Destruction of Medicine and Scheduled Substances

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The General Regulations of the Medicines and Related Substances Act (Act 101 of 1965) as gazetted on 25 August 2017 brought a few changes to some of the Regulations. The previous regulation 27 (destruction of medicine) was substantially updated and rewritten as regulation 44 (destruction of medicine or scheduled substances).

Significance of this regulation

Fundamentally, Regulation 44 (1) can be regarded as the most important Sub Regulation that gives clear instructions on how Destruction of Medicine and Scheduled Substances should be approached.

Regulation 44. (1): Waste treatment facilities

A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

The most important aspects to consider are the fact that medicines or scheduled substances shall only be destroyed by a waste treatment facility that is licensed under the Waste Act (Act 59 of 2008) and that this licence should include the authorisation to destroy medicines or pharmaceuticals.

Regulation 44. (2): Disposal of medicines or scheduled substances

No medicines or scheduled substances other than those as determined by the Authority shall be disposed of into municipal sewage systems.'

Pharmaceuticals in solution are difficult to remove from water and most water treatment facilities, as well as sewage treatment facilities, are not equipped to remove these pharmaceuticals completely. This is a global phenomenon and these pharmaceutical residues in drinking water should be a major cause for concern.

Regulation 44. (3): Denatured medicines or scheduled substances

The destruction or disposal of medicines or scheduled substances must be conducted in such a manner to ensure that the medicines or scheduled substances cannot be salvaged and the medicine or scheduled substance has been denatured.

This regulation is an improvement on the previous Regulation 27 (3) clause, which merely stated that the medicine or scheduled substances should not be retrievable. It is now required that these substances should be denatured.

Regulation 44. (4): Destruction of S0, S1, S2, S3 and S4 substances and medicines

A Schedule 0 medicine or Schedule 1, 2, 3 or 4 substance or medicine must be destroyed at a site in terms of subregulation (1) and such destruction must be certified as determined by the Authority.

S0 medication is now included. This adds a considerable responsibility to manufacturers and wholesalers of these type of products. S0 medicine can be sold in any retail shop, therefore the retrieval of damaged and expired S0 medicine from these retailers should be carried out more regularly and consistently. Retailers should be educated on the importance of handling this medicine in a responsible way in order to protect our society and natural resources.

Regulation 44. (5): Destruction of S5 and S6 substances and medicines

A Schedule 5 or 6 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of-

(a) an inspector;
(b) a pharmacist; or
(c) any other person authorised by the Chief Executive Officer.

Regulation 44. (6): Destruction of S7 and S8 medicines

A Schedule 7 or 8 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of-

(a) an inspector;
(b) two pharmacists; or
(c) any other person authorised by the Chief Executive Officer.

Regulation 44. (7): covers the rules relating to certification and record keeping

The waste treatment facility shall issue a certificate and maintain a record of the destruction contemplated in subregulations (4), (5) and (6) which shall contain the following information:

(a) the name of the medicine or scheduled substance, if known; or the schedule of the medicine or scheduled substance concerned;
(b) the quantity destroyed;
(c) the date of destruction of the medicine or scheduled substance;
(d) the name and designation of the person in whose presence such destruction took place; and
(e) any other information as determined by the Authority.

Different Destruction methods available in South Africa

The previous Regulation 27 of Act 101 stated mainly that medicine and scheduled substances are not allowed to be disposed of in the sewage system and that the product should be non-retrievable. This was offset by the Waste Act that allowed the landfilling of pharmaceuticals and this left an opportunity for companies to follow the landfill route. This practice could be understood if it is taken into account that landfill carries half to a third of the costs incurred using a destruction method. However, disposal to landfill is not an environmentally suitable or responsible choice for disposal of medicines as it may still be recoverable by scavengers (human and animal) and metabolites may leach into the surrounding water-table. The waste is also not treated and is merely kept for future generations.

In the past, the term "disposal" was used to describe landfilling and destruction was used to describe thermal treatment.

In the **'Rules Relating to Good Pharmacy Practice'** as gazetted on 2 March 2012 the two terms are defined clearly as follows:

7(a) ***Disposal*** *in terms of these Rules shall mean the removal of medicines and scheduled substances destined for destruction without the intention of retrieval, in compliance with existing legislation.*

7(b) ***Destruction*** *in terms of these Rules shall mean rendering the medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to health.*

It can therefore be argued that from 2012, according to Good Pharmacy Practice, medicine and scheduled Substances were never meant to be landfilled.

Incineration, cement kiln co-processing and thermal desorption (pyrolysis) are examples of destruction methods. Autoclaving and electro-thermal deactivation (microwave) are NOT suitable for pharmaceutical destruction.

Incineration

- Heat is generated from the combustion of the waste and burning of fossil fuel within the incinerator
- Difficult to interrupt feed of waste
- Larger volume of gas due to introduction of fossil fuel and excess air gives higher CO_2
- Waste volume reduction – 85%
- Weight reduction – 70%
- Combustion gases are required to be cleaned to the required emission standards
- End-Product (ash) can be landfilled at classified landfill site. Must be within regulation concentrations.
- Restrictions with feeding halogenated waste

Co-processing

- Heat is generated from the combustion of waste and burning of fossil fuel within the kiln
- Ash produced can be added to cement mix
- Not fit for purpose
- Lower emissions benchmark
- Contaminated cement
- High NO, SO_2 and CO_2 emission levels
- Restrictions with feeding halogenated waste

Thermal desorption

- Electrical energy can be used to start and reach steady state plant operation before waste is introduced
- Feed can be stopped without affecting operating parameters
- Waste is pyrolysed in the absence of air, produces carbon
- Low volume of gas, small gas clean up plant
- Waste volume reduction – 85%
- Weight reduction – 70%
- The end-product (carbonised residue) is suitable for normal landfill disposal but can be used as an alternative fuel source
- Gas stream is cleaned using an EGC system before vented to atmosphere
- Typically less CO_2
- Relatively higher operating costs

Summary of destruction methods

Category	Incineration	Co-Processing	Thermal Desorption
Tech Fit for Purpose	√	X	√
Correct Gas Clean-up	√	X	√
Complete Destruction (Solids and Gases)	√	X	√
Environmental Impact	Medium	Very high	Low
Emissions Standards	High	Low	High
End Product	Ash to landfill	Clinker to cement	Carbonised fuel

Questions and Answers

Q. *Is my product classified as a foodstuff or a medicine?*

A. The definition of a medicine and veterinary medicine can be found in Act 101 of 1965 (1. Definitions) as of 1 June 2017 (including Act 72 of 2008 and Act 14 of 2015) and the definition and classification of complementary medicine and health supplements can be found in the General Regulations to Act 101 of 1965 as published on 25 Aug 2017.

Q. *Is my unwanted product classified as hazardous waste?*

A. The National Environmental Management: Waste Act (Act 59 of 2008) defines hazardous waste as any waste that contains organic or inorganic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have a detrimental impact on health and the environment.

Q. *Is your policy on handling hazardous waste meeting the following criteria?*

- Is the product destroyed or merely disposed of?
- Service provider licensed for medicine or pharmaceutical waste?
- Does any of the product end in the municipal sewage systems?
- Salvageable?
- Denatured?
- Schedule 0 to Schedule 4 destroyed by licensed facility?
- Does the facility have a permanent pharmacist?
- Destruction certificate or disposal certificate?
- Limited effect on the environment and health?

A. Pharmacists need to ensure that products that were created under their care ends the life cycle in a controlled fashion with the lowest possible impact and risk to health and the environment. Formulate your company's environmental policy and approve a vendor that aligns with your company's policy. The Department of Environmental Affairs that regulates destruction facilities and their law enforcement arm, the Green Scorpions, are keeping a tight control over these facilities and goalposts are being moved constantly. This means that audits should be conducted at these facilities often to verify that your service provider respects the law and delivers a compliant service. This due diligence should also cover any sub-contractors used as a lot of waste management companies are making use of independent destruction facilities which might not be compliant.

Conclusion

It can be argued that the intention of this legislation is clear. Medicine should be destroyed and not merely disposed of to landfill or into sewage. By adopting an approach where the risk of pharmaceuticals ending in drinking water can be eliminated instead of having to be mitigated, the amount of pharmaceuticals ending in our water resources through possible leachate from landfill and also from water treatment facilities, can be greatly reduced. This in turn might assist to improve the quality of our water which will benefit the general health of our society and even help curb problems such as infertility and antibiotic resistance.

About A-Thermal Retort Technologies

A-Thermal Retort Technologies specialises in the thermal treatment of hazardous waste primarily servicing the pharmaceutical and chemical manufacturing industries. The unique Thermal Desorption Plant utilises pyrolysis technology that is capable of achieving a 99.9999 % destruction of all hazardous waste with the formation of a carbonized residue by-product. The carbonized residue has similar properties to coal and can be used as an alternative form of fuel, essentially making A-Thermal a zero-landfill treatment facility. This is by all accounts, a world first for this process.

A-Thermal and its affiliated group of companies are able to offer the following services:

- Thermal treatment of hazardous waste
- Recovery of value added products
- Waste to energy technology
- Waste beneficiation
- Treatment of medical waste
- Treatment and disposal of general waste
- Recycling services
- Transportation of hazardous and general waste
- On-site waste management
- Supply of waste packaging
- In-situ and ex-situ remediation of land
- Gasification technology
- Training on waste management
- Environmental consultancy services

A-Thermal specialises in permanent, secure destruction of pharmaceuticals. Operations are supervised by a full-time pharmacist who monitors conditions of operations and ensures legal compliance with the various Acts that govern the destruction of pharmaceuticals.

Pharmaceutical waste categories:

- Finished pharmaceutical products (expired and discontinued)
- Intermediate products
- Raw materials
- Quality assurance retention samples
- Natural, homeopathic or complimentary medicine
- Clinical trials
- Lab waste in pharmaceutical manufacturing/industries

- Medical devices
- Cosmetic waste
- Schedule 5 – 6 drugs (overseen by full-time on-site pharmacist)

A-Thermal is also proud to be associated with the collaboration between the Department of Health and the Department of Environmental Affairs as well as all other companies involved in assisting with the containment of the Listeria outbreak, Contaminated meat products are thermally treated at high temperature to ensure the complete destruction of these products.

About the Author

Martin McClintock is an industrial pharmacist specialising in the safe destruction of pharmaceuticals in the best possible environmentally friendly way. Martin has completed B.Pharm in 2000 and M.Sc Pharm in 2002 at the University of North West in Potchefstroom. He has vast experience in the formulation, production, QC, QA, RA, sale and destruction of medicine and this gives him a broad understanding in most aspects of pharmacy. Martin started assisting A-Thermal in August 2015 after being involved with destruction of medicine through his previous RP functions in both retail and industry. He enjoys the amount of legislation that is involved and is passionate about the issue of the pharmacist's responsibility and attitude toward responsible destruction of pharmaceuticals as custodians of medication whilst being responsible towards the environment.