ITEMS RECOMMENDED OUT OF SESSION BETWEEN ORDINARY MEETINGS (MARCH 2023 – JULY 2023)

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
BUPRENORPHINE BUPRENORPHINE WITH NALOXONE METHADONE	Opioid dependence	To consider the Interim Report for the Post-Market Review (PMR) of Opioid Dependence Treatment medicines and request Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for the treatment of opioid dependence	Recommended	The PBAC considered the Interim Report for the PMR of Opioid Dependence Treatment Program (ODTP) medicines addressing the Review Terms of Reference and noted the stakeholder input to the PMR, including targeted consultation with people participating in opioid dependence treatment (ODT) programs. Medicines for the treatment of opioid dependence listed on the ODTP include buprenorphine (sublingual tablets and modified release injections), buprenorphine with naloxone (sublingual films) and methadone (oral liquid). The PBAC recommended the current listing of ODT medicines on the PBS Section 100 ODTP be amended and the listings moved to the Section 100 Highly Specialised Drugs (HSD) Program (Community Access) as Authority Required (STREAMLINED) listings. The PBAC noted that listing ODT medicines under the Section 100 HSD Program (Community Access) will benefit patients with access to the PBS co-payment and the PBS Safety-Net and it will also enable important supply to people in correctional facilities and GP clinics. Pharmacists would receive PBS dispensing fees set out under the Section 100 HSD Program. The PBAC also noted the additional activities associated with the dispensing of ODT medicines that have more frequent dispensing requirements (such as oral methadone and sublingual buprenorphine) and recognised that pharmacy remuneration by government for dosing activities would mean private community pharmacy fees would not be charged to patients. The PBAC commented on other interim outcomes of the PMR and requested the government progress discussions with state and territory governments on matters relating to state and territory ODT program service delivery including dosing policies, maintenance

				of access to public treatment options, workforce issues, access for First Nations and other populations with specific needs and updating the *2014 National Guidelines for Medication-Assisted Treatment of Opioid Dependence*.
NIRMATRELVIR AND RITONAVIR Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5 Paxlovid® Department of Health (Commonwealth) (Change to PBS listing)	Mild to moderate COVID-19	To review current Pharmaceutical Benefits Scheme (PBS) eligibility for nirmatrelvir and ritonavir; consider whether broader eligibility is appropriate while the Commonwealth is the Responsible Person; and recommend any changes to restrictions.	Recommended	The PBAC recommended expanding the PBS patient eligibility criteria for nirmatrelvir and ritonavir to include people aged 50-59 years with mild to moderate COVID-19 and one additional risk factor. The PBAC was satisfied that clinical benefit and safety exists for use of nirmatrelvir and ritonavir in the proposed new patient group. The PBAC considered that the listing will be cost-effective in the expanded population for so long as pharmaceutical benefits dispensed are sourced from the stock already purchased by the Commonwealth, and which might otherwise expire unused. As such, the PBAC recommended that this expansion of patient eligibility only apply until the Commonwealth purchased stock is exhausted or has expired.
MIFEPRISTONE AND MISOPROSTOL Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms MS-2 Step® MS Health Pty Ltd (Change to PBS listing)	Termination of an intrauterine pregnancy	To seek PBAC's advice whether it would be appropriate to amend the current PBS restrictions for MS-2 Step® following the changes made approved by the Therapeutic Goods Administration (TGA) to its Product Information (PI) and Risk Management Program (RMP).	Recommended	The PBAC noted the recent decision by the TGA to amend the PI and RMP for MS-2 Step®. The PBAC recommended amending PBS restrictions for MS-2 Step® to align with the TGA changes by removing the treatment criteria '*must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program*.' The PBAC recommended the inclusion of nurse practitioners and authorised midwives as eligible prescriber types for MS-2 Step® on the PBS. The PBAC recalled its March 2023 recommendation, and noted that, consistent with that recommendation, these restriction amendments will be implemented as an Authority Required (STREAMLINED) listing. The PBAC considered that the TGA decision and this recommended change to the PBS listing will assist in

				addressing important access issues for patients who require this medication.

Version 2
Amendment

1. MIFEPRISTONE AND MISOPROSTOL (MS-2 Step®) – Outcome updated

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Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: • A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR • A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR • A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
Category 2	A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.
Category 3	Requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.
Category 4	A request for one or more of the following: • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*). • Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing. • A change/new manner of administration of a listed medicine. • A change to the maximum quantity and/or number of repeats of a listed medicine. • A change or addition to the prescriber type(s) of a listed medicine.
Committee Secretariat	Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following: • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk • Pharmaceutical benefits that can no longer be supplied early • New brand of glucose indicator pharmaceutical item.