

The Pharmaceutical Society of South Africa National Office

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**THE REGISTRAR
SOUTH AFRICAN PHARMACY COUNCIL
PRIVATE BAG X40040
ARCADIA**

Per email: BN@sapc.za.org

Dear Ms Hoffmann

COMMENT ON BOARD NOTICE 100 OF 2020 – DRAFT RULES RELATING TO GOOD PHARMACY PRACTICE: MINIMUM STANDARDS FOR THE DISPOSAL AND DESTRUCTION OF MEDICINES AND SCHEDULED SUBSTANCES

The Pharmaceutical Society of South Africa (PSSA) thanks the South African Pharmacy Council (SAPC) for the opportunity to submit comment on Board Notice (BN) 100 of 2020 regarding the draft Rules relating to good pharmacy practice: Minimum Standards for the disposal and destruction of medicines and scheduled substances.

The PSSA noticed that the draft minimum standards had been amended substantially so as to be in line with Regulation 44 (**Destruction of medicines or scheduled substances**) of the General Regulations published in 2017 under the Medicines and Related Substances Act (Act 101 of 1965).

These changes are positive and will improve the practice of pharmacy.

For instance, the definitions were moved to the beginning instead of the end of the standard and definitions were added. The minimum requirements for the destruction of medicines and scheduled substances have been moved to after the minimum requirements for the disposal of medicines and scheduled substances which is more logical since medicines and scheduled substances are disposed of before they are destroyed. The PSSA commends the SAPC on a well written minimum standard.

The most important changes noted are the following:

1. The standard was expanded from being only applicable to pharmacies, and now refers to pharmacies, medicines rooms or Primary Health Care Clinic (PHC) dispensaries. This was an oversight and should have been amended years ago.
2. The addition of a definition for “waste treatment facility” and more importantly the note at the end of the definition which reads as follows “N.B. Council requires that the waste treatment facility be in possession of a certificate specifically to dispose of medical waste, in line with Section 51(1)(a) of the National Environmental Waste Management Act 59 of 2008” is a very important addition that the PSSA agrees with.
3. Rule 2.32.4 *Legislative requirements* was deleted in totality bringing these standards in line with Regulation 44 as mentioned above:
 - a. Rule 2.32.4.1 allowed for the destruction of medicines by a pharmacist or authorised person instead of a contractor. The PSSA is glad to see this section has been removed as it had the

potential of being abused and could cause harm to the health of the population and/or harm to the environment

- b. Rule 2.32.4.2 required that for schedule 5, 6, 7 or 8 a pharmacist first had to obtain approval for destruction from a person duly authorised by the Director-General: Health. This step was a big stumbling block for many pharmacies as it sometimes took very long to obtain approval and medicines and scheduled substances accumulated in facilities while awaiting the approval.
4. In the proposed rule 2.32.5 *Minimum requirements for the disposal of medicines and scheduled substances*, for specified schedule 5 and schedule 6 medicines and scheduled substances the quantities of the medicines and scheduled substances to be disposed of must be indicated in the relevant register and signed by the witness required in the procedure. This is a significant change from rule 2.32.4.2 of the current standard and will improve the process of disposal of specified schedule 5 and schedule 6 medicines and scheduled substances substantially.
5. The information required on the Certificate of Destruction under rule 2.32.6 was amended and the PSSA fully supports these changes.

We would however propose a minor amendment to the wording of the proposed rule 2.32.5 *Minimum requirements for the disposal of medicines and scheduled substances*. The proposed rule reads as follows: *"The disposal must be properly documented. All quantities removed must be recorded in a pharmacy stock management system..."*, however rule 2.32.4(b) refers to medicines and scheduled substances returned by patients, and these medicines and scheduled substances would not be reflected on the pharmacy stock management system. The PSSA suggests the wording of rule 2.32.5 be amended as follows: *"All quantities removed must be recorded in a pharmacy stock management system (where applicable) ..."*.

The PSSA's view is that there should not be grounds to contest any of these changes and is looking forward to the publication of the final minimum standard for implementation.

One matter that is not part of this draft minimum standard, but that should be clarified is: does a community/institutional pharmacy have an obligation to accept returned medication from patients for disposal and destruction? The cost of disposal and destruction of medicines is quite high, and a number of smaller community pharmacies, especially, cannot afford to accept patient's medication for disposal and destruction.

Yours sincerely



Ivan Kotzé
Executive Director