DEPARTMENT OF HEALTH

NO. 7720 **24 July 2026**

MEDICINES AND RELATED SUBSTANCES ACT, (101 OF 1965 AS AMENDED)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: EXEMPTION OF SCHEDULE 0 MEDICINES

I, PROF. NICHOLAS CRISP, Acting Director-General, have determined in accordance with Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances (Medicines Pricing Regulations) published in Government Gazette number 28214 of 11 November 2005, that a manufacturer, importer of a medicine or scheduled substance, who is the applicant of a medicine and all interested stakeholders must submit information required for the review of Schedule 0 medicines exemption from the operations of Sections 22G and 18A of Act No. 101 of 1965, as amended in accordance with the template named "Template for collecting market data of Schedule 0 medicines" appended to this Notice.

These submissions must be made within three months of the publication of this notice. Submissions can be made either in hard copy or electronically, and delivered to:

The Director-General: National Department of Health **(Attention to the Director: Pharmaceutical Economic Evaluations Directorate, Dr AB Xuma Building, Office D1-14A, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187)); e-mail:** sepupdates@health.gov.za and Ntobeko.Mpanza@health.gov.za.

Kindly note that all comments received will be duly considered prior to the finalisation of any amendments to the existing regulatory framework governing the pricing of Schedule 0 medicines.

SCHEDULE

Definitions

In this schedule,

1. "**the Act**" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and any word or expression to which a meaning has been assigned in the Act shall have such meaning, unless the context indicates otherwise.

2. **"Schedule 0 medicine"** refers to a category of medicines that are considered to have the lowest level of control because they pose minimal risk to the public when used correctly. These are medicines that may be sold to the public without a prescription and without the direct supervision of a pharmacist.

3. **"the Regulations"** means the Regulations Relating to the Transparent Pricing System for Medicine and Scheduled Substances published in terms of Government Notice No. R1102 of November 2005, as amended.

PROF NICHOLAS CRISP
ACTING DIRECTOR-GENERAL OF HEALTH
DATE 05/05/2026.

TEMPLATE FOR COLLECTING MARKET DATA OF SCHEDULE 0 (S0) MEDICINES

To be issued to stakeholders for inputs to support in determining the appropriate regulatory framework for Schedule 0 (S0) medicines excluding category D complementary medicines.

Stakeholders are requested to submit their responses by completing the sections of the template which are applicable to them with accurate information that is available to them. Where necessary, additional information may be submitted. Kindly note that only duly registered companies are eligible to respond; associations or representative bodies of companies will not be considered.

SECTION A: RESPONDENT INFORMATION

Organisation Name	
Contact Person	
Position/Title	
Email Address	
Telephone Number	

Role in the S0 Supply Chain (tick ☑ all applicable):

☐ Applicant
☐ Manufacturer
☐ Distributor
☐ Retail Pharmacy
☐ E-commerce platform
☐ Other please specify: _____
☐ Importer
☐ Wholesaler
☐ Retail franchise chain

SECTION B: PRODUCT IDENTIFICATION INFORMATION AND PRICING STRUCTURE

Provide the following information for all S0 medicines that were marketed during the period 01 January 2021 to 31 December 2025.

PRODUCT NAME	DOSAGE FORM	STRENGTH	PACK SIZE	WHOLESALE MARK-UP	RETAIL SELLING PRICE				
					01 Jan 2021 - 31 Dec 2021	01 Jan 2022 - 31 Dec 2022	01 Jan 2023 - 31 Dec 2023	01 Jan 2024 - 31 Dec 2024	01 Jan 2025 - 31 Dec 2025

1. The retail selling price information provided may be presented in any format that is available to your business.
2. The retail selling price information should be a weighted average figure for the period 01 January to 31 December for each year.

Additional Information Required

Please also provide information on the impact of the following on S0 medicine pricing:

• Exchange rate • Are the medicines exposed to any exchange rate fluctuations?	
• API price fluctuations • Is the API locally source or imported?	
• Changes in manufacturing costs	
• Changes in regulatory or compliance costs	

SECTION C: COMMERCIAL ARRANGEMENTS

Indicate whether the following commercial practices apply to S0 medicines in your organisation by marking the box/boxes that are applicable to you with a tick ☑ and add where necessary:

☐ Front-end discounts
☐ Conditional rebates
☐ Marketing allowances
☐ Category management agreements
☐ Back-end rebates
☐ Volume incentives
☐ Bundling practices
☐ Other, please specify _____

SECTION D: SALES AND MARKET DATA

Provide annual sales data for S0 medicines for each year between 2021 and 2025.

PRODUCT NAME	DOSAGE FORM	STRENGTH	PACK SIZE	01 Jan 2021 - 31 Dec 2021		01 Jan 2022 - 31 Dec 2022		01 Jan 2023 - 31 Dec 2023		01 Jan 2024 - 31 Dec 2024		01 Jan 2025 - 31 Dec 2025	
				Sales Volume	Annual Revenue	Sales Volume	Annual Revenue	Sales Volume	Annual Revenue	Sales Volume	Annual Revenue	Sales Volume	Annual Revenue

SECTION E: COST STRUCTURE

Provide the cost components considered to derive S0 medicines selling prices, tick (☑) where applicable and add where necessary.

☐ API cost
☐ Excipients
☐ Packaging materials
☐ Direct manufacturing labour

☐ Manufacturing overheads
☐ Quality Assurance
☐ Regulatory compliance costs
☐ Marketing and Promotion costs
☐ Distribution and Logistics costs
☐ Import duties and freight
☐ Insurance and Risk costs
☐ Rebate costs
☐ Other, please specify _____

SECTION F: SUPPLY CHAIN AND AVAILABILITY

Provide supply chain annual data for the past five (5) years.

Period	01 Jan 2021 - 31 Dec 2021	01 Jan 2022 - 31 Dec 2022	01 Jan 2023 - 31 Dec 2023	01 Jan 2024 - 31 Dec 2024	01 Jan 2025 - 31 Dec 2025
Average manufacturing lead per annum					
Average import lead time per annum					
Order fill rate (%) per annum					
Stock-out frequency per annum					
Average duration of stock-outs per annum					

SECTION G: MARKET STRUCTURE AND COMPETITION

Molecule/Product	Number of Competitors	Originator/Generic	Exclusive Distribution Agreements (Yes/No)

SECTION H: REGULATORY IMPACT ASSESSMENT

In your view, how could S0 medicines selling price regulation affect consumer affordability?

_____

In your view, how could S0 medicines selling price regulation affect medicine availability?

_____

Could S0 medicines selling price regulation impact supply chain sustainability? Please explain.

_____

In your view what would be the impact of regulating S0 medicines on counterfeit or unregulated medicines?