**S6 Registers.......a measure of control**

**Introduction**

Despite the ease of electronic record keeping, stock control and dispensing systems, there are still many instances of pharmacists getting into trouble for not having their Schedule 6 medicine registers balanced and up to date. Anyone who has worked in a busy dispensary knows how quickly and easily this can happen. Nevertheless, perhaps we need to be reminded of the reasons why it is important to record purchases and supply of S6 medicines accurately and responsibly.

**What does the law say?**

The sale and supply of medicines in South Africa is governed by section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), read together with the supporting Regulations. Control over access to medicines and substances are therefore regulated by the process of scheduling and the control measures provided for in the Act and Regulations. Scheduling allows for different levels of regulatory control over pharmacologically active substances, the higher the scheduling the more stringent the control measures and recording requirements. These legal provisions enable South Africa to comply with its obligations in terms of the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971) and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988), to which it is a signatory.

The primary consideration in scheduling a substance is its safety profile, in relation to the therapeutic indications for its use.¹

The sale of S6 medicines must be recorded in accordance with Section 22A(6) of the Medicines and Related Substances Act 101 of 1965 which specifies that such sale may only take place on condition that—

(6) (a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner²

**Regulation 30** of this Act³ specifies how the record must be kept and **Regulation 28**⁴ specifies the requirements for how the prescription or order for a S6 medicine must be written.

Importantly, an indication of how serious the legal obligations with regard to the control of S6 medicines are considered can be seen in Section 29 of the Medicines Act which specifies that “any person, who contravenes any provision of Section 22A, shall be guilty of an offence”. Section 30 of this Act specifies that any person found guilty of such an offence will face a fine or imprisonment for a period not exceeding 10 years.⁵

**What do Good Pharmacy Practice Rules specify?**

One of the first responsibilities that pharmacists are charged with in the underlying philosophy of GPP Rules is the control of medicines: “Pharmacy as a dynamic, information-driven, patient-orientated profession, through its infrastructure, competence and skills, is committed to fulfil the health care needs of South Africa and its people by being the: (a) custodian of medicine;”⁶

The **Responsible Pharmacist** has a serious professional duty to maintain good recordkeeping and control of S6 medicines. The GPP specifies as follows:

2.1 Duties and Responsibilities of the Responsible Pharmacist (f) (vi) ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.

Section 2.27 of GPP provides for **Minimum Standards for Control of Schedule 6 Medicines or Substances** which include the keeping of registers, secure storage under lock and key, and limited access.⁸

This responsibility is taken very seriously by the SAPC as indicated by the weighting of 7 (extremely important) given to Section (H) Control of Medicines, scheduled substances and active
pharmaceutical ingredients, in the inspection questionnaires for pharmacies.

What are your ethical obligations?

In terms of the Rules relating to the Code of Conduct, the following must be considered:

1.9 Control Over Medicines

**Principle:** A pharmacist must at all time exercise proper and/or reasonable care in respect of and control over medicines. In adhering to this principle the following should be taken into consideration:

1.9.1 General guidelines

(a) A pharmacist has a professional responsibility to exercise control over all medicinal and related products, which are purchased or supplied.9

Exercising proper control over S6 medicines is an important legal and ethical requirement in terms of the Medicines and Related Substances Act 101 of 1965, GPP Rules and the Code of Conduct. If a pharmacist was found to be negligent in this regard he could be found guilty by the SAPC of an offence in terms of the following Ethical Rule:

4. Failure to exercise proper and/or reasonable care in respect of and control over — (a) the acquisition, storage, manufacture, dispensing, sale, supply or disposal of medicines, or of raw materials for the manufacture of medicines, for human or veterinary use.10

What to do about it?

1. “Revise all your systems regularly” – including SOPs for handling S6 medicines, order forms, registers, and computer systems to make sure that they comply with all the legal requirements. Contact gary@pssacwp.co.za for assistance and examples, if necessary.

2. “Too many cooks spoil the broth” – allocate the responsibility of keeping the S6 register to one specific pharmacist per working shift. Experience has shown that having too many pharmacists dipping in and out of the S6 stock and registers increases the margin of error and blurs the lines of responsibility.

3. “Time is of the essence” – provide enough time for writing up of S6 prescriptions, immediately, as they are dispensed. This can be easily achieved if, when handing in a prescription, the patient is informed and told to expect a delay because a S6 prescription needs special attention and additional time for recording. Remember, most patients do not mind waiting a few minutes longer if they understand that the reasons for the delay are in their best interests.

4. “Make technology work for you” – use computerised systems accurately with daily balancing and printouts, if necessary. Computerised registers are legally acceptable, but, what often works best is to keep a manual register and use the computer system as a check and back-up.

5. “Supervise and assess” – the Responsible Pharmacist must do at least a quarterly check, when registers must be balanced in accordance with legal requirements. This affords the RP an opportunity to get an overview of the use of S6 medicines by patients, prescribing habits of the doctors, any misuse and the level of accuracy of the pharmacists issuing S6 medicines. The more often such supervisory checks and assessments can be made, the better.

6. “Minimise the opportunity for error” – keep the minimum stock of S6 medicines needed. Separate damaged or expired stock from the rest. Make proper arrangements for regular destruction of old stock.

7. “SOPs are important” – have SOPs in place for the handling of S6 medicines which include all of the above points.

8. “Train, train, train” – make sure that all dispensary staff are trained in and fully understand the SOP on handling of S6 medicines. Consistently good control, efficiency and patient satisfaction requires a team effort.

9. “Don’t sweep problems under the carpet” – any problems arising with S6 medicines, including shortages, breakages, expired medicines, mislaid orders or prescriptions etc must be reported to the RP who should, in turn, address the problems immediately.

10. “Be the custodian of all medicine” – remember that in hospitals, the RP is responsible for all medicine in the institution whether it is in the dispensaries, theatres, or wards! Check ward and theatre registers against patients’ charts and surgeons notes regularly. If necessary, institute additional registers and control measures such as dual signatures for the issuing of S6 medicines.

Conclusion

By virtue of their training and knowledge of medicines, pharmacists are the only members of the healthcare team specifically charged with the responsible control of medicines. Diligence and accuracy in keeping S6 medicine registers is just one of these responsibilities. In fulfilling this task, let us always be mindful of our undertaking in the Pharmacists’ Oath when we promise:

“To uphold the profession of pharmacy as the custodian of medicine, and regard medicine as the instrument entrusted to me to protect and improve the quality of life”

For further information and copies of reference documents, please contact the author gary@pssacwp.co.za

Disclaimer: This document is a guideline and does not necessarily reflect official policy of the Pharmaceutical Society of SA. Any member wishing to implement proposals made in this document, must do so in accordance with the requirements of the Pharmacy Act 53 of 1974, Medicines & Related Substances Act 101 of 1965 and all other relevant legislation, and, if necessary, should seek legal advice to ensure compliance.

References

1. MCC Scheduling of medicines June 2014
5. Medicines and Related Substances Act 101 of 1965 – Section 29/10 Rules relating to the Acts or Omissions in respect of which the Council may take disciplinary steps
6. BN 129 of 17 December 2004: Rules relating to Good Pharmacy Practice (PSSA Pharmacy Law Compendium page PRE-170/21)
7. BN 129 of 17 December 2004: Rules relating to Good Pharmacy Practice (PSSA Pharmacy Law Compendium page PRE-342/22)
8. BN 129 of 17 December 2004: Rules relating to Good Pharmacy Practice (PSSA Pharmacy Law Compendium page PRE-268/6)
10. 10 Rules relating to the Acts or Omissions in respect of which the Council may take disciplinary steps