

GUIDANCE DOCUMENT FOR THE USE OF WEBSITES AND MOBILE APPLICATIONS FOR THE PURPOSES OF ORDERING, SELLING AND DELIVERING OF MEDICINES

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INTRODUCTION

Section 22A of the Medicines and Related Substance Act, 101 of 1965 states that any medicine from schedule 1 and above must be sold by a pharmacist or pharmacy support personnel under the supervision of a pharmacist.

Section 29 of the Pharmacy Act, 53 of 1974 states that a person who is not registered as a pharmacist, and who practices as a pharmacist, or carries on the business of a pharmacist or for gain, performs any act specifically pertaining to the practice of a pharmacist, shall be guilty of a criminal offence.

Regulation 3 of the *Regulations relating to pharmacy practice* (GNR.1158 of 20 November 2000) details the acts specifically pertaining to the profession of a pharmacist, which includes the selling of any medicine or scheduled substance.

Rule 1.5 of the *Rules relating to good pharmacy practice* (GPP) provides the Minimum standards for community or institutional pharmacies operating websites.

It is against these legislative provisions that the South African Pharmacy Council has provided this guidance document to the pharmacy profession when considering the use of or have implemented websites and mobile applications which allow or have the intention of ordering and selling medicines to the public.

DEFINITIONS

In this guidance document the following terms are defined as:

"pharmacy" specifically means a pharmacy which is licenced and recorded or registered with the South African Pharmacy Council in terms of the Pharmacy Act;

"mobile app" means a mobile device application;

"GPP" mean the Rules relating to good pharmacy practice;

"SAPC" means the South African Pharmacy Council;

"3rd party" means any person who is not registered in any category of registration in terms of regulation 2 of the Registration Regulations;

"Group owner" means a pharmacy owner who owns multiple pharmacies, where the owner of all the pharmacies is the same.

PURPOSE OF THE GUIDELINE

The purpose of this guideline is to outline the conditions under which a pharmacy owner may provide pharmaceutical services using websites and mobile applications either owned by the pharmacy or a 3rd party as well as the prohibition for the use of these platforms.

GENERAL CONSIDERATIONS

- (a) This guidance document must be read together with Rule 1.5 of the GPP which provides the minimum standards for community or institutional pharmacies operating websites.
- (b) Pharmacies selling medicines using websites and mobile apps must ensure that in terms of Rule 2.7.1 of the GPP all three phases of the dispensing process are adhered to.
- (c) This guidance document applies to the ordering by members of the public (consumers/patients), and the supply of schedule 1 and above medicines and substances by a pharmacist or pharmacy support personnel working under personal supervision of a pharmacist, which medicines according to section 22A of the Medicines and Related Substances Act may not be sold in an open shop.

ACCEPTABLE USE OF WEBSITES AND MOBILE APPLICATIONS

- (a) Medicines or scheduled substances may be sold by way of a website or mobile app, where such website or mobile app is owned by a pharmacy or a group of pharmacies.
- (b) A pharmacy or group of pharmacies may use a website or mobile app owned by 3rd party for the <u>collection and delivery</u> of dispensed medicines, in terms of Rule 2.7.1, purchased from their pharmacy subject to compliance to rule 2.7.5.
- (c) Websites and mobile apps which are owned by a pharmacy group may be used for the purchasing of medicine, provided that when the medicine is purchased such transaction is directed to a pharmacy and the details of the pharmacy, as contained in Rule 1.5.4(c) of the GPP, are displayed on the website.
- (d) Websites and mobile apps owned by 3rd parties such as franchise groups, pharmacy buying groups or associations of pharmacies may provide links to individual pharmacy websites or mobile apps, provided that the ordering and purchasing of medicines is concluded on the website or mobile app of the individual pharmacy.

PROHIBITIONS

- (a) No medicines or scheduled substances, above a schedule 0, may be sold by way of a website or mobile app, where such website or mobile app is not owned by a pharmacy or a pharmacy owner and linked to a pharmacy or group of pharmacies.
- (b) The use of websites or mobile apps owned by 3rd parties,
 - (i) where the ordering or buying/selling of medicine, above a schedule 0, is directed to a specific pharmacy but the payment for such purchase is made to the 3rd party is strictly prohibited.
 - (ii) where the purchase of medicines is directed to a specific pharmacy, but where the 3rd party keeps details of the content of the order is prohibited.
- (c) Prescriptions which are sent from an authorised prescriber to a 3rd party operating a website or mobile app, without the patient's consent, and have the effect of such 3rd party sourcing and ordering the medicine on behalf of the patient shall be prohibited.

- (d) The use of websites or mobile apps be it owned by a 3rd party or by a pharmacy owner which directs a patient to purchase medicine from an unregistered facility or organisation is prohibited.
- (e) No wholesale pharmacy or manufacturing pharmacy may use a website or mobile app to sell medicines above schedule 0 directly to an end user, where such end user is not entitled to acquire, possess, store and sell such medicines (i.e., no schedule 1 and above medicines may be sold directly to the patient, who is the end user of the medicine).