DEPARTMENT OF HEALTH

NO. R. 756 **27 August 2021**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

EXCLUSION OF CERTAIN ALCOHOL-BASED HAND-RUBS FROM THE OPERATION OF SPECIFIED PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

I, Ms M.T Kubayi, the Acting Minister of Health, in terms of section 36(1) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Act), and on the recommendation of the South African Health Products Regulatory Authority, hereby exclude, subject to the conditions listed: -

(a) the medicine listed in the Schedule hereto from the operation of sections 14(1) of the Act and regulations 11 and 12 of the General Regulations made in terms of the Act (Government Notice No. R. 859 of 25 August 2017) (the General Regulations), and

(b) the manufacturer, importer or distributor, licensed in terms of section 22C(1)(*b*) of the Act, of alcohol-based handrubs listed in this Schedule from regulations 23(1)(c)(ii), 23(1)(c)(iv), and 23(2)(aa) of the General Regulations made in terms of the Act (Government Notice No. R. 859 of 25 August 2017) (the General Regulations).

This exclusion is effective immediately for a period not exceeding twelve (12) months from the date of signature of this Notice.

Ms T.M KUBAYI, MP
ACTING MINISTER OF HEALTH
DATE 26/07/2021

SCHEDULE

MEDICINE	PROVISIONS FROM WHICH EXCLUDED	CONDITIONS OF EXCLUSION
Category A medicines in class 13 or 20, consisting of alcohol-based handrubs used or purporting to be suitable for use to prevent or treat infection within a health establishment as defined in the National Health Act 61 of 2003, or other high-risk environment.	1. Sections 14(1) of the Act, in respect of the registration requirements for medicines. 2. Regulation 11 and 12, in respect of the requirement for inclusion of professional information and a patient information leaflet. 3. Regulation 23(1)(c)(ii), in respect of the requirement for a responsible pharmacist, registered with the South African Pharmacy Council. 4. Regulation 23(1)(c)(iv), in respect of the requirements for compliance with good manufacturing, wholesaling or distribution practices. 5. Regulation 23(2)(aa), in respect of the appointment and designation of a responsible pharmacist.	1. Any medicine sold in accordance with this notice must be— a. manufactured according to the final formulas as per WHO-recommended Handrub Formulations, as provided for in the "Guide to Local Production: WHO-recommended Handrub Formulations" [1]; and b. labelled in accordance with regulation 10 of the General Regulations, including: i. a statement to the effect that it was "Prepared according to the Guide to Local Production: WHO-recommended Handrub Formulations"; ii. if intended for surgical hand preparation, the recommended method of application (including contact time, volume to be applied and application procedure); and iii. the disclaimer "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use" iv. That the handrub is tested according to and compliant with the test methodology provided in the South African National Standard (SANS) 490:2020 "Alcohol-based hand sanitiser and handrub" 2. An application for a licence in terms of section 22C(1)(*b*) of the Act and regulation 23, to manufacture, import or distribute the alcohol-based handrubs listed in this Schedule, shall be accompanied by the following documentary evidence: i. Submission of Site Master File (SMF) as per SMF guideline[2] based on the Good Manufacturing Practices of alcohol-based handrubs. ii. SANAS and/or International Organization for Standardization (ISO) Accreditation or certification equivalent to ISO 9001 standard.

[1] WHO; Guide to Local Production: WHO-recommended Handrub Formulations
https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf?ua=1
[2] Site Master File
https://www.sahpra.org.za/wp-content/uploads/2020/02/3316a9504.08_SMF_Jun03_v2-final-nov-2019-1.pdf

		iii. A manual of procedures and practices to be implemented to ensure the safety, efficacy, and quality of the said hand rubs; including procedures for the conduct of analytical tests; iv. An inventory of equipment to be used to manufacture said hand rubs; v. The executed master batch manufacturing records (BMR) for each batch manufactured vi. Certificate of Analysis (CoA) of each batch manufactured equivalent to the SANS 490:2020 and WHO requirements and vii. Submission of the label as per SAHPRA alternative regulatory and licensing requirements in accordance with SANS 490:2020 and WHO label requirements viii. a signed declaration by the responsible person of the holder of the application of the licence which contains: (aa) that the hand rub is prepared according to the "Guide to Local Production: WHO-recommended Handrub Formulations"; (bb) that the hand rub is tested according to and compliant with the test methodology provided in the South African National Standard (SANS) 490:2013 "Disinfectant alcohol-based handrub"; (cc) that the concentration of ethyl alcohol or isopropyl alcohol used will be verified for each batch using gas chromatography, alcoholmeter, hydrometer, or other chemical analysis of equivalent or greater accuracy; (dd) that the hand rub is manufactured under sanitary conditions using equipment that is well maintained and fit for purpose; (ee) that records relating to the manufacture of the hand rub will be kept by the manufacturer; and (ff) that the hand rub is safe for its intended use. 3. In order to continue to be sold beyond the expiry of this notice, any such medicines must be registered in terms of section 14(1) of the Act and the manufacturer, importer or distributor of said medicine must comply with all the provisions of regulation 23.