



Legal requirements governing electronic prescriptions

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Introduction

The digitalisation of patient records, transmission and sharing of patient information, orders and prescriptions is a reality with significant advantages for pharmacy practice, if correctly applied. We consider here some of the concerns of pharmacists with regards to the electronic generation, transmission and signing of prescriptions, in particular.

What does the law say?

The preparation (writing), signing and transmission of prescriptions and orders for medicine electronically is permissible provided that appropriate technology is used in compliance with the *Electronic Communications and Transactions Act no. 25 of 2002*. (ECT Act) The purpose of the ECT Act, is to legalise and regularise electronic communications and prevent abuse of communication systems.

This has been accommodated in the **Regulations to the Medicines and Related Substances Act 101 of 1965: General Regulations** as follows:

33. (1) Every prescription for a medicine shall be-
- (a) written in legible print;
 - (b) hand or typewritten; or
 - (c) prepared with an electronic agent as defined by and in compliance with the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002)
- (2) A prescription shall be signed -
- (a) person; or
 - (b) in the case of a prescription prepared in accordance with sub regulation (1) (c), with an advanced electronic signature as per section 13 of the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002), by an authorised prescriber.
34. (1) Every order for a medicine or scheduled substance shall be-
- (a) written in legible print;
 - (b) hand or typewritten; or
 - (c) prepared with an electronic agent as defined by and in compliance with the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002).

- (2) An order for a medicine or scheduled substance shall be signed-
- (a) in person; or
 - (b) in the case of an order prepared in accordance with sub regulation (1) (c), with an advanced electronic signature as per the Electronic Communications and Transactions Act, (Act No. 25 of 2002), by the pharmacist, pharmacist's assistant practising in accordance with the scope of practice prescribed in terms of the Pharmacy Act or authorised prescriber placing the order.

There are therefore **2 important criteria** to be met for an electronic prescription to be valid in accordance with Regulations stated above:

- i. The preparation and transmission of the electronic prescription must be generated on a system (**electronic agent**) whereby
 - the integrity of the information is maintained and the information remains complete and unaltered
 - the prescription can be displayed, reproduced (printed or stored) in its original form (see 14.1 and 14.2 of the ECT Act)
- ii. The prescription must be signed using an **advanced electronic signature (AES)**

Advanced Electronic Signatures

An "**advanced electronic signature**" is defined in the ECT Act as:

"advanced electronic signature" means an electronic signature which results from a process which has been accredited by the Authority as provided for in section 37;"

The "Authority" provided for in this definition has been established by the Department Telecommunications and Postal Services and is known as the South African Accreditation Authority. Providers of authentication products and services which have been accredited by the Accreditation Authority include *Law Trusted Third Party Services (Pty) Limited ("LAWtrust")*, *the South African Post Office Limited ("SAPO Trust Centre")* and *Trust Factory (Pty)Ltd.*

Accredited service providers supply authenticated products and services which include registered advanced electronic signatures (AES) which are stored securely.

Such authenticated advanced electronic signatures must meet the following criteria:

They,

- are uniquely linked to the user;
- are capable of identifying that user;
- are created using a means that can be maintained under the sole control of that user;
- will be linked to the data or data messages to which they relate in such a manner that any subsequent change of the data or data messages is detectable;
- are based on face-to-face identification of the user.

Practical application in prescribing

- The prescriber would subscribe to an authenticated electronic system provided by an accredited service provider in compliance with the ECT Act.
- This includes the registration and use of his AES to be attached to the electronic prescription which can be sent via a secure transmission to the pharmacy of the patient's choice.
- In reading the prescription the pharmacy would have a similar system in place with an access code which is used to open, read, print and store the script securely.
- In each case a unique PIN is provided to access the prescription. This PIN may be given to the patient who could then visit their pharmacy of choice and give the PIN to the pharmacist to access the prescription.
- The patient may use the PIN to see and read his prescription but would only be able to print a copy encrypted with a message stating that this is a "read only" prescription, not for dispensing.

NOTE:

All prescriptions (including S5 and S6 scripts) correctly prepared, written and transmitted using authenticated systems and bearing an AES as described above, are legal, irrespective of the schedule status of the medicine involved.

On 13 June 2023, the PSSA hosted a webinar titled, **Understanding digital scripting (including electronic prescribing and advanced electronic signatures) presented by EM Guidance which not only explains their own system comprehensively, but also covers many of the legal and practical requirements of digital prescribing.** The webinar presentation and handouts, including a Q&A document are available on the Society website.

Whilst the Society cannot endorse any particular product, it does recognise the information provided by EM Guidance as a valuable, useful resource, compliant with the legal requirements of the Medicines Act, Pharmacy Act and the Electronic Communications Act.

What about other forms of electronically prepared prescriptions and signatures?

The ECT Act defines an **"electronic signature"** as:

"electronic signature" means data attached to, incorporated in, or logically associated with other data and which is intended by the user to serve as a signature;

This definition includes any information that is intended to be used as a signature, regardless of the security of the signature or the data with which the signature is associated. This would typically be a signature on a paper document which is scanned onto the computer or signed directly onto a computer/device using something like an electronic pen or a scanned copy of a signature. Prescriptions are sometimes prepared this way and then faxed or sent electronically via SMS, Whatsapp or scanned and e-mailed to the patient or pharmacy.

Such systems and signatures do not comply with the requirements of the Medicines Act Regulations.

Considering the fact that S5 and S6 medicines are often abused and prescriptions forged, pharmacists were reminded of their legal and ethical obligations in a previous newsletter as follows:

Pharmacists are reminded of the requirement of sub-regulation 33(4), which states that "The pharmacist who dispenses a prescription shall verify the authenticity of all prescriptions so dispensed."

The PSSA suggests some of the following measures when receiving a faxed or emailed prescription to prevent abuse and misuse of medicines including Schedule 5 and Schedule 6:

- Only accept an emailed or faxed prescription from the prescriber's rooms directly and not from the patient.
- Ensure that the prescription is legible and that the copy received will last and not fade with time.
- Ensure that the prescriber is an authorised prescriber and registered with the relevant authority.
- Ensure that the prescription is valid and legal, as you would when receiving an original hardcopy prescription.
- When there is any doubt, rather contact the prescriber before dispensing the prescription.
- Ensure that all activities are documented.

The above actions are particularly applicable when dealing with patients and/or doctors who are not known to the pharmacy. If in doubt, and to act in the interests of the patient, a 48-hour emergency supply of medicine could be supplied until the original prescription was obtained.

What about use of an Advanced Electronic signature by a pharmacist?

There is an increasing use of digitalisation of prescriptions, records and communication in pharmacy practice. If digital signatures are to be used by pharmacists where signatures are legally required in practice, only an AES may be used.

Consider the requirements in sections 13(1), (2) and (3) of the ECT Act, more specifically the following:

"Signature" 13.(1) Where the signature of a person is required by law and such law does not specify the type of signature, that requirement in

relation to a data message is met only if an advanced electronic signature is used."

IMPORTANT NOTE: If a digital signature is to be used to authenticate any document or authorise any professional decision/action, only an AES will be legally acceptable.

Firstly: Pharmacists may be required to sign a prescription as the prescriber/initiator of treatment:

As can be seen above, the requirements of using an electronic signature for a prescription (Reg. 33(2)(b)) or order of medicine (Reg. 34(2)(b)) specify that only an Advanced Electronic Signature (AES) may be used.

If pharmacists wish to sign electronically for PIT, EPC or PCDT prescriptions and orders for medicine (e.g. S6 medicine orders) only an AES may be used.

Secondly: Pharmacists' signatures are legally required in various other instances in practice:

There are many other instances where a pharmacist's signature is required by law or which may need to be scrutinised for authenticity including the following:

- a) *Signing of all prescriptions* or copies thereof to verify the authenticity of the dispensed prescription and thereby accepting accountability and liability for the correctness of the dispensing of the medicine and confirming that the medicine was supplied. (see Medicines Act section 22A. *Control of medicines and Scheduled substances(6)(q)* and *Regulation 33(4)* and *GPP 2.7.1.2(f) Signing the prescription.*
- b) *Endorsement of prescriptions:* For example, consider *GPP 2.7.3 Safety in dispensing procedures* and *2.7.3.1 Interpretation of prescription.* The prescription must be endorsed according to any action taken e.g. telephonic confirmation.
- c) *Signing confirmation of test results and referral documents:* e.g. see *GPP 2.13.5 Minimum standards for the performance of HIV tests* and *2.13.5.7 Documentation and record keeping.* All referral documents must be signed by the pharmacist or other health care professional, as a confirmation that the test had been done by a professional person.
- d) *Signing of Scheduled medicine registers*
- e) *Signing off on work done by PAs* e.g. prepacking

Some practical advantages of digital prescriptions

Legibility

Poor handwriting by authorised prescribers leads to misinterpretation by pharmacists and subsequent dispensing errors. Electronically prepared prescriptions will mitigate or eliminate such errors.

Prescriber clearly identified

There are many doctor's group practices which use one format of a script pad on which all the doctor's names appear. It is then sometimes difficult to identify the relevant doctor from the signature. This problem does not arise with correctly prepared digital prescriptions because the AES is uniquely linked to a particular doctor and easily identifiable.

Easy to supply/access the original script

Often, when prescriptions are provided verbally or are supposed to be faxed or e-mailed, they never reach the pharmacy, which has a legal obligation to retain and store the original script. Once the prescriber has generated the prescription on the electronic system it is easily accessible to the pharmacy to be downloaded, printed and stored. The electronic prescription is also retained on the system for the legally required time period.

Endorsement of repeats

Repeats of the prescription are recorded on the electronic record and can be viewed by any pharmacy which the patient visits. i.e. if a patient is travelling, they could get their repeat from a different pharmacy provided the access PIN is available. There is no need for the patient to retain an original, with the possibility of losing it.

More secure, no fraudulent alterations

The use of paper is insecure and can easily lead to fraudulent alterations. This failing is addressed by the use of electronic prescriptions which are generated, signed, and transmitted in accordance with the requirements of the ECT Act.

Furthermore, the practice of "pharmacy hopping" by patients who abuse their prescribed medicine, might be discouraged as the electronic prescription and the recording of each repeat is visible to the pharmacist who is then in a position to question early and/or too frequent refills of the script.

Conclusion

If correctly implemented, the digitalisation of prescriptions, orders, records and communications, hold many advantages for pharmacy practice. Pharmacists should embrace the new technologies available as a solution to many problems currently experienced in the paper-based system but must be aware of the legal requirements and ethical obligations in doing so.

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

For further information please contact gary@pssacwp.co.za.

References

1. Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002)
2. Medicines and Related Substances Act 101 of 1965 and Regulations thereto
3. Pharmacy Act no 53 of 1974. Good Pharmacy Practice Rules
4. PSSA Newsletter #28-7 July 2020
5. Advice: Legal requirements governing electronic prescriptions using advanced electronic signatures: Mark Heyink (B.A. LLB) Information Governance Consulting
6. Webber, Wentzel: Covid-19: Frequently-asked questions on electronic signatures by Carla Collett
7. Webinar: Understanding digital prescribing presented by EM Guidance -- see PSSA website
8. SAPC guidance: Understanding electronic transmission of prescriptions; Pharmaciae e-Vol 9 No 1 (2022)