

The Pharmaceutical Society of South Africa National Office

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The Registrar
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0001

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Dear Mr Masango

SCHEDULE 5 AND 6 PRESCRIPTIONS DURING COVID-19 LOCKDOWN

The Pharmaceutical Society of South Africa (PSSA) is the largest voluntary professional association for pharmacists and pharmacy support personnel in the country. We represent more than 10 000 members across all sectors of pharmacy such as academia, community pharmacy, hospital and institutional pharmacy, and the pharmaceutical industry.

Schedule 2, 3 and 4

The National Department of Health (NDoH) on recommendation of the South African Health Products Regulatory Authority (SAHPRA) have published a notice (exemption) to extend the period of validity of a prescription for all Schedule 2, Schedule 3 and Schedule 4 substances from the requirements of Section 22A(6)(f) of the Medicines and Related Substances Act (Act 101 of 1965) on 30 April 2020.

PSSA welcomes this exemption notice as we believe it bring relieve to some logistical difficulties pharmacists experience when consulting with their patients in their practice setting. Several prescribers have closed their practices temporary and only consult via electronic means which is not always accessible by all patients. We further support the guidelines published by the South African Pharmacy Council (SAPC) on 13 May 2020 to take cognisance of in addressing the exemption.

Schedule 5 and 6

Since the commencement of lockdown on 27 March 2020, several members voiced their difficulty regarding the issue of Schedule 5 and 6 prescriptions from prescribers. As explained above, since the lockdown many prescribers are only consulting with patients virtually and as a result, only issue prescriptions 'electronically'. This has an impact on the legal requirement of Regulation 33(2)(a) of

the General Regulations to the Medicines and Related Substances Act, 101 of 1965, of signing a prescription **in person** in the absence of an electronic signature as defined in Regulation 33(2)(b). As a result of the absence of proper electronic signature systems on the side of the prescriber, prescriptions are thus faxed or emailed to patients or pharmacies, as the patient does not receive the prescription in hardcopy.

Even in the case of verbal (telephonic) prescriptions, these prescribers cannot furnish such pharmacist with a (hardcopy) prescription within seven days confirming such instructions, as per Section 22A(6)(b) of the Medicines Act, due to similar reasons stated above. These verbal (telephonic) instructions is also only for a treatment period that shall not exceed seven days (Section 22A (6)(c)).

Schedule 6 prescriptions may not be repeated and therefor, a new prescription should be issued monthly as per Section 22A(6)(i). Schedule 6 substance may only be sold if the course of treatment does not exceed 30 consecutive days (Section 22A(6)(o)). However, in an emergency a pharmacist may sell any Schedule 5 or 6 substances in a quantity not greater than that required for continuous use for a period of 48 hours, on the verbal instruction of a prescriber, but who is known to the pharmacist. Again, the verbal instruction must be followed by a written prescription within 72 hours (Section 22A(6)(k)).

Suggested solution

Based on the guidelines from SAPC, PSSA would like to request SAPC to enter into discussions with the NDoH and SAPHRA for a midway in addressing the challenges as explained above. We believe that similar guidelines could be developed by SAPC to overcome the logistical challenges currently experienced with regards to Schedule 5 and 6 prescriptions following a similar Section 36 exemption or adjustment. Proposed guidelines could include the following:

- a) make all reasonable attempts to contact the authorised prescriber to verify the legality of the faxed/emailed Schedule 5 and 6 prescription;
- b) on a case by case basis only where the pharmacist can confirm the patient is known to them;
- c) where this patient has been on the medication for a period longer than six months and who are stable on the prescribed maintenance treatment (not applicable to initiation or dose-adjustment therapies);
- d) where no suspicion of misuse, abuse or overuse exists;
- e) consult with the patient to establish stability in terms of their condition and with regards to any COVID-19 symptoms. The pharmacist repeating the prescription may be held liable for any outcomes with regards to repeating the prescription, if they had failed to advice the patient on the impact of the disease on all chronic conditions;
- f) ensure proper record keeping and that any emailed/faxed script is transcribed, dated and signed by the pharmacist;
- g) Ensure to obtain the original prescription from the prescriber after the State of Emergency has ended.

The suggestion in a) above would be necessary to detect where faxed/emailed prescriptions are handed in at more than one pharmacy. When the prescriber is phone with all faxed/emailed

prescriptions for Schedule 5 and 6, they will immediately detect overuse, misuse or abuse, and dispensing of the faxed/emailed prescription should be refused.

PSSA appreciate your immediate and serious attention to this matter and for bringing this issue to the attention of the Minister of Health through the acting Director-General, as per the mandate of the statutory council.

Kind regards

A handwritten signature in black ink, appearing to read 'Ivan Kotzé', written in a cursive style.

Mr Ivan Kotzé
Executive Director