

## SUPPLEMENTARY EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021*

**PB 108 of 2021**

#### **Purpose of supplementary explanatory statement**

This supplementary explanatory statement clarifies the consultation referred to in the explanatory statement to the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021 [F2021L01296]* (the Amendment Instrument). The Amendment Instrument amends the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (the Principal Determination).

#### **Additional notes on consultation**

Consultation was previously undertaken with stakeholders in the development of the Principal Determination. Consultation focused on Pharmaceutical Benefits Scheme (PBS) subsidisation of medicines substituted in accordance with section 30EL of the *Therapeutic Goods Act 1989*. Stakeholders included, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Australian Medical Association, the Consumers Health Forum of Australia, the Royal Australian College of General Practitioners, and the Royal Australian College of Nurse Practitioners. Stakeholders were supportive of the Principal Determination. Stakeholders raised no substantive concerns in relation to the Principal Determination, however they requested improved communication strategies which the Department undertook in response.

Consultation with stakeholders on PBS subsidy undertaken in the development of the Principal Determination. As the Amendment Determination reflects the intention of that previous consultation, no further industry stakeholder consultation was considered necessary.

However, consultation with experts in relation to the Amendment Determination was undertaken. Consultation occurred with the Chair and relevant expert members of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body that recommends medicines for listing on the PBS. Consultation with PBAC experts focused on specific advice about the appropriateness of PBS subsidisation for the Amendment Instrument. The PBAC experts endorsed the proposed approach as it was considered that the substitution arrangement is necessary, with limited other options available for patients needing replacement as quickly as possible.