Health Technology Assessment Policy and Methods Review – Expression of interest for a Deep Dive Discussion

Asthma Australia Submission, September 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.

TOPIC AREA TO BE COVERED THROUGH THE DEEP-DIVE

THE ACCESSIBILITY AND QUALITY USE OF ASTHMA MEDICINES FOR CHILDREN IN AUSTRALIA

To identify our deep dive issue for the HTA Review, Asthma Australia consulted our Professional Advisory Council, which consists of experts from across the health and social sectors, who have a wealth of knowledge and experience in the health system. Together, we agreed that the HTA Review must resolve the longstanding issue of the lack of accessibility of asthma medicines for children in Australia.

Children with asthma in Australia bear a disproportionate burden of the disease, and this reality should be reflected in the relative availability of effective treatments. However, despite many medicines being registered for children with asthma in similar economies, too few are registered for use in Australia and only around 7% of applications to the PBAC for PBS subsidy are for new paediatric indications. Purported reasons for this include Australia's small pharmaceutical market, representing less than 1% of the global market (and even less for paediatric medicines), which influences the priorities and engagement of sponsors with HTA processes, and sponsor-driven HTA processes. They mean sponsors may not pursue a registration of a medicine or an application for subsidisation if they can see no viable commercial reason to do so and hence children will not be able to access these medicines.

Limited access to paediatric medicines in Australia denies children and prescribers the ability to select the most appropriate medicine to manage their individual condition and/or support their personal circumstance. As a result, they may be restricted to using medicines that are not suitable for their individual circumstances, including medicines with prohibitive costs, medicines with technical delivery device features, and medicines with significant side effects, all of which may compromise the quality use of medicines. For children with asthma, limited choice may contribute to or compound the poor use and adherence of asthma preventer medicines, with data showing that less than 20% of patients in Australia are being dispensed enough of preventer medicines (inhaled corticosteroids, ICS) to be taking their treatment in accordance with guidelines.

For example, there is only one ICS registered by the TGA and covered by PBS for children under 5 years of age (fluticasone propionate), and only one biologic asthma treatment registered by the TGA and covered by PBS for children under 12 years of age (Omalizumab). The PBS restrictions for common combination asthma inhalers for the 6-12 year age group mean that several efficacious medicines are not available where they could be effective. In addition, some preparations that are licensed for use in children with asthma in other countries are not available in Australia (e.g. fluticasone furoate 50mcg). The restrictions and lack of asthma medicines for children mean healthcare professionals often prescribe medicines off-label (which may be clinically appropriate but comes with associated increased cost, risk and liability) or according to sub-standard product awareness (product information is only provided for the age group for which the product is registered).

Australia has previously sought to address poor access to paediatric medicines. Previous reviews into this issue resulted in the creation of the Paediatric Medicines Advisory Group (PMAG, from 2007-2011), charged with advocating for children in relation to access to new medicines/formulations. PMAG's achievements included increasing the number of medicines under the PBS and introducing a

requirement that a new drug sponsor applying for TGA registration must provide information about that product trials with children, where it existed.

The HTA Review presents a real opportunity to make a significant difference to the availability of medicines by considering how to reform HTA policies and processes to better support earlier and more equitable access of paediatric medicines in Australia. Despite recognition of the issue previously and some policy reforms, the issue persists to the detriment of the health and wellbeing of children and young people in Australia. An up-to-date review of the accessibility of paediatric medicines is needed to assess the scale of the issue today and to determine the most appropriate approach and delivery mechanisms to improve access to paediatric medicines in the country. Asthma Australia would welcome the opportunity to discuss this issue with the Committee in more detail.

DECLARATIONS OF INTEREST

Asthma Australia has published our submission on the HTA Review on our website, which makes statements about HTA policies. We may make similar public statements about HTA policies in submissions relating to other government consultations and/or the ongoing HTA Review.