



MONASH University



**Return  
Unwanted  
Medicines  
(The RUM Project)**

# **The National Return and Disposal of Unwanted Medicines (NatRUM) Project Audit**

**Final Report**

**December 2013**

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## Acknowledgements

We would like to acknowledge the support provided by:

### Monash University

*Project Manager:* Dr Sreeja Sudhakaran for managing the data entry, data analysis and the preparation of the report.

*Data collection supervisors:* Pamela Campbell and Denise van den Bosch

*Data collection team:* Rita Breare, Esa Chen, Linda Chuang, Lyn Diep, Souhiela Fakih, Jessica Foster, Siow Chin Heng, Bonnie Jongue, Ivy Jing, Lewis Karapanos, Cynthia Lau, Angelina Lim, Zoe Lim, Jeenal Patel, Christine Pho, Amanda Pozzebon, Nadine Tey, Dennis Thomas, Rachel Vorlander, Olivia Walpole, Clare Walsh, Melissa Warner, Harris Xiao and Evonne Yan.

*Pharmacy undergraduate student recruitment:* Andreia Marques

*Access<sup>TM</sup> database development and SQL queries:* Paulina Stehlik

*Data entry team:* Rita Breare, Tan Doan, Siow Chin Heng, Angelina Lim, Ching-Jou Lim, Dennis Thomas, Denise van den Bosch, Clare Walsh and Elida Zairina.

*Monash Occupational Health and Safety:* David Hurst

### NatRUM Limited

Simon Appel (Project Manager) for providing guidance throughout the NatRUM project audit.

### Bamganie Environmental Services

Andrew Buchanan (Manager) and Jill Buchanan for facilitating data collection at Bamganie Environmental Services.

### Funding

This audit was conducted with the financial assistance of the Australian Government Department of Health and Ageing, from the Quality Use of Diagnostics, Therapeutics and Pathology Fund.

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## Acronyms

Acronym	Explanation
ACT	Australian Capital Territory
API	Australian Pharmaceutical Industries
ATC	Anatomical Therapeutic Chemical
CAM	Complementary and Alternative Medicines
DAA	Dose Administration Aid
DoHA	Department of Health and Ageing
EPA	Environment Protection Authority
MDI	Metered Dose Inhaler
NatRUM	National Return and Disposal of Unwanted Medicines
NSW	New South Wales
NT	Northern Territory
PBS	Pharmaceutical Benefits Scheme
QLD	Queensland
QUM	Quality Use of Medicines
RUM	Return Unwanted Medicines
SA	South Australia
SQL	Structured Query Language
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TAS	Tasmania
VIC	Victoria

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## Executive Summary

- Unsafe disposal of medicines has adverse consequences for both public health and the environment. The National Return and Disposal of Unwanted Medicines (NatRUM) program in Australia provides a safe method of disposal for unwanted and/or expired medicines via community pharmacies. However, the utilisation by pharmacists and consumers of the Return of Unwanted Medicines (RUM) bins has not been previously investigated.
- The NatRUM project audit aimed to scrutinise RUM bins returned from across Australia. The specific objectives were to: (i) describe the quantity and type of unwanted and/or expired medicines returned by consumers via the NatRUM program; (ii) extrapolate the audit results to a 12 month period and compare with Pharmaceutical Benefits Scheme (PBS) data to estimate the annual cost of unwanted and/or expired medicines disposed of nationally; and (iii) to determine the extent of adherence by community pharmacists to NatRUM protocols.
- A quantitative approach was employed to review the amount and type of unwanted and/or expired medicines. It was determined that in order to achieve statistical validation a minimum of 377 RUM bins randomly selected from community pharmacies from States and Territories across Australia required auditing. The audit was conducted at Bamganie Environmental Services, Lethbridge, Victoria in accordance with safety and legal requirements.
- A total of 784 RUM bins were identified for auditing; 98 met the exclusion criteria.
- The remaining **686 RUM bins** were audited:
  - The majority of RUM bins contained medicines; very few (2%) contained inappropriate items;
  - Most RUM bins (93.7%) were full by volume (i.e. >76-100% full);
  - Half of all RUM bins (48.5%) contained dose administration aids;
  - 12.1% of RUM bins contained sharps; and
  - Most returned medicines were scheduled (85.4%); of these, 80.9% were Schedule 4, and 9.1%, 7.8%, and 2.3% were Schedule 2, 3, and 8, respectively.
- The majority of medicines (68%) belonged to five therapeutic classes – cardiovascular (17.9%), nervous system (17.5%), alimentary tract (15.7%), respiratory (8.8%) and anti-infective (8.1%) – which correlated well with PBS dispensing data. Almost half (43.7%) of all medicines discarded had not expired.
- For medicines dispensed under the PBS, those that were discarded in the greatest proportion relative to the quantities dispensed were paracetamol/codeine (500/30 mg tablets) (0.95%) and salbutamol (100 mcg MDI) (0.8%). Six of the most commonly discarded medicines (salbutamol, paracetamol, paracetamol/codeine combination, atorvastatin, amoxycillin and cephalixin) were also the most frequently dispensed on the PBS. On extrapolation to annual PBS cost data (excluding sample packs, unlabeled and expired stock), the medicines with highest cost associated with wastage were tiotropium (\$271,000), fluticasone/salmeterol (\$244,000) and paracetamol (\$178,000).



The total government cost for the 31 most frequently discarded medicines was approximately \$2.05 million.

- The NatRUM audit provided valuable insight into the utilisation of the program by pharmacists and consumers. Consumers predominately returned scheduled medicines; only a small percentage were unscheduled. Almost half of all returned medicines had not expired.
- Limitations are acknowledged: (i) RUM bins from Western Australia (WA) were not included in the audit; (ii) all medicines were assessed by expiry date against the first date of the audit and therefore not all medicines considered expired would have been so at the time of disposal; (iii) comparisons of the most frequently discarded medicines to PBS data were assessed based on individual medicine items, irrespective of whether full quantities were present; and (iv) unscheduled medicines and medicines belonging to more than one therapeutic category were analysed as a group.
- Further studies are required to investigate:
  - the reasons why some pharmacists' failed to correctly comply with NatRUM protocols regarding the correct disposal of Schedule 8 medicines and sharps; and
  - the reasons why consumers returned medicines, especially non-expired medicines
- The NatRUM program is utilised well by pharmacists and consumers and makes a significant contribution to the quality use of medicines nationally.

The audit findings demonstrate that the NatRUM program is an important and viable public health initiative safeguarding the health of consumers in Australia, and the environment. They justify the continued funding of this important program to ensure its availability into the future.

## 1. Background

Many unwanted and/or expired medicines in the community are disposed of via general waste or sewerage [1]. These methods of disposal are unsafe and may adversely impact the environment, as well as social and economic determinants of health. For example, medicines disposed of in household rubbish bins end up in landfill, damaging the environment, whilst medicines discarded down sinks and toilets contaminate waterways and harm marine life [1]. In Australia, every year more than 500 tonnes of medicines end up in landfill and waterways [1]. From a health perspective, such practices lead to the potential for cumulative, long-term exposure of communities to trace amounts of pharmaceuticals, which is of particular concern for vulnerable populations such as pregnant women and children. Unsafe disposal of antimicrobials (e.g. antibiotics, antivirals, and antifungals) may also contribute to the development of antimicrobial resistance [2]. Furthermore, medicines disposed of in household bins may be accessible to unintended recipients including children and pets, increasing the risk of poisonings, misuse and abuse. On the other hand, medicines retained beyond their expiry date increase the likelihood of formation of toxic products, potentially resulting in adverse effects. Thus, it is critical that unwanted and/or expired medicines are disposed of safely.

In 1998 the Australian Federal Government introduced the National Return and Disposal of Unwanted Medicines (NatRUM) program to provide a safe method for disposal of unwanted and/or expired medicines in the community [1]. Through the NatRUM program anyone (e.g. consumers, pharmacists, doctors) in possession of unwanted and/or expired medicines can dispose of medications in their possession via Return of Unwanted Medicines (RUM) bins (Figure 1), located in participating community pharmacies.



**Figure 1:** RUM Bins

RUM bins are subsequently collected via pharmaceutical wholesalers, transported to a central location where they are repackaged onto pallets, and transported to a final location for incinerations in accordance with regulatory and Environment Protection Authority (EPA) requirements. RUM bins from all States and Territories, with the exception of Western Australia, are transported to Bamganie Environmental Services (Lethbridge, VIC, 3332) for incineration. To minimise transportation costs, RUM bins from Western Australia are incinerated at a Western Australian facility. The NatRUM program is

offered free of charge to all consumers and community pharmacies. Importantly, the majority of the 6,000 community pharmacies across Australia have chosen to participate in this program [1]. As the NatRUM program offers a safe and easily accessible method of disposal of unwanted and/or expired medicines, it significantly contributes to the quality use of medicines (QUM) in Australia.

The NatRUM program is one of only a few national programs available worldwide for the safe disposal of unwanted and/or expired medicines. Similar programs exist in France, Portugal, Spain and Sweden [3]. In Australia, the method of destruction is via high temperature incineration, as approved by the EPA [1]; likewise, incineration is also used in France, Portugal, and Sweden [2]. However, there are differences in the funding of these programs between countries. In Australia and Sweden, funding is provided by the Federal Government, whereas in France, Portugal and Spain, funding is provided by the pharmaceutical industry, stakeholder groups and wholesalers [3].

To date only two studies have evaluated the implementation of the NatRUM program. A 2002 study indicated that approximately 11% of all pharmaceutical waste generated in Australia passed through the NatRUM program [1]. Subsequently, a 2005 survey conducted by Brushin investigated community pharmacists' attitudes towards the NatRUM program, as well as consumers' behaviour regarding the type of medicines returned and the reasons for disposal [4]. However, this survey was limited to only 605 consumers in the Melbourne metropolitan area and focused only on prescription medicines.

A more extensive investigation into the use and efficiency of the NatRUM program is therefore required to determine the amount and type of unwanted and/or expired medicines, including both prescription and non-prescription medicines, returned by consumers, and to assess pharmacists' adherence to NatRUM protocols. To address this need, Monash University was commissioned by NatRUM and the Australian Government's Department of Health and Ageing (DoHA) to undertake an audit of the contents of a statistically valid sample of RUM bins. The results of this audit will assist NatRUM Limited, in association with DoHA, to evaluate the success of the NatRUM program and establish an evidence base for the success of quality use of medicines initiatives in Australia. Additionally, it will identify any 'inappropriate' collection or other practices undertaken by pharmacists, including non-pharmaceutical inclusions.

## 2. Aim and Objectives

The overall aim of this project was to audit the contents of RUM bins returned from across Australia, in order to provide the NatRUM Project Board of Directors and the Pharmaceutical Policy Branch of DoHA information to make decisions regarding the NatRUM program management, including the program's efficiency, feasibility and sustainability. Furthermore, the audit will provide information for consideration and use in the broader post-market monitoring program of medicine use.

The key objectives of the audit were:

- To describe the quantity and type of unwanted and/or expired medicines returned by consumers via the NatRUM program. More specifically:
  - the quantities of scheduled medicines collected (total and by individual schedule);
  - the quantities of unscheduled medicines collected (total);
    - for the two objectives above, to further categorise by Anatomical Therapeutic Chemical (ATC) classification (total and the top ten medicines in the major classes)
  - the fraction of expired to non-expired medicines collected; and
  - the accuracy of labeling of dispensed medicines, as well as the nature of the directions supplied.
- To extrapolate the audit results to a 12 month period, and compare with PBS data to estimate the annual cost of unwanted and/or expired medicines disposed of nationally.
- To determine the extent of adherence by community pharmacists to the NatRUM program protocols.

## 3. Methods

### 3.1. Setting

The project examined RUM bins returned from community pharmacies from all Australian States and Territories (except Western Australia) to Bamganie Environmental Services (Lethbridge, VIC, 3332) for incineration, according to the NatRUM protocols (Appendix 1).

### 3.2. Sampling and sample size

Each month, approximately 10,000 RUM bins are returned to Bamganie Environmental Services for incineration. The sample of RUM bins to be audited was calculated using the Raosoft® sample size calculator (2004, Raosoft Inc., Seattle, WA, USA, available at <http://www.raosoft.com/samplesize.html>). Assuming a 5% margin of error and 95% confidence level with a 50% response distribution, a minimum of 377 RUM bins were required for a statistically valid sample.

To meet the minimum sample size (377 RUM bins) and ensure an Australia-wide representative sample, an approximate target number of RUM bins from each State/Territory in Australia was calculated as shown in Table 1.

**Table 1:** Approximate number of RUM bins required from each State/Territory in Australia

State/Territory <sup>#</sup>	Average number of RUM bins delivered to pharmacies per month* (~% of total)	Approximate number of RUM bins to be audited (~% of total)
ACT	106 (1%)	4 (1%)
NSW	3,613 (36%)	136 (36%)
QLD	2,201 (22%)	82 (22%)
SA	1,357 (13%)	49 (13%)
TAS	240 (2%)	8 (2%)
VIC	2,654 (26%)	98 (26%)
<b>TOTAL</b>	<b>10,171</b>	<b>377</b>

<sup>#</sup> WA was not included as RUM bins from WA are not sent to Bamganie Environmental Services; NT was not included in the calculations given the small number of returned RUM bins from this Territory.

\* Data supplied by NatRUM Limited (Mr Simon Appel)

Bamganie Environmental Services staff randomly removed and securely stored on-site four RUM bins from sequential pallets arriving from all States/Territories across Australia for one month prior to the audit (i.e. January 2013; see

Figure 2).



**Figure 2:** RUM bins stored at Bamganie Environmental Services prior to NatRUM audit

## 3.3. Audit procedures

The audit procedures were developed by academic pharmacists from Monash University in consultation with Monash University Occupational Health and Safety. The procedures were designed to protect the safety of auditing staff, meet legal requirements and maximise the amount and consistency of collected data.

### 3.3.1. Pre-audit

A data collection form was specifically developed and validated for the NatRUM audit. Following face and content validity testing, the form was pilot tested on several RUM bins, which resulted in modifications being made to improve utility. The final form (Appendix 2) captured information on the characteristics and content of each RUM bin.

Workshops on safety and legal requirements during the audit were conducted for all staff involved in the data collection process. These included a demonstration of data collection procedures using an actual RUM bin and specific auditing equipment including protective clothing (gloves, safety glasses, fitted P2 dust masks, coveralls and closed toed shoes), tongs, tweezers and the data collection form. A representative from Monash University Occupational Health and Safety was present at each workshop.

### 3.3.2. Audit

The audit was performed on-site at Bamganie Environmental Services from the 16<sup>th</sup> to 23<sup>rd</sup> of February inclusive (2013). The exclusion criteria were RUM bins that contained noxious or biological material, non-medicinal products, non-therapeutic goods, and/or greater than 50% of loose tablets, capsules or blister strips. All other RUM bins were included in the audit. The quantity and type of unwanted and/or expired medicines disposed of via the NatRUM program were audited, and the adherence to NatRUM protocols was examined. To ensure privacy, no information identifying consumers, community pharmacies/pharmacists or prescribers was collected.

The audit was supervised by two registered pharmacists, with a Level 2 first aider always in attendance. In addition, Dr Phillip Bergen (Researcher and Lecturer, Monash University) and Mr Simon Appel (Project Manager, NatRUM Limited) were also present onsite periodically. The audit was conducted by a team of 26 data collectors consisting of registered pharmacists, postgraduate and undergraduate pharmacy students, and pharmacy technicians, most affiliated with Monash University. The data collectors worked in pairs, with one inspecting contents of the RUM bin and the other recording information on the data collection form.

The full details of the data collection process are provided in Appendix 3. Briefly, the RUM bins were audited for their:

- i) **Characteristics** including the source of the RUM bin (State/Territory), wholesaler involved, weight of contents and the volume occupied. The content weight of individual RUM bins was analysed according to three categories: less than 2 kg, 2 – 6 kg, and greater than 6 kg. The volume of the RUM bin occupied by contents was divided into four categories: ≤25%, 26-50%, 51-75% and 76-100%.
- ii) **Content** including:
  - a. The generic name of the medicine, strength, dose form, quantity (in both the original [unopened] pack and remaining in pack), and expiry date. Medicines were considered expired (i.e. out of date) if the manufacturer's expiry date was prior to February 16<sup>th</sup>, 2013, the commencement date of the audit. For the purposes of this audit, an individual item of medicine (excluding Schedule 8 medicines) was defined as 'a full pack of the item' (i.e. containing the full dispensed amount) irrespective of the actual quantity of medicine remaining in the primary or secondary container at the time of audit; this corresponded to a single entry for that medicine in the Access database (see below). For example, one box of medication (e.g. a box of amoxycillin capsules), one metered dose inhaler (MDI), one tube of cream or one bottle of liquid were all considered individually as one item, irrespective of the quantity of medicine remaining at the time of audit. For Schedule 8 medicines, the count for the individual items included loose strips of medicines within the bins in addition to medicines

in the primary or secondary container as defined above. For these medicines, loose strips were individually entered as separate items into the database.

- b. The presence of a dispensing label and, where applicable, whether the directions on the label were specific or '*mdu*' (i.e. take as directed). Note that for items such as vaccines and warfarin, respectively, directions of 'For doctor's use only' or 'Take as directed according to INR result' were considered specific;
- c. Whether the medicine was from a sample pack; and
- d. The presence of dose administration aids (DAAs; e.g. Dosette<sup>®</sup> boxes, Webster<sup>®</sup> packs) and sharps (e.g. needles and lancets but excluding prefilled capped syringes).

Given the nature of the NatRUM audit, institutional ethics committee approval was not required.

### **3.3.3. Post-audit**

#### **3.3.3.1. Data entry, quality control and storage**

An Access database (Microsoft Access, 2007, Redmond, USA) was purpose-built by Monash University to manage the data collected. Data entry conventions were developed to ensure consistency (Appendix 4). A team of ten registered pharmacists and post-graduate pharmacy students were recruited for data entry. Each team member was trained on data entry conventions, including assigning medicines to: (i) a poisons schedule according to the Poisons Standard 2012 (Standard for the Uniform Scheduling of Medicines and Poisons; SUSMP); one of Schedules 2, 3, 4, 8, or unscheduled, and (ii) one of fourteen ATC classifications according to the World Health Organisation (WHO). Medicines that belonged to multiple therapeutic categories and/or unscheduled medicines were included in the 'various' class.

A quality assurance procedure was implemented during and following data entry. Staff were advised to bring to the attention of the Project Manager any potential issues regarding the consistency and reliability of entered data. Additionally, information from one in ten data collection forms was individually checked for accuracy and consistency by the Project Manager against the corresponding information entered into the Access database. In both situations, any inconsistencies or other issues identified were immediately communicated to the data entry team, and quality assurance procedures updated if required. Additionally, at the time of discovery of any error or inconsistency, the database was immediately examined to correct any errors or inconsistencies that may have occurred prior to detection. Following completion of data entry, further data checking was performed within the Access database to ensure the accuracy and consistency of entered data.



The data from the NatRUM audit, including the hard copy data collection forms and the Access database, were and remain stored securely at Monash University, Parkville, in accordance with Monash University policies. Access to all information is restricted to only NatRUM researchers.

### **3.3.3.2. Data analysis**

Data were analysed using Structured Query Language (SQL) queries within the Access database. Separate SQL queries were developed for each RUM bin characteristic (i.e. location, wholesaler, weight, volume) and content of interest (i.e. medicine name, sample packs, DAAs, sharps, scheduling, therapeutic category, labelling and expiry date). The results were expressed as a mean (range) or percentage.

Using data for the annual number of RUM bins returned for incineration from community pharmacies across all Australian States and Territories excluding WA (129,581 bins; information provided by Mr Simon Appel), NatRUM audit data for weight (kg) and quantity of medication (by item) discarded were extrapolated to estimate the total weight and individual quantities of medicines discarded over a 12 month period. For the ten most frequently discarded medicines within each ATC classification, the extrapolated data for each dispensed medicine was compared to the number of prescriptions dispensed for the corresponding medicine under the PBS (matched for dosage form and strength when data available) for the financial year ending June 2012. This provided an estimate of the percentage of each medicine which is discarded annually. For NatRUM data, a medicine was considered dispensed if it was a prescription only medicine (excluding sample packs) and/or contained a dispensing label.

Using the calculated percentages for discarded medicines (described above) and the annual cost incurred by the PBS for the specific medication in 2012, cost estimates for the amount of discarded medications for the financial year ending June 2012 were calculated. This 'cost' represents the annual estimated cost to the government of medicines dispensed under the PBS, which are then ultimately discarded (i.e. wasted). All PBS dispensing and cost data was accessed from <http://www.pbs.gov.au/info/statistics/expenditure-and-prescriptions-30-06-2012>.

## 4. Results

### 4.1. RUM bins

A random sample of 784 RUM bins was examined. Of these, 98 bins fulfilled the exclusion criteria and were not audited. The major reason for exclusion was that the bin contained greater than 50% of loose tablets, capsules or blister strips ( $n = 62$ ; 63.3%). The remaining sample size was 686 bins which greatly exceeded the nominal sample size of 377 bins required for statistical validity.

### 4.2. RUM bin characteristics

#### 4.2.1. Location

The RUM bins were from all States and Territories (excluding WA). More than three quarters of the bins audited were from NSW ( $n = 221$ , 32.2%), VIC ( $n = 202$ , 29.4%), and QLD ( $n = 152$ , 22.2%) (Figure 3). The percentage of total bins audited from each State/Territory correlated well with the percentage of total prescriptions dispensed in each State/Territory under the PBS for the financial year ending June 2012 (NSW, 33.8%; VIC, 25.2%; QLD, 19.4%; WA, 8.8%; SA, 8.4%; TAS, 2.9%; ACT, 1.1%; NT, 0.3%).

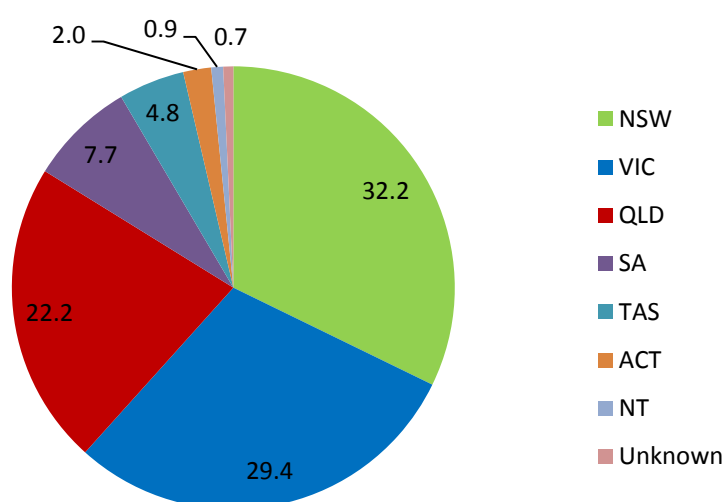


Figure 3: RUM bins by State and Territory (%)

### 4.2.2. Wholesaler

All pharmaceutical wholesalers involved in the NatRUM program were represented, with Symbion ( $n = 397$ , 57.9%) the predominant wholesaler (Figure 4). Due to non-standardised labelling, wholesalers were not able to be identified for more than a quarter of the bins ( $n = 189$ , 27.6%).

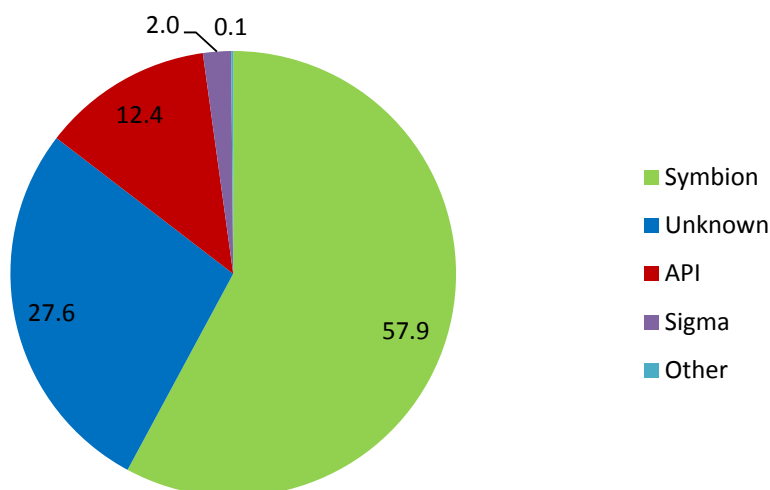


Figure 4: RUM bins by wholesaler (%)

### 4.2.3. Weight and volume occupied

The average net weight of the contents of a RUM bin was 4.2 kg ( $n = 686$ ; range 1.0 – 14.8 kg). The total weight of the contents for all 686 audited bins was 2,829.6 kg. When extrapolated to all NatRUM bins collected throughout Australia (excluding WA) over a 12 month period, this would give an estimated total weight of approximately 540,000 kg (i.e. 540 tonnes). The number (%) of bins in each weight category (less than 2 kg, 2 – 6 kg, and greater than 6 kg) was 10 (1.5%), 605 (88.2%), and 71 (10.3%), respectively. Bins weighing greater than 6 kg generally contained large quantities of loose tablets and/or blister strips, but nevertheless met the inclusion criteria.

The number (%) of bins in each volume category ( $\leq 25\%$ , 26 – 50%, 51 – 75% and 76 – 100% full) was 2 (0.3%), 4 (0.6%), 37 (5.4%), and 637 (93.7%), respectively, with information on the volume filled missing for six RUM bins.

### 4.3. RUM bin content

A total of 24,400 individual items of medicine (see 3.3.2 for definition) containing over 700 different named active ingredients were disposed of in the 686 RUM bins audited.

#### 4.3.1. Top twenty medicines

The twenty most commonly discarded medicines (by number of items) were compared to the twenty most commonly dispensed medicines on the PBS in the financial year ending 2012, as listed in Table 2; six medicines (shown in green) were common to both groups, although the absolute rank did not match.

**Table 2:** Top 20 Medicines from NatRUM Audit and 2012 PBS Dispensing data

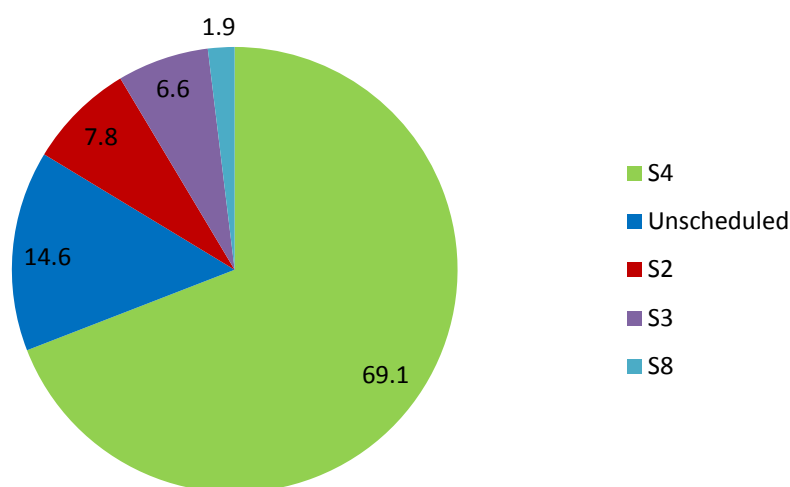
Rank	NatRUM Audit	PBS Dispensing Data
1 (most common)	Salbutamol	Atorvastatin
2	Insulin	Paracetamol
3	Frusemide	Rosuvastatin
4	Prednisolone	Esomeprazole
5	Glyceryl Trinitrate	Atenolol
6	Telmisartan / Amlodipine	Pantoprazole
7	Fluticasone / Salmeterol	Salbutamol
8	Paracetamol	Cephalexin
9	Metoclopramide	Clopidogrel
10	Warfarin	Rabeprazole
11	Influenza Vaccine	Tiotropium
12	Perindopril	Simvastatin
13	Metoprolol	Temazepam
14	Paracetamol / Codeine	Amoxycillin / Clavulanic Acid
15	Atorvastatin	Irbesartan / Hydrochlorothiazide
16	Amoxycillin	Diazepam
17	Betamethasone	Latanoprost
18	Oxycodone	Amoxycillin
19	Cephalexin	Paracetamol / Codeine
20	Ipratropium	Irbesartan

### 4.3.2. Sample packs, dose administration aids (DAA) and sharps

A total of 1,514 sample packs were counted, distributed across 98 individual RUM bins (i.e. 14.3% of all bins). The most common sample pack medicines (by number of items and percentage of total sample packs) were telmisartan/amlodipine in combination ( $n = 284$ , 18.8%), losartan ( $n = 64$ , 4.2%), and atorvastatin ( $n = 51$ , 3.4%). A total of 3,500 DAA items such as Dosette® boxes or Webster® packs were counted, distributed across 333 (48.5%). Most DAAs were full ( $n = 1488$ , 42.5%) or partly full ( $n = 1837$ , 52.5%), with only a small number empty ( $n = 145$ , 4.1%). Information was missing for 30 (0.9%) DAAs. Eighty three bins (12.1%) contained sharps other than prefilled capped syringes.

### 4.3.3. Scheduling

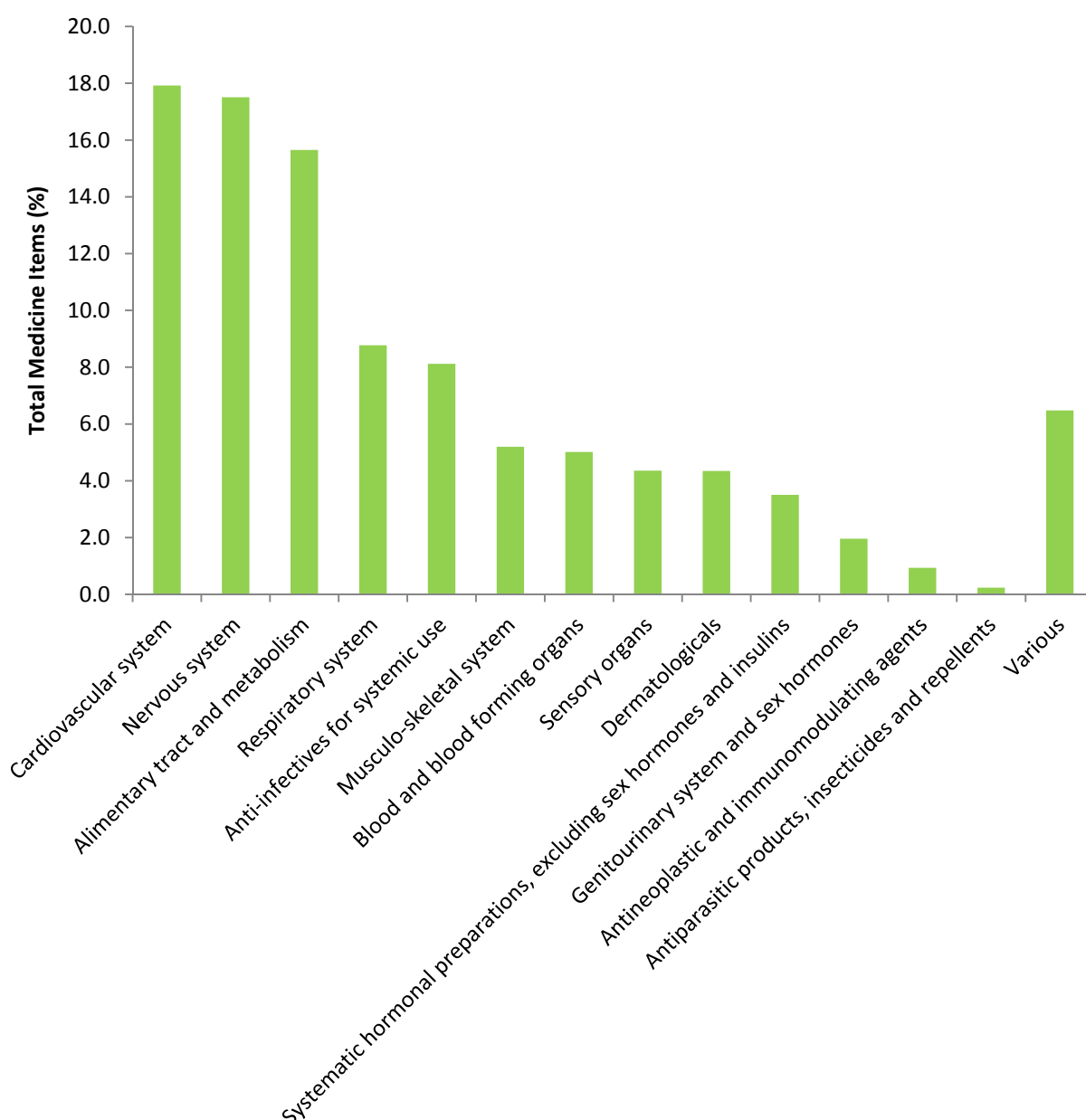
The majority of total medicines discarded (by number of items) were scheduled (85.4%), as shown in Figure 5.



**Figure 5:** Medicines within each schedule or unscheduled medicines (%)

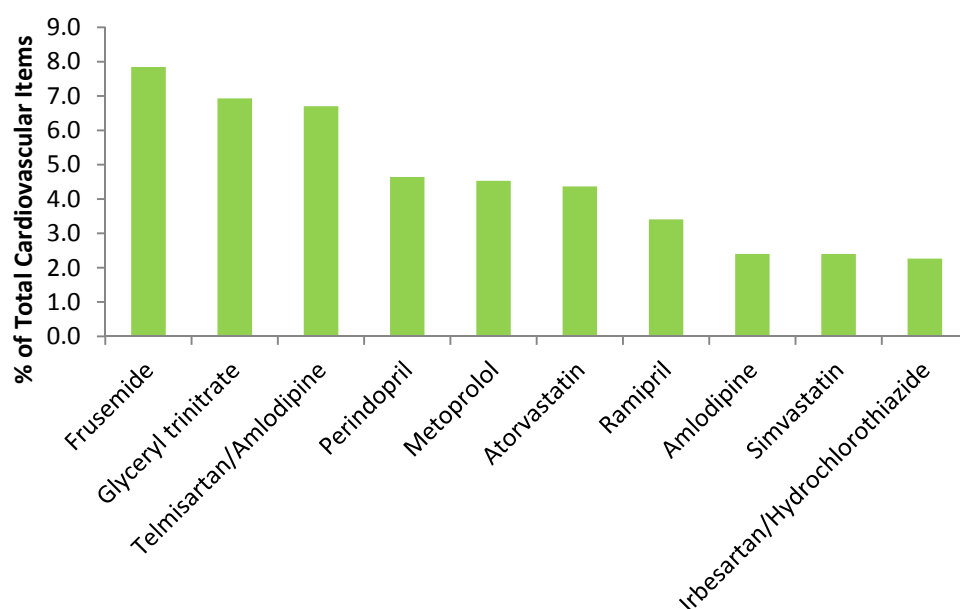
#### 4.3.4. ATC classification

The percentages of total medicines discarded (by number of items) according to ATC classification are shown in Figure 6. Medicines belonging to multiple ATC classes and/or unscheduled medicines are included in the 'Various' class. Most of the discarded medicines belonged to five classes: cardiovascular (17.9%), nervous system (17.5%), alimentary tract and metabolism (15.7%), respiratory (8.8%) and anti-infective (8.1%), as shown in Figure 6.

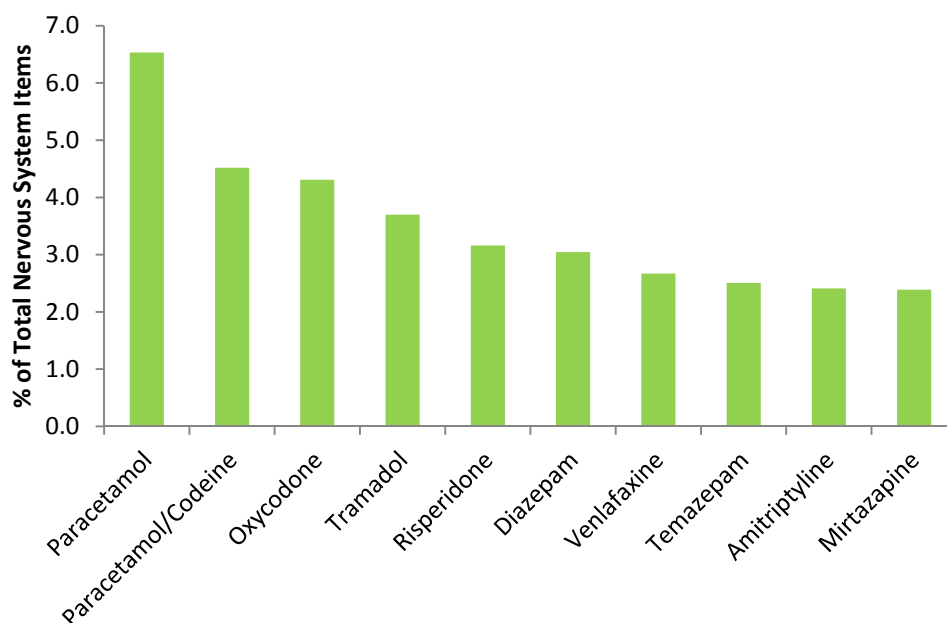


**Figure 6:** Medicines by ATC classification.

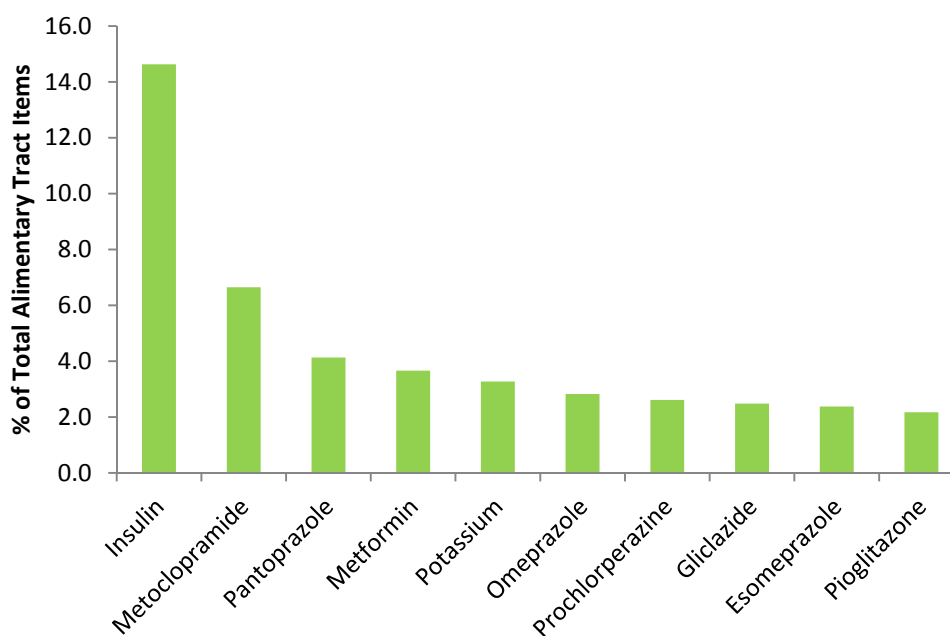
For each of the top five ATC classes identified above, the top ten most commonly discarded medicines as a percentage in that ATC class are presented in Figure 7-11. Salbutamol (28.8%) and insulin (15.4%), the latter consisting of all insulin products combined, were the most commonly discarded medicines for the respiratory and alimentary tract classes, respectively. The most commonly discarded medicines in each of the remaining classes were: frusemide (9.7%) in the cardiovascular class; paracetamol (1.2%) in the nervous system class, and influenza vaccine (6.9%) in the anti-infective class. Interestingly, oxycodone (4.5%) was the third most commonly discarded nervous system medicine despite State/Territory legislation requiring Schedule 8 medicines to be rendered unusable (and therefore for the purposes of this audit, unidentifiable) prior to inclusion in the RUM bins.



**Figure 7:** Cardiovascular - top ten medicines

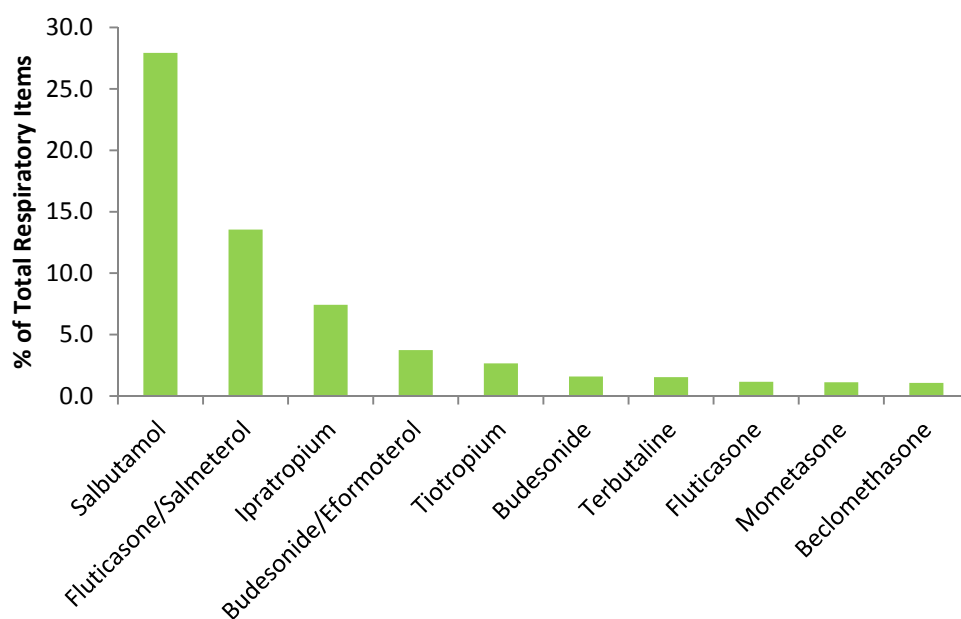


**Figure 8:** Nervous system - top ten medicines

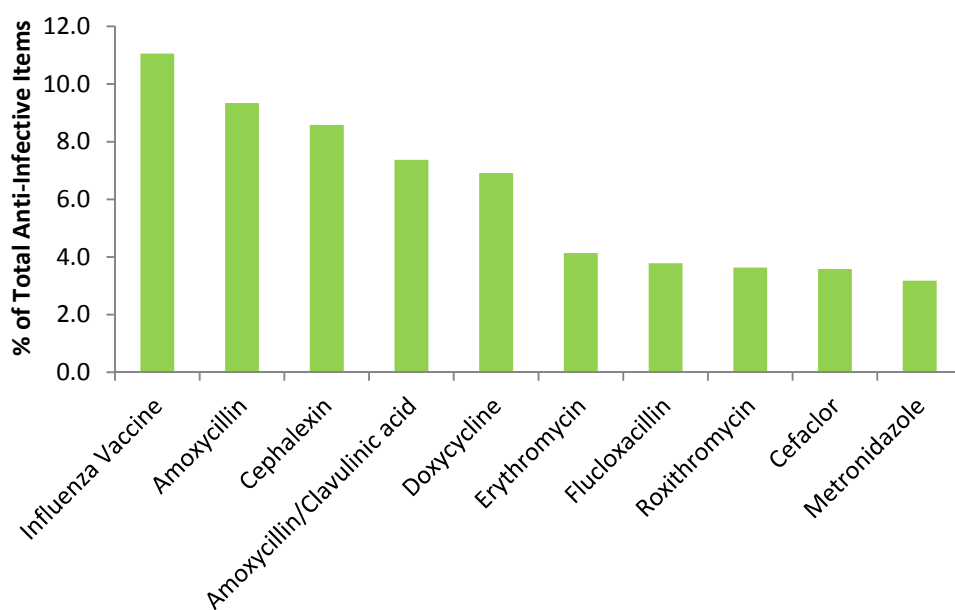


**Figure 9:** Alimentary Tract - top ten medicines





**Figure 10:** Respiratory - top ten medicines



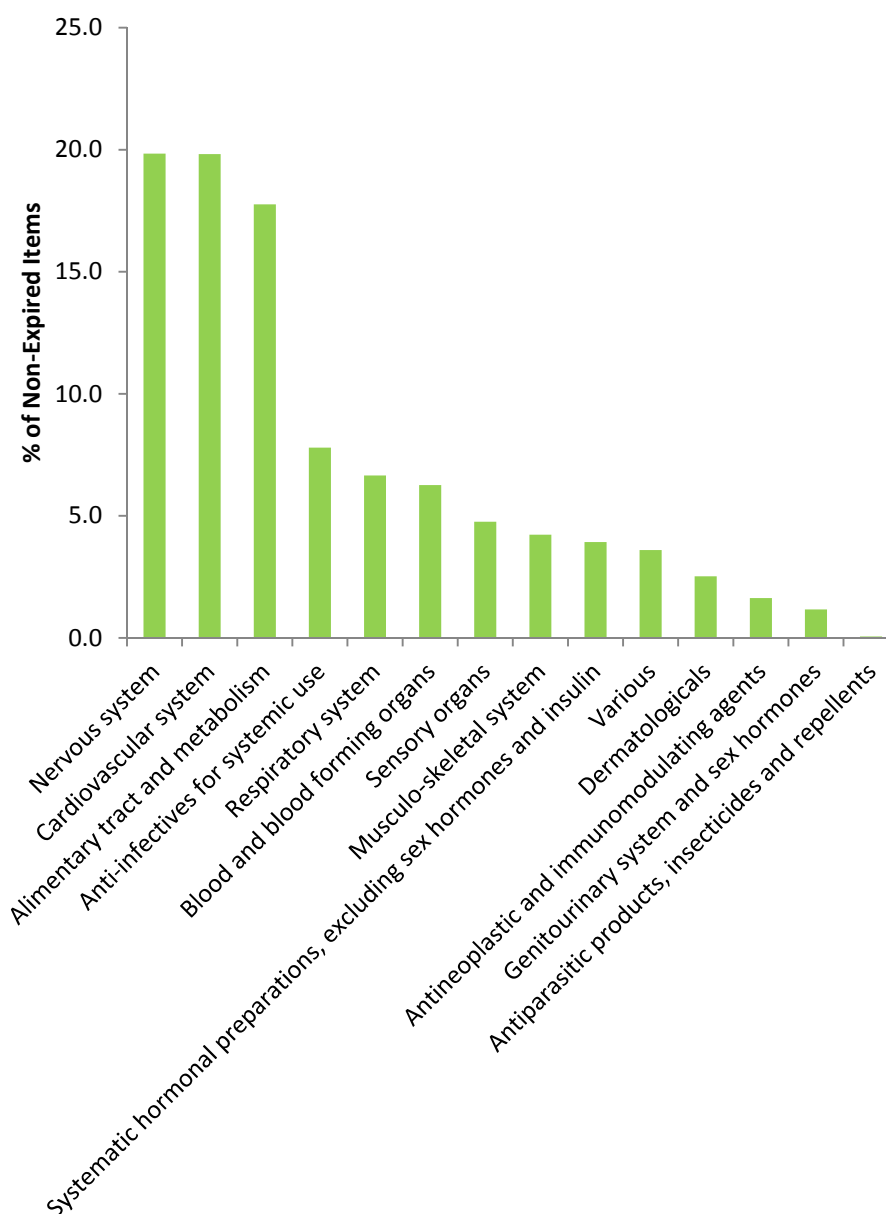
**Figure 11:** Anti-infective - top ten medicines

### **4.3.5. Labelling**

A dispensing label affixed to the packaging was found on approximately half (50.3%) of all discarded medicines. Of these, the drug name on the dispensing label correctly matched the drug name on the product (i.e. the name provided by the manufacturer on the container) in 96.4% of cases. The majority of labels (94.8%) included specific directions for use of the medicine, whereas the remaining 5.2% were labelled only with 'take as directed' or similar.

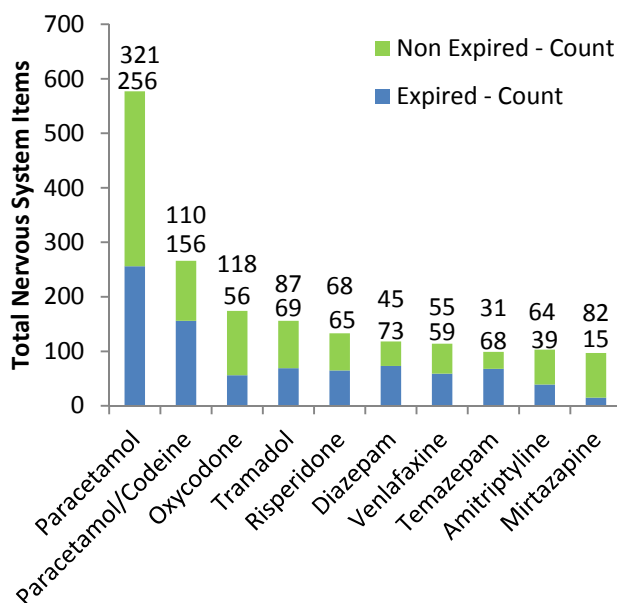
### **4.3.6. Expired (out-of-date)/non-expired (in-date) medicines**

Just over half of all medicines (51.4%) were expired at the time of data collection. Expiry dates on a small proportion of medicines (4.8%) could not be determined, mostly due to the dispensing label covering the date or the segment of packaging containing the date having been removed. The remaining medicines (43.7%) were in-date. For total non-expired medicines (i.e. 43.7% of all medicines by item), the majority belonged to the following five ATC classes (Figure 12): nervous system (19.8%), cardiovascular (19.8%), alimentary system (17.8%), anti-infective (7.8%) and respiratory (6.7%).

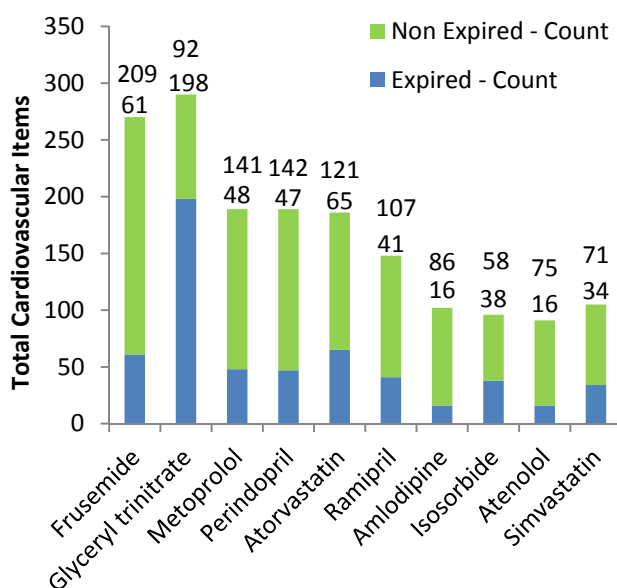


**Figure 12:** Percentage of non-expired medicines by ATC class.

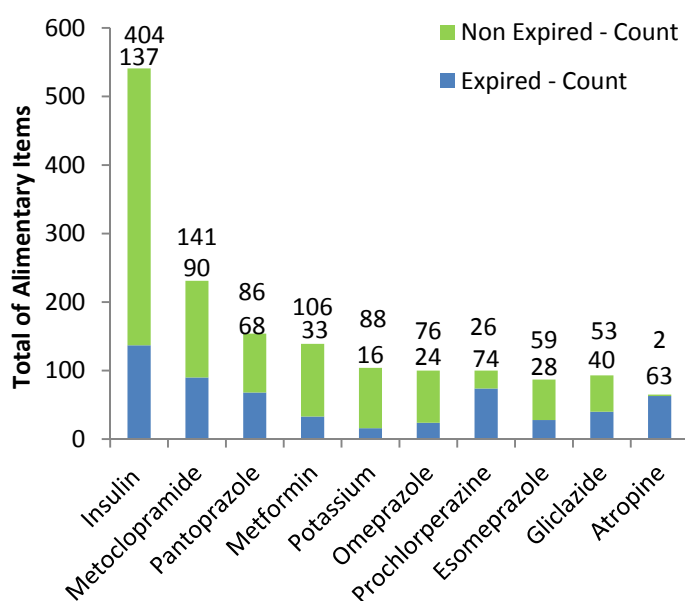
Within each of the top five ATC classes which contained the majority of non-expired medicines, identified above, the total number of items for each of the top ten medicines within each category (excluding sample packs) which were expired/not expired at the time of audit are shown in Figure 13-17.



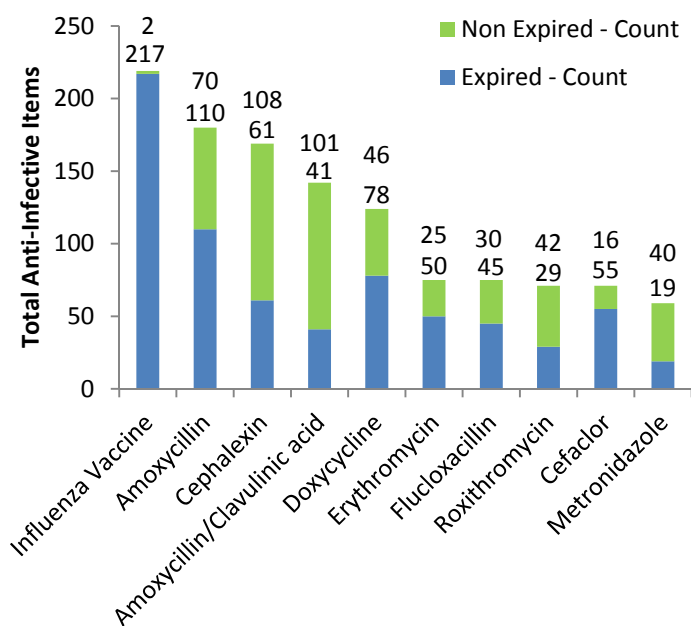
**Figure 13:** Nervous system - top ten medicine items expired/non-expired



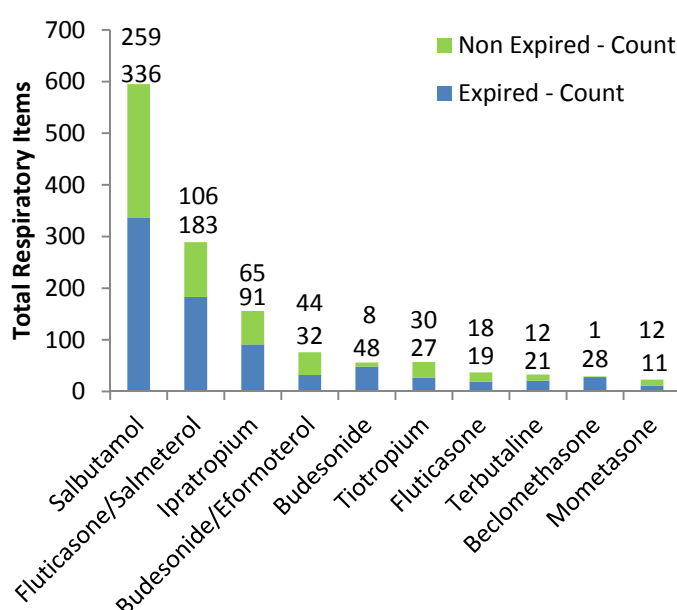
**Figure 14:** Cardiovascular - top ten medicine items expired/non-expired



**Figure 15:** Alimentary – top ten medicine items expired/non-expired



**Figure 16:** Anti-infectives – top ten medicines items expired/non-expired



**Figure 17:** Respiratory – top ten medicine items expired/non-expired

## 4.3.7. Comparison with PBS dispensing data

Following estimation of the quantity of medicines (by item) discarded over a 12 months period, the five ATC classes most commonly encountered for discarded medicines (see Section 4.3.4) correlated well with 2012 PBS dispensing data (Table 3).

**Table 3:** Top five ATC classes of discarded medicines and the five therapeutic categories most commonly dispensed on the PBS in 2012.

Rank	NatRUM audit	PBS dispensing
1	Cardiovascular	Cardiovascular
2	Nervous system	Nervous system
3	Alimentary tract	Alimentary tract
4	Respiratory tract	Anti-infective
5	Anti-infective	Respiratory tract

For the ten most frequently discarded medicines (excluding sample packs, unlabelled and expired stock) within each of these top five ATC classes of discarded medicines, the estimated annual percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program (for the indicated strength and dosage form), as well as the estimated financial loss to the government for each medicine (i.e. expenditure on medicines ultimately discarded and disposed of via the NatRUM program), are shown in

Table 4-8.

**Table 4:** Cardiovascular medicines - Estimated percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program, and the estimated government costs.

Rank	Medicine	Percentage of dispensed PBS items discarded (specific for dosage form and strength(s) indicated)	Estimated cost to the government
1	Frusemide	0.4* (40 mg tablet)	\$22,411* (40 mg tablet)
2	Glyceryl trinitrate	N/A	N/A
3	Telmisartan/Amlodipine	0 <sup>#</sup>	\$0
4	Perindopril	0.06* (5 mg, 10 mg tablet)	\$17,420* (5 mg, 10 mg tablet)
5	Metoprolol	0.6* (50 mg tablet)	\$40,072* (50 mg tablet)
6	Atorvastatin	0.02* (10 mg, 20 mg, 40 mg, 80 mg tablet)	\$114,068* (10 mg, 20 mg, 40 mg, 80 mg tablet)
7	Ramipril	0.04* (10 mg capsule)	\$6,711* (10 mg capsule)
8	Amlodipine	0.16* (5 mg tablet)	\$18,603* (5 mg tablet)
9	Simvastatin	0.06* (20 mg, 40 mg tablet)	\$47,501* (20 mg, 40 mg tablet)
10	Irbesartan/Hydrochlorothiazide	0.11 (300/12.5 mg tablet)	\$43,333

\*Calculation based on dose form and strength; N/A indicates PBS data not available.

<sup>#</sup> Dose form and strength not specified

**Table 5:** Nervous system medicines - Estimated percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program, and the estimated government costs.

Rank	Medicine	Percentage of dispensed PBS items discarded (specific for dosage form and strength(s) indicated)	Estimated cost to the government
1	Paracetamol	0.35* (500mg, 665 mg tablet)	\$178,258* (500mg, 665 mg tablet)
2	Paracetamol/Codeine	0.95* (500/30mg tablet)	\$42,775* (500/30 mg tablet)
3	Oxycodone	0.33* (5 mg tablet)	\$30,001* (5 mg tablet)
4	Tramadol	0.4 <sup>#</sup>	\$89,012 <sup>#</sup>
5	Risperidone	0.15 <sup>#</sup>	\$116,776 <sup>#</sup>
6	Diazepam	0.25* (5 mg tablet)	\$11,581* (5 mg tablet)
7	Venlafaxine	0.03* (75 mg, 150 mg capsule)	\$28,083* (75 mg, 150 mg capsule)
8	Temazepam	0.63* (10 mg tablet)	\$34,925* (10 mg tablet)
9	Amitriptyline	0.49 <sup>#</sup>	\$26,573 <sup>#</sup>
10	Mirtazapine	0.14 <sup>#</sup>	\$41,630 <sup>#</sup>

\*Calculation based on dose form and strength

<sup>#</sup> Dose form and strength not specified

**Table 6:** Alimentary tract medicines - Estimated percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program, and the estimated government costs.

Rank	Medicine	Percentage of dispensed PBS items discarded (specific for dosage form and strength(s) indicated)	Estimated cost to the government
1	Insulin	N/A	N/A
2	Metoclopramide	N/A	N/A
3	Pantoprazole	0.11* (40 mg tablet)	\$82,988* (40 mg tablet)
4	Metformin	0.12* (500 mg, 1 g tablet)	\$36,973* (500 mg, 1 g tablet)
5	Potassium	N/A	N/A
6	Omeprazole	0.28* (20 mg tablet)	\$93,432* (20 mg tablet)
7	Prochlorperazine	N/A	N/A
8	Esomeprazole	0.027* (20 mg, 40 mg tablet)	\$44,668* (20 mg, 40 mg tablet)
9	Gliclazide	0.12* (60 mg tablet)	\$12,351* (60 mg tablet)
10	Pioglitazone	N/A	N/A

\*Calculation based on dose form and strength; N/A indicates PBS data not available.



**Table 7:** Respiratory medicines - Estimated percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program, and the estimated government costs.

Rank	Medicine	Percentage of dispensed PBS items discarded (specific for dosage form and strength(s) indicated)	Estimated cost to the government
1	Salbutamol	0.80* (100 mcg MDI)	\$173,008* (100 mcg MDI)
2	Fluticasone / Salmeterol	0.16* (250 mcg/25 mcg MDI, 250mcg/50mcg Accuhaler, 500mcg/50mcg Accuhaler)	\$244,119* (250 mcg/25 mcg MDI, 250mcg/50mcg Accuhaler, 500mcg/50mcg Accuhaler)
3	Ipratropium	N/A	N/A
4	Budesonide / Eformoterol	0.15* (200 mcg/6 mcg Turbuhaler)	\$65,451* (200 mcg/6 mcg Turbuhaler)
5	Tiotropium	0.23* (18 mcg capsule)	\$271,072* (18 mcg capsule)
6	Budesonide	N/A	N/A
7	Terbutaline	N/A	N/A
8	Fluticasone	N/A	N/A
9	Mometasone	N/A	N/A
10	Beclomethasone	N/A	N/A

\*Calculation based on dose form and strength; N/A indicates PBS data not available.

**Table 8:** Anti-infective medicines - Estimated percentage of medicine items dispensed under the PBS and ultimately discarded via the NatRUM program, and the estimated government costs

Rank	Medicine	Percentage of dispensed PBS items discarded (dosage form and strength)	Estimated cost to the government
1	Influenza Vaccine	N/A	N/A
2	Amoxycillin	0.34* (500 mg capsule)	\$25,520* (500 mg capsule)
3	Cephalexin	0.34* (500 mg capsule)	\$41,413* (500 mg capsule)
4	Amoxycillin / Clavulanic Acid	0.24* (875 mg / 125 mg tablet)	\$33,225* (875 mg / 125 mg tablet)
5	Doxycycline	N/A	N/A
6	Erythromycin	N/A	N/A
7	Flucloxacillin	N/A	N/A
8	Roxithromycin	0.29 <sup>#</sup>	\$20,678 <sup>#</sup>
9	Cefaclor	N/A	N/A
10	Metronidazole	N/A	N/A

\*Calculation based on dose form and strength; N/A indicates PBS data not available.

<sup>#</sup> Dose form and strength not specified

Using only the available PBS data, the total estimated government costs for the top ten discarded medicines within each of the top five ATC classes, in order from highest to lowest were: respiratory, \$753,650; nervous system, \$599,614; cardiovascular, \$310,119; alimentary, \$270,412; anti-infectives \$120,836. The total estimated cost across the five classes is approximately \$2.055 million.

## 5. Discussion

This is the first systematically conducted study to examine the contents of RUM bins from across Australia since the NatRUM program commenced in 1998 [1]. Important insights have been gained into the quantities and types of unwanted and/or expired medicines returned for disposal, costs associated with these medicines, adherence to NatRUM program protocols, and other matters such as labelling. The findings will aid in the development of policies and practices to support the disposal of unwanted and/or expired medicines, and assist relevant agencies in the broader post-market monitoring program of medicine use.

The audit findings revealed that through the NatRUM program, consumers returned large quantities and a diverse range of medicines (over 700 different medicines by drug name were identified). Pharmacists were generally adherent to NatRUM program protocols [1]. The majority of the returned medicines belonged to Schedule 4, with the overall pattern of quantity of returned medicines generally mirroring that of the 2012 PBS dispensing data. The most common medicine returned (by item) was salbutamol. Most returned medicines were accurately labelled and contained specific directions, although a small but important percentage were incorrectly labelled (3.6%). Surprisingly, almost half of the returned medicines had not expired as of the first day of the audit (i.e. 16<sup>th</sup> February, 2012). The largest quantity of medicines discarded was from the cardiovascular ATC class. Accordingly, the discarded cardiovascular medicines were associated with the highest PBS expenditure. The key findings of this audit are discussed below.

### 5.1. Scheduling

Both scheduled and unscheduled medicines were returned for disposal, with the total number (by unit) of scheduled medicines approximately 5.5 times the number of unscheduled medicines. As was observed by Brushin [4], the most common medicines returned for disposal were Schedule 4, which comprises the vast majority of PBS prescriptions. The considerably lower proportion of unscheduled compared to scheduled medicines is interesting given the increasing popularity of complementary and alternative medicine (CAM) in Australia (CAM medicines are almost exclusively unscheduled) [5]. For example, a national survey found that 68.9% of Australians used at least one form of CAM in the previous year, and consumers frequently use CAMs alone or in combination with conventional medicines [6]. However, as

CAM use in the community is not officially documented it is difficult to interpret whether the quantities of CAM returned were proportional to the quantity used in the Australian community. While the reasons for the return of the medicines examined in the current audit were beyond the study scope, it is possible that consumers believe CAMs are 'safe' and therefore do not require disposal in the same manner as scheduled medicines. This is consistent with results from Brushin's RUM survey, which also uncovered poor disposal practices by consumers in relation to non-prescription medicines [4]. A potentially useful future initiative could be an education/informational campaign to raise consumer awareness about 'CAMs' and the appropriate use and disposal thereof.

An interesting finding of this audit was that 2.3% of scheduled medicines returned were Schedule 8, with approximately 500 Schedule 8 items counted. It should be noted, however, that unlike other medicines in the current audit loose strips of Schedule 8 medicines were counted in addition to medicines in their primary container (Section 3.3.2). Therefore, the total number of items counted is likely to be inflated given some loose strips may well have come out of the same original packet. Importantly, State/Territory legislation requires that Schedule 8 medicines be rendered unusable (and therefore unidentifiable) prior to inclusion in the bins [7], and this is clearly indicated in the NatRUM program protocol for Pharmacists (Appendix 1) [1]. Clearly, not all pharmacists are adhering to the requirements for disposal of Schedule 8 medicines. Based on these findings it would seem appropriate for NatRUM Limited and DoHA to remind all participating pharmacists of their legal obligations in this regard.

## 5.2. ATC classification

Audited medicines were assigned to one of 14 ATC classes. The ATC classification was chosen as it is the internationally accepted classification system for presenting drug usage data, recommended by the WHO, and has been adopted for use in Australia by the Pharmaceutical Benefits Advisory Committee and DoHA [8].

By quantity, the five most common ATC classes of medicines returned for disposal were cardiovascular, nervous system, alimentary tract and metabolism, respiratory system and anti-infectives. This correlates well to the 2012 PBS dispensing data [9], with the order of the top three categories matching perfectly. This is also consistent with the Brushin study except that anti-infectives in this audit replaced musculo-skeletal system [4]. These observations would indicate that disposal of medicines is roughly proportional to the quantities dispensed on the PBS.

The observation that antimicrobials are being commonly discarded is a genuine matter of concern, especially given resistance to antimicrobials is becoming increasingly common and the numbers of new antimicrobials being developed are limited [10]. Initiatives to improve the appropriate use of antimicrobials (e.g. Australian National Antimicrobial Awareness Week, developing of guidelines for

antimicrobial use by the Australian Commission on Quality and Safety in Health Care and NPS Medicine Wise) are both timely and critical. Appropriate antimicrobial prescribing can also be facilitated through the PBS criteria/policy.

### 5.3. Labelling

The vast majority of discarded medicines that had a label were correctly labelled, in that the drug name on the label affixed to the container correctly matched the drug name on the product. It is notable, however, that there was a mismatch in this information (i.e. a selection error) in 3.6% of cases, implying that wrong products might have been dispensed. This is a worrying situation given patient safety may have been compromised. It is a legal requirement that each dispensing system is fitted with scanners and pharmacists are required to use scanners to check dispensing accuracy [11, 12]. While there have been reported cases of incorrect bar codes on product labels such that the scanner identifies an incorrect medicine [11, 12], such cases are infrequent. These and other errors should be detected during final checking and counselling. There have been a number of reported cases of selection errors due to pharmacists not using scanners, which is considered poor professional practice by the Pharmacy Board of Australia and constitutes unprofessional conduct [12]. It has been reported that the introduction of scanners reduced selection errors from around 50% of reported errors prior to dispensing to less than 1% currently [12]. The rate of labelling errors observed in this audit may indicate that not all pharmacists are using scanners as legally required. However, it was beyond the scope of this study to examine reasons why such errors may occur or in fact why 5.2% of labelled medicines contained non-specific directions. The use of non-specific directions is not recommended as from a QUM perspective, patients and carers are left to 'second-guess' the prescriber's instructions, which in turn could potentially compromise therapeutic outcomes and lead to adverse events. Of interest is that recent work by the consortium from Monash University, Sydney University and University of South Australia to explore the impact of implementing a 'Near Miss Dispensing Incident Report and Learning System' has shown that such a system raises awareness of dispensary staff to dispensing errors which results in improvements made to the dispensing process within the pharmacy to minimise dispensing errors [13]. Such a system, if implemented nationally, will improve the dispensing process and ultimately increase patient safety. In the interest of patient safety, the labelling error rate observed in this audit should be communicated to the Australian Pharmacy Board and other key pharmacy stakeholders for dissemination to pharmacists to highlight the importance of adhering to mandatory dispensing practices.

## 5.4. Expiry date

It was concerning that almost half of all medicines returned by consumers had not expired, especially given this is an underestimation due to the possibility in-date medicines expiring subsequent to placement in the bins; this is discussed further in Section 5.8. While the reasons why consumers returned medicines were not within the scope of this study, Brushin reported that consumers returned medicines for a variety of reasons [4]. The most common reasons included: concerns about safety and/or efficacy; consumer's death; change in therapy; and consumer's perception regarding the need for the medicines and unwanted effects [4]. Brushin also found that the reasons for returning medicines differed depending on the therapeutic class of the medicine [4]. Cardiovascular medicines were most commonly returned due to a change in medication recommended by a medical practitioner or other healthcare professional. While nervous system medicines were mostly returned due to unwanted effects or perceived ineffectiveness. On the other hand, anti-infective medicines were mostly returned due to consumer perception regarding the lack of further need for the medicine [4]. The reasons why consumers return medicines, including CAMs, via the NatRUM program should be further explored. Nevertheless, the large quantity of non-expired returned medicines discovered in this audit warrant communication of these findings to prescribers and other healthcare professionals in order to promote rational prescribing of medicines, promoting patient adherence and minimise wastage. Initiatives to raise consumer awareness, particularly in association with the potential dangers of non-adherence are also warranted.

## 5.5. Comparison with PBS dispensing data

In order to better estimate the potential wastage of medicines in the community, the NatRUM audit results were compared to PBS dispensing data. For the cardiovascular medicines, ~1.5% of total medicines, and up to ~0.6% of individually dispensed medicines (e.g. metoprolol) were discarded via NatRUM. Medicines discarded included many of the highest volume PBS dispensed medicines (atorvastatin, perindopril, simvastatin, irbesartan/hydrochlorothiazide combination, ramipril and amlodipine) [9]. It is possible that by necessity cardiovascular medicines are started and ceased according to the patient's response, including adverse effects. This approach may require early cessation of initial therapy and a switch to alternative antihypertensive agents. Such a situation was reported by Brushin [4].

In the nervous system class, ~3.7% of total medicines were discarded, paracetamol/codeine combination (500/30mg tablets) being the most frequent individually discarded medicine (~0.95% of the amount dispensed), which is also a high volume PBS medicine [9]. For the remaining individual medicines, which include many of the highest volume PBS dispensed medicines (e.g. paracetamol, oxycodone, diazepam,

temazepam, amitryptiline) [9], the amount discarded was less than  $\leq 0.63\%$ . In the respiratory tract class,  $\sim 1.3\%$  of total medicines, and up to  $\sim 0.80\%$  of individual medicines dispensed, were discarded and once again included several high volume PBS medicines such as fluticasone/salmeterol (in combination), salbutamol, and tiotropium [9]. The extent of disposal observed in this audit may be an overestimation given that all the metered dose inhaler (MDI) devices identified in the audit were treated as being full. Nevertheless, patients with certain respiratory conditions such as asthma, especially during the early stages of diagnosis, may trial different medicines and/or dosage forms until the stabilised, thus necessitating early discontinuation of some medicine(s) [14]. When stabilised on a preventer salbutamol use also tends to decline, which therapeutically is a desired outcome but may lead to wastage.

For alimentary tract medicines,  $\sim 0.7\%$  of total medicines, and up to  $0.28\%$  of individual medicines, were discarded. Several high volume alimentary tract medicines such as the proton pump inhibitors (esomeprazole, pantoprazole, omeprazole) and anti-diabetic agents (metformin, gliclazide) were included [9]. Proton pump inhibitors should be used with caution long-term due to the risk of hypergastrinemia and potential effects on bone metabolism [15], which may explain their disposal given patients routinely do not consume the entire quantity dispensed. Similar to cardiovascular and asthma medicines, anti-diabetic medicines are also commonly trialled and regimens tend to change until the condition is well controlled. Accordingly, for these and other medicines (discussed above), a review of 'appropriate' pack size may potentially be useful in minimising such wastage, including starter packs for some medications.

For anti-infective medicines,  $\sim 1.2\%$  of total medicines, and up to  $0.34\%$  of individual medicines, were discarded with the highest rate of disposal for amoxycillin and cephalexin. Disposal of these medicines may be due to failure to complete prescribed courses even when instructed to do so, or due to switching from one agent to another by the prescriber. As indicated previously antibiotic misuse is of concern because it can significantly contribute to antibiotic resistance [10]. While the NPS Medicine Wise has led the way in dealing with this public health issue by promoting education to general practitioners [16], consumers also need to be made aware of this problem.

## 5.6. Comparison with PBS cost data

As discussed above (Section 5.5) several high cost PBS medicines such as tiotropium, fluticasone/salmeterol, atorvastatin and salbutamol [9] were found to be discarded in large quantities with significant financial loss to the government. Within the limitations associated with the costing strategy used in this audit, the data suggest there may be significant financial wastage with some medicines prescribed under the PBS. Importantly, strategies should be explored to minimise such wastage. In total, the estimated combined cost to the government from wastage due to incineration of the 31 most frequently discarded medicines was estimated to be approximately \$2.055 million. Given that these

medicines are used to treat two of eight National Health Priority areas (cardiovascular health and asthma) in Australia [17], it is important for the relevant departments within the Commonwealth Government of Australia (e.g. Pharmaceutical Benefits Advisory Committee, PBS) to work with bodies like the National Prescribing Service to implement QUM initiatives with the view to decreasing these costs. Indeed, pharmacists together with the medical practitioners will have a pivotal role in optimising how medicine are prescribed and used in patients and minimising wastage. The costs associated with destruction of non-expired discarded medicines is a burden on the health care system and, if minimised, could be better redirected towards other public health efforts to improve the management of these and other National Health Priority areas.

## 5.7. Adherence to NatRUM protocols

In general terms this audit has demonstrated that most pharmacists participating in the NatRUM program were adherent to NatRUM program protocols [1]. As pharmacists play the most significant role of all healthcare professionals in promoting the safe disposal of unwanted and/or expired medicines to consumers, this is an important finding in the context of QUM and the NatRUM program. Adherence to the program was demonstrated as most RUM bins in the audit were full or nearly full and contained only medicines (i.e. prescription and over the counter medicines, including CAMs), as intended. Only a small proportion (2%) of audited bins contained items other than medicines and all were free of intravenously administered cytotoxic medicines. It is noteworthy, however, that a minority of the RUM bins contained Schedule 8 medicines and sharps. The inclusion of usable and identifiable Schedule 8 medicines in some bins has been discussed above (Section 5.1). Additionally, thirty six bins were excluded from auditing because >50% of their contents was not medicines/sharps/therapeutic goods, or the contents was considered noxious, contained biological material or was considered otherwise unsafe for assessment.

Sharps were found in a small but substantial percentage (12.1%) of RUM bins contravening NatRUM protocols as currently expressed (Appendix 1) [1]. The NatRUM program protocol for Pharmacists states that needles and other sharps should not be placed in the RUM bins but rather in a container specifically designed for such waste [1]. Prefilled capped syringes (e.g. vaccines) are not considered sharps and were not included as such in this audit. However, it should be noted that the majority of sharps recorded in the audit included capped needles and lancets, many still in their original packaging. Very few loose, uncapped needles or other sharps were present that would pose a risk to individuals handling the bins. Additionally, the NatRUM Project Board of Directors has no objections to capped needles or sealed lancets being included in the bins. Thus, there appears to be a disconnect between the existing NatRUM protocols made available to pharmacists, and the intention of the NatRUM Board regarding what sharps can and cannot be included in the bins. If the latter formed the basis of our analysis regarding the



inclusion of sharps, then the number of bins containing 'unacceptable sharps' would fall dramatically. If the protocols, as written, are to take precedence in the future then pharmacists require other means by which to dispose of sharps that may be returned by patients or their families. We therefore recommend that the existing guidelines be clarified so that pharmacists are better informed about what 'sharps' are permitted to be included in RUM bins.

## 5.8. Strengths & limitations

To the best of our knowledge no previous study has quantitatively examined the nature and type of medicines discarded within the RUM bins, making this audit the first of its kind nationally and paving the way for future audits in Australia and overseas as a means of post-marketing surveillance. The auditing process was conducted with due diligence as per standard protocols and can be replicated by other researchers in future work. Approximately twice the number of bins required for statistical validity was audited, lending high confidence to the results. The sample was also very representative of the NatRUM bins returned Australia-wide via the program and the audit gathered data on 24,400 individual items of medicine containing over 700 different active ingredients. A comprehensive analysis was conducted, including extrapolating audit data to 12 months and comparing it to PBS dispensing and cost data. This analysis has significantly strengthened the work undertaken as it provides an indication, within the limitations of the methods employed, of the burden of non-expired medicines on Australia's health care system. The findings also make a case for further research in the area, as discussed in Section 5.9.

For logistical reasons, the current audit did not include RUM bins from WA. However, as a large number of bins from all other Australian States and Territories were included there is no reason to expect that the practices of WA consumers and pharmacists in relation to unwanted and/or expired medicines would differ significantly from the rest of Australia. Additionally, although PBS volume and cost data is not separately available for individual States and Territories and thus includes WA, only approximately 9% of total medicines dispensed under the PBS relate to WA and therefore number and cost estimates are not substantially affected. In this study, all medicines were assessed for expiry as of the first day of the audit. This will result in an underestimation of the proportion of non-expired medicines as not all medicines considered expired would have been so at the time of disposal. Conversely, some medicines such as eye and ear drops may have been discarded 30 days after opening (and therefore considered expired), despite remaining within the manufacturer's expiry date. However, given the considerably small number of products in this category relative to other dosage forms, the latter situation is much less likely than the former. Therefore our estimation of the number of expired versus non-expired medicines and associated costs are more likely to be an underestimation of the true numbers and costs of discarded non-expired medicines to the PBS. Finally, the comparisons of the most frequently discarded medicines (both individually and by therapeutic class) to the 2012 PBS data [9] were assessed based on individual items



of medicines, irrespective of whether full quantities were discarded. As such, the amount of medicines discarded relative to the amount dispensed according to the PBS, and the associated costs to the government, are likely an over-estimation. Finally, unscheduled medicines and medicines belonging to more than one therapeutic category were analysed as a group.

## 5.9. Future directions

This audit has provided important insight into the types and quantities of medicines discarded by the Australian community. It has re-affirmed the need to ensure continuity of the NatRUM program into the future. Without this unique program it would be impossible or challenging to provide post-marketing information related to disposal of medicines to guide the development and implementation of strategies or policies associated with medicine use at the local or national level.

Future research should explore the reasons why consumers return medicines, especially non-expired medicines. While we have speculated on possible causes, these need to be verified by conducting surveys or interviews with a valid sample of consumers and pharmacists. Such research will advance Brushin's work which was conducted seven years ago [4]. Indeed, with many more new medicines now available to consumers, and by inference more being returned via the NatRUM program, it is likely that other reasons for disposal may emerge.

The apparently low proportion of unscheduled medicines returned, including CAMs, should also be further investigated as to whether this reflects a different attitude towards disposal of CAMs compared with scheduled medicines, or because they are used until finished (possibly by multiple members of a family [e.g. paracetamol] to treat minor ailments). 'Health locus of control' is defined as a generalised expectation about whether one's health is controlled by their own behavior or forces external to themselves [18]. Health locus of control has two components: 'internal locus of control' and 'external locus of control'. An individual with an 'internal locus of control' believes that health outcomes are a direct result of their own behavior. On the other hand, an individual with an external locus of control believes that outcomes are a result of either chance or 'powerful other people', such as physicians [19]. Previous studies have shown that the use of unscheduled medicines such as CAM is associated with high 'internal locus of control' [20]. Unscheduled medicines allow individuals to be in control of their medicine use, whereas scheduled medicines are used under instructions from 'powerful other people', which may also be contributing to medication non-adherence. Whatever the reasons, these need to be explored in order to develop strategies that can potentially curtail medicine wastage and the associated costs to the PBS.

To further enhance the effectiveness of the NatRUM program, the reasons underlying some pharmacists' lack of compliance towards disposing of sharps and Schedule 8 medicines [7] warrants further investigation so that measures can be implemented to assist with future compliance.

## 5.10. Key recommendations

1. Funding for the NatRUM program should continue at an appropriate level to ensure full sustainability of the program.
2. Communicate results from the current audit to bodies such as the Pharmaceutical Benefits Advisory Committee and other bodies (both professional and government) to facilitate decision-making at a higher level for promoting QUM and minimising wastage
3. Communicate the results from the current audit to healthcare professionals to:
  - Encourage rationale prescribing of medicines, including quantities required. One approach may be to encourage healthcare professionals to increase utilisation of sample packs or prescribe minimal quantities of medicines until consumers are stabilised on therapy;
  - Counsel patients on the importance of taking medicines regularly for the treatment of chronic health conditions; and
  - Counsel consumers on completing the full course of anti-infectives in order to minimise the risk of developing antimicrobial resistance.
4. Increase consumer awareness of the availability of the NatRUM program and its benefits in protecting consumer health and safety, as well as the environment.
5. Advise pharmacists (via relevant pharmacy bodies) on the importance of adhering to the NatRUM protocols for disposal of medicines, especially with respect to sharps and Schedule 8 medicines. The definition for 'sharps' should be further clarified in the NatRUM program protocol.
6. Communicate to key pharmacy stakeholders such as the Pharmacy Board of Australia, for dissemination to pharmacists, the rate of labelling errors detected in this audit and the importance of adhering to mandatory dispensing practices. Encourage the professional bodies to explore implementation of systems such as the 'Near Miss Dispensing Incidents Reporting and Learning' systems to minimise dispensing errors and improve safety.
7. Audits of the RUM bins (such as the current audit) should be conducted periodically to collect data on medicine utilisation and wastage, which in turn would inform decision making about medicines supply and use at the national level.
8. Consumers' reasons for return of medicines for disposal should be explored in depth

## 5.11. Conclusions

In Australia, the NatRUM program offers the only safe method of disposal of unwanted and/or expired medicines from the community [1], and is a fundamental component of the QUM. This audit has generated important information regarding the quantity and diversity of returned medicines. A key finding from this audit is the considerable amount of wastage of medicines dispensed with associated costs to the PBS. The audit confirms that pharmacists' acknowledge their professional responsibility in accessing use of the NatRUM program [1].

The large quantities of medicines collected, in the absence of any significant consumer marketing, suggests community pharmacy does promote the program to consumers and that consumers are favourably disposed towards it. Notwithstanding this, however, consumers may be disposing of a majority of unwanted and/or expired medicines via general waste or sewerage, with potential for adverse health and environmental outcomes.

With an ageing population, who have multiple comorbidities and the likely resultant polypharmacy, the need for a safe and environmentally friendly method of disposal of unwanted medicines will continue to increase. Consequently, the importance of safe disposal of medicines via the NatRUM program will only increase.

Educating health professionals and consumers on the importance of QUM and minimising wastage is critical for a viable and sustainable PBS in this country. Our national QUM strategy must include an appropriately resourced and funded NatRUM program in the pursuit of successful medication management.

## References

1. *Return of Unwanted Medicines (The RUM Project) Australia. The National Return and Disposal of Unwanted Medicines Limited.* 2011. Available at <http://www.returnmed.com.au/> (accessed July 2013).
2. *Healthy Canadians: Proper Use and Disposal Of Medication.* Government of Canada. 2012. Available at <http://www.healthycanadians.gc.ca/health-sante/medicine-medicament/disposal-defaire-eng.php> (accessed November 2012).
3. Gagnon, E., *Pharmaceutical Disposal Programs for the Public: A Canadian Perspective.* Health Canada Environmental Impact Initiative. 2009: p. 1-80.
4. Brushin, B., *Returned Unwanted Medicines Survey: Victorian Report (Melbourne Metropolitan Area).* The National Return and Disposal of Unwanted Medicines Limited, 2005: p. 1-131.
5. Braun, L.A., et al., *Perceptions, use and attitudes of pharmacy customers on complementary medicines and pharmacy practice.* BMC Complement Altern Med, 2010. **10**: p. 38.
6. Xue, C.C., et al., *Complementary and alternative medicine use in Australia: a national population-based survey.* J Altern Complement Med, 2007. **13**(6): p. 643-50.
7. Department of Health, *Management of Schedule 8 Poisons in Pharmacy.* 2012. Available at <http://docs.health.vic.gov.au/docs/doc/Management-of-Schedule-8-poisons-in-pharmacy> (accessed July 2013).
8. Mabbott, V., Robinson, M, Segrave, A, Brennan, Q, *Australian Statistics on Medicines 2010.* 2010.
9. PBS Information Management Section Pharmaceutical Policy Branch, *Expenditure and Prescriptions Twelve Months to 30 June 2012.* Available at <http://pbs.gov.au/info/statistics/expenditure-and-prescriptions-30-06-2012> (accessed July 2013).
10. Gottlieb, T. and G.R. Nimmo, *Antibiotic resistance is an emerging threat to public health: an urgent call to action at the Antimicrobial Resistance Summit 2011.* Med J Aust, 2011. **194**(6): p. 281-3.
11. Marty, S., *Are you registered to practice?* Aust J Pharm, 2012. **93**.
12. Marty, S., *Reducing public deception.* Aust J Pharm, 2012. **93**.
13. Nation RL, D.M., Fois R, Burgess N, Beattie J, Kong D, McLachlan A, Chen T, Meshreky W, Robinson S, Dixon B, *Sharing the lessons learned from near-miss dispensing incidents in the community pharmacy: A near-miss dispensing incident reporting and learning system.* Pharmaceutical Defence Ltd, 2010.
14. National Asthma Council of Australia, *The Asthma Management Handbook 2006,* 2013. Available at <http://www.nationalasthma.org.au/handbook> (accessed July 2013).
15. Nwokediuko, S.C., *Current trends in the management of gastroesophageal reflux disease: a review.* ISRN Gastroenterol, 2012. **2012**: p. 391631.
16. National Prescribing Service, *Join the Fight Against Antibiotic Resistance.* 2013. Available at <http://www.nps.org.au/conditions-and-topics/topics/campaigns-events/antibiotic-resistance-fighter> (accessed July 2013).
17. Australian Institute of Health and Welfare, *National Health Priority Areas.* 2013. Available at <http://www.aihw.gov.au/national-health-priority-areas/> (accessed July 2013).
18. Wallston, K.A., B.S. Wallston, and R. DeVellis, *Development of the Multidimensional Health Locus of Control (MHLC) Scales.* Health Educ Monogr, 1978. **6**(2): p. 160-70.

19. Wallston KA, W.B., *Who is responsible for your health? The construct of Health Locus of Control*. Social Psychology of Health and Illness. New Jersey: Lawrence Erlbaum Associates, 1982: p. 65-95.
20. Thorne, S., et al., *Complementary/alternative medicine in chronic illness as informed self-care decision making*. Int J Nurs Stud, 2002. **39**(7): p. 671-83.

## Appendices

### Appendix 1 – NatRUM Protocols for Pharmacists

#### Pharmacy Collection Protocol - *Western Australia and Northern Territory*

1. A RUM Project approved container (the container) with RUM Project approved liner, lid and liner seal, is delivered by the selected wholesaler to a community pharmacy on request.
2. The container is to be kept in a section of the dispensary or in a room or enclosure in the pharmacy to which the public does not have access. The container may be placed in a visible position, but out of reach of the public, as this will reinforce the message that unwanted medicines can be returned to the pharmacy and that the returned medicines will not be recycled.
3. Any medicines returned by consumers must not be recycled\*. Handling poisons is a professional responsibility, and whenever possible it is recommended that the pharmacist, or pharmacy graduate, accepts the returned medicines and places them in the container. All medicines, including complementary and alternate medicines, received from consumers may be placed in the container.
4. Pharmacists should take reasonable steps to ensure any Schedule 8 medicines returned for disposal are recorded and destroyed in accordance with state/territory regulations. The destroyed medicines, having been rendered unusable, should then be placed in the container for disposal.
5. When accepting unwanted medicines from consumers, pharmacists may take the opportunity to review the medicines returned, especially if the consumer is a regular customer, and thus determine if further consultation is required.
6. Needles, other Sharps and liquid cytotoxic products should not be placed in the container, but in a container specifically designed for such waste.
7. The container lid should be left to rest on the container until the container is almost full.
8. When the container is almost full, a replacement container is ordered from the preferred wholesaler (via the Portable Data Entry (PDE) number provided), the container liner bag sealed with the tamper proof seal and the container lid firmly attached.
9. The wholesaler delivery person collects the "complete" container and the new container (including liner) is placed in use.

Pharmacies serviced by Wholesaler sub-contractors (that is Rural, Remote and Isolated pharmacies), must ensure a Consignment Note accompanies the container, which is returned via the customary collection routine.

\* This arrangement accords with internationally agreed guidelines on drug donations issued by the World Health Organisation (WHO) "Guidelines for Drug Donations" Ref. WHO/DAP/96.2

#### PROTOCOL AT THE WHOLESALER DEPOT

1. Containers from pharmacies are received at the wholesaler depot. Containers are stored in a quarantine area, and palletised for collection by the appointed waste transport organisation. Wholesaler staff must not open containers.
2. When appropriate, the wholesaler will contact the appointed waste transport company to arrange collection of palletised containers.
3. Wholesaler staff will ensure containers returned from waste disposal are intact and clean before recycling to pharmacies.

## Appendix 1 – NatRUM Protocols for Pharmacists

### Pharmacy Collection Protocol - *Queensland, New South Wales, ACT, Victoria, Tasmania and South Australia*

1. A RUM Project approved container (the container) will be delivered by the wholesaler to the participating pharmacy.
2. The container is to be kept in a section of the dispensary or in a room or enclosure in the pharmacy to which the public does not have access. The container may be placed in a visible position, but out of reach of the public, as this will reinforce the message that unwanted medicines can be returned to the pharmacy and that the returned medicines will not be recycled.
3. Any medicines returned by consumers must not be recycled\*. Handling poisons is a professional responsibility, and whenever possible it is recommended that the pharmacist, or pharmacy intern, accepts the returned medicines and places them in the container. All medicines, including complementary and alternate medicines, received from consumers are placed in the container.
4. Pharmacists should take reasonable steps to ensure any Schedule 8 medicines returned for disposal are recorded and destroyed in accordance with state/territory legislation. The destroyed medicines, having been rendered unusable, should then be dispersed within the container for disposal.
5. When accepting unwanted medicines from consumers, pharmacists may take the opportunity to review the medicines returned, especially if the consumer is a regular customer, and thus determine if further consultation is required.
6. Needles, other Sharps and liquid cytotoxic products should not be placed in the container, but in a container specifically designed for such waste.
7. The container lid should be left to rest on the container until the container is almost full.
8. When the container is almost full, a replacement container is ordered from the preferred wholesaler and the container lid firmly attached.
9. The wholesaler delivery person collects the sealed container and the new container is placed in use.

Pharmacies serviced by Wholesaler sub-contractors (that is Rural, Remote and Isolated pharmacies), must ensure a Consignment Note accompanies the container, which is returned via the customary collection routine.

\* This arrangement accords with internationally agreed guidelines on drug donations issued by the World Health Organisation (WHO) "Guidelines for Drug Donations" Ref. WHO/DAP/96.2

#### PROTOCOL AT THE WHOLESALER DEPOT

1. Full containers from pharmacies are received at the wholesaler depot. Containers are stored in a quarantine area, and palletised for collection by the appointed waste transport Agent. Wholesaler staff must not open containers.
2. Palletised containers are collected by Agents who will also deliver replacement containers to wholesaler depots.

#### PROTOCOL FOR WASTE DISPOSAL COMPANY

The appointed incineration company receives the palletised containers from the transport Agent and at the earliest opportunity incinerates the containers and contents.

## Appendix 2 – NatRUM Project Audit Data Collection Form

Bin No (per pair per day): \_\_\_\_\_ State of Origin: ☐ NSW ☐ QLD ☐ SA ☐ VIC

Wholesaler: \_\_\_\_\_

Source of the bin:

☐ Community Pharmacy

☐ Hospital

☐ Other (specify) \_\_\_\_\_

☐ Unknown

Total weight of bin in kilograms (including lid): \_\_\_\_\_

Volume of the bin contents: ☐ ≤25% ☐ 26-50% ☐ 51-75% ☐ 76-100%

If the contents are less than 50% exclude the bin from further scrutiny

Does the bin contain any of the following?

☐ >50% of the contents are not medicines/sharps/therapeutic goods

☐ Contents appear noxious, contains biological material or unsafe for assessment

☐ Contents are non-auditable, e.g. >50% loose tablets, capsules or strips thereof If yes, specify: \_\_\_\_\_

If yes to any of the items above, exclude the bin from further scrutiny

Counted by (initials): \_\_\_\_\_ Recorded by (initials): \_\_\_\_\_

Data entered into computer by (initials): \_\_\_\_\_



**For each whole or substantially whole (i.e. the physical pack; ≥75% intact) Dose Administration Aid (DAA):**

[illegible]

**Were any sachets present in the bin? (tick:)** ☐ Yes ☐ No

☐ **Sharps**

☐ **Needles without syringes**

**Total No.**\_\_\_\_\_

**Any additional notes:**

**For all poisons (S2, 3, 4, 8 and OTC) in their original container (original box) or extemporaneously prepared poisons in packaging as originally supplied by the pharmacy:**

[illegible]

## Appendix 3 – NatRUM Project Audit Data Collection Process

### ***Step 1: Record data on origin of the bin (i.e. wholesaler)***

The wholesaler which collected the bin for destruction from the retail pharmacy and the state from which it was collected will be recorded using the information provided on the label affixed to the bin.

### ***Step 2: Weighing the bin prior to opening***

The weight of the bin is determined by subtracting the average weight of an empty bin from the measured weight of the bin returned.

### ***Step 3: Initial visual assessment of contents and approximate volume of container occupied by contents***

The bin will be opened and an initial visual inspection of the contents performed. Signs of hazardous materials such as biohazard waste will exclude that bin from further examination. In such cases the bin will be immediately resealed and securely stored prior to incineration. Appropriately fitted P2 dust masks compliant to AS1716(1994) will be provided to minimize exposure to aerosols.

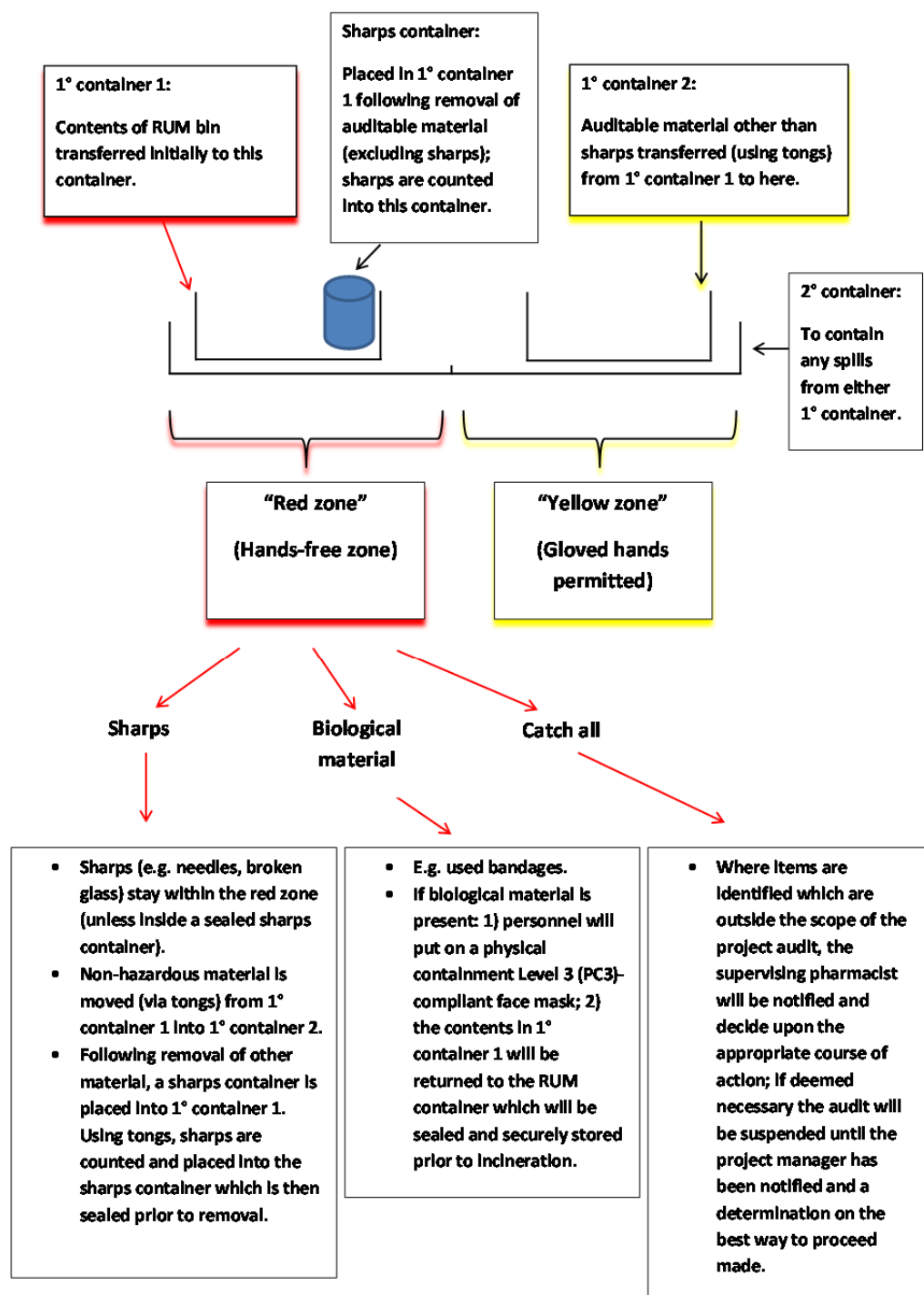
For all other bins, the volume of the container occupied by contents will be measured by comparison with an empty calibrated bin marked with volume measurements for 25%, 50%, 75% and 100% filled.

Steps 4 and 5 below are summarised schematically in Figure 3 and discussed subsequently.

The auditing process will involve transfer of the contents of each NatRUM bin into a larger, flatter container (1° container 1) so that the contents are distributed over a larger area and are more easily observed; this container is located within a demarcated hands-free 'red zone' where only tongs may be used to handle the contents. Long tongs will be used to sort through the material therein, removing medicines in their original box and other relevant material; these will be placed into a second, identical container (1° container 2) located within a demarcated 'yellow zone'. Sharps and other material excluded from the 'yellow zone' will remain in 1° container 1. Inside the yellow zone, gloved hands are permitted to handle the contents within 1° container 2. When all auditable material has been placed into 1° container 2 and data recorded, a sharps container will be placed into 1° container 1 and any sharps present counted and placed into this container. It should be emphasised that at no stage will hands be placed directly into the original NatRUM bin or used to directly handle any of the contents within the red zone. Both 1° containers are located within a 2° container to keep all contents secured in the event of material spilling from a 1° container. Following counting, the contents of the 1° containers will be transferred back into the original NatRUM bin, sealed and stored securely in preparation for incineration (Step 6); when full, the sharps container will also be sealed and stored securely prior to incineration. In the event that an item is identified during auditing that is outside the scope of the project, the supervising pharmacists will be notified and decide upon the appropriate course of action; if deemed necessary the audit will be suspended until the project

manager has been notified. These steps ensure that the likelihood of exposure to any hazardous material by either the study personnel or other parties is minimized so far as is practicable.

**Figure 3: Schematic of Steps 4 and 5 of the audit process**



## ***Step 4: Determine suitability of contents for further assessment***

After the contents of the bin has been tipped into 1° container 1 a second visual examination of the contents will be performed to determine suitability for further assessment. The contents of a particular bin will be excluded from further assessment if:

The majority of the contents are not medicines/sharps/therapeutic goods; OR

The contents appears noxious, contains biological material or is otherwise clearly unsafe for assessment;  
OR

The contents has a high proportion of material (>~50%) which will not be counted (e.g. loose tablets/capsules or strips thereof [See Step 5 below]).

The reason for exclusion will be documented. The supervising pharmacists will make this assessment to ensure safety and consistency.

The contents of bins deemed unsuitable for further assessment will be returned to the original container, resealed and placed in a separate, secure section of the facility for incineration.

## ***Step 5: Counting process***

Record the following data, if available:

Therapeutics:

For Schedule 4 (S4) and Schedule 8 (S8) poisons in their original container (e.g. their original box), record:

Generic name of the poison (brand name for combination products), strength, form and quantity;

Sample pack (yes/no);

Does the product have a dispensing label (yes/no)? If yes, does the drug name on label match the product? Are directions supplied on label (take as directed [mdu] or specific)?;

Expiry date on product;

For S8 (but not S4) poisons, loose (i.e. not in their original box) strips of tablets/capsules or other loose items (e.g. patches) will be counted in addition to those poisons in their original container.

Pre-filled syringes will be counted individually. This is discussed further in the 'Sharps' section below.

For extemporaneously prepared poisons in packaging as originally supplied by the pharmacist/pharmacy, record:

Generic name of the poison(s), strength, form and quantity;

Does the product have a dispensing label (yes/no)? If yes, are directions supplied on the label (take as directed [mdu] or specific)?;

Expiry date on product.

For Schedule 2 (S2) and Schedule 3 (S3) poisons, over the counter (OTC) and unscheduled products (e.g. vitamins, herbal/complementary products) in their original container (e.g. their original box), record:

Generic name of the poison (brand name for combination products), strength, form and quantity;

Expiry date on product.

For dose administration aids (DAAs), only whole or substantially whole DAAs (e.g. Webster® packs, Dosette® boxes), will be counted; each aid will be considered one individual unit. Record:

Empty/contains some medications.

Sharps:

The number of pre-filled syringes; each syringe will be considered one individual unit. Whole boxes of pre-filled syringes will be opened to determine the number of units within the box;

The number of syringe needles with/without syringe.

## ***Step 6: End of counting process***

Return all medicines to the original NatRUM bin;

Seal the bin and place it in a separate, secure section of the facility for incineration;

The completed data forms will be initialled by each student and a supervising pharmacist; the pharmacists will collect all forms for subsequent data analysis.

At the start of all work breaks and the end of each day, hands will be washed in hospital grade disinfectant.

## Appendix 4 – NatRUM Project Audit Data Entry Conventions

### Background

The RUM bin audit successfully audited **577 RUM bins**. The data from each RUM bin was collected, and is required to be entered into a purpose-built Access database, to enable data analysis.

There were **3 hard copy data collection forms** for **each RUM bin** audited. Similarly, the Access database is divided into 3 sections (to match the data collection forms). The table below summarizes the link between the data collection forms, and the description within the Access database.

<b>Hard copy data collection forms</b> <b>(3 forms – per RUM Bin)</b>	<b>Description in Access Database</b> <b>(3 sections – per RUM Bin)</b>
Page 1 (green)	RUM Bin Characteristics
Page 2 (green)	DAA Characteristics
Page 3 (white)	Drug Content
<b>= One Data Pack</b>	<b>= One RUM Bin Entry</b>

### Methods

The **577 data packs** to be entered are filed in “**To enter into database**” box.

To **locate** the database, go to:

- *S drive -> Dept Pharm Prac -> RUM project -> Databases -> RUM Bin Project Database Frontend* (please save this as a shortcut to your desktop)

To **open** the database:

- Double click the “RUM Bin Project” database icon on your desktop.

To **create a new RUM bin entry** within the database:

- Double click the “**RUM Bin**” form which is found on the left hand panel under “Forms”.
- A blank template will open which needs to be populated with the data from your data pack.
- Each RUM bin entry is divided into 3 sections which match the data pack:

- RUM Bin Characteristics
- DAA Characteristics
- Drug Content
- Data can be entered into the database by selecting from drop down menus, tick boxes or entering free text.
  - All drop down menus need to be populated.
  - For fields which have a tick box, tick = 'yes' (no tick, defaults to 'no').
- All data within each data pack needs to be entered into the database, except for Bin Number (on the RUM bin characteristics section).
- Data from one data pack equates to one RUM bin entry.

## Data Entry guidelines

- **Step 1: RUM bin characteristics** section
  - The first field, *ID* will be automatically generated by the database (in chronological order).
    - **Please record this ID number on the top right hand corner of your hard copy data pack, using red pen.**
  - For State, please select from the drop down menu.
  - For Wholesaler, please select from the drop down menu.
  - For Bin source, please select from the drop down menu.
    - If other, please enter using free text.
  - For Weight of the bin, please enter to 1 decimal place.
    - eg 4.6 kg.
  - For Volume of bin contents, please select from the drop down menu.
    - If non-auditable was selected, please specify reason, using free text.
  - For Sachets, please tick if yes.
  - For Sharps, please tick if yes.
  - For Needles without syringes, please tick if yes.
  - For Total number of needles without syringes, enter free text using numerals.
    - (eg. If there were no sharps, please enter '0' into this field).
  - For Additional comments (if required), enter free text.
  - For Who entered, please select your name from the drop down menu.



- Once all data has been entered in this section, please **save** (icon top left hand corner or control+S).
- **Step 2: DAA characteristics** section
  - A blank table appears which needs to be populated with the data (if available) from your data collection forms.
  - The first **column**, *ID* will be automatically generated by the database (please ignore this number).
  - For DAA Type, please select from the drop down menu.
  - For DAA Use, please select from the drop down menu.
  - For Patient identification, please tick if yes.
  - If there was more than one DAA type, (eg. Webster × 4), please enter a new **row** for each.
    - Eg. Webster × 4 (should be entered as **4 separate rows**)
  - Once all data has been entered in this section, please **save**.
- **Step 3: Drug content** section
  - A blank table appears which needs to be populated with the data from your data collection forms.
  - The first column, *ID* will be automatically generated by the database (please ignore this number).
  - Select your Drug from the drop down menu
    - Listed as generic names
    - **Combination drug names entered in the order as appears on the PI / CMI for the product refer to TGA website ([www.ebs.tga.gov.au](http://www.ebs.tga.gov.au) and search for the PI / CMI for the drug)**
      - Eg. Amoxicillin / clavulanic acid
    - Complementary meds, unscheduled drugs -> unscheduled
    - Pain meds -> combination pain
    - Iron supplements -> iron and iron combination
    - Risendronate and risendronate combination
    - Insulin -> insulin all forms
    - Oral contraceptive pill

- Vaccines -> vaccine (influenza)
- Interferon all types
- Cold and Flu, Multiple Combination, Pain, and Other
- Other -> used for old drugs
- Enter Strength as free text (as specified in the PI / CMI)
  - Eg. 500/30 (with no spaces)
- Enter Units from the drop down menu
  - Eg. mg
- Enter Dose Form from the drop down menu
  - Eg. Tablets.
- Enter Pack Size using free text
  - Eg. For devices, please enter 1.
- If Loose S8, please tick if answer is 'yes'.
- If Sample Pack, please tick if answer is 'yes'.
- Enter Quantity Remaining using free text
  - Eg. For devices, please enter 1.
- If Expiry Date present, please tick if answer is 'yes'.
- Enter Expiry Date using free text or calendar.
  - Please enter the **last date** of the month
    - eg. 02/13 should be entered as 28/02/2013.
- If Label is present, please tick if answer is 'yes'.
- If Directions on label, please tick if answer is 'yes'.
- If MDU directions, please tick if answer is 'yes'.
- Enter Schedule from the drop down menu
  - To check schedule, please refer to **TGA website** ([www.ebs.tga.gov.au](http://www.ebs.tga.gov.au) and search for the PI / CMI for the drug) or poisons schedule.
- Select Therapeutic Category from the drop down menu. There are 14 Therapeutic Categories, based on the WHO classification.
  - To choose the correct Therapeutic Categories for each drug, please refer to **PBS website** ([www.pbs.gov.au/pbs/home](http://www.pbs.gov.au/pbs/home)), type in the drug name, and document **body system** given.

- Eg. Paracetamol, belongs to PBS body system = “Nervous system”; this should be selected as the Therapeutic Category within the database.
- If a drug belongs to more than one therapeutic category, please select “various”
- Can also refer to WHO website ([www.who.int](http://www.who.int))
  - To enter data for **additional drugs**, please enter a **new row**.
    - Eg. Panadeine, Amoxycillin (should be entered as **2 separate rows**)
  - Once all data has been entered, please **save**.
- This completes the data entry for **one data pack = one RUM bin**.
- Please enter your initials on your hard copy data pack, using red pen (bottom right hand corner).

## Filing

Please file the completed form into your own “**Completed data entry**” box.

## Further information

If you have any questions, please feel free to contact Phil or Sreeja at anytime.

**22786**

## References

- PBS website ([www.pbs.gov.au/pbs/home](http://www.pbs.gov.au/pbs/home))
- TGA website ([www.ebs.tga.gov.au](http://www.ebs.tga.gov.au))
- WHO website ([www.who.int](http://www.who.int))

Thank you for your help ☺