

## Agenda item 14.06

### Continued Dispensing Arrangements

#### 1. Purpose of Item

1.1. To request that the PBAC:

- NOTE that the Continued Dispensing Emergency Measures are due to cease on 30 June 2022;
- CONSIDER the stakeholder feedback on the proposed changes to ongoing Continued Dispensing arrangements recommended by PBAC in May 2020;
- CONSIDER making changes to the May 2020 recommendations, including the list of medicines and principles, to ongoing Continued Dispensing arrangements, in response to stakeholder feedback.

#### 2. Context

*Revised PBS Medicines under ongoing Continued Dispensing Arrangements*

- 2.1. In March 2020, the PBAC considered a proposal from the Pharmacy Guild of Australia (Guild) to expand Continued Dispensing arrangements to all PBS medicines, with particular exclusions.
- 2.2. The PBAC did not support this approach, and instead requested that the Department develop a list of medicines that would be appropriate for a Continued Dispensing supply on the basis that they would be safe and well-tolerated for the treatment of chronic and stable disease.
- 2.3. A list of medicines was endorsed by the PBAC in May 2020. The PBAC also endorsed a set of principles for consideration of new medicines for inclusion in Continued Dispensing arrangements.
- 2.4. The medicines recommended by the PBAC are predominantly chronic disease medicines (such as those used to treat asthma, lung disease, diabetes, heart disease) and supplied under the PBS General Schedule (s85). However, the PBAC also endorsed the inclusion of medicines for human immunodeficiency virus (HIV), which are available under the s100 Highly Specialised Drugs (HSD) Program.
- 2.5. The PBAC also supported a proposal that the Closing the Gap PBS Copayment Program (the CTG Program), which reduces or removes the PBS copayment for eligible Aboriginal and Torres Strait Islander people, should apply to medicines supplied under Continued Dispensing.

### *Stakeholder Consultations*

- 2.6. On 1 February 2021, the Department wrote to the following stakeholders to seek comments about the proposed changes to Continued Dispensing as recommended by the PBAC:
- Guild;
  - Pharmaceutical Society of Australia (PSA);
  - Australian Medical Association (AMA);
  - Royal Australian College of General Practitioners (RACGP);
  - Consumer Health Forum (CHF); and
  - Australian Federation of AIDS Organisations (AFAO).
- 2.7. The feedback received from stakeholder groups was varied, with medical groups generally expressing concerns with the proposal. Key feedback from medical, pharmacy and consumer groups was considered by the PBAC.
- 2.8. As part of the consultation process, the Department offered stakeholders the opportunity to meet with the Chair of the PBAC.
- 2.9. The PBAC noted that, since its recommendations in May 2020, there have been significant changes in the health sector in response to the COVID-19 pandemic, including a range of new measures which can support patients to continue receiving their PBS medicines.

## **3. Background**

### *Continued Dispensing Arrangements*

- 3.1. The Continued Dispensing Initiative commenced in 2013, as part of the Fifth Community Pharmacy Agreement. It enables an approved pharmacist to supply a PBS quantity of an eligible medicine to a person when there is an immediate need for that medicine but it is not practicable to obtain a prescription. In this context, practicable is where “it is not possible to contact a prescriber to obtain a prescription (hard or electronic copy) or a telephone order to supply the medicine”.
- 3.2. In conducting a continued dispensing supply, pharmacists are required to consider the Pharmaceutical Society of Australia’s Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists. Pharmacists must be satisfied that the patient has previously been prescribed the medicine, therapy is stable, and the medicine is safe and appropriate for the consumer. A person may only receive one continued dispensing supply per eligible medicine within a twelve-month period. When first established, Continued Dispensing arrangements only applied to certain oral contraceptives and lipid-lowering medicines (statins). These (ongoing)

arrangements are legally underpinned by the *National Health (Continued Dispensing) Determination 2012*.

#### *Continued Dispensing Emergency Measures*

- 3.3. In response to the bushfire crisis in January 2020, the range of PBS-subsidised medicines that could be supplied without a prescription under continued dispensing arrangements was temporarily expanded until 31 March 2020 through the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*. Due to the ongoing impact of the COVID-19 pandemic, the Government extended these arrangements on several occasions, most recently until 30 June 2022.
- 3.4. From 13 January 2020 to 30 June 2021, over 360,000 people received at least one supply of medicine under the Emergency Measures, with 75% receiving one supply, and the remainder receiving two or more supplies for different medicines. In addition, more than 3,800 community pharmacies supplied a PBS medicine under these arrangements during that time. These numbers exclude supplies of oral contraceptives and lipid-lowering medicines (statins).

## **4. PBAC Outcome**

- 4.1. The PBAC noted the Continued Dispensing Emergency Measures were to cease on 31 December 2021, but on 5 November 2021 it was announced that the Continuing Dispensing Emergency Measures were extended until 30 June 2022.
- 4.2. The PBAC reviewed and acknowledged the concerns raised by stakeholder groups. The PBAC noted the general support for the proposed changes to ongoing Continued Dispensing arrangements endorsed by PBAC in May 2020.
- 4.3. The PBAC reviewed the list of medicines for inclusion out of the May 2020 recommendations and did not propose changes to the list. However, the PBAC recommended the following changes to the Continued Dispensing principles:

<b>Original wording of general principles from May 2020</b>	<b>Revised wording</b>
It is not practicable for the person to obtain a valid prescription from an authorised prescriber (including via a telehealth consultation)	The usual prescriber must be unable to be contacted and/or is unable to provide an e-prescription or owing prescription
The medicine has been supplied to the person in the last six (6) months and their condition is stable	The medicine has been supplied to the person in the last three (3) months and their condition is stable
The pharmacists must consider all other options prior to utilising Continued Dispensing.	Nil (Removed)

## 5. Recommended Listing

List of medicines endorsed by the PBAC for continued dispensing

ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
A10AB	Insulins and Analogues for injection, fast acting	Insulin aspart	Injection	Unrestricted	
		Insulin glulisine	Injection	Unrestricted	
		Insulin lispro	Injection	Unrestricted	
		Insulin neutral human	Injection	Unrestricted	
A10AC	Insulins and Analogues for injection, intermediate acting	Insulin isophane human	Injection	Unrestricted	
A10AD	Insulins and Analogues for injection, intermediate or long acting combined with fast acting	Insulin aspart + insulin aspart protamine	Injection	Unrestricted	
		Insulin degludec + insulin aspart	Injection	Unrestricted	
		Insulin isophane human + insulin neutral human	Injection	Unrestricted	
		Insulin lispro + insulin lispro protamine	Injection	Unrestricted	
A10AE	Insulins and Analogues for injection, long acting	Insulin detemir	Injection	Restricted	
		Insulin glargine	Injection	Unrestricted	
A10BA	Biguanides	Metformin	Tablet	Unrestricted	
A10BB	Sulfonylureas	Glibenclamide	Tablet	Unrestricted	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Gliclazide	Modified release	Unrestricted	
		Glimepiride	Tablet	Unrestricted	
		Glipizide	Tablet	Unrestricted	
A10BC	Combinations of oral blood glucose lowering drugs	Alogliptin + metformin	Tablet	Streamlined	
		Dapagliflozin + metformin	Tablet	Streamlined	
		Empagliflozin + linagliptin	Tablet	Streamlined	
		Empagliflozin + metformin	Tablet	Streamlined	
		Ertugliflozin + metformin	Tablet	Streamlined	
		Ertugliflozin + sitagliptin	Tablet	Streamlined	
		Linagliptin + metformin	Tablet	Streamlined	
		Metformin + glibenclamide	Tablet	Unrestricted	
		Saxagliptin + dapagliflozin	Tablet	Streamlined	
		Saxagliptin + metformin	Tablet	Streamlined	
		Sitagliptin + metformin	Tablet	Streamlined	
		Vildagliptin + metformin	Tablet	Streamlined	
A10BF	Alpha glucosidase inhibitors	Acarbose	Tablet	Unrestricted	
A10BG	Thiazolidinediones	Pioglitazone	Tablet	Streamlined	
A10BH	Dipeptidyl peptidase 4 (DPP-4) inhibitors	Alogliptin	Tablet	Streamlined	
		Linagliptin	Tablet	Streamlined	
		Saxagliptin	Tablet	Streamlined	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Sitagliptin	Tablet	Streamlined	
		Vildagliptin	Tablet	Streamlined	
A10BJ	Glucagon-like peptide-1 (GLP-1) analogues	Dulaglutide	Injection	Streamlined	
		Exenatide	Injection	Streamlined	
		Semaglutide	Injection	Streamlined	
A10BK	Sodium-glucose co-transporter 2 (SGLT2) inhibitors	Dapagliflozin	Tablet	Streamlined	
		Empagliflozin	Tablet	Streamlined	
		Ertugliflozin	Tablet	Streamlined	
C03AA	Low-ceiling diuretics - thiazides, plain	Hydrochlorothiazide	Tablet	Unrestricted	
C03BA	Low-ceiling diuretics - sulfonamides, plain	Chlortalidone	Tablet	Unrestricted	
		Indapamide	Tablet	Unrestricted	
C03CA	High-ceiling diuretics - sulfonamides, plain	Furosemide (frusemide)	Tablet	Unrestricted	
C03CC	High-ceiling diuretics - aryloxyacetic acid derivatives	Etacrynic acid	Tablet	Restricted	
C03DA	Potassium-sparing agents - aldosterone antagonists	Eplerenone	Tablet	Streamlined	
		Spirolactone	Tablet	Unrestricted	
C03EA	Diuretics and potassium-sparing agents in combination	Amiloride +hydrochlorothiazide	Tablet	Unrestricted	
C07AA	Beta blocking agents, non-selective	Oxprenolol	Tablet	Unrestricted	
		Pindolol	Tablet	Unrestricted	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Propranolol	Tablet	Unrestricted	
C07AB	Beta blocking agents, selective	Atenolol	Tablet	Unrestricted	
		Bisoprolol	Tablet	Restricted	
		Metoprolol succinate	Tablet	Restricted	
		Metoprolol tartrate	Tablet	Unrestricted	
		Nebivolol	Tablet	Restricted	
C07AG	Alpha and beta blocking agents	Carvedilol	Tablet	Restricted	
		Labetalol	Tablet	Unrestricted	
C08CA	Selective calcium channel blockers with mainly vascular effects - dihydropyridine derivatives	Amlodipine	Tablet	Unrestricted	
		Felodipine	Tablet	Unrestricted	
		Lercanidipine	Tablet	Unrestricted	
		Nifedipine	Tablet	Unrestricted	
C08DA	Selective calcium channel blockers with direct cardiac effects vascular - phenylalkylamine derivatives	Verapamil	Tablet	Unrestricted	
C08DB	Selective calcium channel blockers with direct cardiac effects vascular - benzothiazepine derivatives	Diltiazem	Tablet, capsule	Unrestricted	
C09AA	ACE inhibitors, plain	Captopril	Tablet	Unrestricted	
		Enalapril	Tablet	Unrestricted	
		Fosinopril	Tablet	Unrestricted	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Lisinopril	Tablet	Unrestricted	
		Perindopril	Tablet	Unrestricted	
		Quinapril	Tablet	Unrestricted	
		Ramipril	Tablet	Unrestricted	
		Trandolapril	Capsule	Unrestricted	
C09BA	ACE inhibitors + diuretics	Enalapril + hydrochlorothiazide	Tablet	Restricted	
		Fosinopril + hydrochlorothiazide	Tablet	Restricted	
		Perindopril + indapamide	Tablet	Restricted	
		Quinapril + hydrochlorothiazide	Tablet	Restricted	
C09BB	ACE inhibitors + calcium channel blockers	Lercanidipine + enalapril	Tablet	Restricted	
		Perindopril + amlodipine	Tablet	Restricted	
		Ramipril + felodipine	Tablet	Restricted	
		Trandolapril + verapamil	Tablet	Restricted	
C09CA	Angiotensin II receptor blockers (ARBS), plain	Candesartan	Tablet	Unrestricted	
		Eprosartan	Tablet	UNCLEAR	
		Irbesartan	Tablet	Unrestricted	
		Losartan	Tablet	Unrestricted	
		Olmesartan	Tablet	Unrestricted	
		Telmisartan	Tablet	Unrestricted	
		Valsartan	Tablet	Unrestricted	
C09DA	Angiotensin II receptor blockers (ARBS) and diuretics	Candesartan + hydrochlorothiazide	Tablet	Restricted	
		Eprosartan + hydrochlorothiazide	Tablet	Restricted	
		Irbesartan + hydrochlorothiazide	Tablet	Restricted	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Olmesartan + hydrochlorothiazide	Tablet	Restricted	
		Telmisartan + hydrochlorothiazide	Tablet	Restricted	
		Valsartan + hydrochlorothiazide	Tablet	Restricted	
C09DB	Angiotensin II receptor blockers (ARBS) and calcium channel blockers	Amlodipine + valsartan	Tablet	Restricted	
		Olmesartan medoxomil + amlodipine	Tablet	Restricted	
		Telmisartan + amlodipine	Tablet	Restricted	
C09DX	Angiotensin II receptor blockers (ARBS), other combinations	Amlodipine + valsartan + hydrochlorothiazide	Tablet	Restricted	
		Olmesartan + amlodipine + hydrochlorothiazide	Tablet	Restricted	
		Sacubitril + valsartan	Tablet	Restricted	
C10BA	HMG CoA reductase inhibitors in combination with other lipid modifying agents	Ezetimibe + rosuvastatin	Tablet	Streamlined	
		Ezetimibe + atorvastatin	Tablet	Streamlined	
		Ezetimibe + simvastatin	Tablet	Streamlined	
C10BX	HMG CoA reductase inhibitors, other combinations	Amlodipine + atorvastatin	Tablet	Unrestricted	
J05AE	Protease inhibitors	Atazanavir	Capsule	Streamlined	S100 HSD Community Access
		Atazanavir + cobicistat	Tablet	Streamlined	S100 HSD Community Access
		Darunavir	Tablet	Streamlined	S100 HSD Community Access

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Fosamprenavir	Tablet	Streamlined	\$100 HSD Community Access
		Ritonavir	Tablet	Streamlined	\$100 HSD Community Access
		Saquinavir	Tablet	Streamlined	\$100 HSD Community Access
		Tipranavir	Capsule	Streamlined	\$100 HSD Community Access
J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors	Abacavir	Tablet and liquid	Streamlined	\$100 HSD Community Access
		Adefovir	Tablet	Streamlined	\$100 HSD Community Access
		Entecavir	Tablet	Streamlined	\$100 HSD Community Access
		Lamivudine	Tablet	Streamlined	\$100 HSD Community Access
		Tenofovir disoproxil	Tablet	Streamlined	\$100 HSD Community Access
		Zidovudine	Capsule and liquid	Streamlined	\$100 HSD Community Access
J05AG	Non-nucleoside reverse transcriptase inhibitors	Efavirenz	Tablet and liquid	Streamlined	\$100 HSD Community Access

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Etravirine	Tablet	Streamlined	\$100 HSD Community Access
		Nevirapine	Tablet and liquid	Streamlined	\$100 HSD Community Access
		Rilpivirine	Tablet	Streamlined	\$100 HSD Community Access
J05AJ	Integrase inhibitors	Dolutegravir	Tablet	Streamlined	\$100 HSD Community Access
		Raltegravir	Tablet	Streamlined	\$100 HSD Community Access
J05AR	Antivirals for treatment of HIV infections, combinations	Abacavir + lamivudine	Tablet	Streamlined	\$100 HSD Community Access
		Abacavir + lamivudine + zidovudine	Tablet	Streamlined	\$100 HSD Community Access
		Bictegravir + emtricitabine + tenofovir alafenamide	Tablet	Streamlined	\$100 HSD Community Access
		Darunavir + cobicistat	Tablet	Streamlined	\$100 HSD Community Access
		Darunavir + cobicistat + emtricitabine + tenofovir alafenamide	Tablet	Streamlined	\$100 HSD Community Access
		Dolutegravir + abacavir + lamivudine	Tablet	Streamlined	\$100 HSD Community Access
		Dolutegravir + lamivudine	Tablet	Streamlined	\$100 HSD Community Access

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
		Dolutegravir + rilpivirine	Tablet	Streamlined	\$100 HSD Community Access
		Emtricitabine + rilpivirine + tenofovir alafenamide	Tablet	Streamlined	\$100 HSD Community Access
		Emtricitabine + tenofovir alafenamide	Tablet	Streamlined	\$100 HSD Community Access
		Lamivudine + zidovudine	Tablet	Streamlined	\$100 HSD Community Access
		Lopinavir + ritonavir	Tablet	Streamlined	\$100 HSD Community Access
		Tenofovir + emtricitabine	Tablet	Streamlined	\$100 HSD Community Access
		Tenofovir + emtricitabine + efavirenz	Tablet	Streamlined	\$100 HSD Community Access
		Tenofovir alafenamide + emtricitabine + elvitegravir + cobicistat	Tablet	Streamlined	\$100 HSD Community Access
J05AX	Other antivirals	Enfuvirtide	Injection	Streamlined	\$100 HSD Community Access
		Maraviroc	Tablet	Streamlined	\$100 HSD Community Access
R03AC	Selective beta-2-adrenoreceptor agonists	Formoterol (eformoterol)	Inhalation	Restricted	
		Indacaterol	Inhalation	Restricted	
		Salbutamol	Inhalation	Restricted	
		Salmeterol	Inhalation	Restricted	
		Terbutaline	Inhalation	Streamlined	

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ATC	DRUG CLASS	ACTIVE INGREDIENT	FORM	RESTRICTIONS	COMMENTS
R03AK	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics	Beclometasone + Formoterol (eformoterol)	Inhalation	Streamlined	
		Budesonide + Formoterol (eformoterol)	Several	Streamlined	
		Fluticasone furoate + Vilanterol	Inhalation	Streamlined	
		Fluticasone propionate + Formoterol (eformoterol)	Inhalation	Streamlined	
		Fluticasone propionate + Salmeterol	Inhalation	Streamlined	
		Indacaterol + Mometasone	Inhalation	Streamlined	
R03BA	Glucocorticoids	Beclometasone	Inhalation	Unrestricted	
			Activated inhalation	Restricted	
		Budesonide	Inhalation Powder	Unrestricted	
			Inhalation Solution	Streamlined	
		Ciclesonide	Inhalation	Unrestricted	
		Fluticasone furoate	Inhalation	Unrestricted	
		Fluticasone propionate	Inhalation	Unrestricted	
R03BC	Antiallergic agents, excl. corticosteroids	Cromoglycate	Inhalation	Unrestricted	
		Nedocromil	Inhalation	Unrestricted	