MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

GUIDELINES FOR THE DESTRUCTION OF SCHEDULE 6 MEDICINES AND SUBSTANCES

This document has been prepared to serve as a recommendation to applicants wishing to destroy any Schedule 6 medicines and/ or substances. It is not intended as an exclusive approach. Council reserves the right to request for any additional information to establish the safe destruction of any Schedule 6 medicine and / or substances.

REGISTRAR OF MEDICINES
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DATE: 29/04/2003

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1 SCOPE OF THE GUIDELINES

These guidelines should be read in conjunction with the Medicines and Related Substances Control Act (Act 101 of 1965), and its supporting Regulations.

As these guidelines are constantly evolving due to harmonisation initiatives as well as due to new scientific developments, applicants are advised to always consult the latest information available. The Medicines Control Council endeavours to keep abreast of such developments and to keep its application requirements and evaluation procedures and policies in line with “best international practice”.

The destruction of Schedule 6 medicines and substances may only take place in accordance with the Medicines and Related Substances Control Act (Act 101 of 1965)

2 DESTRUCTION AUTHORISED BY AN INSPECTOR

The destruction of Schedule 6 medicines and substances that have been entered into a register, may take place under the supervision of an inspector designated in terms of Section 40(1) of the Act, an officer of the SAPS or other person authorised in terms of the legislation to supervise this action.

2.1 All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The applicant (person requesting destruction) may be requested to prove that the method of destruction is in accordance with such regulations.

2.2 All medicines or substances must be destroyed in such a manner that does not allow recovery.

2.3 The inspector must, on behalf of the Medicines Regulatory Authority (MRA), provide a certificate of destruction and in the case of an officer of the SAPS, a case number must be provided which must be kept with the register for a period of 5 years.

2.4 All quantities destroyed must be indicated in the relevant register on the date of destruction and signed by the applicant, indicating the reference to the destruction certificate or case number.

3 PROCEDURE FOR WRITTEN AUTHORISATION OF DESTRUCTION FROM THE MEDICINES REGULATORY AUTHORITY

The MRA may authorise the destruction of Schedule 6 medicines or substances in writing, without the presence of an inspector, if a pharmaceutical company or other institution in question, has sufficient personnel, procedures and capacity to follow the procedure described below.

4 APPLICATION FOR AUTHORISED DESTRUCTION

4.1 The Applicant must request permission for destruction of specific quantities of the medicines or substances in question in writing.

4.2 The request will indicate -

- the name of each medicine or substance to be destroyed,
- the exact quantities and batch numbers (if applicable) of the medicines or substances to be destroyed,
- the reason for the destruction and
- the names of the two pharmacists who will witness the destruction as required by the procedure. The MRA may consider a deviation from the requirement of two pharmacists in exceptional cases only. This will depend on the motivation supplied and on alternative arrangements to obtain sufficient control.

4.3 The MRA will authorise the destruction of the medicines or substances in question in writing, specifying the quantities indicated in the request, provided that the following procedure be followed:

5 GENERAL

5.1 Destruction may only take place after the written authorisation from the MRA has been received.

5.2 All destruction must take place in accordance with the local municipal regulations regarding the disposal of chemical or medicinal waste. The applicant may be requested to prove that the method of destruction is in accordance with such regulations.

5.3 All medicines and substances must be destroyed in such a manner that prevents their recovery.

5.4 The destruction must be properly documented:

- All quantities destroyed must be indicated in the relevant registers and signed by the witnesses required in the procedure. (See registers below)
- Destruction certificates (where applicable) and the letter of authorisation must be referenced in, or attached to the relevant Schedule 6 register and retained for the same period of time as the register itself. (5 years)

6 METHOD OF DESTRUCTION

6.1 Potent or large quantities of medicines and substances

6.1.1 Depending on the municipal regulations regarding the disposal of chemical or medicinal waste, the applicant may choose an appropriate method of destruction such as incineration or destruction by a reliable contractor who specialises in waste disposal.

6.1.2 If a contractor is not used (eg. incineration), **two pharmacists** employed by the applicant must witness the **removal and destruction** of the correct quantities of the medicines or substances authorised for destruction, regardless of the where destruction will take place.

6 Method of destruction continued

6.1.3 In the case of a contractor, where destruction does not take place at the premises of the applicant, and a certificate of destruction will be provided, **two** pharmacists employed by the applicant must witness the **removal from the stock** of the correct quantities of the medicines or substances authorised for destruction and at least **one** of the **pharmacist** should accompany the goods to the place of **destruction**, to witness that these have actually been destroyed or disposed of in such a manner that precludes their recovery.

6.1.4 In the case of a contractor, a valid certificate of destruction must be obtained.

6.2 Small quantities

6.2.1 Small amounts of medicines or substances may be destroyed on the premises where these are kept. Appropriate methods must be used which are unlikely to cause any adverse health or environmental consequences, must be in accordance with local municipal regulations and will not allow the drugs to be readily recovered. Two pharmacists employed by the company must witness the removal from stock and the destruction of the correct quantities of each medicine or substance.

7 SCHEDULE 6 REGISTER

7.1 The quantities of any medicines or substances destroyed must be entered into the register on the date of destruction.

7.2 The inscription in the register must be signed by the two pharmacists employed by the company, who witnessed their removal from stock destruction. The Managing Director must co-sign, unless the Managing Director was one of the pharmacists involved with the removal and destruction.

7.3 The letter of authorisation and the destruction certificate (if applicable) must be referenced in or attached to the schedule 6 register and retained for a period of 5 years.

8 LEGAL REPORTING REQUIREMENTS

8.1 If the amount of substance destroyed according to any method above, is more than :

- 1 milligram for potent narcotic drugs (fentanyl, sufentanil, alfentanil, etc.),
- more than 1 gram for all other narcotic drugs or
- more than 1 kilogram for any psychotropic substance,

the base amount of each substance destroyed must be indicated on the annual returns of specified Schedule 6 substances in terms of Regulation 29 of the Medicines and Related Substances Control Act (Act 101 of 1965), relating to the year in which the destruction took place.