estimate local footprints, test feasible device-mix changes consistent with the recommendations of the Global Initiative for Asthma (GINA) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD), and use these estimates to inform medicines-use decarbonisation plans.

### Aim

This study therefore aimed to describe national prescribing patterns of inhaled respiratory medicines in Irish primary care between 2020 and 2022, and to estimate the associated $CO_2$e emissions using published emission conversion factors. By providing Ireland-specific evidence, this analysis highlights the contribution of inhaler prescribing to the healthcare sector's carbon footprint.

## Method

### Data source

This was a retrospective, observational study using dispensing data from the Health Service Executive–Primary Care Reimbursement Service (HSE-PCRS) covering the period January 2020 to December 2022. The PCRS database captures reimbursed medicines dispensed in community pharmacies under national public health schemes, including the General Medical Services (GMS), Drugs Payment Scheme (DPS), Long-Term Illness (LTI), and High-Tech arrangements. Collectively, these schemes cover approximately 43% of the Irish population, predominantly older adults and socioeconomically disadvantaged groups, and thus represent a large and policy-relevant subset of the population [18].

### Data extraction and eligibility criteria

All inhaled respiratory medicines were identified using the Anatomical Therapeutic Chemical (ATC) classification system (R03: Drugs for obstructive airway diseases). Data were extracted at the product level and aggregated annually. Information obtained included ATC code, product name, number of dispensed items, and device type. All MDIs, DPIs, and SMIs dispensed under PCRS schemes during 2020–2022

were included. Nebulised formulations, oral respiratory drugs, and non-inhaled formulations were excluded because they are not the source of carbon emission.

## Classification of inhaler types

1. *MDIs (metered-dose inhalers)*: propellant-based devices using hydrofluoroalkane (HFA) propellants.
2. *NPIs (non-propellant inhalers)*: DPIs and SMIs, which do not require propellants.

Combination products were classified by their device type (e.g., an ICS/LABA DPI was counted as an NPI). Table 1 provides examples of product classifications and corresponding ATC codes.

## Estimation of carbon emission

This carbon emission estimation is in line with the approach used by Have et al. 2022 [19]. We first obtained per-inhaler $CO_2$e conversion factors for each MDIs therapeutic class from 2 sources (Wilkinson; Jeswani & Azapagic) [8, 20]. For each class, we report both values in Table 2 and use their mean as the class-specific factor in subsequent calculations. Not all the inhaler types were listed in the emissions tables published by Wilkinson et al. or Jeswani and Azapagic. Where data were unavailable, assumptions used in other comparable studies were applied which is adopted by Have et al. [19]. We then computed annual emissions by multiplying dispensed number of inhalers by these class-specific mean factors (for MDIs) or by 1 kg $CO_2$e per pack for all NPIs (DPIs/SMIs) [19]. For each year, we calculated a dispensing-weighted mean $CO_2$e per MDI by applying the fixed, product-level $CO_2$e conversion factors (Table 2) to annual dispensing volumes and averaging across all MDI products. Thus, any year-on-year (YOY) change in the mean reflects changes in the

**Table 2** Conversion table for carbon emission (Step-by-step calculation process)

| Therapeutic class | $CO_2$e per inhaler (Wilkinson) [8] | $CO_2$e per inhaler (Jeswani) [18] | Assumption applied Mean value used |
|---|---|---|---|
| SABA (MDI) | 17.2 kg | 19.5 kg | 18.4 kg |
| ICS (MDI) | 14.3 kg | 16.8 kg | 15.6 kg |
| LABA (MDI) | 15.1 kg | 16.0 kg | 15.6 kg |
| ICS/LABA (MDI) | 18.9 kg | 20.1 kg | 19.5 kg |
| LABA/LAMA/ ICS triple (MDI) | 19.0 kg | 21.0 kg | 20.0 kg |

*ICS* Inhaled Corticosteroids, *LABA* Long-acting beta-agonists, *LAMA* Long-acting muscarinic antagonist, *SABA* Short-acting beta-agonists, *SAMA* Short-acting muscarinic antagonist. *Source* Emission factors/per-inhaler $CO_2$e adapted from Wilkinson et al., [8] and Jeswani HK & Azapagic A., [18]

**Table 1** Classification of inhalers by ATC code and device type

| ATC codes | Class of drug | Drug name | Formulation |
|---|---|---|---|
| R03AC02 | SABA | Salbutamol | MDI/NPI |
| R03AC03 | | Terbutaline | NPI |
| R03AC12 | LABA | Salmeterol | MDI/NPI |
| R03AC13 | | Formoterol | NPI |
| R03AC18 | | Indacaterol | NPI |
| R03BA01 | ICS | Beclomethasone | MDI |
| R03BA02 | | Budesonide | NPI |
| R03BB01 | SAMA | Ipratropium | MDI |
| R03BB04 | LAMA | Tiotropium | NPI |
| R03BB07 | | Umeclidinium | NPI |
| R03AK06 | LABA + ICS | Salmeterol & Fluticasone | MDI/NPI |
| R03AK07 | | Formoterol & Budesonide | NPI |
| R03AK10 | | Vilanterol & Fluticasone | NPI |
| R03AL03 | LABA + LAMA | Vilanterol & Umeclidinium | NPI |
| R03AL04 | | Indacaterol & Glycopyrronium | NPI |
| R03AL05 | | Formoterol & Aclidinium | NPI |
| R03AL08 | LABA + LAMA + ICS | Vilanterol & Umeclidinium Bromide & Fluticasone | NPI |
| R03AL11 | | Formoterol & Glycopyrronium & Budesonide | MDI |

*ATC* Anatomical Therapeutic Chemical code, *ICS* Inhaled Corticosteroids, *LABA* Long-acting beta-agonists, *LAMA* Long-acting muscarinic antagonist, *MDIs* Metered Dose Inhalers, *NPIs* Non-propellant Inhalers, *SABA* Short-acting beta-agonists, *SAMA* Short-acting muscarinic antagonist

dispensing mix of MDI products/classes, not a change in the per-device factor.

### Statistical analysis

Descriptive statistics summarised annual counts and proportions. YOY percentage changes were calculated. Potential $CO_2e$ savings were estimated if 10%, 25%, or 50% of MDIs dispensed in 2022 were substituted with NPIs by using scenario analysis.

### Ethics approval

This is an observational study using anonymised, aggregated national dispensing data. Ethical approval was not required in accordance with national regulations.

## Results

Between 2020 and 2022, a total of 9.94 million inhalers were dispensed under HSE-PCRS schemes. Annual volumes increased steadily, from 3.04 million in 2020 to 3.60 million in 2022. MDIs accounted for 1.50 million items in 2020, rising to 1.79 million in 2021 and 1.95 million in 2022 (Table 3). YOY changes showed a + 19.6% increase from 2020 to 2021 and a further + 9.0% increase from 2021 to 2022. NPI use decreased by 15.7% between 2020 and 2021, but rebounded by + 26.8% in 2022. The proportion of MDIs among all inhalers increased from 49.2% in 2020 to 57.9% in 2021, before slightly declining to 54.2% in 2022 as shown in Table 3.

### Carbon emissions

Estimated emissions from MDIs were 28.6 kt $CO_2e$ in 2020**,** 34.6 kt in 2021, and 37.6 kt in 2022 shown in Table 4**.** NPIs contributed 1.54, 1.30, and 1.65 kt $CO_2e$, respectively. MDIs consistently accounted for 95–96% of inhaler-related emissions annually. Using fixed, product-specific $CO_2e$ factors, the dispensing-weighted mean $CO_2e$ per MDI was approximately 19.3 kg/inhaler and varied minimally across years, indicating limited year-on-year change in the MDI product mix. Table 5 shows that NPIs contributed only 1.3–1.6 kt $CO_2e$ annually, representing about 4–5% of total inhaler emissions. Their relative stability contrasts with the consistent rise in MDI emissions.

### Scenario analysis

If 10% of MDIs dispensed in 2022 had been substituted with NPIs, total emissions would have decreased by approximately 3.6 kt $CO_2e$. A 25% switch would have reduced emissions by 8.9 kt, and a 50% switch by 17.9 kt, demonstrating the potential carbon savings achievable through sustainable prescribing strategies.

## Discussion

This study demonstrates the first evaluation of inhaler-related carbon emissions that is unique to Ireland. Overall inhaler use rose steadily between 2020 and 2022, with MDIs increasing by about 20% and 9% annually, while NPIs use first declined before increasing again. MDIs, primarily SABA, were responsible for 95–96% of inhaler emissions annually. According to the scenario modelling, emissions could be reduced by about 3.6 kt $CO_2e$ if only 10% of MDIs were swapped out for NPIs. For comparison, the inhaler footprint under HSE-PCRS was approximately 30.1 kt $CO_2e$ in 2020, 35.9 kt in 2021, and 39.3 kt in 2022. This amounts to approximately 3.4%, 4.1%, and 4.5% of the HSE's 2019 baseline (~ 881.9 kt $CO_2e$). These percentages represent approximate estimates of the contribution of inhalers to national healthcare emissions because approximately 43% of the population is covered by PCRS [21]. Inhalers contribute about 3% of the NHS's carbon footprint in England; compared to the NHS's 2019 baseline of about 25 Mt $CO_2e$, that amounts to about 0.75 Mt$CO_2e$ annually, with MDIs. According to recent sales-based analyses, MDIs in Europe are responsible for approximately 3.9 to 4.0 Mt $CO_2e$ annually and with the UK contributing ~ 1.24 Mt $CO_2e$ [22]**.** Hydrofluoroalkane (HFA) propellants, primarily HFA-134a ($GWP_{100} \approx 1{,}300$) and HFA-227ea ($GWP_{100} \approx 3{,}350$), are the cause of this significant impact; therefore, even small propellant masses result in large $CO_2e$ totals [23]. Despite making up only about 2.3% of global GHG emissions, MDIs are expected to increase in proportion as other industries switch off HFCs, highlighting the need for lower-GWP propellants and the clinically appropriate use of non-propellant devices [24]. The climate crisis makes reducing healthcare's greenhouse gas emissions both a moral obligation and a practical necessity.

The results of our study showed an alarming trend of MDIs prescriptions rising in Ireland between 2020 and 2022, greater than the use of NPIs. Although Ireland's MDI prescription rate is lower than in countries such as the UK—where more than 70% of inhalers prescribed are MDIs [25] that is the higher than the European mean i.e. 47–50%—it is higher than in countries with more environment friendly healthcare policies, such as Sweden, where MDIs account for only 13% of prescriptions [26]. These prescribing differences reflect not only clinical preferences but also systemic influences such as healthcare infrastructure, regulatory frameworks, and climate-related policies. For example, Sweden's low MDI usage has been attributed to national climate

**Table 3** Annual counts of MDIs and NPIs dispensed, year-on-year (YOY) percentage change, and MDIs share

| Year | MDIs (n) | YOY % change | NPIs (n) | YOY % change | Total inhalers (n) | MDI share (%) |
|---|---|---|---|---|---|---|
| 2020 | 1,496,438 | – | 1542,223 | – | 3,038,661 | 49.2 |
| 2021 | 1,789,329 | +19.6 | 1299,823 | –15.7 | 3,089,152 | 57.9 |
| 2022 | 1,951,380 | +9.0 | 1648,865 | +26.8 | 3,600,245 | 54.2 |

*MDIs:* Metered Dose Inhalers*NPIs:* Non-propellant Inhalers YOY = Year-on-year change relative to the prior year. MDIs share = MDIs as a percentage of all inhalers dispensed

**Table 4** Estimated emissions from MDIs by therapeutic class (kt $CO_2$e)

| MDIs | MDIs prescribed N (%) | | | Carbon emission (kt) | | |
|---|---|---|---|---|---|---|
| Years | 2020 | 2021 | 2022 | 2020 | 2021 | 2022 |
| SABA | 954,839 (63.8) | 1,255,124 (70.2) | 1,363,459 (70.1) | 19.4 | 25.0 | 27.7 |
| LABA | 5,776 (0.4) | 5,762 (0.3) | 5792 (0.3) | 0.09 | 0.1 | 0.1 |
| ICS | 324,111(21.6) | 306,981 (17.1) | 341,612 (17.5) | 5.6 | 5.4 | 5.9 |
| SAMA | 28,325(1.9) | 27,919 (1.7) | 29,803 (1.5) | 0.4 | 0.3 | 0.4 |
| LABA + ICS | 183,387 (12.3) | 192,945 (10.8) | 197,583 (10.1) | 3.1 | 3.2 | 3.4 |
| LABA + LAMA + ICS | 0 | 212 (0.01) | 8518 (0.4) | 0 | 0.003 | 0.2 |
| Total | 1,496,438 | 1,788,946 | 1,946,767 | 28.6 | 34.6 | 37.6 |

*ICS* Inhaled Corticosteroids, *LABA* Long-acting beta-agonists, *LAMA* Long-acting muscarinic antagonist, *MDIs* Metered Dose Inhalers, *SABA* Short-acting beta-agonists, *SAMA* Short-acting muscarinic antagonist. *Note* Numbers in brackets indicate row-wise percentage of all MDIs in that year

goals and targeted efforts by health authorities to encourage environmentally sustainable prescribing [25]. This suggests that while clinical efficacy remains a key factor, environmental concerns and policy initiatives also play a significant role in shaping inhaler use across countries.

In our data, SABAs comprise ~ 70% of MDI prescriptions and ~ 67% of MDI-related emissions—consistent with SABA CARBON-Europe/Canada, which found SABAs generated ~ 66% of inhaler-related GHGs [27]. These results reflect a broader global trend in respiratory prescribing practices, where SABAs are widely used as first-line treatment for the rapid relief of symptoms in asthma and COPD patients [28].

Healthcare system urgently needs interventions to control MDIs overuse—especially SABAs—by promoting evidence-based inhaler use to optimize respiratory care and cut healthcare-related carbon emissions. Without action, environmental harm and suboptimal patient outcomes will persist; aligning policies with international benchmarks can help meet global sustainability goals and best practices. [29].

SABAs are typically prescribed for the prompt alleviation of acute respiratory symptoms, proving particularly effective during acute exacerbations [30]. It has been observed that, in the daily management of asthma, two-thirds of patients primarily depend on SABA [31]. This implies that a considerable number of patients rely on SABA to address day-to-day symptoms, instead of employing regular preventing therapy to proactively prevent symptoms and reserving SABA for acute episodes. This matters because over-reliance on, and overuse of, SABA spacer is associated with poor asthma control, increased risk of exacerbations and death [32]. In line with this, the latest GINA guidance recommends AIR (as-needed ICS–formoterol) and MART (maintenance-and-reliever therapy), which improve outcomes and inherently reduce SABA and MDIs use since most licensed AIR/MART products are DPIs—thereby advancing both patient care and environmental goals [33]. Importantly, SABAs remain essential for acute exacerbations, and MDIs used with a spacer are often the most appropriate device in this context.

In Ireland dispensing dataset, SABA reliever inhalers accounted for a substantial portion of propellant use and associated $CO_2$e emissions; focusing on appropriate preventive therapy and on non-propellant devices where clinically suitable could therefore deliver meaningful, immediate emission reductions without compromising care [6, 34]. When patients cannot reduce SABA use, selecting lower-impact

**Table 5** Overview of the NPIs prescribed and their estimated carbon emissions

| Year | NPIs N | Carbon emission (kt) |
|---|---|---|
| 2020 | 1,541,944 | 1.5 |
| 2021 | 1,299,818 | 1.3 |
| 2022 | 1,648,470 | 1.6 |

*NPIs* Non-propellant Inhalers; Assumed 1 kg $CO_2$e per NPI inhaler

inhalers becomes crucial. Switching from high-GWP to low-GWP options can cut both costs and emissions; a BMJ Open analysis of 2017 NHS England data estimated that replacing just 10% of MDIs with the cheapest equivalent DPIs would save ~ £8.2 million per year and reduce emissions by ~ 58 kt $CO_2$e [8, 10].

In line with scenario-modelling across 5 European countries, which projects larger $CO_2$e reductions from transitioning to low-GWP propellant pMDIs than from large-scale device substitution—and additional, though smaller, gains from SABA optimisation—we interpret Ireland's device-mix trends against a spectrum of feasible levers, while recognising clinical appropriateness and patient choice as central considerations [20]. The environmental effect of MDIs is further reduced by programmes like inhaler recycling, which collect propellants and cut waste. In order to choose inhalers that are in line with both healthcare and environmental standards, patients must be educated about the recycling of inhalers and financial, environmental, and clinical issues must be carefully considered [32]. In our study, no significant decreasing trend was observed in MDIs prescriptions over the three-year period. Therefore, it is necessary to identify the factors that drive switching from MDIs to NPIs. In literature, one reason behind the trend towards relying on MDIs over NPIs was the cost in different countries [35]. The second reason is that patients with stable respiratory conditions who are currently using MDIs are reluctant to transit to a DPIs. In these instances, as DPIs and MDIs exhibit clinical comparability in terms of effectiveness but only if the device is used correctly [36], this transition should not impact the patient's health. Moving away from MDIs is an important step in meeting the target of net-zero carbon emission [37].

### Study strengths

This study is based on national prescription claims data for PCRS (2020–2022) to assess the distribution of inhaler types and trends in $CO_2$e emissions, using a transparent, reproducible workflow that multiplies dispensed items by literature-based per-inhaler conversion factors. Medicines were consistently identified via ATC codes and device type (MDIs/NPIs), which enhances comparability and replication in other health systems. The approach is policy-relevant and readily scalable, providing actionable signals for procurement and stewardship without requiring primary clinical data collection.

### Study limitations

The dataset covers ~ 43% of the population and lacks clinical detail (indication, severity, adherence, wastage), also the figures reflected items dispensed rather than dose- or use-adjusted estimates. Because the study period (2020–2022) overlaps acute COVID-19, pandemic-related factors (exacerbations, precautionary use, refill extensions) may have affected the frequency of inhaler use independent of baseline clinical need. $CO_2$-equivalent comparisons for short-lived HFA propellants are sensitive to the selected time horizon (e.g., $GWP_{100}$ vs $GWP_{20}$), so absolute values should be interpreted as directional rather than exact values.

## Conclusion

Our research demonstrates a persistent increase in MDIs prescriptions in Ireland, accompanied by a corresponding rise in associated carbon emissions. SABAs are a significant contributor of the problem of GHG emission. To reach sustainability goals, we need targeted policies that support clinically appropriate device choice, limit unnecessary SABA use, and make NPIs more available. Future research should develop and evaluate healthcare approaches that reduce emissions while maintaining treatment efficacy.

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**Author contributions** All authors contributed to the study conception and design. Data extraction, analysis, and interpretation were performed by Hafsa Kanwal, **Cristin Ryan**, Umm-E-Kalsoom, and Amjad Khan. The first draft of the manuscript was written by Hafsa Kanwal, and all authors (**Theo Ryan, James Quinn, and Cristin Ryan**) commented on and revised previous versions of the manuscript. All authors read and approved the final manuscript.

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**Data availability** The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

**Competing interests** The authors declare no competing interests.

**Ethics approval** This is an observational study using anonymised, aggregated national dispensing data. Ethical approval was not required in accordance with national regulations.

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