South African Health Products
Regulatory Authority
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Loftus Park
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REQUESTS FOR INFORMATION RELATED TO SELLING OF MEDICINES

The objects of SAHPRA as per the Medicines and Related Substances Act, 101 of 1965, as amended, are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest. In order to achieve these objectives, the Authority must ensure that evidence of existing and new adverse events, interactions, and information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon; and ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation. This guideline represents the current approaches of the Authority with regard to the request for information related to the selling of medicines and may be amended when required.

Document History

Final Version	Reason for Amendment	Effective Date
1	New Guideline for Comment	For comment 11 June 2024
2		

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Contents

Glossary

Abbreviation/ Term	Meaning
Medicine	As per the Medicines and Related Substances Act, 101 of 1965, as amended
Medical Device	As per the Medicines and Related Substances Act, 101 of 1965, as amended
IVD	In vitro diagnostic – as defined in the Medicines and Related Substances Act, 101 of 1965, as amended

1. INTRODUCTION

The objects of SAHPRA as per the Medicines and Related Substances Act, 101 of 1965, as amended, are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

In order to achieve these objectives, the Authority must ensure that evidence of existing and new adverse events, interactions, and information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon; ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation.

This guideline articulates the methods in which the Authority will request and receive information related to the selling of medicines from importers, exporters, manufacturers, wholesalers, dispensers and other legitimate sellers of these products in the supply chain.

1.1 Purpose

The purpose of this guideline is to stipulate the manner in which the Authority will request and receive information related to the sales of medicines.

1.2 Scope

The scope of this guideline covers information related to the sales of medicines.

2. LEGAL PROVISION

Sections 19(2) and (3) of the Medicines and Related Substances Act, 101 of 1965, as amended, provide the legal basis on which this guideline relies. The full wording of Section 19 is as follows:

> 19. Prohibition on sale of medicines, medical devices or IVDs which do not comply with prescribed requirements and furnishing of information regarding medicines, medical devices or IVDs to the Authority.—
>
> (1) No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.
>
> (2) The Authority may by notice in writing require any person who manufactures or sells medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine, medical device or IVD.
>
> (3) The Authority may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice.

The records to be kept by manufacturers and sellers of medicines are also outlined in the General Regulations (2017), as follows:

Regulation 35 - Prescription Book or Permanent Record

(1) A prescription book or other permanent record in respect of Schedules 1, 2, 3, 4, 5 and 6 substances shall be kept in hard copy or electronically on all premises where such substances or medicines are sold or dispensed.

(2) In the case of Schedule 1 medicines and substances sold by any person other than a manufacturer or wholesaler, a prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:

(a) The name of the person to whom it was sold;

(b) the name and quantity of the substance or medicine; and

(c) the name of the pharmacist, pharmacist intern or pharmacist's assistant who sold it.

(3) In the case of Schedule 2, 3, 4 and 5 medicines and substances sold by any person other than a manufacturer or wholesaler, the prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:

(a) The name of the medicine or scheduled substance;

(b) the date on which the prescription was dispensed;

(c) the dosage form and quantity of the medicine or scheduled substance;

(d) the name, identification number and address of-

(i) the patient;

(ii) in the case of a prescription for a neonate, the name, identification number and address a parent or guardian; or

(iii) in the case of a prescription issued by a veterinarian, the person to whom the medicine or scheduled substance was sold;

(e) where applicable, the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and

(f) prescription reference number, which is the reference number or unique identifier assigned at the point of dispensing.

(4) The manufacturer or wholesaler shall keep an accessible permanent record of sales of Schedule 2, 3, 4, 5 and 6 medicines and substances in the form of invoices that shall reflect the –

(a) date and transaction of the sale;

(b) name of the medicine;

(c) name and address of the purchaser;

(d) quantities sold;

(e) batch number; and

(f) price at which the medicine was sold.

(5) A prescription book or other permanent record contemplated in this regulation shall be kept for a period of at least five years after the date of the last entry made therein.

There is also specific mention of vigilance requirements in the General Regulations (2017):

Regulation 40 – Vigilance

Subregulation 1

A person who has applied for registration of a medicine in terms of Section 15 of the Act, a holder of a certificate of registration in respect of a medicine or scheduled substance, or a holder of a licence in terms of Section 22C(1)(b) must inform the Authority, in the manner and within the time frame as determined by the Authority, of any -

(a) new or existing quality, safety or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions; and

(b) risk management activities associated with paragraph (a).

Subregulation 4

Any person referred to in subregulation (1) must-

(a) whenever requested by the Authority, conduct a concise critical analysis of the safety, quality or effectiveness of the medicine or Scheduled substance submit the results thereof to the Authority within a specified time frame;

(b) in the case where, after receipt of the results referred to in paragraph (a), the Authority determines that the medicine or Scheduled substance may not be safe to use, submit to the Authority, if required to do so-

(i) case reports of all adverse events or suspected or actual adverse drug reactions in respect of the medicine or Scheduled substance;

(ii) where applicable the usage figures of the medicines or Scheduled substance, as well as periodic safety update reports and performance studies; and

(iii) any other data as requested by the Authority; and

(c) keep and maintain or have access to records of the adverse event data in respect of their medicines or Scheduled substances.

3. REQUESTS FOR INFORMATION RELATED TO SELLING OF MEDICINES

3.1 All persons selling medicines

Section 19 of the Act allows for the Authority to request, in writing, any person who manufactures or sells medicines or administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine.

Regulation 35 stipulates the regulated information that a person selling Schedules 1, 2, 3, 4, 5, and 6 medicines/substances must capture in a permanent record or prescription book.

Specific persons

In the event that the Authority requires information from specific persons, the Authority shall request this in writing to the specific person/persons. The information shall be provided to the Authority in a specified manner which may include electronic submissions through electronic portal, email or through submission of physical documentation.

All persons in the Republic selling Schedules 1, 2, 3, 4, 5 and 6 medicines/substances

In the event that the Authority requires information regarding the selling of medicines at a national level, the Authority shall request the information by way of notice published on its website and/or through communication with the appropriate stakeholders.

The information shall be provided to the Authority in the specified manner. Submissions may either be through electronic submissions, email or through submission of physical documentation.

Validity of Section 19(2) Requests

Section 19 enables a discrete, time-limited request for information. Section 19(2) requires that the Authority specify the period of notice for the information requested. Section 19(3) stipulates that the Authority may extend the notice period. However, each request must relate to a specified set of information, to be submitted within a specified time frame.

In addition, requests for information will consider the need to respect patient confidentiality, as outlined in both the National Health Act, 61 of 2003, and the Protection of Personal Information Act, 4 of 2013.

3.2 Information related to sale of medicines by Manufacturers and Wholesalers

Although manufacturers and wholesalers are subject to Section 19 of the Act and General Regulation 35, they are also subject to General Regulation 40, where, through vigilance activities, such entities must provide the Authority with required information, including regarding medicines utilisation. The request for information, as in Section 3.1, may be specific to identified manufacturers/wholesalers or on a national level.

3.3 Submission of requested information

The notice for request for information issued in terms of Section 19(2) shall specify how information must be submitted.

For manufacturers and wholesalers, the minimum information requested will be (but not limited to):

- Product Nappi Code,
- Product SAHPRA Registration number,
- Product Description,
- dosage form,
- pack size,
- number of packs/sales units manufactured - by batch,
- number of packs/sales units sold – by batch,
- Related Transaction date,
- purchaser name (individual or legal entity),
- purchaser South African Pharmacy Council (SAPC) licence number and/or purchaser SAHPRA licence number and/or purchaser National Department of Health (NDoH) license number,
- Licensed delivery address

3.4 Offences

Section 29 of the Medicines and Related Substances Act stipulates that any person who contravenes the provisions of Section 19(1) or fails to comply with a notice issued under Section 19(2) shall be guilty of an offence. Any person who is convicted of an offence referred to in Section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

4. REFERENCES

The following related documents are referenced:

1. Medicines and Related Substances Act, 101 of 1965, as amended

2. General Regulations to the Medicines and Related Substances Act issued in 2017

5. VALIDITY

This guideline is valid for a period of five (5) years from the effective date of revision. It will be reviewed on this timeframe or as and when required.