



Return of Unwanted Medicines PHC Remote Guideline

Target Audience	All Clinical Employees
Jurisdiction Jurisdiction Exclusions	Primary Health Care Remote CAHS; Primary Health Care Remote TEHS N/A
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Approval Authority	Chairs Clinical Governance Committee PHC CAHS; Primary Health Care Safety and Quality Committee TEHS
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Purpose

To provide Primary Health Care remote staff with guidelines for the return of unwanted and/or expired medicines from remote health centres.

Guideline

1. General Information

Unwanted medicines refer to pharmaceutical supplies that are no longer required at a health centre, including those:

- in excess of required stock level
- that are expired
- have been returned from a client
- that have their integrity / viability in doubt due to damage or uncertain storage.

While this document provides guidelines for some specific types of unwanted medicines (see 2.1 – 2.5), the return of most unwanted medicines is to be managed utilising the <u>Return of Unwanted Medicines</u> (<u>RUM</u>) <u>Project</u> protocols. This Project is a funded Commonwealth Government initiative aimed at promoting the safe disposal of unwanted medicines.

Appropriate management of unwanted medicines is important for a variety of reasons, including cost containment, environmental safety, accountability and incident prevention.

Whilst the information provided in this document guides the appropriate management of unwanted medicines, it is important to remember that it is judicious ordering, and sound stock management and dispensing practices that will most significantly contribute to minimal levels of unwanted medicines.

PHC does not support the use of expired stock beyond the manufacturers nominated expiry date. A caveat exists in that emergency medicines that have expired, but for which there is no immediate replacement available on site, should be kept until replacement is available. Where an expired medicine is considered for use in an emergency, this must be assessed according to the situation and in consultation with the ordering Medical Officer.

The information in this item relates to:

- Schedule 8 and Restricted Schedule 4 Medicines
- Vaccines
- Cytotoxic Drugs
- Medicines in Syringes with Needles Attached
- Excess Viable Medicine Stock
- All Other Medicines (Return of Unwanted Medicines Project)
- RUM Documentation for Standard Drug List Medicines (SDL)

Note: Unwanted medicines should not be considered for donation. The World Health Organisation - <u>Guidelines for Medicine</u> <u>Donations</u> (2010) and <u>Australian guidelines for drug donations to developing countries</u> (2000) provide core principles for donation of medicines. There should be no double standards. If the quality of an item is not acceptable in Australia it is unacceptable as a donation. Therefore the collection and redistribution of patient's unused medicines is not permitted. (Australian guidelines for drug donations to developing countries p3)

2. Procedure

2.1 Schedule 8 and Restricted Schedule 4 Medicines

Regardless of the supplying pharmacy (S100 or Hospital) or whether the medicines are supplied for general health centre stock or stock from client prescriptions, there are two options for managing unwanted or expired S8 / RS4 stock. Details for the appropriate procedure are provided in the Information Sheet – Return or Disposal of Unwanted or Expired S8 / RS4 Medicines.

2.2 Vaccines

Vaccines that have expired or have been opened and are not useful for further supply, may be disposed of utilising the sharps container or RUM container as detailed in <u>section 2.6</u>. Where vaccines have been affected by a breach in the cold chain and there is uncertainty about how to manage the vaccines staff should contact Centre for Disease Contol (CDC) as soon as possible to discuss the issue/s. Disposal of vaccines must be recorded on the <u>Vaccine Wastage Report Form</u> and the completed form sent to CDC.

See Cold Chain for further information regarding management of vaccines.

2.3 Cytotoxic drugs

Unwanted oral cytotoxic drugs must not be placed in the RUM container but must be packed directly into a purple colour coded, secure, labelled, leak proof, robust container for incineration. Where these are not available, a sharps disposal container may be appropriate¹, but must have a cytotoxic warning label attached. See <u>Cytotoxic Therapy</u> for further details.

2.4 Medicines in Syringes with Needles Attached

The disposal of any medicine in a syringe with needle attached should be discarded into an appropriate sharps container. This includes both used and unopened medicines.

2.5 Excess Viable Medicine Stock

Excess viable stock cannot be returned to the supplying pharmacy for re-use. It is therefore imperative that good ordering and management practices of pharmaceutical stock are applied. Excess stock may be:

- re-distributed to a nearby health centre for use. This will need to be organised locally between health centres to minimise transportation time and ensure viability of medicines is maintained. Medicines must not be sent to PHC regional offices for re-distribution.

Material Safety Data Sheet Chemwatch 4635-19, 29/01/2010 - Bristol Myers Hydrea Capsules.

- returned to the Pharmacy via the RUM process for disposal

2.6 All Other Medicines (Return of Unwanted Medicines Project)

Medicines that have expired, have uncertain storage history, have been returned by clients or have been opened and are not useful for further supply, should be disposed of utilising the dedicated yellow RUM container.

RUM containers are available from the S100 contracted pharmacies at no charge. It is suggested that health centres would keep two containers in stock; one in use and one in store. RUM containers are ordered via the S100 Order form or by phone request from the S100 contracted pharmacy. Staff must factor in the time it may take to receive the RUM container from the S100 pharmacy.

When placing medicines in the RUM container it is worth reducing the bulk of what is being disposed of so that the container is not filled prematurely which in turn adds to freight costs funded under the RUM project. If it is simple to remove outer packaging that may quickly and effectively reduce overall bulk, then this is encouraged.

<u>S100 contracted pharmacies</u> will supply delivery labels and instructions to facilitate return of the RUM containers. Please refer to the S100 Pharmacy Manual and for further information contact S100 contracted pharmacy providing services to the health centre. When the RUM container is full:

- it must be sealed with the lid supplied ensuring that it cannot be opened again
- must be kept in a locked room until transfer to which the public does not have access. Both for convenience and to meet security requirements, the <u>drug storage room</u> is the recommended location for RUM containers.
- attach delivery label provided by S100 pharmacy to the lid of the RUM container
- **PHC CAHS:** delivery instruction is to deliver to the S100 Pharmacy in Alice Springs / Tennant Creek. Note: only after hours deliveries may be left in the Peter Sitzler Building per the information mentioned below in 2.6.1 Central Australia
- **PHC TEHS:** contact Transport Provider to transport the bucket/s to S100 Pharmacy. The Consignment note must be marked as Receiver to Pay. Contact the S100 pharmacy and alert them that there are RUM buckets on their way.

Monitor and where required facilitate disposal of expired <u>Schedule 8 (S8) and Restricted Schedule 4 (RS4)</u>
<u>Medicines</u> during health centre visits. See guidelines in Information Sheet – <u>Return or Disposal of Unwanted or Expired S8 / RS4 Medicines</u>.

2.6.1 Central Australia

If full RUM bins are returned to the Primary Health Care Peter Sitzler Building the following process should occur:

- the full RUM bins should be locked up in the sharps cage (located at rear of the building) using the key from reception
- notify the Senior Remote Pharmacist OR
- contact the Contracted Pharmacy to come and collect the full bins

2.7 RUM Documentation for Standard Drug List Medicines (SDL)

Each health centre must maintain a record of all <u>SDL</u> items that are discarded using the <u>Record for Return of Unwanted Medicines (RUM)</u> - <u>Standard Drug List Medicines Only Form</u>. Monitoring RUM for SDL medicines promotes quality use of medicines and minimises wastage.

Health centre staff	- complete the Form whenever they are discarding SDL medicines
	- send completed form to S100 pharmacy
	- send completed form relevant Senior Pharmacist PHC CAHS or TEHS via e-mail:
	PharmacyRemoteHealth.ths@nt.gov.au
	- adjust health centre medicine stock levels according to reconciliation advice

S100 pharmacy	 reconcile the form six monthly against the usage / order quantity reports use the reconcilliation to adjust minimum / maximum S100 medicine levels to minimise wastage
Senior Pharmacist PHC CAHS and TEHS	 reconcile the form six monthly against the usage / order quantity reports use the reconcilliation to adjust minimum / maximum non-S100 medicine levels to minimise wastage

Forms must be filed in the health centre and retained for two (2) years from the date of last entry. After this time they may be sent to Secondary Storage for appraisal and destruction. See Records Disposal Schedule - Pharmacy Services Department of Health Disposal Schedule No. 2015/22 1.8.3.

Compliance

Completion of the Record for Return of Unwanted
Medicines (RUM) - Standard Drug List Medicines Only
Form when returning unwanted SDL Medicines is
monitored and reconciled to adjust minimum / maximum
medicine levels.

Primary Health Care Manager S100 Pharmacist (during site visits) Senior Pharmacist PHC CAHS and TEHS

Document Quality Assurance

	Method	Responsibility
Implementation	Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas	Health Policy Guidelines Program
Review	Document is to be reviewed within three years, or as changes in practice occur	Senior PHC Pharmacist CAHS & Senior PHC Pharmacist TEHS
Evaluation	Evaluation will be ongoing and informal, based on feedback.	Senior PHC Pharmacist CAHS & Senior PHC Pharmacist TEHS

Key Associated Documents

Forms	Record for Return of Unwanted Medicines (RUM) – Standard Drug List Medicines Only PHC Remote CAHS Form S8 and RS4 Delivery Notification PHC Remote Form Vaccine Wastage Report Form	
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	Cold Chain PHC Remote Guideline Cytotoxic Therapy PHC Remote Guideline Drug Storage Room Standards PHC Remote Guideline Schedule 8 and Restricted Schedule 4 Medicines PHC Remote Guideline Section 100 Pharmacy Arrangements PHC Remote Guideline Standard Drug List PHC Remote Guideline Return or Disposal of Unwanted or Expired S8 / RS4 Medicines Information Sheet	

	Standard Drug List PHC Remote Master Document
	Standard Drug List Pric Remote Master Document
	Schedule 8 and Restricted Schedule 4 Delivery PHC Remote Pharmacy Group Communiqué
	NT Medicines, Poisons and Therapeutic Goods Act and Regulations
	Return of Unwanted Medicines Project website
	Medicines and Poisons Control website
	DoH Retention, Disposal and Destruction intranet site, scroll down to Disposal Schedules for
	Pharmacy Services DS 2015/22 - October 2015 (Records Disposal Schedule Pharmacy Services Department of Health Disposal Schedule No. 2015/22)
	Material Safety Data Sheet Chemwatch 4635-19, 29/01/2010 – Bristol Myers Hydrea Capsules
References	As above

Definitions

Preferred Term	Description
Pharmaceutical Benefits Scheme (PBS):	a scheme through which the Australian Government subsidises the cost of prescription medicines.
Section 100 (S100):	a section of the National Health Act 1953 which allows for special supply arrangements to be made by the Minister for Health to ensure appropriate access to a pharmaceutical service to all Australians where general PBS mechanisms aren't easily applied. For PHC remote health centres \$100 provisions relate to people "who are living in isolated areas." Pharmaceuticals provided under this scheme to PHC remote clients include all PBS listed medicines with the exception of Schedule 8, extemporaneous products (ie products that need to be manufactured at the pharmacy) AND Highly Specialised Drugs.
Standard Drug List (SDL):	an agreed <u>list</u> of pharmaceuticals held in remote health centres throughout the NT. It contains mandatory pharmaceuticals which must be held in every health centre and non- mandatory or optional pharmaceuticals. See <u>Standard Drug List PHC Remote Guideline</u> for further information.

Evidence Table

Reference	Method	Evidence level (I-V)	Summary of recommendation from this reference
N/A	N/A	N/A	N/A