Australian Government
Department of Health
Therapeutic Goods Administration

Building a more robust medicine supply

Proposals to help prevent, mitigate and manage medicine shortages

Version 1.0, March 2021

TGA Health Safety Regulation

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Consultation overview

The Therapeutic Goods Administration (TGA) is seeking feedback on proposals to help ensure ongoing, reliable supply of important medicines.

Medicine shortages have been of particular concern during the COVID-19 pandemic. We have been reviewing the ways in which we can better assist affected Australian patients and their healthcare providers. Specifically, we are seeking feedback on possible reforms that would:

- prioritise the evaluation and registration process for certain important generic prescription medicines, to reduce the risk of shortages
- encourage registration of more generic versions of medicines known to be affected by shortages, to mitigate the impact of those shortages
- support a more reliable supply of overseas-registered medicines imported into Australia as substitutes when the Australian medicine is in longstanding or repeated shortage.

Why are we consulting?

We have an important role in managing medicine shortages, to assist patients when they cannot access their usual medicines. While we have mechanisms to allow supply of overseas products to assist with a shortage in Australia, patients still experience difficulties and uncertainty using these options. The proposals in this paper aim to improve supply of Australian-registered goods, as a more robust supply will reduce the impact of an individual medicine going into shortage.

There are currently no specific regulatory pathways designed explicitly to facilitate registration on the Australian Register of Therapeutic Goods (the ARTG) of medicines with the aim of supporting on-going supply or reducing the likelihood of shortages. However, we have various legislative, regulatory and administrative mechanisms to reduce regulatory burden on applicants under certain circumstances. These all rely on one or more of the following concepts:

- fee/charge waivers or reduced fees
- expedited evaluation
- additional support to prepare applications for evaluation (for example, pre-submission meetings and requests for Early Scientific Advice service)
- varying evidentiary requirements (for example, literature-based submissions rather than de novo data).

We have identified four approaches, incorporating various combinations of these, as possible medicine shortage mitigation or management strategies.

Consultation scope

We are unable to compel sponsors to make an application for registration and the TGA has no powers to compel ongoing supply of any approved goods. Inclusion on the ARTG often doesn't equate to supply in the market and stakeholders have raised this with us as a concern. Possible alignment with Pharmaceutical Benefits Scheme (PBS) processes may be required to achieve the full benefits of our proposals; however, consideration of alignment of ARTG registration and PBS listing is outside the scope of this consultation.

How to respond

We have posed questions within this consultation paper to help guide your feedback. You can also give us any additional comment and attach a separate response document if you wish.

You do not have to answer all the questions, none are compulsory.

You can

- submit your views by clicking the link below – this will step you through our questions

  OR

- download the full consultation paper and upload a response document on the final page.

Background

Preliminary consultation

We have had active involvement of peak pharmaceutical industry and wholesaler bodies in our review of processes for managing medicine shortages. We have also had input from the Medicine Shortages Working Party (Working Party), a multi-stakeholder group first convened by the Government in 2015 to assist us to develop strategies to improve the management of medicine shortages.

The Working Party comprises representatives from pharmaceutical industry and wholesaler peak bodies (Medicines Australia, Generic and Biosimilar Medicines Association, Consumer Health Products Australia and the National Pharmaceutical Services Association), health professional organisations (Australian Medical Association, The Pharmacy Guild, Pharmaceutical Society of Australia, Society of Hospital Pharmacists of Australia) and is chaired by the Department of Health.

In 2019, the *Therapeutic Goods Act 1989* (the Act) was amended to require sponsors (usually pharmaceutical companies) to tell us of shortages of prescription and certain over-the-counter medicines. At the end of 2019, the Working Party reviewed the performance of the mandatory reporting scheme and recommended enhancements to improve the identification, communication and management of medicine shortages. The Working Party met frequently during 2020 to coordinate solutions to medicine supply issues related to the COVID-19 pandemic.

In 2020-21, our focus has been on four main areas:

- enhancements to the Medicine Shortage Information Initiative to improve the clarity and currency of information provided about notified shortages through the TGA website
- expansion of data collection and analysis to allow early identification of potential shortages
- development of new education and communication initiatives for medicine shortages in collaboration with health professional organisations, pharmacy associations and consumer groups
- consideration of mechanisms to prevent and mitigate medicine shortages.

The proposed mechanisms to prevent and mitigate medicine shortages are explored in this consultation paper.

Proposed actions

Proposal 1 – Prioritising evaluation of important generic medicines

The cause of medicine shortages is a complex and diverse interaction of many factors. These can include manufacturing problems, difficulties in procurement, global acquisition of sponsor companies, political instability and natural disasters.

There are actions we can take in response to a medicine shortage, including arrangements for alternative sources of supply once it is recognised. A more proactive approach would be to diversify supply by encouraging more generic versions to be registered on the ARTG, particularly for those medicines with only one supplier or manufacturer. This could reduce the likelihood of medicine shortages happening.

Other regulatory agencies have adopted such schemes. For example, the United States Food and Drug Administration (US FDA) has a review process designed to prioritise submissions for generic medicines that would have a '*meaningful impact on generic drug access*'. US FDA Guidance sets out eight public health priorities (or 'prioritisation factors') that may qualify a generic medicine for a prioritised review.

Some of these priorities are specific to the US context, but two may have relevance to our considerations of medicine shortages. These are 'sole-source' drug products (i.e., in an Australian context, a drug product with a single sponsor and no blocking patents) and '*submissions containing certain patent certifications and exclusivity statements*' (in an Australian context amounting to a submission for a first generic that anticipates expiry of relevant patents). It is important to note critical differences in the public health systems in each country that may affect consideration of adoption of similar schemes in Australia, particularly market exclusivity provisions given to first generics in the US.

In 2019, we consulted publicly on a proposal to prioritise our evaluation and registration of two groups of medicines: those known to be subject to shortage in Australia; and first and second generics of medicines coming off patent. The aim was to make alternative versions of the same medicine available in the Australian marketplace as quickly as possible, to help ensure robust supply.

Several stakeholder groups told us that our intended benefits were unlikely to be realised as the TGA evaluation time was not seen as an impediment to timely availability of new generic medicines. They suggested that, because the TGA does not have a mechanism to ensure supply, additional registrations would not address shortages. Industry stakeholders suggested that 'priority' assessment of variations to existing medicines would be of greater benefit in mitigating medicine shortages.

In response to this last suggestion, we implemented a new internal process in late 2019. This allows sponsors to identify, as part of their shortage notification and their variation request, that the variation is sought as part of a mitigation or management strategy for a medicine shortage. The relevant TGA business areas then coordinate to ensure we process the request as quickly as possible.

Questions

Q1. Do you think that prioritising TGA's evaluation of first and second generic versions of innovator medicines will assist in preventing medicine shortages? Why?

Q2. If the TGA were to prioritise the evaluation of first and second generic versions of innovator medicines, how would this affect you? Can you quantify the effect for us?

Q3. Do you think that prioritising TGA's evaluation of new generic versions of 'sole source' medicines will assist in preventing medicine shortages? Why?

Q4. If the TGA were to prioritise the evaluation of new generic versions of 'sole source' medicines, how would this affect you? Can you quantify the effect for us?

Q5. If you gave us feedback on this proposal as part of our 2019 consultation on 'Reforms to the generic medicine market authorisation process', has there been any change to your stated position? If so why?

Q6. Do you have any other suggestions on how the TGA could change evaluation, or any other business, processes to support the registration of new generic medicines?

Proposal 2 – Mitigating the effects of a medicine shortage

Commercial viability is an important consideration for companies considering supplying a medicine in Australia, especially for medicines with a small market share relative to the costs of preparing a regulatory submission. It could be that the costs associated with seeking approval and registration on the ARTG are a disincentive, particularly when the intended patient population is small or profit margins are low. Under our current cost recovery framework, application fees cover the administrative costs associated with an application and evaluation fees cover the cost of our assessment of the accompanying dossier. Only in limited circumstances do we perform these functions without cost to the applicant or sponsor.

One example is a legal requirement to waive various fees when a medicine has been designated as an orphan drug. These medicines are usually new entities, or an existing molecule being used in a new way, for a small patient population.

Otherwise, we can consider waiving or reducing evaluation fees only in very limited circumstances. This can occur

- if the application is for a prescription medicine necessary to address a public health emergency and
- where the evaluation can be abridged and
- if the reduction or waiver is necessary to enable supply.

It would be difficult for a medicine currently or previously in supply (either as a medicine supplied under section 19A of the Act or with limited registered brands), but at risk of shortage, to meet the criteria in either of these circumstances. If reduced fees can assist in mitigating medicine shortages, we need to develop new criteria.

We are proposing that this new set of criteria be tailored to support medicines with limited commercial viability or in longstanding shortage. A list of medicines that have been subject to repeated shortage in the last two years is at **Attachment 1**. This gives you examples where we may be able to better assist patients if more companies were able to sponsor additional medicines on the ARTG. Other situations that might be assisted are niche medicines needed by small patient populations but not in reliable supply due to commercial reasons.

Important considerations in determining any fee reduction or waiver include the number of eligible medicines, how the costs of the evaluation effort could be funded and the relative impact on TGA resources committed to cost-recovered activities.

Questions

Q7. Do you think that waiving or reducing application and/or evaluation fees for new generic versions of medicines known to be often in shortage or limited supply in Australia will assist in preventing future shortages? Please tell us the reasons for your answer.

Q8. If we waived or reduced application and evaluation fees for new generic versions of certain medicines, how would this affect you? Can you quantify the effect for us?

Q9. Do you have any suggestions on which criteria could be used to identify medicines eligible for a fee waiver or reduction?

Proposal 3 – Improving reliability of supply for known shortages

One of the actions we can take to address individual medicine shortages, and assist affected patients, is to grant approval for importation and supply of an overseas product while the Australian registered medicine is unavailable or in short supply. This decision is made under section 19A of the Act but only when it is necessary in the interest of public health and there are no suitable alternatives on the ARTG.

'Section 19A approval' is intended for short-term interim solutions to critical shortages. However, a number of medicines are being supplied in Australia under a section 19A approval on a long-term or repeat basis. Allowing on-going approvals to support near permanent supply of medicines without ARTG registration could be perceived as undermining the integrity of the registration process. Further, the uncertainty of the extent of a section 19A results in financial risks to the sponsor which can constrain or disrupt supply.

Types of medicines in long-term shortage in Australia

We have analysed the type of medicines for which substitutes have been approved under section 19A and a list of recent 'long-standing section 19A medicines' is at **Attachment 2.** Review of the list shows us there are varied reasons for the shortages but it could be that registering the substitute medicines on the ARTG would assist us to improve reliable supply.

Additional registered generic versions are unlikely to have a direct impact where supply constraints are caused by manufacturing complexities or issues associated with shelf-life, storage or transportation. For these medicines, overall supply at any point in time is typically limited as sponsors avoid holding excess stock, attempting to match supply with usual demand to limit wastage. This restricts sponsors' ability to fill a gap in supply that arises due to unexpected supply or demand changes. Improvements to the reliability of supply may only be achieved if there is an expansion in overall supply capacity or different manufacturing sites are utilised by other sponsors.

Other medicines are subject to specific manufacturing issues, dispensing complexities or are affected by the role of unregistered products in the clinical settings in which they are used. Examples are radiopharmaceuticals and venom products. It is likely that these will require separate consideration in terms of any regulatory reforms, as a targeted approach would be necessary to address the unique issues affecting their supply and registration status.

The medicines most likely to benefit from measures that facilitate ARTG registration are new generic versions of older medicines, especially those that also have low volumes of demand and low profit margins. From our preliminary discussions with sponsors of section 19A -approved medicines, barriers to seeking registration include

- difficulties in compiling a data dossier
- time delays associated with the evaluation and approval process
- cost.

Our review indicated that many of the off-patent medicines would only require bioequivalence data (equivalence to the Australian reference product) to establish efficacy and safety in an application for registration. From our experience, evaluation of such a dossier would be unlikely to require the full statutory (255 days) evaluation time period. For example, decisions on good quality dossiers for non-complex generic medicines have been made after one round of evaluation.

Data requirements relevant to these type of medicines are already included in the current mandatory application guidelines. Consequently, it doesn't appear that any reduction in evidentiary requirements is called for. To assist sponsors considering registration, we are proposing a process that allows eligible applications to be assessed for a lower fee and within a shorter time period.

Improving confidence in supply

We are considering development of a transparent process to define medicines in very long-term (extended or repeated) shortage, for which there is a strong public health justification for encouraging their ongoing availability in Australia. That is, generic versions of medicines that are of limited profitability but with a known patient population, as evidenced by a history of section 19A approvals.

If a company could establish that the data dossier to support their application requires less evaluation, and we could confirm this to be the case, it would attract a lower fee and a shorter evaluation time.

We are proposing that this process should rely on a designation process closely aligned to the current considerations for section 19A approval. This would allow us to assess the merits of the proposed application prior to formal submission to confirm that the medicine is one of those targeted from a shortages perspective and that the data dossier can be evaluated with a simplified approach while maintaining regulatory standards.

In designating an application, each new medicine would be assessed to confirm that

- it is approved for supply in a recognised foreign country (as set out subsection 19A(3) of the Act)
- there is evidence of compliance with default standards (monographs in European Pharmacopoeia, British Pharmacopoeia, or United States Pharmacopeia-National Formulary)
- established manufacturing sites, acceptable to the TGA, are used
- existing registered medicine(s) are not in sufficient supply to meet demand
- its supply is necessary in the interests of public health and there is evidence of a strong clinical need for the supply of the product

- there is evidence that insufficient supply has occurred in the past and the reasons for those shortages are expected to continue.

To support this process, we are proposing to increase education and awareness of the existing streamlined evidence requirements applicable in appropriate circumstances, such as

- existing data requirements for established generic medicines
- use of literature-based submissions
- use of dossiers submitted to comparable overseas regulators (in our COR-A or COR-B report-based pathways)
- pre-submission meetings or discussions with the TGA for assistance in compiling a dossier.

A further consideration is that any proposal based on reduced fees and/or charges must be considered in the context of TGA's cost-recovery framework, as evaluation efforts must have appropriate funding.

Questions

Q10. Would implementation of a new TGA process that provided faster evaluation times and lower fees encourage you to make an application to register one of the medicines that are subject to longstanding section 19A approvals?

Q11. What value do you see in having a designation step to confirm the eligibility of an application before it is formally submitted to the TGA?

Q12. Do you think introduction of the proposed process will assist in supporting a more reliable supply of overseas-registered medicines currently imported under section 19A?

Q13. Do you have any other suggestions to encourage ARTG registration of medicines currently supplied under section 19A?

Proposal 4 – Managing alternative supply if medicines are discontinued

Approving temporary supply of overseas medicines is one of the important ways we assist patients during a shortage of an Australian-registered medicine. However, approval under section 19A of the Act relies on the Australian-registered medicine being on the ARTG. If a sponsor discontinues supply in Australia and cancels their ARTG entry, we cannot consider a section 19A medicine as an alternative. Retaining their ARTG entry doesn't mean the sponsor must supply the medicine but they will incur an annual charge.

We are therefore proposing a new annual charge waiver, targeted at retaining certain medicines on the ARTG when they are no longer marketed (discontinued). Retaining an entry allows the sponsor to more easily return to supply when needed, as well as allowing consideration of approval to supply a substitute medicine under section 19A of the Act. We will need criteria to identify medicines that are of limited commercial viability, where their discontinuation would result in a shortage of critical patient impact.

Existing annual charge waivers

We have the 'Annual Charge Exemption' (ACE) scheme under which sponsors must seek and confirm their eligibility each financial year. The primary intention of the scheme is to assist companies with newly registered goods that have not generated a profit.

There is an additional mechanism, regulation 43AAH(7) in the *Therapeutic Goods Regulations 1990* (the Regulations). This applies to prescription medicines but requires evidence of the medicine not being financially viable without the waiver and that its ongoing supply is necessary in the interests of public health.

Medicines with a history of supply in Australia but which are to be discontinued do not meet either of these two sets of requirements: they are ineligible for the ACE scheme because profits have been earned up until that time and regulation 43AAH(7) cannot be used because there will be no ongoing supply.

Proposal for a new annual charge waiver

We are proposing an amendment to the Regulations (namely regulation 43AAH) to include new criteria for waiving annual charges, tailored to support certain discontinued medicines. The fundamental principle would remain as a lack of therapeutic alternatives registered on the ARTG, with consideration given to

- generic versions
- dosage form equivalents
- different strengths (in limited circumstances)

We expect the proposed new waiver to only apply to a very limited number of medicines. As an indicator, only two medicines substituted with a section 19A approved overseas product were discontinued in the 2019 calendar year; and a further four section 19A related medicines were discontinued in the first half of 2020. However, if approximately 20 medicines are currently discontinued but remain on the ARTG to support a section 19A approved substitute, and more are added each year, there will be a gradually increasing cumulative tally of eligible medicines. The effect of its implementation on our cost recovery framework would need careful consideration.

There is a risk that if the eligibility criteria are too broad, we will forego revenue needed for post-market activities such as pharmacovigilance, laboratory testing, compliance and enforcement. If large numbers of waivers are granted, there is also a risk of undermining TGA's cost-recovery framework.

Questions

Q14. Would introduction of a new annual charge waiver encourage you to retain your ARTG entry, if it was eligible?

Q15. Do you think introduction of a new annual charge waiver will assist in supporting a more reliable supply of overseas-registered medicines imported into Australia as substitutes when the Australian medicine is in longstanding or repeated shortage?

Q16. Do you see any risks associated with introduction of a new annual charge waiver for medicines where there is a lack of therapeutic alternatives on the ARTG?

Q17. Do you have any comments or suggestions on the proposed criteria to establish eligibility for the new annual charge waiver?

Q18. Do you have any other suggestions on ways to prevent, mitigate or manage medicine shortages in Australia?

Attachments

Attachment 1 – List of medicines that have been subject to repeated shortage

Attachment 2 – List of medicines subject to long-standing s19A approvals

Attachment 1

This list includes medicines that have been in shortage more than three times since 2019.

List of medicines that have been subject to repeated shortages (2019-2021)

ARTG Active ingredient	ARTG ID	ARTG Name
acamprosate calcium	286652	APO-ACAMPROSATE acamprosate calcium 333 mg enteric coated tablets blister
adrenaline (epinephrine)	131782	ASPEN ADRENALINE adrenaline (epinephrine) 1 mg/1 mL injection solution ampoule
adrenaline (epinephrine)	162463	ASPEN ADRENALINE INJECTION adrenaline (epinephrine) 1 mg/10 mL solution for injection ampoule
adrenaline (epinephrine) acid tartrate	119194	ADRENALINE-LINK 1:10,000 1mg/10mL adrenaline (epinephrine) acid tartrate injection BP ampoule
adrenaline (epinephrine) acid tartrate	12048	ADRENALINE-LINK 1:1,000 1mg/1mL adrenaline (epinephrine) acid tartrate injection BP ampoule
allopurinol	17708	PROGOUT 300 Allopurinol 300mg tablet bottlet
allopurinol	269638	ALLOPURINOL APOTEX allopurinol 300 mg tablet blister pack
amisulpride	156048	SULPRIX amisulpride 200 mg tablets blister pack
amisulpride	178904	APO-Amisulpride 100 mg tablet blister pack
amlodipine besilate	199214	CADIVAST 5/40 amlodipine (as besilate) and atorvastatin (as calcium) 5 mg/40 mg tablets bottle
amlodipine besilate	199225	CADIVAST 10/40 amlodipine (as besilate) and atorvastatin (as calcium) 10 mg/40 mg tablets bottle
atorvastatin calcium trihydrate	181409	LORSTAT 40 atorvastatin (as calcium) 40 mg tablets bottle

ARTG Active ingredient	ARTG ID	ARTG Name
atorvastatin calcium trihydrate	181410	LORSTAT 20 atorvastatin (as calcium) 20 mg tablets bottle
atorvastatin calcium trihydrate	199222	CADIVAST 5/20 amlodipine (as besilate) and atorvastatin (as calcium) 5 mg/20 mg tablets bottle
baclofen	42146	CLOFEN 10 baclofen 10mg tablet bottle
baclofen	42147	CLOFEN 25
bicisate dihydrochloride	73014	NEUROLITE bicisate dihydrochloride 0.9mg/mL kit for the preparation of technetium [99Tc] bicisate
bisoprolol fumarate	81608	BICOR bisoprolol furarate 10 mg tablet blister pack
candesartan cilexetil	163670	ADESAN HCT 16/12.5 candesartan cilexetil/hydrochlorothiazide 16 mg/12.5 mg tablet blister pack
candesartan cilexetil	171017	ADESAN candesartan cilexetil 32 mg tablet blister pack
candesartan cilexetil	195279	CANDESARTAN/HCT SANDOZ 32/12.5mg candesartan cilexetil/hydrochlorothiazide 32mg/12.5mg tablet blister pack
candesartan cilexetil	195509	CANDESAN candesartan cilexetil 8 mg tablet blister pack
candesartan cilexetil	206485	ADESAN HCT 32/12.5 candesartan cilexetil/hydrochlorothiazide 32 mg/12.5 mg tablet blister pack
candesartan cilexetil	210529	APO-CANDESARTAN candesartan cilexetil 4 mg tablet blister pack
candesartan cilexetil	210530	APO-CANDESARTAN candesartan cilexetil 8 mg tablet blister pack
candesartan cilexetil	210531	APO-CANDESARTAN candesartan cilexetil 16 mg tablet blister pack
candesartan cilexetil	260096	BLOOMS THE CHEMIST CANDESARTAN candesartan cilexetil 4 mg tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
carbimazole	194296	Neo-mercazole 5mg
cefalexin monohydrate	73524	IBILEX 250 cefalexin 250mg capsule (NF)
cefalexin monohydrate	73525	IBILEX 500 cefalexin 500mg capsule (NF)
cefalexin monohydrate	92972	IBILEX 125 cefalexin 125mg/5mL powder for oral liquid bottle
ceftriaxone sodium	164920	CEFTRIAXONE ALPHAPHARM ceftriaxone (as sodium) 1 g powder for injection vial
celecoxib	296388	CELAXIB celecoxib 200 mg capsule blister pack
celecoxib	296389	CELAXIB celecoxib 100 mg capsule blister pack
cisatracurium besilate	226857	CISATRACURIUM JUNO cisatracurium (as besilate) 10mg/5mL Solution for Injection ampoule
citalopram hydrobromide	212219	TALAM citalopram 20mg (as hydrobrobimide) tablet blister pack
citalopram hydrobromide	93542	CELAPRAM citalopram 10mg (as hydrobromide) tablet blister pack
clarithromycin	117197	CLARITHRO 250 clarithromycin 250mg tablets blister pack
clindamycin phosphate	67060	DALACIN T 1% clindamycin 10mg/mL (as phosphate) lotion bottle
clopidogrel besilate	164870	CLOPIDOGREL GH clopidogrel (as besilate) 75mg film-coated tablet blister pack
clopidogrel hydrogen sulfate	148947	CLOPIDOGREL WINTHROP clopidogrel (as hydrogen sulfate) 75 mg tablet blister pack
clopidogrel hydrogen sulfate	168926	PIAX clopidogrel (as hydrogen sulfate) 75mg film-coated tablet bottle
clopidogrel hydrogen sulfate	168927	PIAX clopidogrel (as hydrogen sulfate) 75mg film-coated tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
dicloxacillin sodium	289105	DICLOXACILLIN MYLAN 250 dicloxacillin (as sodium) 250mg capsule bottle
dicloxacillin sodium	289107	DICLOXACILLIN MYLAN 500 dicloxacillin (as sodium) 500 mg capsule bottle
donepezil hydrochloride	167693	ARAZIL donepezil hydrochloride 10 mg tablet blister pack
dosulepin (dothiepin) hydrochloride	62910	DOTHEP 75
doxepin hydrochloride	308999	DEPTRAN 10 doxepin 10mg (as hydrochloride) capsule blister pack
doxepin hydrochloride	60448	DEPTRAN 25 doxepin 25mg (as hydrochloride) capsule blister pack
doxycycline hyclate (hydrochloride)	63512	DOXYLIN 50 Doxycycline 50mg (as hydrochloride) tablet bottle
drospirenone	114816	ANGELIQ 1/2 tablet blister pack
dutasteride	212047	APO-Dutasteride dutasteride 500 microgram soft capsule blister pack
eletriptan hydrobromide	68356	RELPAX eletriptan hydrobromide 40mg tablet blister pack
eprosartan mesilate	64400	TEVETEN eprosartan 400mg (as mesilate) tablet blister pack
escitalopram oxalate	119964	LOXALATE escitalopram oxalate 10mg tablets blister packs
esomeprazole	246914	NOXICID CAPS esomeprazole 20mg (as magnesium) enteric capsule bottle
exemestane	174337	EXEMESTANE SANDOZ
famciclovir	157788	EZOVIR famciclovir 250 mg tablet blister pack
famciclovir	160556	APO-FAMCICLOVIR famciclovir 250mg tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
famciclovir	172443	APO-FAMCICLOVIR famciclovir 500 mg tablet blister pack
famciclovir	51389	FAMVIR famciclovir 250mg tablets
famciclovir	67391	FAMVIR famciclovir 500mg tablets
famotidine	93789	AUSFAM 40 famotidine 40mg tablet blister pack
fentanyl citrate	201871	Fentanyl GH Solution for Injection 500 microgram/10 mL ampoule
flucloxacillin	209368	FLOPEN flucloxacillin 500mg (as sodium) capsule blister pack
fluconazole	132789	DIZOLE 200 fluconazole 200 mg capsule blister pack
fluconazole	47462	DIFLUCAN fluconazole 200mg/100mL injection
fluoxetine hydrochloride	53773	ZACTIN fluoxetine 20mg (as hydrochloride) capsule blister pack
fluoxetine hydrochloride	90913	ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack
fluvoxamine maleate	57632	LUVOX fluvoxamine maleate 50mg tablet blister pack
foscarnet sodium	37310	FOSCAVIR 6g/250mL injection bottle
furosemide (frusemide)	34494	UREX furosemide (frusemide) 40 mg tablet blister pack
gabapentin	101694	NUPENTIN 100 gabapentin 100 mg capsule blister pack
gabapentin	101696	NUPENTIN 300 gabapentin 300 mg capsule blister pack
gallium (67Ga) citrate	19144	LANTHEUS GALLIUM(67Ga) CITRATE 74MBq/mL injection USP

ARTG Active ingredient	ARTG ID	ARTG Name
Hepatitis a virus antigen	194815	AVAXIM inactivated hepatitis A vaccine 160U/0.5mL injection needle free syringe
hydralazine hydrochloride	43190	APRESOLINE 20mg powder for injection ampoule
hydrochlorothiazide	102086	AVAPRO HCT 300/12.5 irbesartan 300 mg and hydrochlorothiazide 12.5 mg tablet blister pack
hydrochlorothiazide	174724	IRBESARTAN/HCT SANDOZ 300/12.5 irbesartan 300 mg/hydrochlorothiazide 12.5 mg film-coated tablet blister pack
hydrochlorothiazide	195278	CANDESARTAN/HCT SANDOZ 32mg/25mg candesartan cilexetil/hydrochlorothiazide 32mg/25mg tablet blister pack
hydrochlorothiazide	213305	APO-IRBESARTAN HCTZ 300/25 irbesartan and hydrochlorothiazide 300/25mg tablet blister pack
hydrochlorothiazide	221116	APO-OLMESARTAN HCTZ 20/12.5 olmesartan medoxomil/hydrochlorothiazide 20/12.5 mg film coated tablets blister pack
hydrochlorothiazide	221131	Olmertan Combi 40/25 olmesartan medoxomil/hydrochlorothiazide 40/25 mg film coated tablets blister pack
hydrochlorothiazide	259612	BLOOMS THE CHEMIST IRBESARTAN HCTZ 300/25 irbesartan and hydrochlorothiazide 300/25mg tablet blister pack
hydrochlorothiazide	302148	ABISART HCTZ 300/12.5 irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet blister pack
indometacin	17586	Arthrexin 25 mg capsule bottle
Interferon gamma-1b	48404	IMUKIN Interferon Gamma-1b recombinant human (2 million IU)/100microgram/0.5mL
irbesartan	167407	IRBESARTAN SANDOZ irbesartan 300mg film coated tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
irbesartan	167409	IRBESARTAN SANDOZ irbesartan 150mg film coated tablet blister pack
irbesartan	191084	IRBESARTAN GH irbesartan 300mg tablet blister pack
irbesartan	191404	IRBESARTAN GH irbesartan 150mg tablet blister pack
irbesartan	213302	APO-IRBESARTAN HCTZ 150/12.5 irbesartan and hydrochlorothiazide 150/12.5mg tablet blister pack
irbesartan	213303	APO-IRBESARTAN HCTZ 300/12.5 irbesartan and hydrochlorothiazide 300/12.5mg tablet blister pack
irbesartan	213310	APO-IRBESARTAN irbesartan 150mg film-coated tablet blister pack
irbesartan	213311	APO-IRBESARTAN irbesartan 300mg film-coated tablet blister pack
irbesartan	213325	APO-IRBESARTAN irbesartan 75mg film-coated tablet blister pack
irbesartan	259884	BLOOMS THE CHEMIST IRBESARTAN irbesartan 150mg film-coated tablet blister pack
irbesartan	259885	BLOOMS THE CHEMIST IRBESARTAN irbesartan 300mg film-coated tablet blister pack
irbesartan	268774	AVSARTAN irbesartan 150 mg film-coated tablet blister pack
irbesartan	268780	AVSARTAN irbesartan 75mg film-coated tablet blister pack
irbesartan	272655	AVSARTAN HCT 150/12.5 irbesartan 150 mg and hydrochlorothiazide 12.5 mg tablets blister pack
irbesartan	272659	AVSARTAN HCT 300/12.5 irbesartan 300 mg and hydrochlorothiazide 12.5 mg tablets blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
irbesartan	302149	ABISART HCTZ 300/25 irbesartan 300 mg + hydrochlorothiazide 25 mg tablet blister pack
irinotecan hydrochloride trihydrate	209857	IRINOTECAN ACCORD irinotecan hydrochloride trihydrate 100 mg/5 mL concentrated injection vial
labetalol hydrochloride	56476	PRESOLOL 200 labetalol hydrochloride 200mg bottle
lamotrigine	99062	LOGEM 100 lamotrigine 100mg chewable/dispersible tablet blister pack
lansoprazole	153575	ZOTON FasTabs lansoprazole 15 mg orally disintegrating tablets blister pack
lansoprazole	187430	ZOPRAL ODT lansoprazole 15 mg orally disintegrating tablet blister pack
levetiracetam	161295	LEVETIRACETAM-GH levetiracetam 500 mg tablet blister pack
memantine hydrochloride	207782	APO-MEMANTINE memantine hydrochloride 20mg film-coated tablet blister pack
methotrexate	10778	METHOTREXATE INJECTION BP 1000 MG IN 10 ML
methotrexate	233717	TREXJECT methotrexate (as sodium) 15mg/0.30mL solution for injection pre-filled syringe
metoprolol tartrate	34408	MINAX 50 metoprolol tartrate 50 mg tablet bottle
metoprolol tartrate	34410	MINAX 100 metoprolol tartrate 100 mg tablet bottle
metronidazole	17654	METROGYL 200 metronidazole 200mg tablet bottlet
misoprostol	63983	CYTOTEC Misoprostol 200 microgram tablet blister pack
modafinil	269913	MODAFINIL MYLAN modafinil 100 mg tablets blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
morphine sulfate pentahydrate	121755	DBL MORPHINE SULFATE 30mg/1mL Injection
nebivolol hydrochloride	281795	APO-NEBIVOLOL nebivolol (as hydrochloride) 5 mg tablet blister pack
nebivolol hydrochloride	281799	APO-NEBIVOLOL nebivolol (as hydrochloride) 1.25 mg tablet blister pack
nicorandil	218689	IKOTAB nicorandil 20 mg tablet blister pack
nizatidine	284130	TAZAC PULVULES nizatidine 150mg capsule
nizatidine	94205	TACIDINE nizatidine 300mg capsule blister pack
nizatidine	96963	NIZAC nizatidine 300mg capsule blister pack
norethisterone	10052	NORIDAY 28 DAY norethisterone 350 microgram tablet blister pack
norethisterone	62133	NORIMIN 28 Day tablet blister pack
olanzapine	175773	ZYPINE ODT olanzapine 5 mg orally disintegrating tablet blister pack
olanzapine	189673	ZYPINE ODT olanzapine 20 mg orally disintegrating tablet blister pack
olmesartan medoxomil	157565	SEVIKAR 20/5 olmesartan medoxomil / amlodipine (as besilate) 20/5 mg tablet blister pack
olmesartan medoxomil	221050	Olmertan olmesartan medoxomil 40 mg film coated tablets blister pack
olmesartan medoxomil	221052	APO-OLMESARTAN olmesartan medoxomil 20 mg film coated tablets blister pack
olmesartan medoxomil	221063	APO-OLMESARTAN olmesartan medoxomil 40 mg film coated tablets blister pack
olmesartan medoxomil	221121	APO-OLMESARTAN HCTZ 40/25 olmesartan medoxomil/hydrochlorothiazide 40/25 mg film coated tablets blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
olmesartan medoxomil	221128	OLMERTAN COMBI 40/12.5 olmesartan medoxomil/hydrochlorothiazide 40/12.5 mg film-coated tablet blister pack
ondansetron hydrochloride dihydrate	155843	ONDANSETRON ALPHAPHARM ondansetron (as hydrochloride) 8 mg/4 mL solution for injection ampoule
pantoprazole sodium sesquihydrate	213715	PANTOPRAZOLE APOTEX pantoprazole (as sodium sesquihydrate) 20 mg enteric-coated tablet blister pack.
perindopril arginine	224306	APO-Perindopril Arginine/Amlodipine 5/5 perindopril arginine 5 mg and amlodipine (as besilate) 5 mg uncoated tablet bottle
phenelzine sulfate	93600	NARDIL phenelzine 15mg (as sulfate) tablet bottle
phenoxymethylpenicillin	66511	LPV phenoxymethylpenicllin 500mg (as potassium) capsule blister pack
phenoxymethylpenicillin potassium	55675	CILICAINE VK 500mg capsule blister pack
piroxicam	53284	MOBILIS D-20 piroxicam 20mg dispersible tablet blister pack
prazosin hydrochloride	10758	Minipress 5mg tablets
prazosin hydrochloride	73858	APO-PRAZOSIN prazosin (as hydrochloride) 1mg tablet blister pack
prazosin hydrochloride	73862	APO-PRAZOSIN prazosin (as hydrochloride) 2mg tablet blister pack
prazosin hydrochloride	73866	APO-PRAZOSIN prazosin (as hydrochloride) 5mg tablet blister pack
propofol	98271	FRESOFOL 1% propofol 500mg/50mL injection vial
propofol	98275	FRESOFOL 1% propofol 1g/100mL injection vial
rabeprazole sodium	189756	Parbezol rabeprazole sodium 10mg enteric coated tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
rabeprazole sodium	245232	APO-RABEPRAZOLE rabeprazole sodium 10mg enteric coated tablet blister pack
ramipril	128847	RAMIPRIL WINTHROP ramipril 2.5mg tablet blister pack
ramipril	129916	TRYZAN TABS 2.5 ramipril 2.5 mg tablets blister pack
ramipril	129921	TRYZAN TABS 10 ramipril 10 mg tablets blister pack
ramipril	231162	APO-RAMIPRIL ramipril 10 mg tablets blister pack
rifabutin	55038	MYCOBUTIN Rifabutin 150mg capsule blister pack
rocuronium bromide	161275	DBL ROCURONIUM BROMIDE INJECTION rocuronium bromide 50mg/5mL injection solution vial
Salmonella typhi Vi polysaccharide	45073	TYPHIM Vi 0.025mg/0.5mL injection syringe
sertraline hydrochloride	107067	SERTRA 50 sertraline (as hydrochloride) 50 mg tablet blister pack
sertraline hydrochloride	107071	SERTRA 100 sertraline (as hydrochloride) 100 mg tablet blister pack
sertraline hydrochloride	213177	APO-SERTRALINE sertraline (as hydrochloride) 50mg tablet blister pack
sertraline hydrochloride	95581	ELEVA 50 sertraline hydrochloride 50mg tablet blister pack
sertraline hydrochloride	95583	ELEVA 100 sertraline hydrochloride 100mg tablet blister pack
simvastatin	223448	APO-SIMVASTATIN simvastatin 10 mg tablet blister pack
simvastatin	95681	ZIMSTAT simvastatin 80mg tablet bottle

ARTG Active ingredient	ARTG ID	ARTG Name
sodium pertechnetate(99mTc)	72820	GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate
sodium pertechnetate(99mTc)	75859	GENTECH molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechneta
spironolactone	46689	SPIRACTIN 25 spironolactone 25mg tablets
spironolactone	46691	SPIRACTIN 100 spironolactone 100mg tablets
spironolactone	68953	Aldactone 25mg tablet blister pack
sumatriptan succinate	124086	IPTAM sumatriptan (as succinate) 50mg tablet blister pack
sumatriptan succinate	124087	IPTAM sumatriptan (as succinate) 100mg tablet blister pack
sumatriptan succinate	187216	SUMATRAN sumatriptan (as succinate) 50 mg tablet blister pack
temozolomide	231527	APO-TEMOZOLOMIDE temozolomide 100 mg capsule bottle
tetracosactide (tetracosactrin)	11058	Synacthen 0.25mg/1mL injection ampoule
thallous(201Tl) chloride	112603	LANTHEUS THALLIUM[201Tl] CHLORIDE 74MBq/mL injection multidose vial
tobramycin	10776	PFIZER (PERTH) TOBRAMYCIN INJECTION BP 80MG IN 2ML
topiramate	124730	APO-TOPIRAMATE topiramate 50 mg tablet blister pack
tranexamic acid	14463	CYKLOKAPRON tranexamic acid 500mg tablet bottle
tranexamic acid	272732	APO-TRANEXAMIC ACID tranexamic acid 500 mg tablet blister pack

ARTG Active ingredient	ARTG ID	ARTG Name
tranylcypromine sulfate	174086	PARNATE Tranylcypromine 10mg film coated tablet
trihexyphenidyl (benzhexol) hydrochloride	15125	ARTANE 2mg trihexyphenidyl (benzhexol) hydrochloride 2mg tablet bottle
trimethoprim	17681	RESPRIM trimethoprim/sulfamethoxazole 80 mg/400 mg tablet blister pack
trimethoprim	63518	ALPRIM trimethoprim 300mg tablet blister pack
valaciclovir hydrochloride	153822	VACLOVIR 500 valaciclovir (as hydrochloride) 500 mg tablet blister pack
valaciclovir hydrochloride	153823	VACLOVIR 500 valaciclovir (as hydrochloride) 500 mg tablet bottle pack
valaciclovir hydrochloride monohydrate	170178	VALACICLOVIR GENERICHEALTH valaciclovir hydrochloride 500mg tablet blister pack
vancomycin	14674	VANCOCIN vancomycin 125mg (125,000IU as hydrochloride) capsule blister pack
vancomycin hydrochloride	153438	VANCOMYCIN ALPHAPHARM 500 mg (as hydrochloride) powder for injection vial
verapamil hydrochloride	104664	TARKA 4/240 trandolapril 4mg & verapamil hydrochloride 240mg tablet
verapamil hydrochloride	10681	CORDILOX SR 240 mg Tablets
zoledronic acid monohydrate	188261	DBL ZOLEDRONIC ACID IV INFUSION zoledronic acid solution for infusion 4 mg/100 mL bag

List of medicines that have been in shortage more than three times since 2019.

Attachment 2

This list includes medicines that have

- been in shortage for long periods of time or been discontinued

  and

- an alternative overseas medicine has been approved for supply in Australia under section 19A of the *Therapeutic Goods Act 1989.*

List of medicines subject to long-standing section 19A approvals

ARTG Product	ATC Therapeutic Classification	Sponsor's Reason for Shortage
Aciclovir 30mg/g eye ointment	J	Discontinued
Adrenaline 1mg/mL injection 1:1,000	C	Manufacturing issues leading to unexpected increases in demand
Atropine sulfate PFS	C	Discontinued
Auranofin 3mg tablets (marketed as Ridaura tablets)	M	Discontinued
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain), powder and solvent for suspension for intravesical use (marketed as Oncotice)	L	Increased global demand
Bacillus Calmette-Guerin (BCG)-Vaccine	J	Discontinued due to manufacturing difficulties
Biperiden hydrochloride tablets (Marketed as Akineton)	N	Discontinued – Manufacturing
Carbidopa/Levodopa extended-release tablets 50mg/200mg (marketed as Sinemet)	N	Manufacturing
Carbidopa/Levodopa tablets 25mg/250mg (marketed as Sinemet)	N	Manufacturing
Clomiphene 50mg tablets (marketed as Clomid)	G	Manufacturing problem sourcing API

ARTG Product	ATC Therapeutic Classification	Sponsor's Reason for Shortage
Clozapine suspension (marketed as Clopine Suspension)	N	Manufacturing
Colloid kit for the preparation of Technetium(99mTc) calcium phytate injection composite pack	V	Manufacturing due to availability of API
Dantrolene sodium capsules (marketed as Dantrium)	M	Manufacturing- manufacturer ceased supply
Dantrolene sodium injection (marketed as Dantrium)	M	Manufacturing
Glyceryl trinitrate sublingual tablets (marketed as Anginine and Lycinate)	C	Discontinued – reformulation issues
Heparin sodium	B	Manufacturing
Isoprenaline 0.2mg/mL injection (marketed as Isuprel)	C	Discontinued. Manufacturing – Problem sourcing API
LYMPH-FLO injection composite pack (antimony trisulfide)	V	Change of manufacturing site
MAA aggregated albumin injection for technetium imaging (Canada) or MAKRO-ALBUMON 2mg powder for suspension for injection, kit for the preparation of technetium [99mTc] human albumin macroaggregates injection (99mTc-MAA)	V	Commercial changes and manufacturing issues
Molybdenum (99Mo) / technetium (99mTc) sterile generator for production of sodium pertechnetate (99mTc) injection multidose vial (marketed as Gentech)	V	Manufacturing
Naloxone hydrochloride PFS (marketed as MIN-I-JET NALOXONE)	V	Discontinued- commercial changes
Pethidine injection	N	Manufacturing constraint supply

ARTG Product	ATC Therapeutic Classification	Sponsor's Reason for Shortage
Phenelzine 15mg tablets (marketed as Nardil)	N	Discontinued- global manufacturing issue.
Phenoxybenzamine capsules (marketed as Dibenyline)	C	Manufacturing, API issue
Potassium chloride sustained release tablets 600mg (marketed as Span-K, Slow-K and Duro-K)	A	SLOW-K - ARTG 76769 and DURO-K - ARTG 79739 discontinued due to unacceptable lead content leading to unexpected increase in demand for SPAN K - ARTG 27978
Sulfamethoxazole/trimethoprim Syrup (marketed as Septrin Sugar-free Paediatric Suspension)	J	BACTRIM SUGAR-FREE oral liquid bottle (ARTG 119404) discontinued due to commercial reasons, leading to an unexpected increase in demand
Sulfamethoxazole/trimethoprim injection (marketed as DBL SULFAMETHOXAZOLE 400 mg AND TRIMETHOPRIM 80 mg CONCENTRATE INJECTION BP 5mL injection ampoule)	J	Manufacturing
Technetium (99mTc) succimer powder for injection multidose vial (RADPHARM DMSA kit for the production of Technetium (99mTc) succimer powder for injection multidose vial)	V	Manufacturing, API issue
Technetium(99mTc) disofenin powder for injection multidose vial (HEPATOLITE kit for production of Technetium(99mTc) disofenin powder for injection multidose vial)	V	Commercial Changes
Venom products (Paper wasp, Yellow Jacket and Bee)	V	Manufacturing. Reduced supply available to Australian market due to increased demand overseas.

List of medicines which have long standing s19A approvals for alternative overseas registered products.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medicine Shortages Section, Pharmacovigilance and Special Access Branch	February 2021

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Reference/Publication #