Health Technology Assessment Policy and Methods Review – Consultation 1

Asthma Australia Submission, June 2023

ABOUT ASTHMA AUSTRALIA

Asthma Australia is a for-purpose, consumer organisation that has been improving the lives of people with asthma since 1962. Asthma affects one in nine Australians or 2.7 million people. Asthma is an inflammatory condition of the airways, restricting airflow and can be fatal. There is no cure, but most people with asthma can experience good control.

Our purpose is to help people breathe better so they can live freely. We deliver evidence-based prevention and health strategies to more than half a million people each year.

OUR SURVEY RESPONSE

1. ELEMENTS AND FEATURES THAT ARE WORKING EFFECTIVELY

Understanding the elements and features of HTA policy and methods that are working effectively, will help to ensure they are preserved and continue to provide positive outcomes for Australians.

Are there any elements and features of HTA policy and methods in Australia that are working effectively?

Yes.

Are you able to provide detail of any elements and features of HTA policy and methods that are working effectively? Please use specific details where possible.

We welcome the Health Technology Assessment (HTA) Policy and Methods Review (the Review) and acknowledge the critical role of HTA in supporting the implementation of the National Medicines Policy (NMP) and provision of medical services to provide many people in Australia with access to high quality, reliable and affordable healthcare. We welcome the Review's Terms of Reference[1] and the opportunity they provide to reform key elements of the current HTA system, particularly in relation to increasing equity in access to medicines and improving consumer engagement in HTA processes.

We note two key features of HTA that work effectively: 1) reliable access to a range of high quality medicines for many people with asthma, and 2) elements of the public consultation processes on market authorisation and subsidisation of new listings.

ACCESS TO MEDICINES FOR PEOPLE WITH ASTHMA

Asthma is a chronic condition with no cure that affects one in nine Australians or 2.7 million people. It is an inflammatory condition of the airways, restricting airflow and can be fatal. There is no cure, but most people with asthma can experience good control. Asthma is primarily self-managed by the individual or their carer using medicines and devices under the guidance of a healthcare professional, making **access to medicines key to asthma treatment and control**. Asthma medicines can help prevent escalating asthma symptoms and life-threatening flare-ups, and consequently reduce the need for people with asthma to access healthcare and emergency services.

A range of asthma medicines are covered by Pharmaceutical Benefits Scheme (PBS) subsidies that include relievers for the rapid relief of asthma symptoms as they occur, preventers used every day to prevent symptoms and reduce the likelihood of exacerbations, and add-on therapies used for severe asthma and/or asthma that is difficult to control.

[1] https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-terms-of-reference?language=en

HTA supports policies and decision-making on market authorisation and subsidisation, providing many people with asthma with access to high quality, safe and effective medicines that are more affordable. When combined with concession card and PBS safety net policies, PBS subsidised medicines reduce the issue of cost as a barrier to asthma medicine adherence for many Australians (although not all, as discussed in our response to Q3), and thereby help control their asthma, reduce escalating symptoms and use of healthcare services, and improve their quality of life.

NEW LISTINGS: EFFECTIVE PROCESSES

Asthma Australia dedicates resources to monitoring and engaging with HTA to ensure that issues affecting our consumers are appropriately considered in the HTA processes currently open to public feedback. As sponsors regularly seek Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) approval for new asthma medicines, we engage with several public consultations that TGA and PBAC run in preparation for new registration, subsidisation and related policies and processes. Our staff are experienced in engaging with these processes and hence find the portal and steps involved into providing a response to a medicine straightforward. In addition, the Committees are open to our advice and suggestions, as often reflected in the decision-making outcome whereby decisions on asthma medicines have often highlighted Asthma Australia's contributions.

Are you able to provide details of positive outcomes resulting from Australia's HTA policies and methods? Please use specific examples where possible.

We note two key examples of HTA policies and methods being responsive to Asthma Australia's concerns, among those of other stakeholders', including the decision to revise the listing change made to Fluticasone Propionate 50 mcg recently (discussed in detail in response to Q3 of this survey) and the TGA decision not to down-schedule budesonide and formoterol in fixed dose combination form (DuoResp Spiromax® 200/6, Symbicort Rapihaler® 100/3, Symbicort Turbuhaler® 200/6 - herein referred to as B/F FDC) to become an over-the-counter medicine.

BUDESONIDE AND FORMOTEROL SCHEDULING

Since 2019, B/F FDC has been registered for use on an as-needed basis for people with mild asthma without concomitant regular preventer therapy. This registration for use was a notable move from its previously sole authorisation for use in maintenance and reliever therapy (MART) and conventional twice daily therapy for people with moderate to severe asthma. B/F FDC use for people with mild asthma, recommended in the Australian Asthma Handbook (AAH)[2], was subsequently added to the PBS with an authority required (streamlined) classification.

In 2020, the sponsor of B/F FDC applied for it to be down-scheduled to become an over-the-counter (OTC) medicine citing evidence, amongst others, demonstrating the superiority of B/F FDC when compared to using an OTC Short-Acting Beta Agonist (SABA) in asthma exacerbation prevention.

[2] National Asthma Council Australia. Australian Asthma Handbook. National Asthma Council Australia, Melbourne, 2023. Website. Available from: http://www.asthmahandbook.org.au

However, we had significant concerns about the application and the OTC availability of B/F FDC in relation to the loss of supervision and follow-up by a healthcare professional for people with this complex disease.[3] We noted that the current accessibility of SABA OTC under Schedule 3 is a major problem rather than justification for down-scheduling B/F FDC, and that the many uncertainties about the proposed change constituted unacceptable risk to consumers.

The Advisory Committee on Medicines Scheduling recommended that the current scheduling of B/F FDC remains appropriate and the TGA decided not to amend the current Poisons Standard, noting our submission in its explanation.[4]

2. CURRENT OR FUTURE BARRIERS TO EARLIEST POSSIBLE ACCESS

Reducing time to access for Australians so that they can access new health technologies as early as possible is recognised as a shared goal of both the Government and Medicines Australia as agreed under clause 5.1 of the Strategic Agreement.

What are the elements and features of HTA policy and methods that may act as a future barrier to earliest possible access?

ACCESS TO ASTHMA MEDICINES FOR CHILDREN

Among all medicines available for children with asthma in similar economies around the world, comparably few are registered for use in Australia, and around 7% of applications to the PBAC for PBS subsidy are for new paediatric indications.[5] Children with asthma in Australia bear a disproportionate burden from this disease and the relative availability of effective treatments should reflect this fact. This has been a long-standing issue, which restricts both the access children have to medicines as well as their choice in using alternative medicines that may be more appropriate to their condition or personal circumstance (e.g. cost/side effects). For example, for children under 6 years old with asthma, there is only one asthma preventer inhaler available in Australia.[6] The lack of medicines for children may also lead to off-label prescribing.

Europe and the US are the only two geographical areas globally that have improved the authorised availability of medicines for children through legislative reforms that incentivise and mandate paediatric research and require the provision of evidence-based paediatric labelling and age-appropriate medication formulations.[7] For compliance, pharmaceutical companies commonly need to develop a number of different medicine formulations, strengths and/or administration devices for

[3] aa-submission---tga-poisons-standards-application-to-reschedule-budesonide-formoterol.pdf
[4] https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/notice-interim-decisions-proposed-amendments-poisons-standard-acms-accs-and-joint-acms-accs-meetings-november-2020/23-budesonide-formoterol
[5] https://onlinelibrary.wiley.com/doi/10.1111/jpc.12629
[6] Australian Burden of Disease Study 2015: Interactive data on disease burden. Cat. no. BOD 24. Canberra: AIHW.
[7] Volodina A, Shah-Rohlfs R, Jahn A. Does EU and US paediatric legislation improve the authorization availability of medicines for children in other countries? Br J Clin Pharmacol. 2023;89(3):1056-1066. d

children. EU (and UK and Swiss) and US legislation has therefore helped overcome the barriers to medicine development for the paediatric markets, including ethical issues and concerns with using children in research, recruitment challenges, research infrastructure barriers and small/low market demand.[8/9]

In the past, Australia has sought to address poor access to paediatric medicines including through creating the Paediatric Medicines Advisory Group (PMAG, from 2007-2011), charged with advising PBAC and advocating for children in relation to access to new medicines and formulations relevant to children. PMAG's achievements included increasing the number of medicines on the PBS, identifying those which needed prioritisation for PBS listing, improving quality use of medicine and introducing the requirement that a sponsor of a new drug provide information, where it existed, in relation to children when applying for TGA registration.[10]

Government policy initiatives are needed if Australia is to ensure that children have timely access to appropriate medicines. These initiatives could include following the same legislative paths taken by Europe and America, which have resulted in notable success, or by developing pathways for European and American approved medicines to more easily be authorised here. **A review into the issue is required to determine the most appropriate approach and delivery mechanisms to improve access to paediatric medicines in Australia.**

Would you like to provide feasible options or suggestions you have to improve elements of HTA policy and methods that are acting as a current or future barrier to earliest possible access?

RECOMMENDATIONS

Recommendation 1: That the Department of Health and Aged Care (DoHAC) undertake a review of policy initiatives and supporting mechanisms needed to ensure that children with asthma have timely and equitable access to appropriate medicines in Australia.

[8] Ibid.
[9] https://onlinelibrary.wiley.com/doi/10.1111/jpc.12629#jpc12629-bib-0016
[10] https://onlinelibrary.wiley.com/doi/10.1111/jpc.12629

3. CURRENT OR FUTURE BARRIERS TO EQUITABLE ACCESS

What are the elements and features of HTA policy and methods that are acting as a current or future barrier to equitable access? Where possible, please detail:

COST OF MEDICINES

Although HTA supports Government subsidy programs that improve access to medicines for many people in Australia by reducing consumer costs and making medicines more affordable, for some people with asthma the cost of medicines remains a barrier to medicine adherence. This means that some population groups may not be able to afford their medicine/s or have to ration and miss doses of their medicines. This can result in reduced control of asthma symptoms at great cost to the individual's health and the healthcare system.

We have identified a number of ways that HTA policies, processes and mechanisms have reduced equity in access to medicines. We set them out below, framing them through the issues our consumers commonly experience, including the compounding costs of living with comorbidities and of having to buy inhaler devices to effectively use some asthma medicines and the cost barriers of accessing preventer medicines. We highlight the HTA policy, process or mechanisms that have contributed to each of these issues. We also provide an in-depth case study into a recent PBAC listing change (of Fluticasone Propionate 50mcg) and set out how this decision, which is now in the process of being revised, resulted in significant access inequity for children with asthma.

COMPOUNDING COSTS: COMORBIDITIES

Asthma affects 2.7 million people and 1.6 million (59%) people with asthma have comorbidities.[11] This means that people with asthma are much more likely to need to access other medicines (and devices) to support their health. Management of comorbid conditions often also supports asthma control as obesity, mental illness, allergic rhinitis and obstructive sleep apnoea detrimentally affect asthma control and the risk of flare-ups.[12]

Treating comorbidities alongside asthma can make medicine costs very high, even with a concession card or after reaching the PBS Safety Net. Further, the thresholds for reaching the PBS Safety Net are high. The threshold currently sits at $262.80 for concession cardholders and $1,563.50 for general patients, the latter being a significant equity issue for those people whose incomes sit just above concession card eligibility. In addition, consumers must keep records of prescriptions to evidence they have met the Safety Net themselves, which can prove difficult for people who visit many different pharmacies, have low health system literacy or have competing priorities to juggle in their busy lives. In addition, specific HTA processes – such as down-scheduling - can reduce the affordability of medicines needed by some people with asthma and comorbidities as set out in the example below.

[11] https://www.aihw.gov.au/reports/chronic-respiratory-conditions/chronic-respiratory-conditions/contents/asthma

[12] National Asthma Council Australia 2019. Australian Asthma Handbook, Version 2.0. Melbourne: National Asthma Council Australia.

- **Down-scheduling medicines for allergic rhinitis**

Allergic rhinitis (hay fever) is closely linked to asthma: it is the most common type of allergy that overlaps with asthma and at least 75% of people with asthma also have it.[13/14] While hay fever has a myriad of symptoms, which can be severe and disrupt quality of life, uncontrolled hay fever can trigger asthma symptoms and reduce asthma control. People with asthma and hay fever will typically be advised to use hay fever preventer and reliever medicines alongside their asthma medicines. Additionally, genetic susceptibility can increase the likelihood of developing both asthma and hay fever. Some families therefore spend significant amounts of money on medicines to treat and control asthma and comorbidities like hay fever.

Hence, having access to affordable hay fever medicines is critical for many people with asthma. However, **the TGA's down-scheduling of effective and commonly used medicines (e.g. intranasal corticosteroids) for the management of hay fever from Schedule 4 'prescription only' to Schedule 3 'pharmacist only' was not conducive to improving equitable affordability.** While down-scheduling can make medicines easier for consumers to access by reducing travel and visits to GPs since they need only visit and consult their pharmacist, it can often result in higher and/or significantly inequitable consumer costs for OTC medicines (such as Nasonex®) depending on where medicines are purchased (e.g. community pharmacy, retail pharmacy chain or online, or in rural and remote communities or urban areas). Higher out-of-pocket costs arise from down-scheduled medicines typically no longer being available under the PBS (since sponsors commonly do not apply for subsidies for down-scheduled medicines) and therefore also not contributing to the PBS safety net.

- **Reducing the compounding costs of comorbidities**

Asthma Australia has welcomed the Australian Government's recently announced policy to help ease the financial burden of chronic conditions and comorbidities by increasing maximum dispensed quantities on selected PBS items to treat chronic conditions from one to two months' supply. There are a number of other ways the HTA system could also help reduce these compounding costs, including by:

1. **Developing a mechanism to consider the unintended consequence of scheduling changes on equitable consumer access.** For example, TGA scheduling processes could systematically include consultation with PBAC on proposed changes.

2. **Reforming the current process for identifying medicines to be assessed by PBAC for PBS subsidy so it is not, in practice, solely sponsor-led.** Sponsors commonly do not apply for PBS subsidies for down-scheduled medicines and while the system allows other stakeholders to make PBS subsidy applications, given the time, expense and knowledge required to do means that in practice this infrequently occurs. HTA processes should be designed to make it easier for all stakeholders to make applications for subsidy. In addition, PBAC could also be responsible for identifying additional medicines for subsidy through using HTA medicine utilisation data and appropriate consumer consultation.

[13] Hay fever allergic rhinitis and your asthma - National Asthma Council Australia
[14] https://asthmarp.biomedcentral.com/articles/10.1186/s40733-015-0008-0#:~:text=Abstract,underdiagnosed%20in%20subjects%20with%20asthma

3. **Reviewing the current processes for when and how medicines contribute to the PBS Safety Net and supporting mechanisms with the aim of improving equitable access. The review should consider:**
    - The development of processes to enable OTC or down-scheduled medicines, which support chronic conditions and are not listed under the PBS, to contribute to the PBS safety net.
    - The centralisation of patients' prescription pharmacy records so they automatically can access reduced medicines on reaching the safety net.
    - The reduction or recalibration of the PBS Safety Net threshold of $1,563.50 for general patients, especially in view of the recently announced change to dispensing policy.

RECOMMENDATIONS

Recommendation 2: That TGA and PBAC develop mechanisms to support their parallel consideration of unintended consequences of scheduling changes on equitable consumer access.

Recommendation 3: That DoHAC consider how to reform the current process for identifying medicines to be assessed by PBAC for PBS subsidy to make it more accessible to all stakeholders.

Recommendation 4: That the Australian Government review the current processes for when and how medicines contribute to the PBS safety net with the aim of increasing equity in access to medicines.

COMPOUNDING COSTS: INHALER DEVICES AND AID DEVICES

Inhaled medication is the mainstay of asthma treatment and control, which sets asthma apart from the pharmacological approach to many other chronic conditions since: 1) a device such as a pressurised metered dose inhaler (pMDI) is necessary to administer inhaled medicines, and 2) aid devices are required to support consumer use of inhaler devices. We set out below how each of these factors exacerbates costs of medicines for people with asthma and how these factors are effectively overlooked by HTA processes.

1. Inhaler devices

People with asthma commonly use inhaled medicines that require inhaler devices (pMDI, Accuhaler®, Turbuhaler®, Ellipta®, Breezhaler®) to get the medicines into the airways. Although other medicines require certain equipment to support their administration, such as injection equipment provided for free for people with diabetes, PBS mechanisms do not account for the higher manufacturing costs of asthma medicine administration devices and instead people with asthma pay higher costs for their medicines. **To increase equitable access, HTA processes should be adapted to account for essential health technologies where the higher manufacturing costs result in higher market prices.**

2. Inhaler aid devices

Good inhalation technique is critical to asthma management yet up to 94% of people with asthma do not use their inhalers correctly.[15] This has detrimental implications for asthma outcomes, including a 50% increase in the risk of hospitalisation.[16] To improve technique and ensure patients receive the correct dose of medicine into their lungs, as well as to reduce side effects, Australian guidelines recommend that children use a spacer (with a mask for very young children) with all pressurised metered-dose inhalers (pMDI). [17] They also recommend that adults using pMDI that contain inhaled-corticosteroids use a spacer.[18]

Spacers are a highly effective way to take inhaler medicines as they slow down delivery and enable the patient to breathe in the medicine at their own pace without needing to coordinate breathing and puffer release. They also help get the medicine straight to the lungs, with less medication depositing in the mouth and throat where it can lead to irritation or mild infections.

Most children use pMDI reliever medicines and therefore may need 2-3 spacers to ensure they have access to them at critical times (e.g. at school, at home, at sports clubs). Adults who use them may also need more than one spacer. Costs mount alongside the costs of inhalers and other asthma medicines. **Given how critical spacers are in the effective administration of asthma pMDI inhalers for children and adults, we would like to see them included under the PBS and ask that the DoHAC considers how this can be accommodated in the reformed approach to HTA.**

Access to spacers under the PBS would not only ensure equitable access to important health technologies for people regardless of income but would also increase the quality and efficiency in the use of these medicines, thereby limiting waste and preventing patient symptom escalation and associated demand on healthcare services. **These outcomes would contribute to helping HTA meet the objective, as set out in the Review's Terms of Reference, of: 'further[ing] the objectives of the National Medicines Policy (NMP)', which includes that medicines should be 'affordable' and 'used safely, optimally and judiciously'.**

RECOMMENDATION

Recommendation 5: That DoHAC consider how to reform HTA policy so that it appropriately accounts for the high cost associated with inhaler devices, which are critical to the administration of inhaled asthma medicines.

Recommendation 6: That the Australian Government enable access to spacers and masks under the PBS to support equitable access given their importance in effectively and efficiently administering asthma medicines, particularly to children.

[15] Ninety per cent of Australians with asthma use their inhalers incorrectly - National Asthma Council Australia
[16] Ibid.
[17] https://www.asthmahandbook.org.au/management/devices
[18] Ibid.

COSTS OF PREVENTER MEDICINES

For most people with asthma, asthma symptoms can be effectively managed using inhaled corticosteroid (ICS) preventer medicines. ICS preventer medicines, typically prescribed for daily use, can help ensure that asthma is controlled over the long-term and prevent the risk of asthma flare-ups by making airways less sensitive, reducing redness, swelling and excess mucus.[19] ICS preventers include ICS-alone inhalers and ICS-combination inhalers that contain both an ICS medicine and one or two bronchodilator medicines.

Consistent with findings across the world, too few consumers in Australia control their asthma using inhaled corticosteroids (ICS) preventer medicines. Australian data shows that less than 20% of patients are being dispensed enough of ICS-alone or combination preventer inhalers to be taking their treatment in accordance with guidelines.[20] This means a significant proportion of people with asthma will not have good control of their asthma and instead risk symptom escalation and/or may inappropriately rely on reliever medicine,[21] the use of oral corticosteroids and emergency healthcare services to manage their asthma all to the detriment of their quality of life. [22,23,24]

Further, despite clinical trial evidence showing that around 70% of adults with asthma can achieve good asthma control on ICS alone,[25] 89% of ICS-containing medicines in Australia are dispensed as ICS-long-acting b2-agonists (LABA) combination devices, which are generally more expensive than ICS-alone preventers.[26] **This approach to asthma control is in contrast to Asthma Handbook guidelines and the stepped approach to asthma management.[27] It is also more costly to consumers and the PBS.** For consumers, the monthly out-of-pocket cost for ICS-alone can be as little as 15% of that of ICS-LABA preventers.[28]

- **Asthma Australia Research into ICS use**

In response to concerns raised by consumers about the cost of ICS being a barrier to use in their asthma management, Asthma Australia has undertaken research to better understand barriers to ICS use and how they can be addressed. **Costs of ICS preventers disproportionately affect certain**

[19] https://asthma.org.au/medicines/combination-preventers/#:~:text=Combination%20preventers%20contain%20two%20or,to%20dry%20up%20excess%20mucus

[20] AIHW: Correll PK, Poulos LM, Ampon R, Reddel HK & Marks GB 2015. Respiratory medication use in Australia 2003–2013: treatment of asthma and COPD. Cat. no. ACM 31. Canberra: AIHW.

[21] Correll PK, Poulos LM, Ampon R, Reddel HK, Marks GB. *Respiratory Medicine Use in Australia 2003-2013: Treatment of Asthma and COPD*. Canberra (AUST): Australian Institute of Health and Welfare; 2015.

[22] Suissa S, Ernst P, Benayoun S, Baltzan M et al. Low dose inhaled corticosteroids and the prevention of death from asthma. *N Engl J Med.* 2000; **343**: 332– 6.

[23] Suissa S, Ernst P, Kezouh A. Regular use of inhaled corticosteroids and the long term prevention of hospitalisation for asthma. *Thorax.* 2002; **57**: 880– 4.

[24] Williams LK, Peterson EL, Wells K, Ahmedani BK, Kumar R, Burchard EG, et al. Quantifying the proportion of severe asthma exacerbations attributable to inhaled corticosteroid nonadherence. *J Allergy Clin Immunol.* 2011;**128**:1185–91.e2.

[25] Bateman ED, Boushey HA, Bousquet J, Busse WW, Clark TJ, Pauwels RA, et al. Can guideline-defined asthma control be achieved? The Gaining Optimal Asthma Control study. American journal of respiratory and critical care medicine. 2004;170(8):836-44. Epub 2004/07/17.

[26] Australian Centre for Asthma Monitoring. Asthma in Australia 2008. Canberra: AIHW, 2008 AIHW Asthma Series no. 3. Cat. no. ACM 14.

[27] https://www.asthmahandbook.org.au/

[28] Reddel HK, Lembke K, Zwar NJ. The cost of asthma medicines. *Aust Prescr.* 2018; **41**: 34– 6.

population groups, including concession card holders and those whose incomes are just above the eligibility threshold, people who have comorbidities and related illnesses and allergies, and families with multiple members who have asthma and/or other chronic illnesses. Our research found the impact of out-of-pocket costs as a barrier to ICS use was complex, with many interrelated variables, affecting different population groups in different ways.

Our findings from research with consumers[29] and with GPs[30] on ICS use and out-of-pocket costs point to the lack of consumer informed choice and of GP knowledge about the costs of different preventers and their quality use:

- Most consumer participants did not consider themselves to be the primary decision-maker about the choice of medicine, instead deferring to the expertise of the GP.
- GP participants favoured combination ICS–LABA inhalers over ICS alone because they perceived them to be more effective and to promote patient adherence.
- Consumer participants most often cited the perceived side effects of asthma medicines, particularly of inhaled corticosteroids, as a barrier to their use/adherence.
- Consumer participants mentioned cost issues as a barrier to preventer use but it was not a focus for most participants. Most prioritised health over medicine cost.
- GPs rarely discussed medicine costs with patients and had little knowledge of medicine costs to patients or the health system. They reported that patients rarely raised cost concerns.
- Several consumer participants, eligible for concessional co-payments, expressed that they still struggled with medicine costs and may need to go without medicine, lower their dose or frequency of use temporarily, or make savings in some other way.
- GPs felt that having lower patient co-payments for ICS would have little effect on their prescribing practices.

- **HTA barriers and costs of asthma preventer medicines**

There are four key reasons why the cost and adherence to ICS-alone or ICS-combination medicines is important to the HTA Review:

1. **The prescribing of ICS-combination medicines instead of ICS-alone medicines evidences the lack of informed choice and quality use of medicines (QUM), both central pillars of the NMP.**

Despite extensive work being undertaken by PBAC on the quality use of medicine (QUM) when making an assessment to list a new medicine, this information is not effectively passed on and used by enough healthcare professionals when treating patients with asthma. Further, too little information is being shared with patients by healthcare professionals so they might make an informed choice about their use of preventer medicines. While there are other sources of information that a healthcare professional may consult when treating a patient (e.g. the Australian Asthma Handbook), this is a missed opportunity and we would like to see processes in place to ensure that PBAC information about medicines and their use is not confined to assessment but instead used and applied in real world contexts.

[29] "You've got to breathe, you know" – asthma patients and carers' perceptions around purchase and use of asthma preventer medicines - Davis - 2019 - Australian and New Zealand Journal of Public Health - Wiley Online Library

[30] Tudball J, Reddel HK, Laba TL, Jan S, Flynn A, Goldman M, Lembke K, Roughead E, Marks GB, Zwar N. General practitioners' views on the influence of cost on the prescribing of asthma preventer medicines: a qualitative study. Aust Health Rev. 2019 Jul;43(3):246-253. doi: 10.1071/AH17030. PMID: 29754592.

The NPS MedicineWise used to provide education and resources on the quality use of medicines and medicines safety in Australia and hence used to help to bridge this gap. To this end, it worked closely with health professionals and consumers and was a well-respected and known independent body. However, since it was disbanded in December 2022, it is unclear to what extent the Australian Commission on Safety and Quality in Health will fulfill the same tasks. **A respected, independent body delivering an education and support service on medicines to healthcare professionals and consumers is needed to ensure QUM, safety and informed choice are principles embedded in the daily practice of the healthcare system.**

2. **The prescribing of ICS-combination medicines instead of ICS-alone medicines costs consumers and the PBS more.**

This practice is a significant opportunity cost, unnecessarily draining the finite resources of both consumers and the PBS.

3. **The higher out-of-pocket expense for ICS medicines can be an access barrier to adherence, which is inequitable, for people with lower incomes and/or compounding medicine costs.**

To address this equity barrier, we ask that Government considers the implementation of HTA mechanisms that enable the PBS to provide higher co-payments for more costly medicines – such as ICS - that prevent chronic conditions from deteriorating and that keep people out of hospital and emergency departments.

4. **ICS non-adherence results in additional repercussions for the consumer and healthcare system through increased asthma exacerbations and oral corticosteroid use leading to increased healthcare use.** Please see our response to question 5 for more on oral corticosteroids.

RECOMMENDATION

Recommendation 7: That DoHAC seek to increase equity in access to asthma preventer medicines by:

1. Establishing a communications and education support service for health care professionals and consumers in relation to the quality use of medicines to ensure they are used 'safely, optimally and judiciously, with a focus on informed choice'.[31]
2. Developing mechanisms to enable the PBS to provide higher co-payments for more costly medicines – such as ICS - that prevent chronic conditions from deteriorating and that keep people out of hospital and emergency departments.
3. Making costs of medications visible to prescribers by providing real-time data on the relative costs of therapeutically equivalent medicines and by cost per dose.

[31] https://www.health.gov.au/resources/publications/national-medicines-policy?language=en

CASE STUDY: FLUTICASONE PROPIONATE 50MCG (FLIXOTIDE/AXOTIDE JUNIOR)

- On 1 April 2023, PBAC changed the PBS listing, population and treatment criteria for Fluticasone Propionate 50mcg (FP 50 mcg), an ICS-alone preventer inhaler. This was a consequence of **a request for ministerial discretion by the sponsor to avoid** a **Statutory Price Reduction (SPR)** for FP 50 mcg. **No new evidence had emerged to justify this change.**

- The listing change (current today but revised in PBAC's May 2023 meeting[32]) means that:
  - only children aged 1 to 5 years old can still access FP 50 mcg under the PBS (as the only pMDI for use in patients aged 1 to 5 years old) but prescribers must now have an authority required (telephone/online) to prescribe it and its initiation must be authorised by a respiratory physician or paediatrician.
  - children aged 6 years and over are not able to access FP 50 mcg under the PBS and must instead use alternative medicines if they wish to access them under the PBS, risking disruption to their asthma control.

  No reason for these any of these changes to the listing was given.

- Asthma Australia is not aware of the exact process that lead to these restrictions but it seems that **no significant consultation** with healthcare professionals, consumers organisations or consumers more widely was undertaken prior to the decision being made by PBAC**. Given the lack of information around SPR processes, it is not clear if any assessments,** including a risk assessment**,** were undertaken to consider the impact of the change on the cohorts affected.

- Our concerns about this listing change included that the younger cohort - and particularly those who depend on concession cards, have co-morbidities, are from families on low incomes or have family members with chronic conditions - now face significant cost and other access barriers to the only pMDI available to them. The need to see a specialist is particularly problematic given paediatricians have long waitlists nation-wide, are not available in some rural and remote communities and have fees that are unaffordable for many families.

  We were concerned by the need for the older cohort to change medicine at the risk of good asthma control in order to retain access to PBS subsidies, and that they may be prescribed a higher dose of (subsidised) fluticasone propionate, which is not consistent with QUM.

- **Asthma Australia wrote to PBAC in March 2023 about our concerns but did not receive a response despite follow up via email and phone.** We worked with colleagues in partner organisations, including the Royal Australian College of General Practitioners, Thoracic Society of Australia and New Zealand and National Asthma Council, to advocate on this issue. We collectively wrote to the Health Minister, Mark Butler, and to the Chair of PBAC highlighting the equity impact of the listing change. We met with the **Co-Chair of the PBAC who was receptive to our concerns** and later advised us that the issue would be discussed at the PBAC's May meeting**. The Health Minister also then raised his concerns with PBAC**.

- Following the PBAC's meeting on 5 May 2023, we were advised that PBAC had decided to revise its decision, noting concerns from organisations such as ours, and set out a new treatment and listing criteria for the medicine.[33] The new criteria still includes the need for an

[32] may-2023-PBAC-web-outcomes-fluticasone.pdf (pbs.gov.au)
[33] Ibid.

authority prescription for FP 50 mcg, sending an inappropriate message about the safety and effectiveness of ICS. **No reason has been given for this.**

- While Asthma Australia welcomes the impending listing change revision, we are aware that:
  - **The listing change has already caused consumers anxiety.** Many consumers told us about their financial concerns about this decision, particularly in view of the cost-of-living crisis. Some were worried about the impact on their children's quality of life of potentially going without an inhaler (until/if a specialist can be accessed), while others were concerned about the impact of changing inhaler medicine on their child's health.
  - Several healthcare professionals have reportedly already prescribed higher doses of fluticasone propionate (125mcg) to patients aged 6 years and older to enable PBS access. Others have reportedly had to find time to ring for an authority number to be able to prescribe FP 50 mcg to the younger cohort.
  - Significant energy has been expended by organisations like ours to work to reverse the decision, while keeping consumers informed about what has happened.

- **It is clear that the current processes PBAC follows in relation to SPRs are not fit for purpose. Improvements, including in consumer engagement, are required to ensure that decisions with similar repercussions cannot be implemented again.**

RECOMMENDATION

Recommendation 8: That the Australian Government initiate a review into the PBAC decision-making process that resulted in the inequitable listing change to Fluticasone Propionate 50mcg. The review should consider how processes can be improved, including those relating to equitable access as well as risk, transparency and consultation processes with consumers, to ensure that the Statutory Price Reduction process cannot produce similar outcomes in future.

ACCESS TO MEDICAL SERVICES

In this section, we present cost barriers to medical services that detrimentally affect their equitable access to people with asthma across the country, including in relation to diagnostic and monitoring tests and pulmonary rehabilitation.

COST OF ASTHMA DIAGNOSTIC AND MONITORING TESTS

- **Spirometry**

In 2019, the Medical Services Advisory Committee (MSAC) authorised a new higher-rebated MBS item for spirometry to encourage its use in general practice. This followed MSAC's acknowledgement of the importance of spirometry in confirming the diagnosis of asthma, chronic obstructive pulmonary disease (COPD) and other causes of airflow impairment. It also recognised that these conditions are both under and over-diagnosed, and consequently, that patients may not

be receiving the best therapies to treat their condition. However, the MBS rebate has not been adequate and the implementation and uptake of spirometry in primary healthcare has declined.[34]

General practice requires rebates for spirometry that appropriately reflect the costs in delivering the service, which include the time and expertise required to complete high quality tests, as well as consumables and maintenance of equipment. The HTA process should include real-world implementation processes to ensure MSAC recommendations and decisions are feasible in practice.

RECOMMENDATION

Recommendation 9: That DoHAC reviews HTA processes for MSAC to ensure they support assessment of all costs associated with delivering spirometry in general practice to result in adequate MBS reimbursement.

- **Other asthma diagnostic and monitoring services**

There is a suite of different diagnostic and monitoring services that can help accurately diagnose and monitor asthma. These include fractional exhaled nitric oxide (FeNO) tests, Forced Oscillation Testing (FOT) and electrical impedance tomography (EIT). Each have their advantages such as speed, ease of use, and ability to provide the clinician with unique information useful to make critical clinical decisions. There is also a range of diagnostic equipment to help to more effectively distinguish and diagnose comorbid conditions, such as Inducible Laryngeal Obstruction and dysfunctional breathing, including endoscopes and plethysmographs. In addition, there are a number of portable and home-based diagnostic and monitoring technologies accumulating high quality evidence around their efficacy.

However, while equitable access to these services would improve the treatment and control of asthma and other respiratory conditions and subsequently reduce the burden of these conditions on the healthcare system, they are far from the mainstream. It would seem that HTA processes do not accommodate or are deterrent to stakeholders to register these technologies for public health benefit.

HTA processes for MSAC should be reviewed with a view to how they can better facilitate mainstream access to critical respiratory diagnostic and monitoring services.

RECOMMENDATION

Recommendation 10: That DoHAC reviews HTA processes for MSAC to establish how they can better facilitate routine access to critical respiratory diagnostic and monitoring services.

[34] Gibson, PG. Spirometry, you have an image problem!. Respirology. 2023; 28(6): 577.

COST OF PULMONARY REHABILITATION

Pulmonary rehabilitation (PR) is an effective therapy for people with long-term lung conditions. It consists of a 6-8 week group treatment program for people with long-term lung conditions, including chronic obstructive pulmonary disease (COPD), bronchiectasis, pulmonary fibrosis and severe asthma. The program includes both educational and exercise elements delivered by a team of healthcare professionals such as physiotherapists, nurses and occupational therapists. Through exercise, PR aims to improve people's exercise tolerance so they can live more independently and undertake daily activities. Through education, PR seeks to provide people with information about looking after their body and lungs, advice on managing their lung condition and using their medicines, and techniques to manage breathlessness.

Evidence shows that pulmonary rehabilitation improves people's ability to walk further and to feel less tired and breathless, with patients completing a program reporting higher activity and exercise levels, and an improved quality of life.[35] Pulmonary rehabilitation has been shown to support better self-management, fewer exacerbations, fewer admissions to emergency and fewer appointment in primary care.[36]

PR is currently available in hospital under the MBS but not via community healthcare providers, thereby depriving people in the community with equitable access to an effective therapy. PR should be resourced with adequate MBS item numbers to ensure it can be provided to everyone who needs it, regardless of income and including people with severe asthma.

RECOMMENDATION

Recommendation 11: That the Australian Government include additional item numbers on the Medicare Benefits Schedule for pulmonary rehabilitation for people with complex chronic respiratory illnesses.

[35] https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-021-01674-3
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6196907/

Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are acting as a current or future barrier to equitable access?

Below, we provide a summary of our recommendations to address the issues we have identified above.

RECOMMENDATIONS

- **ACCESS TO ASTHMA MEDICINES FOR CHILDREN**

Recommendation 1: That DoHAC undertake a review of policy initiatives and supporting mechanisms needed to ensure that children with asthma have timely and equitable access to appropriate medicines in Australia.

- **COMPOUNDING COSTS: COMORBIDITIES**

Recommendation 2: That TGA and PBAC develop mechanisms to support their parallel consideration of unintended consequences of scheduling changes on equitable consumer access.

Recommendation 3: That DoHAC consider how to reform the current process for identifying medicines to be assessed by PBAC for PBS subsidy to make it more accessible to all stakeholders.

Recommendation 4: That the Australian Government review the current processes for when and how medicines contribute to the PBS safety net with the aim of increasing equity in access to medicines.

- **COMPOUNDING COSTS: INHALER DEVICES AND AID DEVICES**

Recommendation 5: That DoHAC consider how to reform HTA policy so that it appropriately accounts for the high cost associated with inhaler devices, which are critical to the administration of inhaled asthma medicines.

Recommendation 6: That the Australian Government enable access to spacers and masks under the PBS to support equitable access given their importance in effectively and efficiently administering asthma medicines, particularly to children.

- **COSTS OF PREVENTERS**

Recommendation 7: That DoHAC seek to increase equity in access to asthma preventer medicines by:

1. Establishing a communications and education support service for health care professionals and consumers in relation to the quality use of medicines to ensure they are used 'safely, optimally and judiciously, with a focus on informed choice'.[37]
2. Developing mechanisms to enable the PBS to provide higher co-payments for more costly medicines – such as ICS - that prevent chronic conditions from deteriorating and that keep people out of hospital and emergency departments.

[37] https://www.health.gov.au/resources/publications/national-medicines-policy?language=en

3. Making costs of medications visible to prescribers by providing real-time data on the relative costs of therapeutically equivalent medicines and by cost per dose.

- **CASE STUDY: FLUTICASONE PROPIONATE 50MCG (FLIXOTIDE/AXOTIDE JUNIOR)**

Recommendation 8: That the Australian Government initiate a review into the PBAC decision-making process that resulted in the inequitable listing change to Fluticasone Propionate 50mcg. The review should consider how processes can be improved, including those relating to equitable access as well as risk, transparency and consultation processes with consumers, to ensure that the Statutory Price Reduction process cannot produce similar outcomes in future.

- **COST OF ASTHMA DIAGNOSTIC AND MONITORING TESTS**

Recommendation 9: That DoHAC reviews HTA processes for MSAC to ensure they support assessment of all costs associated with delivering spirometry in general practice to result in adequate MBS reimbursement.

Recommendation 10: That DoHAC reviews HTA processes for MSAC to establish how they can better facilitate routine access to critical respiratory diagnostic and monitoring services.

- **COST OF PULMONARY REHABILITATION**

Recommendation 11: That the Australian Government include additional item numbers on the Medicare Benefits Schedule for pulmonary rehabilitation for people with complex chronic respiratory illnesses.

4. ELEMENTS AND FEATURES THAT DETRACT FROM PERSON CENTREDNESS

Are you able to provide details of any elements and features of HTA policy and methods that may be detracting from person centeredness?

HTA COMMUNICATION AND CONSULTATION WITH CONSUMERS

By providing channels to include their real-life experiences, effective communication and consultation with consumers are key tools in the development of person-centred policies. However, HTA communication and consultation with consumers and their representatives is inadequate and inconsistently applied in relation to different HTA processes, including in terms of accessibility of language, website and information on the workings of the regulatory system as a whole. HTA and regulatory processes can lack the real-life insight of those people who will ultimately use (or choose not to use) the medicine or health technology in question. At its worst, this can result in poorly considered decision-making that detracts from person centeredness and equitable access - as seen

in our case study of the PBAC's recent listing change to Fluticasone Propionate 50mcg. Hence despite steps having been taken in recent years to improve HTA consumer engagement, further reforms are required. Below, we set out areas for improvement in HTA consumer engagement policies and processes:

1. **Appropriately accommodate different levels of health literacy in all communications**. HTA communications are not consumer-friendly and therefore act as a barrier to their participation in HTA. HTA communications should ensure all consumers affected by a decision can engage with it and this will require ensuring that the language used is clear and meaningful to consumers. To this end, substantive approaches to upskill and educate consumers are needed (including via association with peaks organisations) to engage with HTA processes, and Asthma Australia would welcome involvement in the development of this work. As a first step, we suggest the reframing of the external-facing presentation of HTA, its processes and the regulatory bodies responsible for them to ensure that HTA is understood as a process to support regulatory bodies in their decision-making. In addition, summaries of TGA and PBAC assessments should be provided with consumer audiences in mind.

2. **Put consumer needs at the centre of all decision-making processes**. Ultimately, HTA is a function to support consumer access to the healthcare and treatment they require in a timely and affordable way and hence their needs should be at the centre of all HTA decisions and outcomes. How consumer needs are considered should be clear to see in assessment summaries and decision-making communications.

3. **Be transparent in relation to all decision-making processes so that consumers can understand why decisions have been made.** In relation to the PBAC listing change to Fluticasone Propionate 50mcg, there was no explanation as to why PBAC changed the criteria with some stakeholders questioning whether new evidence had emerged (it had not). In the absence of information, people can speculate on why changes or decisions have been made, which can cause anxiety. Transparent decision-making helps people not only understand reasons behind decisions but accept them also.

4. **Invite timely consumer feedback in all processes that relate to decision-making that affects them, and before during and after HTA consideration.**

5. **Reform the TGA and PBAC parallel assessment process.** While we note that the parallel assessment for market authorisation and PBS subsidy was introduced to reduce the time it takes for new medicines to be listed, consumers now have access to very little information on which to provide feedback into the new listing process. Specifically, consumers are now expected to provide comments on the potential benefits of a medicine without having access to key regulatory documents such as the Consumer Medicine Information and the Product Information. PBAC also has to regularly defer its decision-making about medicines since TGA have not completed its assessment. Hence, we would recommend that new ways are found to streamline the listing process, which do not prevent meaningful consumer engagement, and that ensure consumers can access necessary information well ahead of providing feedback.

6. **Provide consumer representation on all Committees** to help ensure decision-making

encompasses the breadth of issues that consumers might face in relation to accessing medicines and health care services.

7. **Adequately resource consumer tailored and targeted communications and consultations.**

Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are detracting from person-centeredness?

RECOMMENDATION

Recommendation 12: That the Australian Government increase consumer engagement in TGA regulatory, PBAC subsidisation and HTA processes by appropriately resourcing consumer engagement strategies and tailoring communications to the range of needs and health literacy of consumers. This will require:

- Putting consumer needs at the centre of all decision-making processes,
- Being transparent in relation to all decision-making processes,
- Inviting timely feedback from consumers to all decision-making processes,
- Reforming the TGA and PBAC parallel assessment process, and
- Ensuring and resourcing adequate/meaningful consumer representation on all relevant Committees.

5. PERVERSE INCENTIVES

HTA helps to ensure equitable and sustainable access to safe, cost effective, and affordable health technologies for all Australians. A perverse incentive is where an element or feature of HTA policy and methods may be creating an unintended incentive that results in negative consequences.

Are you able to provide details of elements of features of HTA policy and methods that are causing or could cause unintended consequence or perverse incentives?

(OVER)USE OF ORAL CORTICOSTEROIDS

The underuse of asthma ICS preventer medicines results in escalating asthma symptoms that healthcare professionals and consumers often seek to control using rescue medicines including SABA and oral corticosteroids. Oral corticosteroids (OCS) can be life-saving and remain the cornerstone of managing acute asthma attacks until symptom control has been regained, while some people require OCS daily to maintain control of severe asthma. However, while OCS provide fast-acting relief of asthma symptoms, they have significant adverse effects, including increased risk of heart disease, renal impairment, cardiovascular disease, blood clots, diabetes, obesity, stomach ulcers,

osteoporosis, cataracts, mood disorders and decreased bone density leading to fractures.[38] The risk of developing these toxic side effects have been shown to significantly increase after a cumulative lifetime dose of 1000 mg prednisolone-equivalent (some as low as 500 mg), with a quarter of people with asthma who use an ICS-containing preventer in Australia having been exposed to cumulative doses of OCS above levels considered toxic.[39] Additionally, the adverse effects of OCS are associated with significant healthcare costs, with cost estimates increasing with the severity of asthma.

Significant caution should therefore be taken when prescribing and using OCS. However, PBS dispensing data demonstrates overuse of and overreliance on OCS for asthma management in Australia.[40] The HTA system unwittingly fosters perverse incentives for OCS use in the following ways:

1. **The relative affordability of OCS,** compared to higher out-of-pocket consumer costs of ICS preventer medicines.

2. **The dispensing of rescue OCS treatment in a bottle of 30 x 25mg tablets**. Currently in the event of an acute exacerbation, patients are usually dispensed a bottle of 30 x 25mg tablets. The prescription for an acute attack varies between 50mg per day for 3-5 days. This requires a total of 10 tablets from a 30-tablet bottle, leaving 20 tablets spare, which increases the likelihood of patients self-medicating oral corticosteroids without a prescription or review from a practitioner. As asthma exacerbations are often unexpected events, a rescue pack of 10 x 25mg tablets would be a suitable alternative to allow access to OCS when required. This would support a review with a healthcare professional before another rescue packet can be dispensed. The present dispensing of 30 x 25 mg tablets can be retained for people who require daily doses of OCS to manage their severe asthma.

3. **The current scheduling of OCS.** Despite their side effects, OCS are unrestricted medicines, which enables healthcare professionals to easily prescribe them (unlike, for example, much less problematic ICS medicines such as FP 50 mcg). OCS should be rescheduled to authority prescription for people with asthma to help restrict their ease of access and thereby reduce their overuse. It would also provide a mechanism to monitor the number and frequency of OCS prescriptions being dispensed to people with asthma. This data could then be used to identify patients with uncontrolled or severe asthma who may benefit from specialist review and care and an alternative treatment plan.

4. **The requirement of OCS use before access to monoclonal antibody therapies (biologics therapies).** People with severe asthma face significant steps to be able to access biologics therapies under the PBS, due in part to the cost of these medicines. Eligibility criteria require the daily use of OCS for at least 6 weeks or receiving a cumulative dose of at least 500 mg prednisolone-equivalent in the previous 12 months. Whilst this reflects a good intention of sensible stewardship of finite resources, the processes that support access to biologics therapies for the treatment of asthma must not result in people with severe asthma relying on OCS to the detriment of their long-term health, when biologics therapies might be a more appropriate

[38] Blakey J, Chung LP, McDonald VM, Ruane L, Gornall J, Barton C, Bosnic-Anticevich S, Harrington J, Hew M, Holland AE, Hopkins T, Jayaram L, Reddel H, Upham JW, Gibson PG, Bardin P. Oral corticosteroids stewardship for asthma in adults and adolescents: A position paper from the Thoracic Society of Australia and New Zealand. Respirology. 2021 Dec;26(12):1112-1130.
[39] Ibid.
[40] Cumulative dispensing of high oral corticosteroid doses for treating asthma in Australia - PMC (nih.gov)

treatment for them. **A review of the processes for accessing biologics for people with severe asthma should be undertaken** to ensure that identification of consumers who would most benefit from the use of these therapies is as streamlined as possible.

Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are creating unintended outcomes or perverse incentives either currently or in the future?

RECOMMENDATION

Recommendation 13: That DoHAC identify overuse of oral corticosteroids in asthma management as a priority, and reduce it by working with:

- Sponsors to create an oral corticosteroid rescue pack with 10 x 25mg tablets only (with the current provision of 30 tablets to be indicated only for use by people with severe asthma who require OCS for asthma control)
- PBAC to reschedule oral corticosteroid use to authority prescription only, and
- PBAC to review processes determining access to monoclonal antibody therapies to ensure that people with severe asthma are not required to use potentially toxic cumulative doses of oral corticosteroids when biologics would be more a beneficial treatment for them.

6. AREAS FOR FURTHER INVESTIGATION OR ANALYSIS

Under section 5.3 of the Strategic Agreement it was agreed that an expert in HTA would be engaged, to undertake an analysis of current methods used by the PBAC, contemporary research and relevant methodologies and purchasing practices used by comparable international jurisdictions as guided by the terms of reference. Draft versions of initial findings from this analysis will be available to stakeholders through Consultation 2 later in the year.

Noting the overall scope of the analysis from the HTA expert will be in line with the ToR and agreed by the Reference Committee, are there any HTA or reimbursement models, or elements thereof, utilised in other countries that you believe should be considered for potential adoption in Australia, or that it would be good for the Reference Committee to understand?

N/A.

7. OTHER DETAILS OF IMPORTANCE TO THE HTA POLICY AND METHODS REVIEW NOT COVERED ABOVE + DOCUMENT / ATTACHMENT UPLOAD POINT

The HTA Review **terms of reference** sets out:
- the background to the HTA Review
- how the HTA Review will take account of recent and concurrent reform processes that impact HTA
- HTA Review objectives
- areas under consideration by the HTA Review.

Noting the objectives of the review set out in the Terms of Reference, is there any other information relevant to the Review not provided above that you would like to add?

SUSTAINABILITY

The health care system's carbon footprint has been estimated to be around 7% of Australia's total carbon emissions, 18% of this total is attributable to medicines.[41] Asthma inhalers contribute significantly to medicine-related carbon emissions, with different inhalers having vastly different footprints. For example, pMDI inhalers have large carbon footprints with a Ventolin Evohaler™ having a carbon footprint of 28kg per inhaler while a dry powder inhaler has a carbon footprint of less than 1kg per inhaler.[42] Some pMDI inhalers, such as Flutiform® and Symbicort®, use a particularly damaging type of hydrofluorocarbon, giving them a far greater carbon footprint.[43]

When tackling climate change, Australian Governments must therefore reduce the carbon footprint of the health care system. Climate change is particularly concerning for people with some health conditions, including asthma. It is already impacting the health and quality of life of many people with asthma in Australia, causing and exacerbating symptoms through events such as severe and prolonged bushfires and flooding, and thereby increasing the consumer need for access to medicines and health care. Certain climate change driven phenomena are associated with the development of asthma, such as mould, pollen, and ground level ozone.[44] Additionally, the emissions that drive climate change can trigger asthma symptoms and increase the risk of developing asthma. Increasing asthma prevalence and symptoms leads to further healthcare use, completing an adverse feedback cycle which drive further emissions.

Asthma Australia asks that DoHAC finds an appropriate mechanism to consider sustainability in terms of environmental impact in HTA and regulatory processes. **It is important that such a mechanism does not prevent consumer access to critical medicines and services but rather results in favouring submissions for new and reviewed medicine and service listings with reduced carbon impact when there are alternative efficacious medicines and services to choose from.**

[41] https://www.thelancet.com/journals/lanplh/article/PIIS2542-51961730180-8/fulltext#:~:text=We%20found%20that%20the%20carbon,the%20state%20of%20South%20Australia
[42] The Problem with Inhalers – Green Inhaler
[43] Ibid.
[44] Asthma Australia Climate Change Position Statement: https://asthma.org.au/wp-content/uploads/2022/10/AA-CLIMATE-CHANGE-POLICY-POSITION-OCTOBER-2022.pdf

Associated waste and water footprints should also be considered a part of DoHAC's environmental stewardship, and recycling options should be available where necessary. **DoHAC should work closely with manufacturers to minimise the environmental impact of the medicines and medical products.**

RECOMMENDATION

Recommendation 14: That DoHAC embed environmental sustainability in its medicine and medical service regulatory framework and HTA processes. This should include sponsors/manufacturers taking responsibility for the life cycle of a product and packaging so that carbon footprints and waste are minimised and recycling options are available where necessary.

Would you like to upload any attachments/supporting evidence to your submission?

No.