Situation

A number of antiseptic agents were discontinued from the Australian market or divested from one sponsor to another in 2022. For those that have been divested (i.e., ownership of the product has transferred from one sponsor to another) it is unclear when the product will be made available by the new sponsor. The below table has been prepared to outline the products affected by this discontinuation and potential alternatives for consideration by LHDs/SHNs.

Impacts of this communication on clinical practice

Actions to address the discontinuation of the following antiseptic products should be coordinated and implemented by the local Drug and Therapeutics Committee in consultation with the relevant stakeholders (including, but not limited to: Clinical Product Managers, representatives from Pharmacy, Infectious Diseases, Surgical Services and Infection Prevention and Control) considering the local context and identified indications for use.

Escalate concerns that are not able to be managed locally to <u>CEC-MedicationSafety@health.nsw.gov.au</u>.

General principles

- Multi-dosing is not routinely recommended outside of Operating Theatre settings where multi-dosing is considered ensure local guidelines and recommendations are followed.
- Non-sterile antiseptic preparations may be used for surgical skin preparation ensuring sterile fields are maintained.
- Chlorhexidine is an alternative antiseptic agent to povidone-iodine for skin preparation (see <u>WHO Global guidelines for the</u> prevention of surgical site infection, 2nd edition).
- Antiseptic products containing alcohol (such as chlorhexidine in alcohol) are flammable, may cause burns and should be used with care during cauterisation. These antiseptics should be used as per product instructions to minimise patient safety risks.

Specific to povidone-iodine

- TGA registered indications for povidone-iodine solution are for external use only. Use outside of the registered indications is off-label. The ACI Surgical Services Taskforce does not recommend off-label use of povidone iodine products.
- Povidone-iodine should be reserved for procedures where chlorhexidine is not appropriate/contraindicated (for example, use in the middle ear) and for patients with chlorhexidine allergy.



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Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image
Acquired	PFIZER Chlorhexidine gluconate 0.015% + cetrimide 0.15% 30 mL plastic steritube <i>ARTG: 57021</i>	For cleansing and irrigating the skin and dirty wounds where an added surfactant effect is required.	Sterile		BAXTER (AHF7971) Chlorhexidine acetate 0.015% + cetrimide 0.15% 100 mL bottle ARTG: 329548 HPPL ID: 11752	For the cleaning and disinfecting of wounds and the antiseptic treatment of burns.	Sterile	
	 Important considerations relating to the suggested alternative: Alternative comes in a different volume. Consider look-alike, sound-alike risk with other Baxter products. Chlorhexidine salt of the alternative product is acetate. Theoretically, the smaller chemical size of the acetate salt may result in deeper skin penetration and thus a greater number of adverse effects compared to the gluconate salt. NEW INFORMATION (UPDATED AUGUST 2023) Bridgewest Perth Pharma have acquired this Pfizer product and it is now available from wholesalers. (Note – ARTG number remains the same) 							



Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image
Divested	PFIZER Chlorhexidine gluconate 0.05% + cetrimide 0.5% 30 mL plastic steritube <i>ARTG: 57011</i> Important consider	-		sested alternative: Consider look-alike, so	BAXTER (AHF7979) Chlorhexidine acetate 0.05% + cetrimide 0.5% 100 mL bottle ARTG: 19460 HPPL ID: 18499	For the cleaning and disinfecting of wounds as an antiseptic treatment for burns.	Sterile	



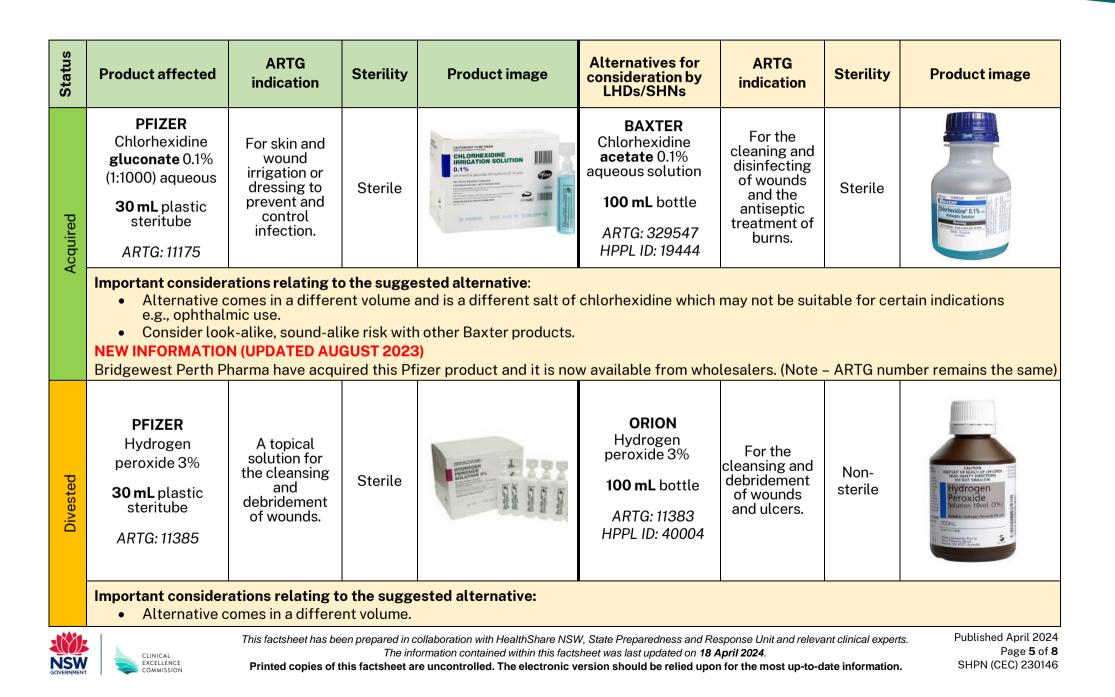
Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image
Discontinued	PFIZER Chlorhexidine gluconate 0.5% + alcohol 70% 25 mL plastic tube <i>ARTG: 11294</i>	For topical antisepsis.	Non- sterile	REAL EXPERIMENTAL AND ALL AND	PERRIGO (Surgi- Prep C) Chlorhexidine gluconate 0.5% + alcohol 70% 30 mL bottle ARTG: 319262 HPPL ID: 45805	Tinted antiseptic applied to patient's skin prior to invasive medical procedures. Reduces bacteria that can cause skin infection.	Non- sterile	CAUTION REP OUT OF FRACE OF OFFICE DO NOT SWALLOW DO NOT SWALLOW Prings Surgi-Prep Cpick Dishorder glaconate 0.5% w and Ethanal 705 v/v 30mL Application Maximum 155 Managaint Maximum 155 Managaint

Important considerations relating to the suggested alternative:

- Alternative comes in different volume, presented in 30 mL bottle (100 mL and 500 mL bottle sizes also available).
- Discontinued product was tinted pink, alternative available in both pink (non-staining, listed in table above) and red (staining) tint.
- Suggested alternative (Surgi-Prep C) should not be confused with Surgi-Prep C+ which contains 2% of chlorhexidine.



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Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image
Discontinued	PFIZER Povidone iodine 10% 100 mL bottle ARTG: 10796	A topical antiseptic for use as pre- operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections.	Non- sterile		HERRON (Riodine) Povidone iodine 10% 500 mL bottle ARTG: 21199 HPPL ID: 12363	For antisepsis of minor cuts, wounds and abrasions and treatment of minor skin infections.	Non- sterile	
		-		e-operative skin antisep	osis.			
Discontinued	PFIZER Povidone iodine 5% (Half strength) 100 mL bottle <i>ARTG: 11375</i>	A skin antiseptic for eyelid and eyebrow preparation before ophthalmo- logical procedures and surgery.	Non- sterile		No identified alternative – Riodine 10% product (not sterile, see above) can be diluted to desired concentration.			



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Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image
d	PFIZER (Alcoholic Povidone-lodine Solution) Povidone iodine 10% + alcohol 70%	A skin marking antiseptic for	Non-		SANOFI (Betadine Alcoholic Skin Prep) Povidine iodine 10% + alcohol 30% 100 mL bottle ARTG: 29557 HPPL ID: 14969	A non- staining (to skin and natural fabrics) and film- forming antiseptic.	Non- sterile	
Discontinued	100 mL bottle ARTG: 11298	pre-operative skin preparation.	sterile	ALCOHOLUC Posidone-Iodine Selection Univer codeness Institute DomL	ORION Iodine 1% + alcohol 70% 100 mL bottle ARTG: 21232 HPPL ID: 12932	Disinfection of unbroken skin prior to surgery.	Non- sterile	

Important considerations relating to the suggested alternatives:

- Note difference in alcohol concentrations between the Sanofi and originator Pfizer product which may diminish antiseptic action.
- Sanofi product is non-staining. It is also film forming which may prolong duration of action.
- The alcohol content in Sanofi alternative is present as a vehicle to assist drying on the skin. Follow local guidelines and recommendations as multi-dosing of alternative is not routinely recommended.
- Alcohol in both identified alternatives is ethanol compared to isopropyl alcohol in discontinued product.



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Status	Product affected	ARTG indication	Sterility	Product image	Alternatives for consideration by LHDs/SHNs	ARTG indication	Sterility	Product image		
Divested	PFIZER Povidone iodine 10% 30 mL steritube <i>ARTG: 12643</i>	A topical antiseptic for use as a pre- operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections.	Sterile	ting munitimeters ting munitime	IMPORTED BY REACH PHARM (Dukal) Povidine iodine 10% 3⁄4 oz (~ 22 mL) pouch Available via Section 19A (S19A) HPPL ID: 48379	A topical antiseptic for use as a pre- operative skin antiseptic.	Sterile			
	Important considerations relating to the suggested alternative: Alternative comes in a different volume. NEW INFORMATION (UPDATED APRIL 2024) Alternative is not suitable for use in the eyes as per the product label and contains alkyl glucoside, an ocular irritant.									
Discontinued	PERRIGO/ORION (Pre-op wash) Triclosan 1% 40 mL tube <i>ARTG: 10851</i>	A foaming emollient antiseptic soap for pre- operative washing to cleanse and disinfect the skin.	Non- sterile	Protection of Name Program One Watch Protection of the Street One Watch Protection of the Street One of the Accelerations	PERRIGO/ORION (Pre-op wash) Chlorhexidine 4% 50 mL tube ARTG: 11329 HPPL ID: 12927/41362	For disinfection of the skin prior to surgery.	Non- sterile	Chipchexidine Pro-Op Constantine Occupie How Participation of the data of the inter- ance of the data of the inter- section of the data of the data of the inter- section of the data of the inter- section of the data of the dat		
	-	-		ested alternative: Chlor identified to date. Furt			in neonate	S.		



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