DEPARTMENT OF HEALTH

NO. 8011 **16 October 2026**

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

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965): AMENDMENT, 2026

The Acting Minister of Health has, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and after consultation with the South African Health Products Regulatory Authority, made the regulations in the Schedule.

MS S.T NDABENI, MP
ACTING MINISTER OF HEALTH
DATE: 15/09/2026

SCHEDULE

Definitions

1. In these Regulations, any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned, unless the context indicates otherwise: -

"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and

"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017.

Amendment of regulation 1

2. Regulation 1 is hereby amended —

(*a*) by the deletion of the definition of **"counterfeit medicine"**;

(*b*) by the insertion after the definition of "Site Master File" of the following definition:

"substandard medicine" means a medicine that fails to meet either its quality standards or specifications or both."

(*c*) by the insertion after the definition of "expiry date" of the following definition:

"falsified medicine" means a medicine for which the identity, composition or source is deliberately or fraudulently misrepresented".

Amendment of regulation 6

3. Regulation 6 is hereby amended —

(*a*) by the substitution in sub-regulation (1) of the following paragraph:

"(1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, into the Republic except through one of the following ports of entry, in a manner as determined by the Authority:

(*a*) Cape Town International Airport or Cape Town harbour;

(*b*) Chief Dawid Stuurman International Airport, Port Elizabeth harbour or Ngqura harbour;

(*c*) King Shaka International Airport or Durban harbour; or

(*d*) O.R. Tambo International Airport."

(*b*) by the insertion after sub-regulation (1) of the following sub-regulation:

"(1A) Despite sub-regulation (1), a person may import any medicine or scheduled substance in a manner as determined by the Authority through:

(a) Beit Bridge border post (Zimbabwe border);

(b) Vioolsdrift border post (Namibia border);

(c) Kopfontein border post (Botswana border);

(d) Maseru Bridge border post (Lesotho border);

(e) Lebombo border post (Mozambique border);

(f) Oshoek border post (Eswatini border),."

Amendment of Regulation 51

4. Regulation 51 is hereby amended by the substitution in sub-regulation (1) for paragraph (b) of the following:

"(*b*) is suspected of being falsified."

Repeal of laws

5. The General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965): Amendment, 2026 published in under Notice No. 7780 in Government *Gazette* No. 55152 of 07 August 2026 are hereby repealed.

Short title

6. These Regulations are called the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965): Amendment, 2026.

DEPARTEMENT VAN GESONDHEID

NO. 8011 **16 Oktober 2026**

WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)

ALGEMENE REGULASIES GEMAAK IN TERME VAN DIE WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965): WYSIGING, 2026

Die Waarnemend Minister van Gesondheid het kragtens artikel 35 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965) en na oorlegpleging met die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte, die regulasies in die Bylae gemaak.

ME S.T NDABENI, LP
WAARNEMEND MINISTER VAN GESONDHEID
DATUM: 15/09/2026

BYLAE

Woordomskrywings

1. In die Regulasies druk enige woord of uitdrukking waaraan 'n betekenis toegeken is in die Wet die betekenis wat daaraan toegeken is uit, tensy die konteks anders aandui: -

"die Wet" beteken die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965); en

"Regulasies" beteken die Algemene Regulasies soos gepubliseer onder Goewermentskennisgewing 859 in *Staatskoerant* 41064 van 25 Augustus 2017.

Wysigings van regulasie 1

2. Regulasie 1 word hierby gewysig—

(a) deur die omskrywing van "nagemaakte medisyne" te skrap;

(b) deur die volgende omskrywing na die omskrywing van "Perseel Meesterlêer" in te voeg:

"substandaard medisyne" medisyne wat versuim om óf sy gehalte standaarde óf spesifikasies of beide te haal."

(c) deur na die omskrywing van "vervaldatum" die volgende omskrywing in te voeg:

"Vervalste medisyne" medisyne waarvan die identiteit, samestelling of bron opsetlik of op 'n bedrieglike wyse wanvoorgestel word".

Wysigings van regulasie 6

3. Regulasie 6 word hierby gewysig—

(a) deur in subparagraaf (1) die volgende paragraaf te vervang:

"(1) Geen persoon sal enige medisyne of geskeduleerde stof in die Republiek invoer nie, met inbegrip van medisyne ingevoer kragtens artikel 15C van die Wet, behalwe deur een van die volgende inklaringshawes in 'n wyse soos bepaal deur die Owerheid:

(a) Kaapstad Internasionale Lughawe of Kaapstad hawe;

(b) Hoofman Dawid Stuurman Internasionale Lughawe, Port Elizabeth hawe of Ngqura hawe;

(c) Koning Shaka Internasionale Lughawe of Durban hawe; of

(d) O.R. Tambo Internasionale Lughawe."

(b) deur die volgende subregulasie na subregulasie (1) in te voeg:

"(1A) Ondanks subregulasie (1), mag 'n persoon enige medisyne of geskeduleerde stof invoer in 'n wyse soos bepaal deur die Owerheid deur:

(a) Beitbrug-grenspos (Zimbabwe grens);

(b) Vioolsdrift-grenspos (Namibia grens);

(c) Kopfontein-grenspos (Botswana grens);

(d) Maserubrug-grenspos (Lesotho grens);

(e) Lebombo-grenspos (Mosambiek grens);

(f) Oshoek-grenspos (Eswatini grens)."

Wysigings van regulasie 51

4. Regulasie 51 word hierby gewysig deur in subregulasie (1) paragraaf (b) met die volgende te vervang:

"*(b)* vermoed vervals te wees."

Herroeping van wetgewing

5. Die Algemene Regulasies gemaak ingevolge die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 Van 1965): Wysiging, 2026 gepubliseer kragtens Kennisgewing No. 7780 in *Staatskoerant* No. 55152 van 07 Augustus 2026 word hierby herroep.

Kort titel

6. Hierdie Regulasies word die Algemene Regulasies gemaak in terme van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965): Wysiging, 2026 genoem.

TSEBIŠO YA MMUŠO

KGORO YA MAPHELO

MOLAO WA DIHLARE LE DILO TŠEO DI AMANAGO, WA 1965 (MOLAO WA NO. YA 101 WA 1965)

MELAWANA YA KAKARETŠO YEO E DIRILWEGO GO YA KA MOLAO WA DIHLARE LE DILO TŠEO DI AMANAGO, WA 1965 (MOLAO WA NO. YA 101 WA 1965): PHETOŠO, YA 2026

Tona ya Maphelo ya Sebaka, go ya ka karolo ya 35 ya Molao wa Dihlare le Dilo tše di Amanago, wa 1965 (Molao wa No. ya 101 wa 1965), ebile ka morago ga go rerišana le Bolaodi bja Taolo ya Ditšweletšwa tša Maphelo bja Afrika Borwa, o dirile melawana yeo e lego ka go Šetule.

MOHUMAGADI S.T NDABENI, LELOKO LA PALAMENTE
TONA YA MAPHELO YA SEBAKA
LETŠATŠIKGWEDI: 15/09/2026

ŠETULE

Ditlhalošo

1. Ka go Melawana ye, lentšu goba polelo efe goba efe ye e filwego tlhalošo ka go Molao e swanetše go šomiša tlhalošo yeo e filwego, ntle le ge diteng di laetša ka tsela ye nngwe: -

"Molao" e ra Molao wa Dihlare le Dilo tše di Amanago, wa 1965 (Molao wa No. ya 101 wa 1965); le

"Melawana" e ra Melawana ya Kakaretšo bjalo ka ge e gatišitšwe ka fase ga Tsebišo ya Mmušo ya No. ya 859 ka go Kuranta ya Mmušo ya No. ya 41064 ya di 25 Agosetose 2017.

Phetošo ya molawana wa 1

2. Molawana wa 1 o fetošwa —

(*a*) ke go phumolwa ga tlhalošo ya **"dihlare tše etšišitšwego"**;

(*b*) ke go tsenywa ga tlhalošo ye e latelago ka morago ga tlhalošo ya "Faele ya Molaodi wa Lefelo la Tšweletšo":

"maemo a fase a dihlare" e ra dihlare tšeo di palelwago ke go fihlelela maemo a boleng goba a tlhathollo ya tšona goba bobedi bja tše."

(*c*) ke go tsenywa ga tlhalošo ye e latelago ka morago ga tlhalošo ya "letšatšikgwedi la go felelwa ke nako":

"dihlare tša bofora" e ra dihlare tšeo boitšhupo, tlhamo goba mothopo wa tšona o fošitšwego ka boomo goba ka bofora".

Phetošo ya molawana wa 6

3. Molawana wa 6 o fetošwa —

(*a*) ke go tsenywa ga temana ye e latelago ka go molawana wa ka fase ga (1):

"(1) Ga go motho yo a tla tsenyago ditšwantle tša dihlare goba dihlare tše di laolwago ke mmušo, go akaretšwa dihlare tša ditšwantle tše di

tsentšwego ka go Repabliki go ya ka karolo ya 15C ya Molao, ntle le go šomiša e tee ya mafelo a go tsena ka nageng, ka tsela yeo e hlathilwego ke Bolaodi:

(*a*) Boemafofane bja Boditšhabatšhaba bja Cape Town goba boemakepe bja Cape Town;

(*b*) Boemafofane bja Boditšhabatšhaba bja Chief Dawid Stuurman, boemakepe bja Port Elizabeth goba boemakepe bja Ngqura;

(*c*) Boemafofane bja Boditšhabatšhaba bja King Shaka goba boemakepe bja Durban; goba

(*d*) Boemafofane bja Boditšhabatšhaba bja O.R. Tambo."

(*b*) ke go tsenywa ga molawana wo o latelago ka morago ga molawana wa ka fase ga (1):

"(1A) Go sa šetšwe molawana wa ka fase ga (1), motho a ka tsenya ditšwantle tša dihlare goba dihlare tše di laolwago ke mmušo dife goba dife ka tsela yeo e hlathilwego ke bolaodi ka go šomiša:

(a) Mollwane wa Beit Bridge (mollwane wa Zimbabwe);

(b) Mollwane wa Vioolsdrift (mollwane wa Namibia);

(c) Mollwane wa Kopfontein (mollwane wa Botswana);

(d) Mollwane wa Maseru Bridge (mollwane wa Lesotho);

(e) Mollwane wa Lebombo (mollwane wa Mozambique);

(f) Mollwane wa Oshoek (mollwane wa Eswatini),."

Phetošo ya Molawana wa 51

4. Molawana wa 51 o fetošwa ke go tsenywa ga temana ye e latelago legatong la temana ya (b) ka go molawana wa ka fase ga (1):

"(*b*) di gononwa go ba di fošitšwe."

Go fediša ga melao

5. Melawana ya Kakaretšo yeo e dirilwego go ya ka Molao wa Dihlare le Dilo tše di Amanago, wa 1965 (Molao wa No. ya 101 wa 1965): Phetošo, ya 2026 yeo e

gatišitšwego ka fase ga Tsebišo ya No. ya 7780 ka go Kuranta ya Mmušo ya No. ya 55152 ya di 07 Agosetose 2026 e a fediswa.

Thaetlele ye kopana

6. Melawana ye e bitšwa Melawana ya Kakaretšo yeo e dirilwego go ya ka Molao wa Dihlare le Dilo tše di Amanago, wa 1965 (Molao wa No. ya 101 wa 1965): Phetošo, ya 2026.

SATISO SAHULUMENDE

LITIKO LETEMPHILO

UMTSETFO WEMITSI NETIDZAKAMIVA, 1965 (UMTSETFO NO.101 WANGA 1965)

IMITSETFOMGOMO LEJWAYELEKILE LEYENTIWE NGEKULANDZELA UMTSETFO WEMITSI KANYE NALETINYE TINTFO LETIHLOBENE NAYO, 1965 (UMTSETFO 101 WANGA 1965): KUCHITJIYELWA, 2026

INdvuna Yetemphilo Lelibamba Likhatsi , ngekulandzela sigaba 35 seMtsetfo weMitsi kanye Naletinye Tintfo Letihlobene nayo, 1965 (uMtsetfo No. 101 wanga-1965), futsi ngemuva kwekubonisana neSigungu Lesengamele Semikhicito Yetemphilo eNingizimu Afrika, yente imitsetfomgomo kuleShejuli.

NKOSATANA S.T NDABENI, MP
INDVUNA YETEMPHILO LELIBAMBA LIKHATSI
LUSUKU: 15/09/2026

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LUHLELO

Tinchazelo

1. Kulemitsetfomgomo, nobe nguliphi ligama nobe inkhulumo leniketwe inchazelo kuloMtsetfo itawuba naleyonchazelo leniketwe yona, ngaphandle uma ingcikitsi isho ngalenye indlela: -

"loMtsetfo" kusho uMtsetfo weMitsi kanye naletinye tintfo letihlobene nayo, 1965 (uMtsetfo 101 wanga 1965); futsi

"leMtsetfomgomo" kusho uMtsetfomgomo Lojwayelekile lolushicilelwe ngeSatiso saHulumende 859 *kuGazethi yaHulumende* 41064 yamhlaka 25 Ingci 2017.

Kuchitjiyelwa kwemtsetfomgomo 1

2. Umtsetfomgomo 1 uyachitjiyelwa—

(*a*) ngekususa **lenchazelo"yemitsi lengemanga**";

(*b*) ngekufaka lenchazelo lelandzelako ngemuva kwenchazelo Lifayile leMlawuli Wendzawo":

"umutsi longekho ezingeni lelifanele" kusho umutsi lowehluleka kuhlangabetana nemigomo yelizinga nobe tinchazelo nobe kokubili."

(*c*) ngekufaka lenchazelo lelandzelako ngemuva kwenchazelo "yemhla wekuphelelwa sikhatsi:

"umutsi longemanga" kusho umutsi lapho khona buwena, kwakheka kwawo nobe imvelaphi yawo kucaciswe kabi ngenhloso nobe ngekukhohlisa".

Kuchitjiyelwa kweMtsetfomgomo 6

3. Umtsetfomgomo 6 uyachitjiyelwa —

(*a*) ngekufaka esikhundleni sendzima lelandzelako kumtsetfomgomo lomncane (1):

"(1) Kute umuntfu lotawungenisa eveni nobe ngumuphi umutsi noma intfo lehleliwe, lokufaka ekhatsi imitsi lengenisiwe ngekwesigaba 15C saloMtsetfo, eRiphabhulikhi ngaphandle kwekutsi angene kulenye yaletindzawo tekungena letilandzelako, ngendlela lencunywe nguLuphiko:

(*a*) Sikhumulo Setindiza Semhlaba wonkhe saseKapa nobe sikhumulo semikhumbi saseKapa;

(b) Sikhumulo Setindiza Semhlaba wonkhe e-Chief Dawid Stuurman, sikhumulo semikhumbi e-Port Elizabeth nobe e-Ngqura;

(c) Sikhumulo Setindiza Semhlaba wonkhe i-King Shaka nobe sikhumulo semikhumbi saseThekwini; nobe

(d) Sikhungo setindiza semhlaba wonkhe i-O.R. Tambo."

(*b*) ngekwengeta ngemuva kwemtsemgomo lomncane (1) walomtsetfomgomo lolandzelako:

"(1A) Nanobe kunjalo ngekulandzela sigatjana (1), umuntfu angangenisa nobe ngumuphi umutsi nobe intfo lehleliwe ngendlela lencunywe nguMtimba ngekusebentisa:

(a) Indzawo yekungena emnceleni iBeit Bridge (ngasemnceleni weZimbabwe);

(b) Indzawo yekungena emnceleni iVioolsdrift (ngasemnceleni waseNamibia);

(c) Indzawo yekungena yemcele yaseKopfontein (ngasemceleni waseBotswana);

(d) Indzawo yekungena emceleni yaseMaseru Bridge (ngesemceleni waseLesotho);

(e) Indzawo yekungena yemncele yaseLebombo (ngasemnceleni waseMozambique);

(f) Indzawo yekungena emnceleni we-Oshoek (emnceleni we-Eswatini),."

Kuchitjiyelwa kweMtsetfomgomo 51 Amendment of Regulation 51

4. Umtsetfomgomo 51 uyachitjiyelwa ngekutsi kufakwe lolokulandzelako esikhundleni sendzima *(b)* kumtsetfosimiso lomncane (1):

"(*b*) kusolwa kutsi kungemanga."

Kucitfwa kweMitsetfo

5. Lemitsetfomgomo lemiswe ngekweMtsetfo weMitsi kanye naletinye tintfo letihlobene nayo, 1965 (uMtsetfo No. 101 wanga 1965): Kuchitjiyelwa, 2026 loshicilelwe *kuGazethi yaHulumende* No. 55152 yamhlaka 07 Ingci 2026, ngekwesatiso No. 7780 iyacitfwa.

Sihloko lesifishane

6. Lemitsetfomgomo ubitwa ngekutsi iMitsetfomgomo Lojwayelekile lemiswe ngekweMtsetfo weMitsi kanye naletinye tintfo letihlobene nayo, 1965 (uMtsetfo No. 101 wanga 1965): Kuchitjiyelwa, 2026.