

Pharmaceutical waste disposal

Practice Recommendations for Community Pharmacy in South Africa

Jameel Kariem,
Independent community pharmacist, Cape Town

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Introduction

This recommendation document is designed for community pharmacies to ensure the management of pharmaceutical waste disposal is performed correctly, in accordance with guidelines issued by the South African Pharmacy Council (SAPC), the regulations of Good Pharmacy Practice (GPP), and according to municipal by-laws¹. Before writing this document, I found that useful practice guidelines on pharmaceutical waste disposal were not readily available, and current Standard Operating Procedures (SOP) insufficient for my requirements. As I am based in Cape Town, I have developed practice settings commonly used in the Western Cape.

Scope

The destruction of medicines and scheduled substances is governed by the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and other applicable legislation¹. According to the South African Pharmacy Council (SAPC), and Good Pharmacy Practice (GPP) guidelines, all community pharmacies should have and implement a standard operating procedure (SOP) for pharmaceutical waste destruction where applicable. Community pharmacists may refer to this practice recommendation for clarity. Pharmacies should register with a Pharmaceutical Waste Management service provider, or adhere to suitable waste destruction protocols, ensuring compliance with municipal laws. Additionally, pharmacies must maintain proper record-keeping for the storage, transportation, and destruction of pharmaceutical and medical waste².

Good Pharmacy Practice Manual and Associated SAPC rules

GPP guidelines on the minimum standards (Chapter 2.32)

It is the responsibility of a pharmacist to ensure that the disposal and destruction of medicines and scheduled substances in a community pharmacy is done in accordance with the guidelines set out in the Good Pharmacy Practice (GPP). These guidelines can be found in chapter 2.32 of the GPP on the minimum standards regarding the destruction and disposal of medicines and scheduled substances. Although not all components of destruction and disposal may be relevant, it does state that "Some of the elements in this standard are not statutory requirements but are good practice which pharmacists would be expected to follow whenever practicable." (GPP 2.32.3)

Some of these applications are:

1. A medicine and scheduled substance may be destroyed by a contractor who specialises in waste disposal regarding the disposal of chemical or medicinal waste (GPP 2.32.5.1).
2. The GPP guidelines further suggest that pharmaceutical waste should be separated into six types and labelled accordingly: solid dosage form (tablets and capsules); creams, ointments, and powders; ampoules and liquids in glass; aerosols; radioactive drugs, and cytostatic and cytotoxic medication and scheduled substances (GPP 2.32.6).
3. In all situations, a pharmacist must use his pharmaceutical knowledge and skill, together with any necessary expert advice from a Local Authority/Provincial Department of Health, to segregate and dispose of materials, and bio-medical waste safely and in accordance with regulations (GPP 1.2.11.3e)².

Other legislation – responsible persons

Note that the GPP rule 2.32.3.1 mandates that "All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The person responsible for the destruction may be asked to prove that the method used complies with these regulations."

Additionally, GPP rule 2.32.4.1 states that "If a contractor is not used, medicines containing Schedule 1, 2, 3, and 4 substances may only be destroyed in the presence of a pharmacist or an authorized person in charge of a place where medicines and scheduled substances are kept. The pharmacist or authorized person must certify the destruction."

Process Flow - Pharmaceutical Waste Management

The following recommendations could serve as a guide for pharmacists, as practiced by a community pharmacy in the Western Cape. Municipal by-laws may vary in other provinces, and waste disposal SOP steps might differ across pharmacies. Below is a recommended step-by-step process flow summary, followed by details on each step.

Healthcare Risk Waste Management Service Providers

This section outlines how Healthcare Risk Waste Management (HCRW) service providers operate, what to expect, and some practice guidelines for you as the pharmacist on what your

1	Register with a waste management service provider and order containers	Some examples of providers: • Compass Medical Waste® • Averda SA®
2	• Register with your local Dept of Environmental Health • Register with iPWIS (WC)	• City of Cape Town or your local municipality
3	Pharmacy to collect waste for destruction in at least 4 separate types of containers	• S0 to S4 • S5 to S6 • Sharps & infectious materials (if applicable)
4	Waste Management service provider collects waste-filled containers and sends them to an incinerator	• Receive a waste destruction manifest per container
5	Pharmacy to record the type and weight of waste generated on the iPWIS website, or similar, & file all documents	• Registration document with the waste provider • Registration document as a waste generator with municipality • Signed waste destruction manifest for each container collected

Figure 1: Summary of process flow for pharmaceutical waste management in a community pharmacy

responsibilities and duties will be when working with HCRW management service providers.

1. Choose your healthcare Risk Waste (HCRW) management service provider, also known as the Pharmaceutical Waste Management service provider. This pharmacy uses Compass Medical Waste®. Other service providers include Averda SA® and several others.
2. This is the company that will supply the empty disposal containers, collect the filled ones, transport them to their depot for sorting (Medical Waste Transporter). It will then dispose of the waste (Medical Waste Disposer), either internally or at an approved incinerator site, or both.
3. Register with the HCRW provider for the type of waste you intend to generate. This would be: "Pharmaceutical Waste" and/or "Medical Waste" (sharps and infectious material waste).
4. Pharmaceutical waste includes capsules, tablets, liquids, suppositories, pessaries, and topical applications.
5. You will need at least two green containers for pharmaceutical waste. One for schedules 0-4 and another for schedules 5 and 6, as these need to be separated.
6. Medical waste includes needles, vials, dressings, and infectious and pathological materials. For medical waste, you will need a sharps container and a fibre board box for pathological material.
7. You may choose not to register for medical waste if you will not be generating sharps and pathological waste.
8. Once registered, you will receive a registration certificate. You may be required to produce this certificate during an inspection.
9. For the Western Cape, waste is disposed of by incineration at Vissershok on the West Coast.
10. When your pharmaceutical waste containers are full, email your HCRW management service provider to collect your filled container. Request an empty one at the same time. You may also order empty containers ahead of time.
11. You will receive an invoice from your HCRW management service provider to pay for the container only. The cost for collection of a filled container is noted as zero on the invoice,

as this is included as part of the purchase order of an empty container.

12. Start filling your containers up to two-thirds full. Your HCRW management service provider will send you an SOP on the further management of pharmaceutical waste.
13. Incinerator operators recommend that pharmaceutical cardboard packaging is disposed of alongside pharmaceuticals in single-use green pharmaceutical waste containers, to allow for optimal combustion conditions inside the incinerator.
14. A separate green container is required for schedule 5 and 6 pharmaceuticals.
15. For pharmaceutical waste, it is recommended that you use a 10L or 20L for schedules 0-4, and a 5L or 10L for schedules 5 and 6. You may use bigger sizes depending on the waste generated. A 10L container can hold 6-9kg of waste.
16. Once your container is filled as per the protocol document from the HCRW management service provider, send an email to the provider to collect the container.
17. Do not forget to order an empty container at the same time.
18. The HCRW management service provider driver will collect the filled container and weigh it immediately with their scales.
19. You will receive a waste manifest document with a unique number and bar code for that specific container.
20. Take note of the weight (for example 6.5kg). You will need this later for declaration on the online iPWIS submission form to the City of Cape Town. Your own local municipality may have a different process to follow to declare waste.
21. You may be required to present this waste manifest whenever the Department of Health inspects you³.

Costs associated with the collection of pharmaceutical waste

The following are the costs for collecting of pharmaceutical waste for this pharmacy, as of July 2024, inclusive of VAT. Please note, there is no other cost to be paid upon collection.

- The cost per single green container with lid, for pharmaceutical waste is: R82.90 (5L), R161.32 (10L) and R341.64 (20L).

- The cost for a 50L Medical Waste fibre board box with lid and red liner is R190.25.
- The cost for an 8L yellow rectangular sharps container is R93.86.

Refer to the iPWIS site or your local municipality for a more comprehensive list of service providers in your area.

Disposal of Schedule 5 and 6 Pharmaceutical Waste

This pharmacy uses Compass Medical Waste®.

1. In addition to the above, when it comes to the destruction of schedule 5 and 6 medicines, you are required to submit a request on a specific form to SAHPRA. The completed form is available from SAHPRA. The completed form must be forwarded to SAHPRA at the address or email found below.
2. It is recommended that you contact SAHPRA or your waste management company for the schedule 5 and 6 destruction forms.
3. Compass Medical Waste® has a similar form for the recording of schedule 5 and 6 medicines for destruction. This form may also be used.
4. Copy your HCRW management service provider on the same email to SAHPRA. The waste management service will then send you their approval documentation for the collection of schedules 5 and 6 medicines with their driver. This will be done by the HCRW management service provider once permission has been obtained from SAHPRA. It is the responsibility of the pharmacist to ensure that a representative witnesses and signs the Pharmaceutical Waste Manifest.
5. Any schedule 5 and 6 medicines to be destroyed must be recorded and in the case of schedule 6 medicines, the quantities of medicines to be destroyed must be indicated in the relevant register and signed by the witnesses required in the procedure¹.
6. At the time of this publication, there were no additional costs payable to SAHPRA or the Department of Health for the destruction of scheduled 5 and 6 medicines⁴.

Disposal of Sharps and Infectious Material (Medical Waste)

Medical waste includes needles, vials, dressings, and infectious and pathological materials. Besides the steps mentioned above, you must also ensure the following for the proper disposal of sharps and infectious materials:

1. You must be registered as a generator of sharps and infectious/hazardous waste with your HCRW management service provider.
2. You also need to be registered with the Department of Environmental Health in your municipality as an infectious/hazardous waste generator.
3. Ensure that you have ordered the correct containers, i.e., the rectangular yellow 8L sharps container and the 50L Medical Waste fibre board box with lid and red liner.
4. This process is only applicable if you intend to generate medical waste³.

City of Cape Town Department of Environmental Health (for Registrations & Inspections)

Once registered with a HCRW management service provider, the next step will be to register with your local municipality's Department of Environmental Health as a waste generator.

Below is a recommended guideline of the process to follow for the recording of waste disposal with your local municipality.

1. In the Western Cape, you will need to register with the Environmental Affairs and Development Planning department. Other provinces will have a similar department.
2. Choose the type of waste you intend to generate:
 - a. Retail trade in pharmaceutical, medical, cosmetic, and toilet articles.
 - b. Healthcare Risk waste (for sharps and infectious and pathological materials).
3. Once registered you will receive your certificate of registration as a medical waste generator.
4. This has your unique pharmacy WIR number (waste information registration) and iPWIS number (Integrated Pollutant and Waste Information System) number.
5. iPWIS is an IT system developed by the Department of Environmental Affairs and Development Planning for the Western Cape Government.
6. Create a username and password on the iPWIS website and register your details.
7. Complete and submit your monthly waste generation report on the Western Cape Government's iPWIS website.
8. You will then receive a waste activity management report for each report you submit.
9. File your waste activity management report. The health inspector may request it when you have an inspection.
10. If your container is not full and has not been collected yet by your waste management company, and you are due to submit your monthly report, then you will need to submit a zero-kilogram quantity monthly on the website, until then.

Steps 3 to 10 are based on the protocol for the Western Cape's Department of Environmental Health. Although other provinces have similar requirements, there will be variations across municipalities.

Department of Health Inspections - local municipality

The City of Cape Town's Department of Environmental Health does bi-annual inspections. These inspections are done by the Environmental Health Officers and will include your Pharmaceutical Waste Management reports, and iPWIS reports. Officers are dispatched from your closest district or sub-district office. Upon inspection, the health officer will draft a report on site and present you with a copy of the report⁶.

Essential Checklist for Community Pharmacies

To be considered compliant with the relevant regulations, this pharmacy has put the following essential checklist in place:

- Register with a waste management service provider and your local department of environmental health.
- Adjust your SOPs to reflect your waste disposal activity and procedures, listing all service providers.
- Incorporate your registration certificates issued by your waste management service provider and municipal health authority into your SOPs.
- File all documents in a single file. This should include certificates, invoices, schedule 5 and 6 destruction forms, and inspection reports.
- Ensure you have all the necessary documents on file for any inspections by the SAPC, Department of Health, and Department of Labour.
- Ensure you have access to your iPWIS website and e-mail notifications from iPWIS.
- Familiarize yourself with Chapter 2.32 of the GPP.

Conclusion

Pharmacists in community pharmacies must ensure that the disposal and destruction of medicines are undertaken safely and that the requirements of regulation 27 of the Medicines and Related Substances Act, 101 of 1965, and other municipal regulations are followed. The disposal and destruction processes must have due regard for the environment and reduce harm to public health. It is also important for pharmacists to ensure that any medicine purchase policies and patient-use, are such that it limits the need for destruction, primarily due to none-use and expiration⁵. As pharmacists, we also find ourselves involved in the entire medicines-use chain, including manufacturing and distribution. It is vital that all the role players, including manufacturers, contribute to the safe disposal of unused and expired medicines in a manner that assists all members of the supply chain. This will contribute significantly to the reduction in the discharge of waste into the environment and reduce harm.

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Required Contact Details

Compass Medical Waste®

email compass@compass.za.net and orderswc@compass.za.net
telephone number 031 2679700 or <https://www.compasswasteservices.co.za/>

Averda SA®

email westerncape@averda.co.za and orderswc@compass.za.net
telephone number 010 1415722 or <https://www.averda.com/rsa>

SAHPRA Contact Details (July 2024)

Ms Rirhandzu Doris Hlungwani, National Department of Health (NDOH)

South African Health Products Regulatory Authority (SAHPRA)
CSIR Campus SAHPRA Reception

Building 38, 10 Meiring Naude Drive, Brummeria, PRETORIA, 0002

iPWIS contact Details

email ipwis@westerncape.gov.za and <https://ipwis.westerncape.gov.za/ipwis3/>

Waste Containers – Starter Kit Recommendations

The following are examples of recommended containers and sizes, as a starter kit for community pharmacies. Other sizes are available, depending on the amount of waste you intend to generate.

Figure 1: 20L green plastic pharmaceutical waste container with lid. Ideal for schedule 0 - 4

Figure 2: 5L green plastic pharmaceutical waste container with lid marked for schedule 5 and 6.

Figure 3: 8L yellow plastic sharps disposal container with a red lid

Figure 4: 50L fibre board box with lid and red plastic liner for medical/pathological waste

References

1. SAPC Board Notice 105 of 2011
2. Good Pharmacy Practice Manual and Associated SAPC rules <https://www.pharmcouncil.co.za/>
3. Compass Training Brief Management of pharmaceutical waste document <https://ipwis.westerncape.gov.za/ipwis3/resources/doc/IPWISUserGuideSeptember2014.pdf>
4. SAHPRA <https://www.sahpra.org.za/wp-content/uploads/2021/11/Medicines-Act-General-Regulations-2017.pdf>
5. FIP statement of policy Environmentally Sustainable pharmacy practice: Green Pharmacy <https://www.fip.org/file/1535>
6. IPWIS user guide <https://ipwis.westerncape.gov.za/ipwis3/resources/doc/IPWISUserGuide-September2014.pdf>



Figure 1



Figure 2



Figure 3



Figure 4