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Climate conscious prescription of inhaled medication

S2k-Guideline

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und Beatmungsmedizin e.V.

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DEGAM

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List of abbreviations

CFC	Chlorofluorocarbons
COPD	Chronic Obstructive Pulmonary Disease
DDD	Defined Daily Dose
DMP	Disease management program
DPI	Dry Powder Inhaler
EU	European Union
GWP	Global Warming Potential
HFA	Hydrofluoroalkanes
ICS	Inhaled Corticosteroids
LABA	Long-Acting Beta-2 Agonist
LAMA	Long-acting muscarinic antogonists
MDI	metered dose inhaler
NCG	National Care Guidelines
NVL	Nationale Versorgungsleitlinie (national guideline)
SABA	Short-Acting Beta-2 Agonist

Table of content

1 Background

The healthcare sector in Germany is accountable for 5.2 % of CO_2 emissions, while healthcare systems in other countries contribute between 4.7 % (EU average) and 7.6 % (USA) to these emissions [1]. Within primary care, the prescription of medications accounts for the largest portion of the carbon footprint, followed by emissions from patient and staff mobility and heating [2,3].

Chronic respiratory diseases such as bronchial asthma and chronic obstructive pulmonary disease (COPD) are exacerbated by climate change and its causes, such as particulate matter pollution. Both conditions are common and their incidence is steadily rising [4]. Various types of inhalable medications are used in their treatment, and in turn, these contribute to climate change to varying degrees.

Inhalable medications are classified into propellant-driven metered-dose inhalers and dry powder inhalers (DPIs). DPIs contain the active ingredient(s) in powdered form, released and dispersed through inhalation, requiring a sufficient inspiration for an effective therapy. Conversely, metered-dose inhalers (MDIs) employ propellants to deliver the active ingredient(s) into the lungs.

Previously used chlorofluorocarbons (CFCs) as propellants were largely banned due to their impact on the ozone layer and were replaced by hydrofluoroalkanes (HFAs) in 1989 [5]. The comparison between DPIs and MDIs reveals a significantly higher potential for atmospheric damage (global warming potential - GWP) in MDI. While CO_2 has a GWP of 1, the commonly used norflurane (HFA 134a) in most DAs has a GWP of 1530, apaflurane (HFA-227ea) has a GWP of 3600 [6]. In total, MDIs account for 3.5 % of the total greenhouse gas emissions in the entire British healthcare system [7]. At the same time, the market share of DAs varies significantly worldwide (from 34 % in Japan to 88 % in the USA) [8]. In addition, production, packaging, and distribution of medications contribute to the overall climate footprint. Currently, these factors play a minor role compared to the propellant used [9] and are therefore not further addressed in this guideline.

Regarding the waste reduction, complete utilisation is also relevant. Only when inhalers are equipped with a built-in dose counter or an external dose counter is used, the number of remaining doses can be accurately tracked. Technically, MDIs still contain propellants even after the active ingredient is fully depleted [10,11]. This can lead to increased consumption due to premature reordering and higher risk of inadequate treatment when used without the active ingredient) [12,13].

2 Healthcare provision in Germany

In 2022, the market-share of metered-dose inhalers in Germany varied significantly between different active ingredients. Short-acting ß-agonists (SABAs) are predominantly prescribed as MDIs, while the share of MDIs for inhaled corticosteroids (ICS) and long-acting beta-2 agonist (LABAs) is considerably lower. The prescription numbers mentioned are from the Drug Prescription Report 2022 [14].

Table 1: Prescription figures

	Total prescription volume	Proportion of metered-dose Inhalers
Salbutamol (SABA)	233.7 million DDDs	98.4 %
Other SABAs	32.82 million DDDs	98.4 %
Combination of SABAs	95.3 million DDDs	97,7 %
LABA Monotherapy	73.0 million DDDs	13.7 - 18.1 %
ICS Monotherapy	134.8 million DDDs	46.1 - 49.3 %
ICS-LABA fixed-dose combination	421.9 million DDDs	10.8 - 48.1 %

3 Clinical Aspects of Therapy with Inhaled Medications

The selection of an inhalation drug device for individuals is influenced not only by empirical evidence but also by motor and cognitive capabilities of the patients. DPIs are generally not advised for children under 5 years [15] due to the need of a forceful inhalation manoeuvre, for elderly patients, and for those experiencing acute exacerbations.

Nevertheless, transitioning to more environmentally sustainable DPI options is viable for many patients. This shift has been proven to substantially decrease greenhouse gas emissions without compromising asthma management [16,17]. Research has demonstrated no clinically significant variance between DPIs and alternative inhaled medications [18,19].

Overall, guideline-based therapy reduces the consumption of potentially climate-damaging inhalants because:

- Non-adherence and inadequate handling technique impair treatment success, and
- Guideline-compliant treatment implies that PRN medication with SABA is very rarely required. Therefore, a high need for SABA indicates inadequate asthma control. Since SABAs have historically been predominantly used as MDIs, there is a potentially significant environmental impact.

4 Objectives of the Guideline

In light of this background, this guideline aims to assist in promoting changes in the prescription patterns of inhalable medications, thereby reducing the healthcare system's overall carbon footprint. It is intended for everyone involved in prescribing and counselling patients. This includes doctors and their practice teams, as well as pharmacists and other healthcare professionals.

The guideline:

- Summarises existing evidence regarding the decision between DPI and MDI, and
- Explicitly addresses the climate impact of propellants when choosing between DPIs and MDIs, and also highlights differences among MDIs.

5 Summary of Recommendations

What is new?

With the upgrade to S2k level, all recommendations from the S1 guideline, the algorithm, and the existing tools were revised. Additional tools and a chapter on disposal have been added.

6.1 Recommendation **Adolescents >12 years of age/adults with obstructive pulmonary disease should receive inhalation therapy (preferably with a DPI) in a climate-conscious manner. This also applies to PRN use.**	Outcome of the consensus process **Strong Consenus 7/7**
6.2 Recommendation **When prescribing an MDI, a preparation with a dose counter should be prescribed whenever possible.**	Outcome of the consensus process **Strong Consenus 7/7**
6.3 Recommendation **Patients with bronchial asthma who are prescribed more than 2x N1 SABA inhalers per calendar year should undergo a prompt therapy review.**	Outcome of the consensus process **Strong Consenus 7/7**
7.1 Recommendation **Combination preparations with the active substances cromoglicic acid/reproterol should not be prescribed.**	Outcome of the consensus process **Strong Consenus 7/7**
8.1 Recommendation **Children and adolescents, along with their guardians or caregivers, should be informed about the reasons for climate-conscious prescription.**	Outcome of the consensus process **Strong Consenus 7/7**
8.2 Recommendation **Inhalation technique and coordination should be reviewed in accordance with the national guideline (NVL) on asthma. If suitable for the patient, consideration should be given to transitioning to a climate-friendly DPI.**	Outcome of the consensus process **Strong Consenus 7/7**

8.3 Recommendation

After switching to a new inhalation device, it is essential to carefully and regularly assess its usage and the control of asthma symptoms.

Outcome of the consensus process
Strong Consenus 7/7

9.1 Statement

An effective disposal concept (similar to the established green cardboard box) must be established for the disposal of pressurised gas cartridges.

Outcome of the consensus process
Strong Consenus 7/7

6 Guideline recommendations for differentiated use

As part of a systematic guideline search, explicit recommendations for the use of specific inhaled medicines were extracted from current German and international guidelines for the treatment of bronchial asthma/chronic obstructive bronchitis.

Current guideline recommendations do not consider climate protection aspects. Potential alternatives for more climate-friendly inhalation should be considered in both acute and long-term management.

The following recommendations were adopted based on available evidence and as a result of the joint consensus process:

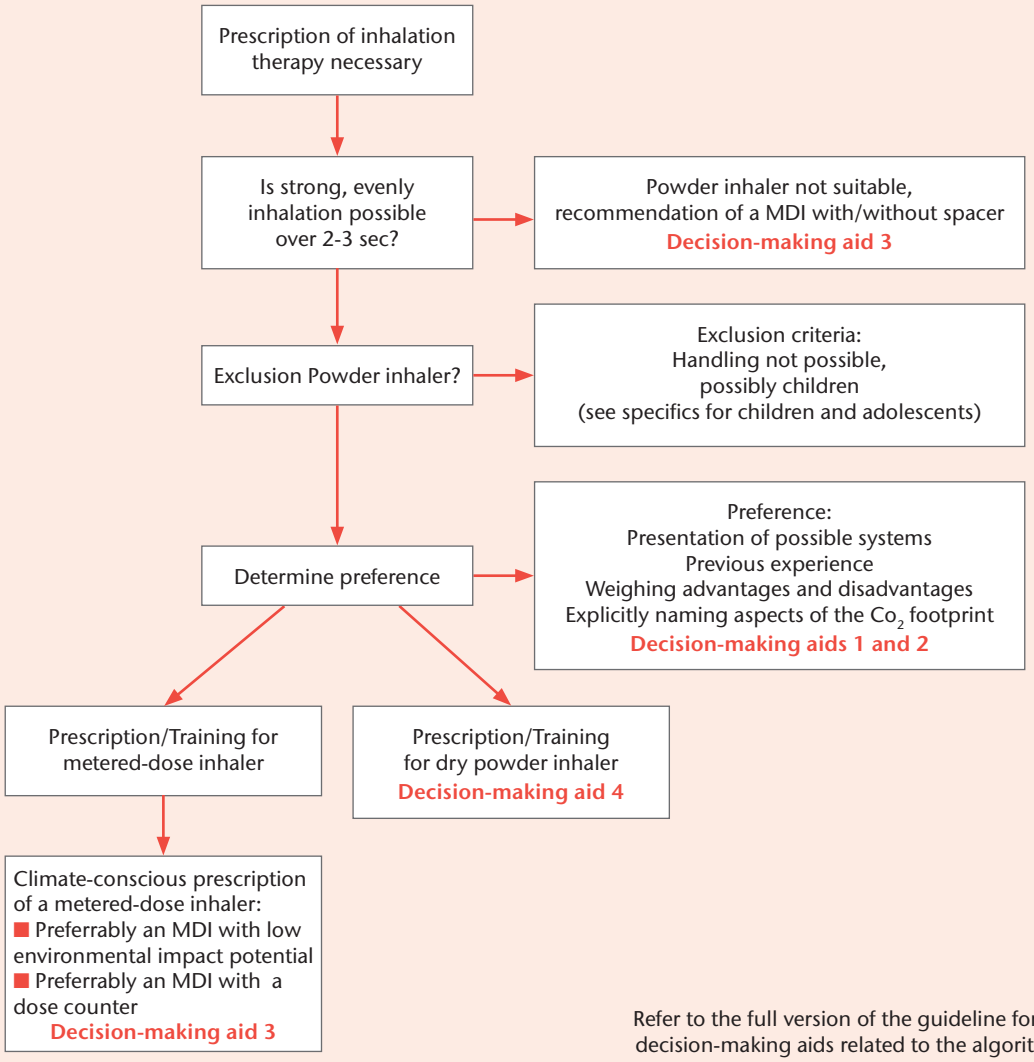
6.1 Recommendation	Outcome of the consensus process
Adolescents >12 years of age/adults with obstructive pulmonary disease should receive inhalation therapy (preferably with a DPI) in a climate-conscious manner. This also applies to PRN use.	**Strong Consenus 7/7**

6.2 Recommendation	Outcome of the consensus process
When prescribing an MDI, a preparation with a dose counter should be prescribed whenever possible.	**Strong Consenus 7/7**

6.3 Recommendation	Outcome of the consensus process
Patients with bronchial asthma who are prescribed more than 2x N1 SABA inhalers per calendar year should undergo a prompt therapy review.	**Strong Consenus 7/7**

7 Decision-making aids

Figure 1: Prescription Algorithm



7.1 Decision-making aid number 1

Differences between metered-dose inhalers and dry powder inhalers

This decision aid summarises the key differences between MDIs and DPIs to facilitate optimal therapy. Additional resources can be found in the patient information of the National Asthma Care Guideline. Video tutorials for each device are available at https://www.atemwegsliga.de/richtig-inhalieren.html.

Another alternative is inhalation using a spray nebuliser (Respimat system). In this system, aerosol generation is passive, ensuring functionality even with low airflow rates. However, spray nebulisers are only available for a limited number of active substances. Compared to an MDI, their footprint is approximately 20 times lower [20].

Table 2: Comparison of Metered-Dose Inhalers and Powder Inhalers

Inhaler	Metered-dose Aerosol (MDI)	Dry Powder Inhaler (DPI)
Inhaler technique	Hand/breath synchronisation is required (exception is with breath-triggered drug release systems)	No synchronisation required (in some cases, breathing flow-triggered)
Breathing technique*	Slow and deep breath**	Slow and deep breath, steady and strong inhalation**
Spacers	Possible	Not possible
Dose Counter	Sometimes	Almost always
Environmental impact due to propellants	Very high	Low***

* The only relevant difference refers to the inspiration technique, i.e. slow with MDIs to avoid oropharyngeal impaction losses vs vigorous with powders for active aerosol generation, ensuring good aerosol quality.

** The type of exhalation (slow vs fast, through the mouth with lip closure or through the nose) has little effect on efficacy once a correctly performed, differentiated inhalation maneuver and a sufficiently long breath-hold have been achieved (these two are crucial!).

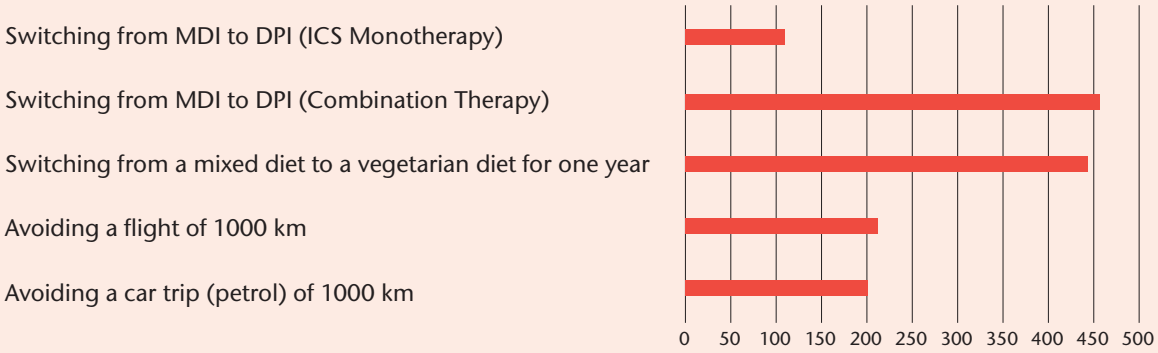
*** DPIs do not use or contain propellants, resulting in no environmental impact from propellants. Any potential environmental impacts from their use stem from other factors, such as manufacturing, transportation, and supply.

7.2 Decision-making aid number 2

The Carbon Footprint of Inhalation Therapy

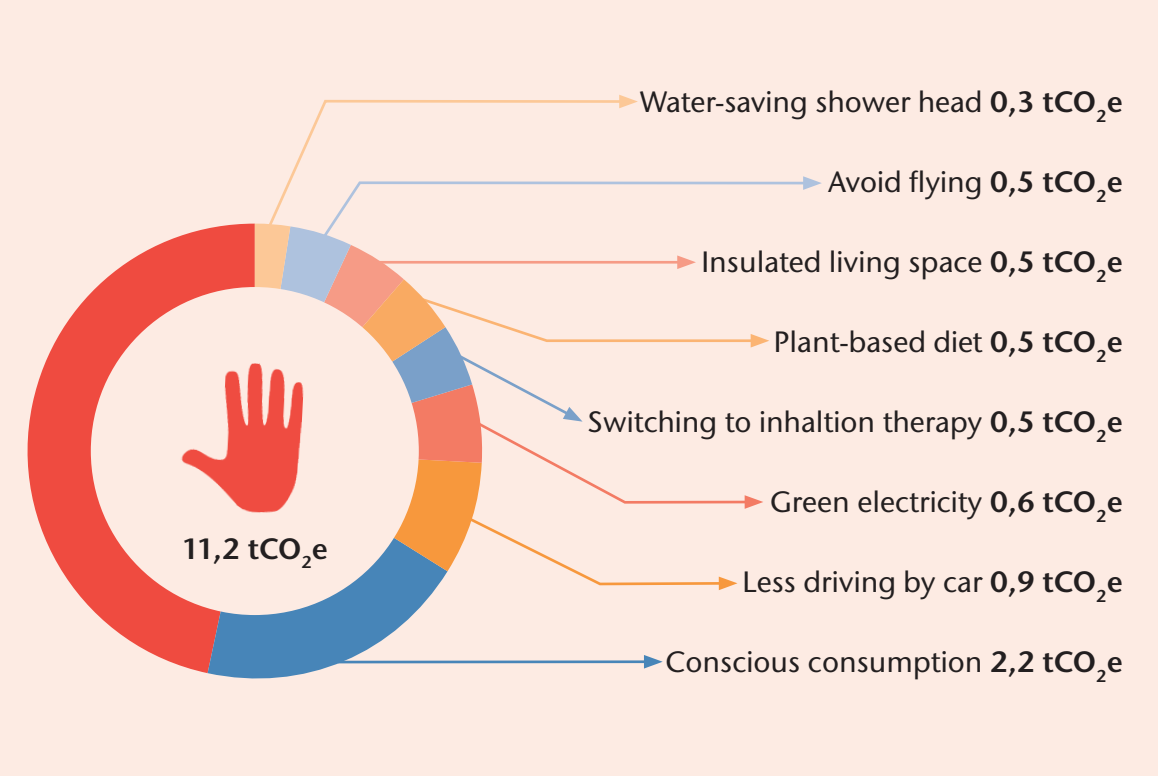
Comparing the carbon footprint of MDIs and DPIs demonstrates the potential for significant CO_2 reduction by selecting the appropriate therapy. Figure 2 illustrates the maximum possible savings from switching from MDIs to DPIs, with a potential reduction of nearly 500 kg CO_2 equivalent [21,22]. The actual reduction in CO_2 footprint depends on the specific therapy and dosage required. For example, switching an inhaled steroid from an MDI to a DPI can save approximately 110 kg CO_2 equivalent [22].

Figure 2: CO_2 footprint/possible savings in CO_2 consumption in kg CO_2
(for details and sources, see Methodology section)



The „handprint“ concept represents the positive ecological impact that can be achieved through our own actions.

Figure 3: Concept of the „handprint“



7.3 Decision-making aid number 3

Differences among metered-dose inhalers

Despite the climate-damaging effects of the propellants they contain, MDIs are occasionally chosen. There are also significant differences between MDIs in their global warming potential. While most MDIs use Norflurane with a GWP of 1530, only a few MDIs use the even more climate-damaging propellant Apaflurane (GWP 3600). Therefore, if possible, MDIs containing Apaflurane should be avoided. MDIs available in Germany with the propellant Apaflurane include the preparations Aarane® and Allergospasmin®. From a medical, economic, and ecological perspective, this combination is not recommended [15,23]. The Fluticasone/Formoterol combination in Flutiform® also uses Apaflurane, and comparable alternatives are available. However, some of these alternatives are not available with a dose counter and may differ in their risk of systemic adverse drug reactions in individual cases.

Table 3:
Inhaled medicines available in Germany with the propellant Apaflurane

Active ingredient	Compoud	Alternative/Rating
Cromoglicic acid/ Reproterol	Aarane®	Combination not recommended [15]; for therapy recommendations see NVL Asthma
Cromoglicic acid/ Reproterol	Allergospasmin®	
Fluticasone propionate/ Formoterol	Flutiform®	Other preparation with a combination of formoterol and inhaled steroid are available.

7.1 Recommendation	Outcome of the consensus process
Combination preparations with the active substances cromoglicic acid/reproterol should not be prescribed.	**Strong Consenus 7/7**

7.4 Decision-making aid number 4

This decision aid is designed to assist in selecting the most suitable dry powder inhaler. A detailed explanation of the table can be found online as supplementary material.

Table 4: Powder Inhalers in Comparison

Device	Device-type	Single dose?	content (number of doses)	Refillable?	Dose-counter	Breathe triggered Inspiration	Inspiratory resistance	Inspiratory flow	Number of perator steps	Force or coordination effort	Which active substances
Breezhaler	Capsule	Yes	1	Yes	⦸	No	+	+++++	11	+++	**4,5,6,7**
Aerolizer	Capsule	Yes	1	Yes	⦸	No	+	+++++	11	+++	**4**
Ellipta	Blister	Yes	30	No	Single dose increments	No	++	++++	4	+	**5,6,8,9**
Forspiro	Blister	Yes	60	No	Single dose increments	No	++	++++	6 (9)	+	**8**
Diskus	Blister	Yes	60	No	Single dose increments	No	++	++++	5	++	**7,8**
Elpenhaler	Blister	Yes	60	Yes	Single dose increments	No	++	++++	13	++++	**8**
Novolizer	Reservoir	No	60/100/200	Yes	Increments of 10	Yes	+++	+++	5	++	**1,4,7,8**
Genuair	Reservoir	No	60	No	Increments of 10	Yes	+++	+++	5	++	**5,6**
Spiromax	Reservoir	No	60/120	No	Increments of 2	No	+++	+++	4	++	**7,8**
Turbohaler I	Reservoir	No	60/120/100/200	No	No (warning color)	No	+++	+++	6	++	**1,4,7**
Nexthaler	Blister	Yes	120	No	Single dose increments	Yes	++++	++	5	+	**8**
Turbohaler II	Reservoir	No	60-120	No	Increments of 10	No	++++	++	6	++	**8**
Twisthaler	Reservoir	No	30/60	No	Increments of 10	No	++++	++	5	++	**7**
Easyhaler	Reservoir	No	100/200	No	Increments of 10	No	+++++	+	7 (9)	++	**1,4,7,8**
Zondahaler	Capsule	Yes	1	Yes	⦸	No	+++++	+	10	+++	**8**
Handihaler	Capsule	Yes	1	Yes	⦸	No	+++++	+	10	+++	**5**

Available for following active substances: 1 = SABA; 2 = SAMA; 3 = SABA/SAMA; 4 = LABA; 5 = LAMA; 6: LABA/LAMA; 7: ICS; 8: ICS/LABA; 9: ICS/LABA/LAMA

7.5 Comparison of Powder Inhalers – Table for Device Selection

DPIs are a largely climate-neutral alternative to hydrofluoroalkane (HFA)-containing metered-dose inhalers (MDI). Like MDIs, DPIs are available across all relevant active substance groups (SABA, SAMA, LABA, LAMA, LABA/LAMA, ICS, ICS-LABA and ICS-LABA-LAMA fixed combinations). However, DPIs require active aerosol generation, which depends on varying inspiratory flows due to internal device resistance. This must be carefully considered in patients with temporary (such as acute asthma), permanent (like advanced COPD) or age-related flow limitation (including infants, small children, and elderly individuals).

Table 4 provides a comparison of available DPI devices. In addition to user-friendliness (number of steps per inhalation, some requiring explanation), these devices notably differ in their internal resistance. Active aerosol generation involves energy from the pressure drop within the device and the shear forces of forced inhalation. Devices with high resistance require lower respiratory flows for effective aerosol generation, thereby reducing the acceleration of released particles and minimizing the risk of oropharyngeal impaction losses. Conversely, devices with low resistance necessitate high to very high inspiratory flows, which can be challenging for patients with airflow limitations. In addition, the strong acceleration of the particles in this case increases the risk of oropharyngeal impaction losses. This contrasts with the subjective perception of patients, who prefer devices with lower inspiratory resistance due to their perceived ease of use. Objectively, the suitability of a given powder inhaler for an individual patient can only be assessed by measuring the peak inspiratory flow achieved with this device. A detailed explanation of the table is available online as supplementary material.

8 Special considerations for Children and Adolescents

In the treatment of children and adolescents, education within the framework of the Disease Management Program (DMP) for asthma in children and adolescents plays a vital role. At least one adult caregiver should be involved in this training. Due to varied motor and cognitive skills among individuals and the existence of different age-specific market authorisations, it is challenging to specify explicit age limits for certain devices. Therefore, the use and prescription of inhalers in this age group require careful consideration of individual capabilities. The role of paediatrics in supporting children, adolescents, and their families in the context of climate awareness should be stated.

8.1 Recommendation	Outcome of the consensus process
Children and adolescents, along with their guardians or caregivers, should be informed about the reasons for climate-conscious prescription.	**Strong Consenus 7/7**

8.2 Recommendation	Outcome of the consensus process
Inhalation technique and coordination should be reviewed in accordance with the national guideline (NVL) on asthma. If suitable for the patient, consideration should be given to transitioning to a climate-friendly DPI.	**Strong Consenus 7/7**

8.3 Recommendation	Outcome of the consensus process
After switching to a new inhalation device, it is essential to carefully and regularly assess its usage and the control of asthma symptoms.	**Strong Consenus 7/7**

9 Disposal

Even in empty metered-dose inhalers, small amounts of gas or active substance remain in the cannister. This means that metered-dose inhalers are hazardous waste and must be disposed of accordingly.

There is no standardised regulation in Germany for the disposal of medicines. With a few exceptions (e.g., cytostatics), medicines can generally be disposed of in household waste. Pharmacies are also not obligated to take back old medicines. The German Federal Environment Agency provides an overview of regional disposal options at:
https://arzneimittelentsorgung.de/home/

Due to the aforementioned risks, metered-dose inhalers must be disposed of according to waste code 150110* (packaging containing or contaminated with residues of hazardous substances) or 160504* (gases in pressurised containers (including halons) containing hazardous substances). [24]

In Germany, waste legislation is governed by each individual federal state, meaning there is no nationally uniform disposal concept and no general obligation for pharmacies to take back compressed gas cartridges containing greenhouse gases.

The guideline commission agrees that a comprehensive disposal concept should be established for pressurised medical gas cartridge. This should follow the established procedure for CFCs (known as „green carton“) and involve all parties equally, including pharmaceutical manufacturers, pharmacies as dispensing and collection points, and central disposal facilities.

9.1 Statement	Outcome of the consensus process
An effective disposal concept (similar to the established green cardboard box) must be established for the disposal of pressurised gas cartridges.	**Strong Consenus 7/7**

10 Methodology

In 10/2021, the search for guidelines on „asthma“/“COPD“/“chronic bronchitis“ was conducted on the following website: Guideline Network International (https://guidelines.ebmportal.com/) The inclusion criteria encompassed publications in German or English published from 2016 onward.

The search was updated in January 2023, revealing a total of 25 guidelines on asthma and 7 on COPD/chronic bronchitis. Upon applying the inclusion criteria, 7 asthma and 10 COPD/chronic bronchitis guidelines remained. Five studies were excluded either due to duplication or because they addressed different topics. The relevant German-language guidelines (NVL Asthma, NVL COPD, S2k guideline on the diagnosis and treatment of patients with chronic obstructive bronchitis and pulmonary emphysema (COPD)) are included in the overview. All statements regarding the selection and differentiation of MDI and DPI were extracted from the included studies and summarised in a synopsis.

The literature search for the background text took the form of a narrative review and feedback from the guideline sponsors and the DEGAM Working Group on Climate Change and Health.

Sources for the calculation of the CO_2 footprint

Change from MDI to DPI assuming daily use of the combination of Relvar Ellipta (9.5 kg CO_2e) and Ventolin Accuhaler (salbutamol) (7.3 kg CO_2e) with an annual footprint of 17 kg CO_2e, compared to a combination of Seretide Evohaler (234 kg CO_2e) and Ventolin Evohaler (salbutamol) (205 kg CO_2e) including production, use and disposal [21]. Comparable savings (474 kg) are also possible when switching from a combination of an ICS (DA with propellant apaflurane) and SABA to a combination therapy [22].

Change to a vegetarian diet = 440 kg/year, calculated according to:
https://uba.co2-rechner.de/de_DE/sc-food#panel-scenario

A short-haul flight (1000 km), 1000 km by car (alone), all calculated according to:
https://www.quarks.de/umwelt/klimawandel/co2-rechner-fuer-auto-flugzeug-und-co/

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