MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Pristinamycin (SAS) tablets – 28 March 2023	
Details of affected product(s)	Pristinamycin (Pyostacine®) 250 mg and 500 mg tablets Not registered in Australia – imported and supplied under the Therapeutic Goods Administration Special Access Scheme.
Reason for communication	Disruption of pristinamycin due to an export ban from overseas supplier.
Date issue made apparent	January 2023
Supply impact dates	Unclear

Main indications and use

Pristinamycin is an antimicrobial agent used in the treatment of infections caused by Staphylococci, and other Gram-positive and anaerobic organisms where:

- infection is unresponsive to other agents, or
- patient cannot tolerate alternative therapy due to adverse effects, drug interactions or contraindications.

Situation

Pristinamycin is an internationally registered product available under the TGA Special Access Scheme (SAS) manufactured in France. Due to manufacturing issues and an inability to meet local demand, the French National Agency for the Safety of Medicines instated an export ban of the tablets to preserve local supply. The length of the export ban has not been provided, and Australian wholesalers remain unable to obtain stock. Minimal stock remains within NSW Health facilities, with current stock on hand to be reserved for existing patients.

Alternative agents and recommendations

Pristinamycin is used as a last-line agent which is commenced on the advice of infectious disease, microbiology and sexual health clinicians. There is no standard alternative which can be recommended. The following recommendations should be followed to ensure patient safety and continuity of care:

- All existing patients should receive urgent review by Infectious Diseases, Microbiology or Sexual Health and have their therapy modified on a case-by-case basis.
- Clearly communicate changes to therapy in the patient's medical record and ensure that this handed over appropriately at transitions of care.
- Further patients **should not** be initiated on pristinamycin until normal supply resumes.
- Facilities should have backorders in place with regular suppliers to ensure they receive supply when it becomes available.

Impacts of this communication on clinical practice

Actions to address the disruption to supply of pristinamycin should be coordinated and implemented by the local Drug and Therapeutics Committee and Infectious Diseases/Microbiology Departments.

Associated regulatory or policy references

PD2022_032 Medication Handling

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au

HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au

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