SUPPLEMENTARY EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination 2021 (No. 3)

PB 96 of 2021

Purpose of Supplementary Explanatory Statement

This supplementary explanatory statement clarifies how the amendments made in the *National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Amendment Determination 2021 (No. 3)* (the Amendment Determination) satisfies the legislative preconditions explained in section 84AH of the *National Health Act 1953* (the Act). The Amendment Determination amends the *National Health (Pharmaceutical Benefits Scheme - Exempt items - Section 84AH) Determination 2017* (the Principal Determination).

Additional notes

Legislative preconditions

At its July 2013 meeting, the Pharmaceutical Benefits Advisory Committee advised the Minister, in accordance with section 101(4AB) of the Act, that it was of the opinion that the following circumstances exist in relation to diazepam oral liquid:

(i) It represents suitable therapy for patients with chronic spasticity;
(ii) It is suitable for use by a particular subgroup of these patients who are paediatric and dysphagic because of their inability to swallow a solid dose form; and
(iii) No other pharmaceutical item that has diazepam is suitable for this subgroup.

Diazepam Elixir continues to be the only brand of diazepam oral liquid listed on the Pharmaceutical Benefits Scheme (PBS). While there are brands of other pharmaceutical items listed on the PBS with the same drug, diazepam, no listed brands are bioequivalent or biosimilar to Diazepam Elixir. Diazepam oral liquid therefore meets the legislative preconditions explained in section 84AH of the Act.

Changes made in the Amendment Determination

The Amendment Determination included an editorial update to the form description of a medicine already listed on the Principal Determination – diazepam oral liquid.

Diazepam oral liquid was listed on the PBS on 1 August 2013. The form description for the product was included as *"Oral liquid 1 mg in 1 mL, 100 mL*" on the PBS Schedule. This form description was subsequently included in the amendments to the Principal Determination.

In 2021, the Australian Digital Health Agency (ADHA) changed the Australian Medicines Terminology (AMT) descriptors for diazepam oral liquid to describe its strength as "10 mg/10 mL". On 1 September 2021, a modification to the form description on the PBS Schedule to *"Oral liquid 10 mg per 10 mL, 100 mL"* was implemented to reflect the new AMT descriptor.

As a result, editorial changes to the Principal Determination to reflect the new AMT descriptor, *"Oral liquid 10 mg per 10 mL, 100 mL",* were made via the Amendment Determination for consistency with the PBS Schedule.

This change does not affect the exempt status of diazepam oral liquid, as the circumstances of the listing have not changed, and the item continues to meet the legislative preconditions outlined in section 84AH of the Act.