

MEDICINE AND THE LAW

Disposal of medical waste: A legal perspective

K du Toit, J Bodenstein

Karen du Toit is an honorary associate professor in the Discipline of Pharmaceutical Sciences (Pharmaceutical Chemistry), University of KwaZulu-Natal, South Africa and candidate attorney at DMKisch Inc. Johannes Bodenstein is a Senior Lecturer in the Discipline of Pharmaceutical Sciences (Pharmacology), University of KwaZulu-Natal, South Africa.

Corresponding author: K du Toit (karend@dmkisch.com)

The Constitution of the Republic of South Africa provides that everyone has the right to an environment that is not harmful to their health and well-being. The illegal dumping of hazardous waste poses a danger to the environment when pollutants migrate into water sources and ultimately cause widespread infection or toxicity, endangering the health of humans who might become exposed to infection and toxins. To give effect to the Constitution, the safe disposal of hazardous waste is governed by legislation in South Africa. Reports of the illegal disposal of waste suggest a general lack of awareness and training in regard to the safe disposal of medical waste.

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The Constitution of the Republic of South Africa^[1] provides that everyone has the right to an environment that is not harmful to their health and well-being. However, the illegal dumping of hazardous waste poses a danger, not only to the health of scavengers who are directly exposed to it, but also to the environment when pollutants migrate into water sources and ultimately cause widespread infection and toxicity. To give effect to the Constitution, the safe disposal of hazardous waste is governed by legislation. However, constant findings of illegal disposal of waste suggest a general lack of awareness and training in this sector.^[2]

According to the Hazardous Substances Act,^[3] waste is classified as general or hazardous waste according to the risk it poses. General waste is defined as waste which does not pose a significant threat to public health or the environment. Hazardous waste, however, has the potential, even in low concentrations, to have a significant adverse effect on public health and on the environment. Waste is accepted to be hazardous and toxic until proven otherwise.^[3] The Act further provides for the classification and control of hazardous substances, which is provided for in the South Africa Bureau of Standards (SABS) Standard 0228.^[4]

Nine classes of hazardous substances are identified, of which one or more will certainly be found in retail pharmacies, including: class 2 – compressed gases such as oxygen in gas cylinders; class 3 – flammable liquids such as acetone or alcohol; class 6 – toxic and infectious substances such as drugs, cytotoxic substances and sharps; and class 7 – radioactive substances.

The SABS Standard determines the minimum requirements for the differential disposal of hazardous waste. Neither the Act nor the SABS Standard specifically provide for healthcare waste generated at healthcare facilities.

The management of healthcare waste is envisaged by the draft Health Care Risk Waste Management Regulations of 2008.^[5] According to these regulations 'healthcare risk waste' is defined as that hazardous portion of healthcare waste which includes infectious waste, infectious sharps, and pharmaceutical waste. Pharmaceutical waste is defined as expired, unused, spilt or contaminated drugs, medicines and vaccines, and includes their packaging materials.

Good pharmacy practice

A generator of waste *inter alia* refers to a person (including healthcare practitioners and facilities) whose actions or activities result in healthcare risk waste, according to the draft Health Care Risk Waste Management Regulations.^[5] Any generator of waste has a 'duty of care' to society to handle, store, transport or dispose of waste in an environmentally sound way.^[6] This is referred to as the 'cradle-to-grave' responsibility,^[7] since it lasts throughout the whole process of waste disposal. Therefore, pharmacies and responsible pharmacists have a duty to handle waste in a responsible manner. It is important that every pharmacy has a standard operating procedure for disposal of waste.

Waste production should be minimised or avoided where possible, e.g. by checking expiry dates of goods on delivery, supplying older batches first, recycling or re-using packaging materials and returning empty gas bottles to the supplier. Generated waste should be segregated at the point of generation in a pharmacy and healthcare risk waste should not be mixed with general waste or other waste streams.^[8] This waste should be contained at the point of generation into specifically designated containers. This entails the use of containers specifically intended for sharps (South African National Standards (SANS) 452),^[9] as well as differently colour-coded containers and liners (SANS 10248-1).^[10] Containers must be rigid, leak-proof and puncture resistant. In addition, containers must be sealed and labelled properly and stored in a secure, designated area until released to the transporters. Pharmaceutical waste may not be stored for longer than 90 days from the date the container is sealed to the date of final disposal.^[5]

The waste generator must ensure that waste is handled only by companies permitted to transport and dispose of it.^[5] Disposal must take place through a waste disposal facility that is licensed in terms of the National Environmental Management: Waste Act.^[6] Chemical waste undergoes physical, chemical or thermal treatment to minimise or eliminate hazardous characteristics before residues are landfilled. Chemical waste is generally incinerated, although care has to be taken with regard to volatile chemicals.^[8] Infectious waste is incinerated and the residual ash evaluated and given a hazard rating, prior to being disposed of at a designated hazardous-waste landfill.

According to the draft Rules relating to Good Pharmacy Practice,^[11] read together with the Medicines and Related Substances Act,^[12] medicines

must be disposed of in an irretrievable manner but not into municipal sewerage systems. A pharmacist or other authorised person may destroy medicine containing a schedule 1, 2, 3 or 4 substance. However, medicine containing a schedule 5, 6, 7 or 8 substance may only be destroyed after obtaining approval from a person authorised by the Director General of Health; furthermore, it may only be destroyed in the presence of an inspector, an officer of the South African Police Service (SAPS) or any other person authorised by the Director General. Furthermore, the South African Medicines Control Council may authorise the destruction of a schedule 5 or 6 substance by the manufacturer in the absence of an inspector. In all cases, the persons responsible for destroying the medicines and scheduled substances must issue a certificate to confirm the destruction of the medicine. If the medicines have been destroyed by an officer of the SAPS, the case number must be entered into the register.

According to the draft Rules relating to Good Pharmacy Practice,^[11] a contractor specialising in the disposal of chemical or medicinal waste may be contracted to destruct medicines and scheduled substances. Two pharmacists must, however, witness the removal from the premises of the correct quantities of medicines and scheduled substances authorised for destruction. The contractor must employ a pharmacist whose task is to ensure irretrievable disposal of the goods. If a contractor is not used, two pharmacists must witness both the removal and destruction of the correct quantities of medicines and scheduled substances.

Failure of pharmacies to comply with the above legislation is a criminal offence. Furthermore, according to the National Environmental Management Act,^[7] a generator of healthcare waste may be held liable for the costs of clearing up waste or of rehabilitating any environmental effects, if the process of waste disposal was not dealt with according to sound principles. The Act provides that not only corporate entities, but also their executives in their personal

capacities, may be held liable for failing to prevent pollution. Therefore, it is in the interest of the generator to obtain information regarding waste disposal and to incorporate it as part of standard operational procedures. Appropriate training programmes will be required to provide employees within pharmacies with knowledge regarding waste management to prevent contravention of applicable laws.

Furthermore, according to the Occupational Health and Safety Act,^[13] an employer should maintain a working environment that is safe and without risk to the health of employees as far as is reasonably practicable.

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1. South African Government. Constitution of the Republic of South Africa, No. 108 of 1996. Pretoria: Government Printer, 1996.
2. Love P. Hazardous waste has health risks. Reputation Matters, 14 February 2013. <http://www.reputationmatters.co.za/hazardous-waste-has-health-risks/> (accessed 25 November 2013).
3. South African Government. Hazardous Substances Act No. 15 of 1973. Pretoria: Government Printer, 1973.
4. South African Bureau of Standards. SABS 0228-5:2010. Pretoria: SABS, 2010.
5. South African Government. Draft Health Care Risk Waste Management Regulations. Government Notice 452, Government Gazette No. 35405, 1 June 2012.
6. South African Government. National Environmental Management: Waste Act No. 59 of 2008. Pretoria: Government Printer, 2008.
7. South African Government. National Environmental Management Act No. 107 of 1998. Pretoria: Government Printer, 1998.
8. South African Government. Framework Document on the Management of Health Care Waste, May 2000. Pretoria: Government Printer, 2000.
9. South African Bureau of Standards. SANS 452:2008. Pretoria: SABS, 2008.
10. South African Bureau of Standards. SANS 10248-1:2008. Pretoria: SABS, 2008.
11. South African Government. Draft Minimum Standards Regarding Destruction and Disposal of Medicines. Government Notice 105 of Government Gazette No. 34330, 27 May 2011.
12. South African Government. Medicines and Related Substances Control Act, No. 101 of 1965. Pretoria: Government Printer, 1965.
13. South African Government. Occupational Health and Safety Act, No. 85 of 1993. Pretoria: Government Printer, 1993.

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