



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Regulation Gazette

No. 11320

Regulasiekoerant

Vol. 674

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N.B. The Government Printing Works will not be held responsible for the quality of "Hard Copies" or "Electronic Files" submitted for publication purposes

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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

IMPORTANT NOTICE:

THE GOVERNMENT PRINTING WORKS WILL NOT BE HELD RESPONSIBLE FOR ANY ERRORS THAT MIGHT OCCUR DUE TO THE SUBMISSION OF INCOMPLETE / INCORRECT / ILLEGIBLE COPY.

No FUTURE QUERIES WILL BE HANDLED IN CONNECTION WITH THE ABOVE.

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government
printing

Department:
Government Printing Works
REPUBLIC OF SOUTH AFRICA

HIGH ALERT: SCAM WARNING!!!

TO ALL SUPPLIERS AND SERVICE PROVIDERS OF THE GOVERNMENT PRINTING WORKS

It has come to the attention of the *GOVERNMENT PRINTING WORKS* that there are certain unscrupulous companies and individuals who are defrauding unsuspecting businesses disguised as representatives of the *Government Printing Works (GPW)*.

The scam involves the fraudsters using the letterhead of *GPW* to send out fake tender bids to companies and requests to supply equipment and goods.

Although the contact person's name on the letter may be of an existing official, the contact details on the letter are not the same as the *Government Printing Works*. When searching on the Internet for the address of the company that has sent the fake tender document, the address does not exist.

The banking details are in a private name and not company name. Government will never ask you to deposit any funds for any business transaction. *GPW* has alerted the relevant law enforcement authorities to investigate this scam to protect legitimate businesses as well as the name of the organisation.

Example of e-mails these fraudsters are using:

PROCUREMENT@GPW-GOV.ORG

Should you suspect that you are a victim of a scam, you must urgently contact the police and inform the *GPW*.

GPW has an official email with the domain as @gpw.gov.za

Government e-mails DO NOT have org in their e-mail addresses. All of these fraudsters also use the same or very similar telephone numbers. Although such number with an area code 012 looks like a landline, it is not fixed to any property.

GPW will never send you an e-mail asking you to supply equipment and goods without a purchase/order number. *GPW* does not procure goods for another level of Government. The organisation will not be liable for actions that result in companies or individuals being resultant victims of such a scam.

Government Printing Works gives businesses the opportunity to supply goods and services through RFQ / Tendering process. In order to be eligible to bid to provide goods and services, suppliers must be registered on the National Treasury's Central Supplier Database (CSD). To be registered, they must meet all current legislative requirements (e.g. have a valid tax clearance certificate and be in good standing with the South African Revenue Services - SARS).

The tender process is managed through the Supply Chain Management (SCM) system of the department. SCM is highly regulated to minimise the risk of fraud, and to meet objectives which include value for money, open and effective competition, equitability, accountability, fair dealing, transparency and an ethical approach. Relevant legislation, regulations, policies, guidelines and instructions can be found on the tender's website.

Fake Tenders

National Treasury's CSD has launched the Government Order Scam campaign to combat fraudulent requests for quotes (RFQs). Such fraudulent requests have resulted in innocent companies losing money. We work hard at preventing and fighting fraud, but criminal activity is always a risk.

How tender scams work

There are many types of tender scams. Here are some of the more frequent scenarios:

Fraudsters use what appears to be government department stationery with fictitious logos and contact details to send a fake RFQ to a company to invite it to urgently supply goods. Shortly after the company has submitted its quote, it receives notification that it has won the tender. The company delivers the goods to someone who poses as an official or at a fake site. The Department has no idea of this transaction made in its name. The company is then never paid and suffers a loss.

OR

Fraudsters use what appears to be government department stationery with fictitious logos and contact details to send a fake RFQ to Company A to invite it to urgently supply goods. Typically, the tender specification is so unique that only Company B (a fictitious company created by the fraudster) can supply the goods in question.

Shortly after Company A has submitted its quote it receives notification that it has won the tender. Company A orders the goods and pays a deposit to the fictitious Company B. Once Company B receives the money, it disappears. Company A's money is stolen in the process.

Protect yourself from being scammed

- If you are registered on the supplier databases and you receive a request to tender or quote that seems to be from a government department, contact the department to confirm that the request is legitimate. Do not use the contact details on the tender document as these might be fraudulent.
- Compare tender details with those that appear in the Tender Bulletin, available online at www.gpwonline.co.za
- Make sure you familiarise yourself with how government procures goods and services. Visit the tender website for more information on how to tender.
- If you are uncomfortable about the request received, consider visiting the government department and/or the place of delivery and/or the service provider from whom you will be sourcing the goods.
- In the unlikely event that you are asked for a deposit to make a bid, contact the SCM unit of the department in question to ask whether this is in fact correct.

Any incidents of corruption, fraud, theft and misuse of government property in the *Government Printing Works* can be reported to:

Supply Chain Management: Ms. Anna Marie Du Toit, Tel. (012) 748 6292.
Email: Annamarie.DuToit@gpw.gov.za

Marketing and Stakeholder Relations: Ms Bonakele Mbhele, at Tel. (012) 748 6193.
Email: Bonakele.Mbhele@gpw.gov.za

Security Services: Mr Daniel Legoabe, at tel. (012) 748 6176.
Email: Daniel.Legoabe@gpw.gov.za

Closing times for **ORDINARY WEEKLY** **2021** **GOVERNMENT GAZETTE**

The closing time is **15:00** sharp on the following days:

- **24 December 2020**, Thursday for the issue of Thursday **31 December 2020**
- **31 December 2020**, Thursday for the issue of Friday **08 January 2021**
- **08 January**, Friday for the issue of Friday **15 January 2021**
- **15 January**, Friday for the issue of Friday **22 January 2021**
- **22 January**, Friday for the issue of Friday **29 January 2021**
- **29 January**, Friday for the issue of Friday **05 February 2021**
- **05 February**, Friday for the issue of Friday **12 February 2021**
- **12 February**, Friday for the issue of Friday **19 February 2021**
- **19 February**, Friday for the issue of Friday **26 February 2021**
- **26 February**, Friday for the issue of Friday **05 March 2021**
- **05 March**, Friday for the issue of Friday **12 March 2021**
- **12 March**, Friday for the issue of Friday **19 March 2021**
- **18 March**, Thursday for the issue of Friday **26 March 2021**
- **25 March**, Thursday for the issue of Thursday **01 April 2021**
- **31 March**, Wednesday for the issue of Friday **09 April 2021**
- **09 April**, Friday for the issue of Friday **16 April 2021**
- **16 April**, Friday for the issue of Friday **23 April 2021**
- **22 April**, Thursday for the issue of Friday **30 April 2021**
- **30 April**, Friday for the issue of Friday **07 May 2021**
- **07 May**, Friday for the issue of Friday **14 May 2021**
- **14 May**, Friday for the issue of Friday **21 May 2021**
- **21 May**, Friday for the issue of Friday **28 May 2021**
- **28 May**, Friday for the issue of Friday **04 June 2021**
- **04 June**, Friday for the issue of Friday **11 June 2021**
- **10 June**, Thursday for the issue of Friday **18 June 2021**
- **18 June**, Friday for the issue of Friday **25 June 2021**
- **25 June**, Friday for the issue of Friday **02 July 2021**
- **02 July**, Friday for the issue of Friday **09 July 2021**
- **09 July**, Friday for the issue of Friday **16 July 2021**
- **16 July**, Friday for the issue of Friday **23 July 2021**
- **23 July**, Friday for the issue of Friday **30 July 2021**
- **30 July**, Friday for the issue of Friday **06 August 2021**
- **05 August**, Thursday for the issue of Friday **13 August 2021**
- **13 August**, Friday for the issue of Friday **20 August 2021**
- **20 August**, Friday for the issue of Friday **27 August 2021**
- **27 August**, Friday for the issue of Friday **03 September 2021**
- **03 September**, Friday for the issue of Friday **10 September 2021**
- **10 September**, Friday for the issue of Friday **17 September 2021**
- **16 September**, Thursday for the issue of Thursday **23 September 2021**
- **23 September**, Thursday for the issue of Friday **01 October 2021**
- **01 October**, Friday for the issue of Friday **08 October 2021**
- **08 October**, Friday for the issue of Friday **15 October 2021**
- **15 October**, Friday for the issue of Friday **22 October 2021**
- **22 October**, Friday for the issue of Friday **29 October 2021**
- **29 October**, Friday for the issue of Friday **05 November 2021**
- **05 November**, Friday for the issue of Friday **12 November 2021**
- **12 November**, Friday for the issue of Friday **19 November 2021**
- **19 November**, Friday for the issue of Friday **26 November 2021**
- **26 November**, Friday for the issue of Friday **03 December 2021**
- **03 December**, Friday for the issue of Friday **10 December 2021**
- **09 December**, Thursday for the issue of Friday **17 December 2021**
- **17 December**, Friday for the issue of Friday **24 December 2021**
- **23 December**, Thursday for the issue of Friday **31 December 2021**

LIST OF TARIFF RATES

FOR PUBLICATION OF NOTICES

COMMENCEMENT: 1 APRIL 2018

NATIONAL AND PROVINCIAL

Notice sizes for National, Provincial & Tender gazettes 1/4, 2/4, 3/4, 4/4 per page. Notices submitted will be charged at R1008.80 per full page, pro-rated based on the above categories.

Pricing for National, Provincial - Variable Priced Notices		
Notice Type	Page Space	New Price (R)
Ordinary National, Provincial	1/4 - Quarter Page	252.20
Ordinary National, Provincial	2/4 - Half Page	504.40
Ordinary National, Provincial	3/4 - Three Quarter Page	756.60
Ordinary National, Provincial	4/4 - Full Page	1008.80

EXTRA-ORDINARY

All Extra-ordinary National and Provincial gazette notices are non-standard notices and attract a variable price based on the number of pages submitted.

The pricing structure for National and Provincial notices which are submitted as **Extra ordinary submissions** will be charged at **R3026.32** per page.

GOVERNMENT PRINTING WORKS - BUSINESS RULES

The **Government Printing Works (GPW)** has established rules for submitting notices in line with its electronic notice processing system, which requires the use of electronic *Adobe Forms*. Please ensure that you adhere to these guidelines when completing and submitting your notice submission.

CLOSING TIMES FOR ACCEPTANCE OF NOTICES

1. The *Government Gazette* and *Government Tender Bulletin* are weekly publications that are published on Fridays and the closing time for the acceptance of notices is strictly applied according to the scheduled time for each gazette.
2. Please refer to the Submission Notice Deadline schedule in the table below. This schedule is also published online on the Government Printing works website www.gpwonline.co.za

All re-submissions will be subject to the standard cut-off times.

All notices received after the closing time will be rejected.

Government Gazette Type	Publication Frequency	Publication Date	Submission Deadline	Cancellations Deadline
National Gazette	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Regulation Gazette	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Petrol Price Gazette	Monthly	Tuesday before 1st Wednesday of the month	One day before publication	1 working day prior to publication
Road Carrier Permits	Weekly	Friday	Thursday 15h00 for next Friday	3 working days prior to publication
Unclaimed Monies (Justice, Labour or Lawyers)	January / September 2 per year	Last Friday	One week before publication	3 working days prior to publication
Parliament (Acts, White Paper, Green Paper)	As required	Any day of the week	None	3 working days prior to publication
Manuals	Bi- Monthly	2nd and last Thursday of the month	One week before publication	3 working days prior to publication
State of Budget (National Treasury)	Monthly	30th or last Friday of the month	One week before publication	3 working days prior to publication
<i>Extraordinary Gazettes</i>	As required	Any day of the week	<i>Before 10h00 on publication date</i>	<i>Before 10h00 on publication date</i>
Legal Gazettes A, B and C	Weekly	Friday	One week before publication	Tuesday, 15h00 - 3 working days prior to publication
Tender Bulletin	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Gauteng	Weekly	Wednesday	Two weeks before publication	3 days after submission deadline
Eastern Cape	Weekly	Monday	One week before publication	3 working days prior to publication
Northern Cape	Weekly	Monday	One week before publication	3 working days prior to publication
North West	Weekly	Tuesday	One week before publication	3 working days prior to publication
KwaZulu-Natal	Weekly	Thursday	One week before publication	3 working days prior to publication
Limpopo	Weekly	Friday	One week before publication	3 working days prior to publication
Mpumalanga	Weekly	Friday	One week before publication	3 working days prior to publication

GOVERNMENT PRINTING WORKS - BUSINESS RULES

Government Gazette Type	Publication Frequency	Publication Date	Submission Deadline	Cancellations Deadline
Gauteng Liquor License Gazette	Monthly	Wednesday before the First Friday of the month	Two weeks before publication	3 working days after submission deadline
Northern Cape Liquor License Gazette	Monthly	First Friday of the month	Two weeks before publication	3 working days after submission deadline
National Liquor License Gazette	Monthly	First Friday of the month	Two weeks before publication	3 working days after submission deadline
Mpumalanga Liquor License Gazette	Bi-Monthly	Second & Fourth Friday	One week before publication	3 working days prior to publication

EXTRAORDINARY GAZETTES

3. *Extraordinary Gazettes* can have only one publication date. If multiple publications of an *Extraordinary Gazette* are required, a separate Z95/Z95Prov *Adobe* Forms for each publication date must be submitted.

NOTICE SUBMISSION PROCESS

4. Download the latest *Adobe* form, for the relevant notice to be placed, from the **Government Printing Works** website www.gpwonline.co.za.
5. The *Adobe* form needs to be completed electronically using *Adobe Acrobat / Acrobat Reader*. Only electronically completed *Adobe* forms will be accepted. No printed, handwritten and/or scanned *Adobe* forms will be accepted.
6. The completed electronic *Adobe* form has to be submitted via email to submit.egazette@gpw.gov.za. The form needs to be submitted in its original electronic *Adobe* format to enable the system to extract the completed information from the form for placement in the publication.
7. Every notice submitted **must** be accompanied by an official **GPW** quotation. This must be obtained from the *eGazette* Contact Centre.
8. Each notice submission should be sent as a single email. The email **must** contain **all documentation relating to a particular notice submission**.
 - 8.1. Each of the following documents must be attached to the email as a separate attachment:
 - 8.1.1. An electronically completed *Adobe* form, specific to the type of notice that is to be placed.
 - 8.1.1.1. For *National Government Gazette* or *Provincial Gazette* notices, the notices must be accompanied by an electronic Z95 or Z95Prov *Adobe* form
 - 8.1.1.2. The notice content (body copy) **MUST** be a separate attachment.
 - 8.1.2. A copy of the official **Government Printing Works** quotation you received for your notice. (*Please see Quotation section below for further details*)
 - 8.1.3. A valid and legible Proof of Payment / Purchase Order: **Government Printing Works** account customer must include a copy of their Purchase Order. **Non-Government Printing Works** account customer needs to submit the proof of payment for the notice
 - 8.1.4. Where separate notice content is applicable (Z95, Z95 Prov and TForm 3, it should **also** be attached as a separate attachment. (*Please see the Copy Section below, for the specifications*).
 - 8.1.5. Any additional notice information if applicable.

GOVERNMENT PRINTING WORKS - BUSINESS RULES

9. The electronic *Adobe* form will be taken as the primary source for the notice information to be published. Instructions that are on the email body or covering letter that contradicts the notice form content will not be considered. The information submitted on the electronic *Adobe* form will be published as-is.
10. To avoid duplicated publication of the same notice and double billing, Please submit your notice **ONLY ONCE**.
11. Notices brought to **GPW** by “walk-in” customers on electronic media can only be submitted in *Adobe* electronic form format. All “walk-in” customers with notices that are not on electronic *Adobe* forms will be routed to the Contact Centre where they will be assisted to complete the forms in the required format.
12. Should a customer submit a bulk submission of hard copy notices delivered by a messenger on behalf of any organisation e.g. newspaper publisher, the messenger will be referred back to the sender as the submission does not adhere to the submission rules.

QUOTATIONS

13. Quotations are valid until the next tariff change.
 - 13.1. **Take note:** **GPW**'s annual tariff increase takes place on **1 April** therefore any quotations issued, accepted and submitted for publication up to **31 March** will keep the old tariff. For notices to be published from 1 April, a quotation must be obtained from **GPW** with the new tariffs. Where a tariff increase is implemented during the year, **GPW** endeavours to provide customers with 30 days' notice of such changes.
14. Each quotation has a unique number.
15. Form Content notices must be emailed to the *eGazette* Contact Centre for a quotation.
 - 15.1. The *Adobe* form supplied is uploaded by the Contact Centre Agent and the system automatically calculates the cost of your notice based on the layout/format of the content supplied.
 - 15.2. It is critical that these *Adobe* Forms are completed correctly and adhere to the guidelines as stipulated by **GPW**.
16. **APPLICABLE ONLY TO GPW ACCOUNT HOLDERS:**
 - 16.1. **GPW** Account Customers must provide a valid **GPW** account number to obtain a quotation.
 - 16.2. Accounts for **GPW** account customers **must** be active with sufficient credit to transact with **GPW** to submit notices.
 - 16.2.1. If you are unsure about or need to resolve the status of your account, please contact the **GPW** Finance Department prior to submitting your notices. (If the account status is not resolved prior to submission of your notice, the notice will be failed during the process).
17. **APPLICABLE ONLY TO CASH CUSTOMERS:**
 - 17.1. Cash customers doing **bulk payments** must use a **single email address** in order to use the **same proof of payment** for submitting multiple notices.
18. The responsibility lies with you, the customer, to ensure that the payment made for your notice(s) to be published is sufficient to cover the cost of the notice(s).
19. Each quotation will be associated with one proof of payment / purchase order / cash receipt.
 - 19.1. This means that **the quotation number can only be used once to make a payment.**

GOVERNMENT PRINTING WORKS - BUSINESS RULES**COPY (SEPARATE NOTICE CONTENT DOCUMENT)**

20. Where the copy is part of a separate attachment document for Z95, Z95Prov and TForm03
- 20.1. Copy of notices must be supplied in a separate document and may not constitute part of any covering letter, purchase order, proof of payment or other attached documents.
- The content document should contain only one notice. (You may include the different translations of the same notice in the same document).
- 20.2. The notice should be set on an A4 page, with margins and fonts set as follows:
- Page size = A4 Portrait with page margins: Top = 40mm, LH/RH = 16mm, Bottom = 40mm;
Use font size: Arial or Helvetica 10pt with 11pt line spacing;
- Page size = A4 Landscape with page margins: Top = 16mm, LH/RH = 40mm, Bottom = 16mm;
Use font size: Arial or Helvetica 10pt with 11pt line spacing;

CANCELLATIONS

21. Cancellation of notice submissions are accepted by **GPW** according to the deadlines stated in the table above in point 2. Non-compliance to these deadlines will result in your request being failed. Please pay special attention to the different deadlines for each gazette. Please note that any notices cancelled after the cancellation deadline will be published and charged at full cost.
22. Requests for cancellation must be sent by the original sender of the notice and must be accompanied by the relevant notice reference number (N-) in the email body.

AMENDMENTS TO NOTICES

23. With effect from 01 October 2015, **GPW** will not longer accept amendments to notices. The cancellation process will need to be followed according to the deadline and a new notice submitted thereafter for the next available publication date.

REJECTIONS

24. All notices not meeting the submission rules will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za). Reasons for rejections include the following:
- 24.1. Incorrectly completed forms and notices submitted in the wrong format, will be rejected.
- 24.2. Any notice submissions not on the correct *Adobe* electronic form, will be rejected.
- 24.3. Any notice submissions not accompanied by the proof of payment / purchase order will be rejected and the notice will not be processed.
- 24.4. Any submissions or re-submissions that miss the submission cut-off times will be rejected to the customer. The Notice needs to be re-submitted with a new publication date.

GOVERNMENT PRINTING WORKS - BUSINESS RULES**APPROVAL OF NOTICES**

25. Any notices other than legal notices are subject to the approval of the Government Printer, who may refuse acceptance or further publication of any notice.
26. No amendments will be accepted in respect to separate notice content that was sent with a Z95 or Z95Prov notice submissions. The copy of notice in layout format (previously known as proof-out) is only provided where requested, for Advertiser to see the notice in final Gazette layout. Should they find that the information submitted was incorrect, they should request for a notice cancellation and resubmit the corrected notice, subject to standard submission deadlines. The cancellation is also subject to the stages in the publishing process, i.e. If cancellation is received when production (printing process) has commenced, then the notice cannot be cancelled.

GOVERNMENT PRINTER INDEMNIFIED AGAINST LIABILITY

27. The Government Printer will assume no liability in respect of—
 - 27.1. any delay in the publication of a notice or publication of such notice on any date other than that stipulated by the advertiser;
 - 27.2. erroneous classification of a notice, or the placement of such notice in any section or under any heading other than the section or heading stipulated by the advertiser;
 - 27.3. any editing, revision, omission, typographical errors or errors resulting from faint or indistinct copy.

LIABILITY OF ADVERTISER

28. Advertisers will be held liable for any compensation and costs arising from any action which may be instituted against the Government Printer in consequence of the publication of any notice.

CUSTOMER INQUIRIES

Many of our customers request immediate feedback/confirmation of notice placement in the gazette from our Contact Centre once they have submitted their notice – While **GPW** deems it one of their highest priorities and responsibilities to provide customers with this requested feedback and the best service at all times, we are only able to do so once we have started processing your notice submission.

GPW has a 2-working day turnaround time for processing notices received according to the business rules and deadline submissions.

Please keep this in mind when making inquiries about your notice submission at the Contact Centre.

29. Requests for information, quotations and inquiries must be sent to the Contact Centre **ONLY**.
30. Requests for Quotations (RFQs) should be received by the Contact Centre at least **2 working days** before the submission deadline for that specific publication.

GOVERNMENT PRINTING WORKS - BUSINESS RULES

PAYMENT OF COST

31. The Request for Quotation for placement of the notice should be sent to the Gazette Contact Centre as indicated above, prior to submission of notice for advertising.
32. Payment should then be made, or Purchase Order prepared based on the received quotation, prior to the submission of the notice for advertising as these documents i.e. proof of payment or Purchase order will be required as part of the notice submission, as indicated earlier.
33. Every proof of payment must have a valid **GPW** quotation number as a reference on the proof of payment document.
34. Where there is any doubt about the cost of publication of a notice, and in the case of copy, an enquiry, accompanied by the relevant copy, should be addressed to the Gazette Contact Centre, **Government Printing Works**, Private Bag X85, Pretoria, 0001 email: info.egazette@gpw.gov.za before publication.
35. Overpayment resulting from miscalculation on the part of the advertiser of the cost of publication of a notice will not be refunded, unless the advertiser furnishes adequate reasons why such miscalculation occurred. In the event of underpayments, the difference will be recovered from the advertiser, and future notice(s) will not be published until such time as the full cost of such publication has been duly paid in cash or electronic funds transfer into the **Government Printing Works** banking account.
36. In the event of a notice being cancelled, a refund will be made only if no cost regarding the placing of the notice has been incurred by the **Government Printing Works**.
37. The **Government Printing Works** reserves the right to levy an additional charge in cases where notices, the cost of which has been calculated in accordance with the List of Fixed Tariff Rates, are subsequently found to be excessively lengthy or to contain overmuch or complicated tabulation.

PROOF OF PUBLICATION

38. Copies of any of the *Government Gazette* or *Provincial Gazette* can be downloaded from the **Government Printing Works** website www.gpwonline.co.za free of charge, should a proof of publication be required.
39. Printed copies may be ordered from the Publications department at the ruling price. The **Government Printing Works** will assume no liability for any failure to post or for any delay in despatching of such *Government Gazette*(s)

GOVERNMENT PRINTING WORKS CONTACT INFORMATION

Physical Address:
Government Printing Works

149 Bosman Street

Pretoria

Postal Address:

Private Bag X85

Pretoria

0001

GPW Banking Details:
Bank: ABSA Bosman Street

Account No.: 405 7114 016

Branch Code: 632-005

For Gazette and Notice submissions: Gazette Submissions:

For queries and quotations, contact: Gazette Contact Centre:

E-mail: submit.egazette@gpw.gov.za
E-mail: info.egazette@gpw.gov.za
Tel: 012-748 6200

Contact person for subscribers: Mrs M. Toka:

E-mail: subscriptions@gpw.gov.za
Tel: 012-748-6066 / 6060 / 6058

Fax: 012-323-9574

GOVERNEMENT NOTICES • GOEWERMENSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 679

6 August 2021

NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

Registration Number	Date Registered	Product name	Dosage form	Applicant	API	Conditions of Registrations
45/2.5/0938	2021/01/26	CONVULEX CR 300	TABLET	TAKEDA (PTY) LTD	EACH TABLET CONTAINS SODIUM VALPROATE 300,0 mg	Annexure A
45/2.5/0947	2021/01/26	CONVULEX CR 500	TABLET	TAKEDA (PTY) LTD	EACH TABLET CONTAINS SODIUM VALPROATE 500,0 mg	Annexure A
53/20.2.8/0484	2021/01/26	TAFTRIMYL	TABLET	XIXIA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DOLUATEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
53/20.2.8/0485.484	2021/01/26	MYLATAF	TABLET	XIXIA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DOLUATEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
53/20.2.8/0468	2021/01/21	KOMYCITAF	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUATEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
53/20.2.8/0469.468	2021/01/21	DOLTRITAF	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUATEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
53/30.5/0223	2021/01/21	XEOMIN 50 UNITS	INJECTION	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS BOTULINUM NEUROTOXIN TYPE A 50,0 UNITS	Annexure A
53/30.5/0224	2021/01/21	XEOMIN 100 UNITS	INJECTION	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS BOTULINUM NEUROTOXIN TYPE A 100,0 UNITS	Annexure A
51/13.12/0879	2021/01/26	DUPIXENT	INJECTION	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	EACH 2,0 ml SOLUTION CONTAINS DUPILUMAB 300,0 mg	Annexure A
51/13.12/0880	2021/01/26	DUBRANTIS	INJECTION	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	EACH 2,0 ml SOLUTION CONTAINS DUPILUMAB 300,0 mg	Annexure A
54/27/347	2021/02/09	DEFKEM 125	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 125,0 mg	Annexure A
54/27/348	2021/02/09	DEFKEM 250	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 250,0 mg	Annexure A
54/27/349	2021/02/09	DEFKEM 500	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 500,0 mg	Annexure A
54/27/350.347	2021/02/09	DEFERASIROX 125 ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 125,0 mg	Annexure A

54/27/351.348	2021/02/09	DEFERASIROX 250 ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 250,0 mg	Annexure A
54/27/352.349	2021/02/09	DEFERASIROX 500 ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 500,0 mg	Annexure A
54/17.1/0866	2021/02/09	MERAXT 10 mg/ml	INJECTION	KAHMA BIOTECH (PTY) LTD	EACH 5,0 ml CONTAINS ROCURONIUM BROMIDE 50,0 mg	Annexure A
55/20.2.8/0333	2021/02/09	XOFLUZA 20 mg	TABLET	ROCHE PRODUCTS (PTY) LTD	EACH TABLET CONTAINS BALOXAVIR MARBOXIL 20,0 mg	Annexure A
55/20.2.8/0334	2021/02/09	XOFLUZA 40 mg	TABLET	ROCHE PRODUCTS (PTY) LTD	EACH TABLET CONTAINS BALOXAVIR MARBOXIL 40,0 mg	Annexure A
55/8.2/0053	2021/02/09	ZYQUIS 2,5	TABLET	ZYDUS HEALTHCARE SA (PTY) LTD	EACH TABLET CONTAINS APIXABAN 2,5 mg	Annexure A
55/8.2/0054	2021/02/09	ZYQUIS 5	TABLET	ZYDUS HEALTHCARE SA (PTY) LTD	EACH TABLET CONTAINS APIXABAN 5 mg	Annexure A
55/8.2/0055.053	2021/02/09	APIXABAN 2,5 ZYDUS	TABLET	ZYDUS HEALTHCARE SA (PTY) LTD	EACH TABLET CONTAINS APIXABAN 2,5 mg	Annexure A
55/8.2/0056.054	2021/02/09	APIXABAN 5 ZYDUS	TABLET	ZYDUS HEALTHCARE SA (PTY) LTD	EACH TABLET CONTAINS APIXABAN 5 mg	Annexure A
55/20.2.8/0111	2021/02/09	VIRLAM	TABLET	PHARMA DYNAMICS (PTY) LTD	EACH TABLET CONTAINS LAMIVUDINE 300,0 mg AND TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
54/21.5.1/0111.109	2021/02/16	SEREFLO DPI 50/100	INHALATION	CIPLA MEDPRO (PTY) LTD	EACH BLISTER CONTAINS SALMETEROL XINAFOATE 50,0 ug AND FLUTICASONE PROPIONATE 100,0 ug	Annexure A
54/21.5.1/0112.110	2021/02/16	SEREFLO DPI 50/250	INHALATION	CIPLA MEDPRO (PTY) LTD	EACH BLISTER CONTAINS SALMETEROL XINAFOATE 50,0 ug AND FLUTICASONE PROPIONATE 250,0 ug	Annexure A
55/16.5/0135	2021/02/16	CEPACOL ANTI- INFLAMMATORY MOUTHWASH	SOLUTION	ADCOCK INGRAM LIMITED	EACH 15,0 ml SOLUTION CONTAINS BENZYLAMINE HYDROCHLORIDE 22,5 mg	Annexure A
18/21/02	2021/02/23	ATOPICA 100 mg/ML ORAL SOLUTION FOR CATS AND DOGS	SOLUTION	ELI LILLY SA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS CICLOSPORIN 100,0 mg	Annexure A
53/5.3/0046	2021/02/23	DONECEPT ODT 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DONEPEZIL HYDROCHLORIDE 5,0 mg	Annexure A
53/5.3/0047	2021/02/23	DONECEPT ODT 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DONEPEZIL HYDROCHLORIDE 10,0 mg	Annexure A
53/20.2.8/0184	2021/02/23	ZIDOCOMB 150/300	TABLET	IPHARMA (PTY) LTD	EACH TABLET CONTAINS LAMIVUDINE 150,0 mg AND ZIDOVUDINE 300,0 mg	Annexure A
53/34/0489	2021/02/23	EVERZOR 2,5	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 2,5 mg	Annexure A
53/34/0490	2021/02/23	EVERZOR 5	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 5 mg	Annexure A
53/34/0491	2021/02/23	EVERZOR 10	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 10 mg	Annexure A

53/34/0492.489	2021/02/23	EVEROLIMUS 2,5 ADCO	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 2,5 mg	Annexure A
53/34/0493.490	2021/02/23	EVEROLIMUS 5 ADCO	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 5 mg	Annexure A
53/34/0494.491	2021/02/23	EVEROLIMUS 10 ADCO	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS EVEROLIMUS 10 mg	Annexure A
53/30.1/0502	2021/02/23	REMIFLIX	INFUSION	CIPLA MEDPRO (PTY) LTD	EACH VIAL CONTAINS INFLIXIMAB 100,0 mg	Annexure A
53/30.3/0726	2021/02/23	NUWVIQ 250 IU	INJECTION	OCTAPHARMA SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 250 IU	Annexure A
53/30.3/0727	2021/02/23	NUWVIQ 500 IU	INJECTION	OCTAPHARMA SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 500 IU	Annexure A
53/30.3/0728	2021/02/23	NUWVIQ 1 000 IU	INJECTION	OCTAPHARMA SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 1 000 IU	Annexure A
53/30.3/0729	2021/02/23	NUWVIQ 2 000 IU	INJECTION	OCTAPHARMA SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 2 000 IU	Annexure A
54/30.1/0001	2021/02/23	IMFINZI 120 mg	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 2,4 ml CONTAINS DURVALUMAB 120,0 mg	Annexure A
54/30.1/0002	2021/02/23	IMFINZI 500 mg	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 10,0 ml CONTAINS DURVALUMAB 500,0 mg	Annexure A
54/30.1/0003.001	2021/02/23	FIDURSI 120 mg	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 2,4 ml CONTAINS DURVALUMAB 120,0 mg	Annexure A
54/30.1/0004.002	2021/02/23	FIDURSI 500 mg	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 10,0 ml CONTAINS DURVALUMAB 500,0 mg	Annexure A
54/7.5/0137	2021/02/23	EZIMVA 10/10	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 10 mg	Annexure A
54/7.5/0138	2021/02/23	EZIMVA 10/20	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 20 mg	Annexure A
54/7.5/0139	2021/02/23	EZIMVA 10/40	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 40 mg	Annexure A
54/7.5/0140	2021/02/23	EZIMVA 10/80	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 80 mg	Annexure A
54/7.5/0141.137	2021/02/23	EZETIMIBE SIMVASTATIN ALKEM 10 mg/10 mg	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 10 mg	Annexure A
54/7.5/0142.138	2021/02/23	EZETIMIBE SIMVASTATIN ALKEM 10 mg/20 mg	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 20 mg	Annexure A
54/7.5/0143.139	2021/02/23	EZETIMIBE SIMVASTATIN ALKEM 10 mg/40 mg	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 40 mg	Annexure A
54/7.5/0144.140	2021/02/23	EZETIMIBE SIMVASTATIN ALKEM 10 mg/80 mg	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 80 mg	Annexure A
54/30.1/0765	2021/02/23	FASENRA 30 mg	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS BENRALIZUMAB 30,0 mg	Annexure A

54/30.1/0766.765	2021/02/23	ARLISPO 30 mg METACAM 0,5 mg ORAL SUSPENSION FOR CATS	SOLUTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS BENRALIZUMAB 30,0 mg	Annexure A
15/3.1.2.1/09	2021/03/02	SEMINTRA 10 mg/ml	SOLUTION	BOEHRINGER INGELHEIM ANIMAL HEALTH SA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS MELOXICAM 0,5 mg	Annexure A
20/5.3.2/12	2021/03/02	CO-AMOXICLAV BD AUSTELL	SOLUTION	BOEHRINGER INGELHEIM ANIMAL HEALTH SA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TELMISARTAN 10,0 mg	Annexure A
53/20.1.2/0464	2021/03/02	CO-AMOXICLAV BD AUSTELL	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg	Annexure A
53/20.1.2/0465	2021/03/02	CO-AMOXICLAV BD CAMOX	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg	Annexure A
53/20.1.2/0466	2021/03/02	AVUTAN 1 000 BD	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg	Annexure A
53/22.1.4/0677	2021/03/02	ZODORAY 1 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 1,0 ug	Annexure A
53/22.1.4/0678	2021/03/02	ZODORAY 0,5 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 0,5 ug	Annexure A
53/22.1.4/0679	2021/03/02	ZODORAY 0,25 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 0,25 ug	Annexure A
53/22.1.4/0680.677	2021/03/02	CALCILOS 1 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 1,0 ug	Annexure A
53/22.1.4/0681.678	2021/03/02	CALCILOS 0,5 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 0,5 ug	Annexure A
53/22.1.4/0682.679	2021/03/02	CALCILOS 0,25 ug	CAPSULE	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS ALFACALCIDOL 0,25 ug	Annexure A
54/34/0425	2021/03/02	OCTREOTIDE TEVA 10 mg	INJECTION	TEVA PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS OCTREOTIDE ACETATE 10,0 mg	Annexure A
54/34/0426	2021/03/02	OCTREOTIDE TEVA 20 mg	INJECTION	TEVA PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS OCTREOTIDE ACETATE 20,0 mg	Annexure A
54/34/0427	2021/03/02	OCTREOTIDE TEVA 30 mg	INJECTION	TEVA PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS OCTREOTIDE ACETATE 30,0 mg	Annexure A
15/3.1.2.2/05	2021/03/09	INFLACAM 330 mg/SACHET	GRANULES	VIRBAC RSA (PTY) LTD	EACH SACHET CONTAINS MELOXICAM 330,0 mg	Annexure A
17/17.1.4/06	2021/03/09	DRAXXIN 25	INJECTION	ZOETIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TULATHROMYCIN 25,0 mg	Annexure A
54/26/0265	2021/03/09	TANICEP 500	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 500,0 mg	Annexure A
54/26/0266.265	2021/03/09	BINECAP 500	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 500,0 mg	Annexure A

54/26/0267.265	2021/03/09	CAPTERO 500	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 500,0 mg	Annexure A
54.20.2.8/0407	2021/03/16	DOVIPSA	TABLET	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg AND LAMIVUDINE 300,0 mg	Annexure A
54/1.2/0589	2021/03/16	DULOXETINE MR 30 UNICORN	CAPSULE	UNICORN PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE 30,0 mg	Annexure A
54/1.2/0590	2021/03/16	DULOXETINE MR 60 UNICORN	CAPSULE	UNICORN PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE 60,0 mg	Annexure A
54/20.2.3/0655	2021/03/16	PRETOMANID MYLAN	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS PRETOMANID 200,0 mg	Annexure A
54/20.2.3/0656.655	2021/03/16	MYPRETO	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS PRETOMANID 200,0 mg	Annexure A
54/20.2.3/0657.655	2021/03/16	PRETAMYL	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS PRETOMANID 200,0 mg	Annexure A
54/20.2.8/0377	2021/03/30	RITOVAZ	TABLET	RANBAXY PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ATAZANAVIR 300,0 mg AND RITONAVIR 100,0 mg	Annexure A
55/26/0297	2021/03/30	IMBRUVICA 140	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS IBRUTINIB 140,0 mg	Annexure A
55/26/0298	2021/03/30	IMBRUVICA 280	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS IBRUTINIB 280,0 mg	Annexure A
55/26/0299	2021/03/30	IMBRUVICA 420	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS IBRUTINIB 420,0 mg	Annexure A
55/26/0300	2021/03/30	IMBRUVICA 560	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS IBRUTINIB 560,0 mg	Annexure A
53/21.2/0227	2021/03/30	METFORMIN TEVA ER 500	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
53/21.2/0228	2021/03/30	METFORMIN TEVA ER 750	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg	Annexure A
53/21.2/0229	2021/03/30	METFORMIN TEVA ER 1000	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
54/34/0338	2021/03/30	FINGOLIMOD ALKEM	CAPSULE	ALKEM LABORATORIES (PTY) LTD	EACH CAPSULE CONTAINS FINGOLIMOD 0,5 mg	Annexure A
54/34/0339.338	2021/03/30	FINKEM	CAPSULE	ALKEM LABORATORIES (PTY) LTD	EACH CAPSULE CONTAINS FINGOLIMOD 0,5 mg	Annexure A
55/30.5/0849	2021/03/30	JANSSEN COVID-19 VACCINE	INJECTION	JANSSEN PHARMACEUTICA (PTY) LTD	EACH 0,5 ml DOSE CONTAINS Ad26.COV2.S, RECOMBINANT 5 x 10 ¹⁰ VIRUS PARTICLES	Annexure B

ANNEXURE A

CONDITIONS OF REGISTRATIONS

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.

ANNEXURE B

CONDITIONS OF REGISTRATION

1. That the vaccine be supplied in accordance with the NDoH Covid -19 vaccination plan.
2. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
3. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The product may be advertised to the professions only.
7. The submitted PI and PIL is in global format and has been provisionally accepted, however the PI and PIL should be aligned with the South African labelling requirements and be compliant with the requirements of the Legal Metrology Act, 2014. This update should be provided within 12 months from the date of approval.
8. Risk Management Plan: The reporting of suspected adverse effects should be according to SAHPRA guidelines and in line with the applicant's risk management plan (RMP). The applicant should submit a RMP that addresses the South African Pharmacovigilance Procedures and South African specific COVID-19 risks. This RMP should be submitted within 90 days from the date of regulatory approval, these should include:
 - epidemiology of COVID-19 in South Africa,
 - persons living with HIV,
 - persons with tuberculosis,
 - and the efficacy of the vaccine in populations exposed to SARS-CoV-2 variants, particularly 501Y.V2.
 The RMP should also have a protocol indicating how breakthrough infections will be detected, investigated and reported.

9. The applicant should provide Periodic Safety Update Reports as per the SAHPRA guidelines. The applicant should submit the first PSUR within 6 months of registration. The applicant shall conform to all pharmacovigilance activities specified in the updated RMP that has been accepted by SAHPRA.
10. The applicant must inform SAHPRA of any correspondence pertaining to the quality, safety and efficacy of the vaccine that is submitted to, or is a response to, queries raised by the EMA or other African Regulatory Authorities.
11. The applicant must inform SAHPRA on the company's response, as they become available, to the list of recommendations included in the CHMP Assessment Report dated 11 March 2021.
12. The applicant must promptly provide to SAHPRA any further data from studies, recommendations or guidance that is generated by them, or which otherwise come into their possession, which is relevant to the risk / benefit profile of the product and/or is relevant to the conditions of use.
13. All vaccine lots (imported and locally manufactured) destined for the South African market is subject to lot release by the South African National Control Laboratory. General guidance for lot release is provided in the Lot Release Guideline for COVID –19 Vaccines available on the SAHPRA website.
14. The applicant is to submit the latest product quality review for the vaccine as it becomes available.
15. Shelf life and stability:
 - a.) Module 3.2.S: Active Substance
A provisional 24-months shelf life is approved for the Active substance for storage at -80 (-5/+10) °C to -50 (+/-10) °C in sterile (gamma irradiated) 10 L polycarbonate bottles, each fitted with a silicone stopper assembly and polycarbonate dip tube. Applicant must inform SAHPRA if an out-of-specification is observed for any shelf-life parameter of the 7 batches currently on stability. Stability data updates must be submitted on a 6-monthly basis until the 24 months provisional shelf life for the active substance has been confirmed.
 - b.) Module 3.2.P: Final Product
A provisional 24-months shelf life for the product filled into Type I glass vials with grey chlorobutyl rubber stoppers and sealed with aluminium flip-off seals for storage at -25°C to -15°C, with a 3 months storage period at 2 to 8 °C during its long-term shelf life after which it must be discarded, is approved. Applicant must submit stability data on batches that are currently in the ongoing stability program and must inform the SAHPRA if an out-of-specification is observed for any of the batches on long term stability. Stability data updates must be submitted on a 6-monthly basis until the 24 months provisional shelf life for the final product has been confirmed.
16. As the rolling submissions were not aligned with the ZA CTD format requirements, the applicant is required to provide an update of the product submission to ZA CTD format. This is subject to review within 12 months of the conditional registration

DEPARTMENT OF JUSTICE AND CONSTITUTIONAL DEVELOPMENT

NO. R. 680

6 August 2021

LEGAL AID SOUTH AFRICA ACT, 2014: AMENDMENT OF REGULATIONS

The Minister of Justice and Correctional Services has, under section 23(1) of the Legal Aid South Africa Act, 2014 (Act No. 39 of 2014), after receipt of recommendations of the Board of Directors of Legal Aid South Africa, made the regulations in the Schedule.

SCHEDULE**Definitions**

1. In this Schedule, the "Regulations" means the regulations published under Government Notice No. R. 745 of 26 July 2017, as amended by Government Notice No. R. 498 of 29 March 2019.

Amendment of regulation 9 of Regulations

2. Regulation 9 of the Regulations is hereby amended—
- (a) by the substitution in subregulation (1) for the words preceding paragraph (a) of the following words:
“(1) Legal Aid South Africa may grant legal aid to a litigant in any civil matter, with or without a waiting period, where—”; and
- (b) by the addition after subregulation (5) of the following subregulation:
“(6) In the event that a waiting period referred to in subregulation (1) is applied, Legal Aid South Africa must prioritise civil matters which have a significant impact on clients’ lives, including, but not limited to, the following matters:
(a) Civil proceedings involving children;
(b) evictions;
(c) social security matters;
(d) educational matters; and
(e) income related matters, such as employment or dismissals, pension and related funds and maintenance.”.

Amendment of regulation 11 of Regulations

3. Regulation 11 of the Regulations is hereby amended by the substitution for subregulation (3) of the following subregulation:
“(3) Subject to regulation 23(8), legal aid may not be granted for any action that can be brought in a small claims court in terms of the Small Claims Courts Act, 1984 (Act No. 61 of 1984): Provided that Legal Aid South Africa may grant legal aid for a claim that exceeds the monetary jurisdiction of the small claims court by more than 50 percent.”.

Amendment of regulation 13 of Regulations

4. Regulation 13 of the Regulations is hereby amended—
- (a) by the substitution for subregulation (1) of the following subregulation:
“(1) In a maintenance case in terms of the Maintenance Act, 1998 (Act No. 99 of 1998), a domestic violence case in terms of the Domestic Violence Act, 1998 (Act No. 116 of 1998), or a matter brought in terms of the Protection from Harassment Act, 2011 (Act No. 17 of 2011), Legal Aid South Africa may grant legal aid to a legal aid applicant for an initial consultation to advise him or her on his or her rights, the procedure he or she can follow and his or her prospects of success.”; and
- (b) by the substitution for subregulation (2) of the following subregulation:
“(2) Legal aid may be granted for legal representation in a court hearing for matters referred to in subregulation (1), if—
(a) in the opinion of Legal Aid South Africa, the legal aid applicant's claim or defence has good prospects of success; and
(b) the—
(i) opposing party is represented by a legal practitioner or is a legal practitioner;
or
(ii) the legal aid applicant is over 60 years of age or disabled.”.

Amendment of regulation 14 of Regulations

5. Regulation 14 of the Regulations is hereby amended by the substitution in subregulation (1) for paragraph (c) of the following paragraph:

- “(c) assistance to enforce an award by the Commission for Conciliation, Mediation and Arbitration established in terms of the Labour Relations Act, 1995, where the Commission for Conciliation, Mediation and Arbitration has already instructed a sheriff at its own cost and a sheriff has been unable to successfully execute, except where there is no prospect of recovery.”.

Amendment of regulation 15 of Regulations

6. Regulation 15 of the Regulations is hereby amended by the substitution for subregulation (2) of the following subregulation:

“(2) Legal Aid South Africa may not grant legal aid for the following matters:

- (a) A divorce appeal;
- (b) a divorce action if the legal aid applicant married a foreigner to enable that foreigner to obtain South African citizenship; and
- (c) a divorce action where there is—
 - (i) no allegation of domestic abuse;
 - (ii) no child, including a disabled or intellectually challenged child;
 - (iii) no immovable property as part of the joint estate;
 - (iv) no pension interest as part of the joint assets; or
 - (v) any other substantial benefit in the joint estate.”.

Amendment of regulation 23 of Regulations

7. Regulation 23 of the Regulations is hereby amended by the substitution for subregulation (8) of the following subregulation:

“(8) Legal aid may be granted to a child for a monetary claim that falls within the small claims court monetary jurisdiction where it is required to protect the best interests of that child and if substantial injustice would otherwise result.”.

Amendment of regulation 27 of Regulations

8. Regulation 27 of the Regulations is hereby amended by the addition after subregulation (6) of the following subregulation:

“(7) The amounts contemplated in subregulations (2), (3), (4), (5) and (6) will increase annually on 1 April on the basis of the Consumer Price Index, rounded off to the next 100.”.

Amendment of regulation 31 of Regulations

9. Regulation 31 of the Regulations is hereby amended—

- (a) by the substitution for subregulation (1) of the following subregulation:

“(1) If a legal aid applicant does not qualify for legal aid in terms of the means test, Legal Aid South Africa may provide partially subsidised legal aid and require from the legal aid applicant to contribute to the cost of the legal aid.”;
- (b) by the substitution in subregulation (2) for the full stop at the end of paragraph (c) of the expression “; and”; and
- (c) by the addition in subregulation (2) after paragraph (c) of the following paragraph:

“(d) whether the requirements of regulation 9(1) are met, in civil matters.”.

Amendment of regulation 32 of Regulations

10. Regulation 32 of the Regulations is hereby amended—

- (a) by the substitution in subregulation (1) for paragraphs (b) and (c) of the following paragraphs:
 - “(b) cessation of the criminal trial;
 - (c) the accused is convicted and sentenced to direct imprisonment; or”;and
- (b) by the addition after paragraph (c) of the following paragraph:

“(d) the finalisation of a civil matter.”.

**TSEBISO YA MMUSO
LEFAPHA LA TOKA LE NTSHETSOPELE YA MOLAO THEO**

THUSO YA MOLAO AFRIKA BORWA, 2014 (MOLAO 39 WA 2014): MELAO

Letona la Toka le Ditshebeletso tsa Tlhabollo ya batshwaruwa le entse melao Shejuleng ka tlasa karolo 23(1) ya Thuso ya Molao Afrika Borwa, 2014 (Molao 39 wa 2014), ka mora ho fumana dikgothaletso tsa Balaodi ba Lekgotla.

SHEJULE

Ditlhaloso

1. Shejuleng sena, "Melao" e hlalosa melao e phatlaladitsweng ka tlasa Tsebiso ya Mmuso Palo. R. 745 ya la 26 Phupu 2017, jwalo ka ha e lokisitswe ka Tsebiso ya Mmuso ya Palo. R. 498 ya la 29 Hlakubele 2019.

Tokiso ya molao 9 ho Melao

2. Molao 9 ho Melao o lokisitswe—

(a) ka phetolo ho molawana (1) bakeng la mantswe a etelletseng pele temana (a) ya mantswe a latelang:

"(1) Thuso ya Molao Afrika Borwa e ka nehelana ka thusa ya molao ho motletlebi nyeweng e nngwe le e nngwe ya baahi, ka, kapa ntle le nako ya kemo, moo—"; le

(b) ka ho kenngwa ka mora molawana (5) ya molawana o latelang:

"(6) Ha ho ka etsahala hore nako ya ho ema e hlalositsweng molawaneng (1) e kenngwe tshebetsong, Thuso ya Molao Afrika Borwa e tshwanetse ho nka dintlha tsa baahi tse nang le sekgahla se sehlo maphelong a bathusuwa e le tsa bohlokwa, ho akga ka hare dintlha tse latelang:

(a) Dinyewe tsa baahi tse akgang bana;

(b) ho ntshwa;

(c) dintlha tsa tshireletso ya baahi;

(d) dintlha tsa thuto: le

(e) dintlha tsa lekeno, jwalo ka mosebetsi kapa ho lelekwa, phenshene le ditjhelete tse amehang le tlhokome."

Tokiso ya molao 11 ho Melao

3. Molao 11 ho Melao e lokisitswe ka phetolo molawaneng (3) ho melao e latelang:

"(3) Ho ipapisitswe le molao 23(8), thuso ya molao e ka se nehelwe bakeng la ketso e nngwe le e nngwe e ka tlišwang lekgotleng la ditleleimi tse nyane ho latela *Small Claims Courts Act, 1984 (Act No. 61 of 1984)*: Ha feela Thuso ya Molao Afrika Borwa e ka nehelana ka thuso ya molao bakeng la tleleimi e fetang matla a tjelete ya lekgotla la dinyewe la ditleleimi tse nyane ka diperesente tse fetang 50."

Tokiso ya molao 13 ho Melao

4. Molao 13 ho Melao o lokisitswe—

(a) ka phetolo bakeng la molawana (1) ya molawana o latelang:

"(1) Nyeweng ya tlhokomelo ho latela *Maintenance Act, 1998 (Act No. 99 of 1998)*, nyeweng ya dikgoka tsa ka lapeng ho latela *Domestic Violence Act, 1998 (Act No. 116 of 1998)*, kapa ntlha e tlesitsweng ho latela *Protection from Harassment Act, 2011 (Act No. 17 of 2011)*, Thuso ya Molao Afrika Borwa e ka nehelana ka thuso ya molao ho mokopi wa thuso ya molao bakeng la kopano ya pele ho ka mo eletsa ka ditokelo tsa hae, tsamaiso eo a tshwanetseng ho e latela le kgonahalo ya hae ya tlhoko."; le

(b) ka phetolo bakeng la molawana (2) ho molawana o latelang:

"(2) Thuso ya molao e ka nehelwa bakeng la kemedi ya molao ho mamelweng ha lekgotla la dinyewe ho dintlha tse hlalositsweng ho molawana (1), e bang—

(a) ho ya ka mohopolo wa Thuso ya Molao Afrika Borwa, tleleimi kapa boitshireletso ba mokopi wa thuso ya molao e na le kgonahalo e ntle ya tlhoko;

(b) le—

- (i) ya kgahlano ya emetsweng ke mosebeletsi wa molao kapa e le mosebeletsi wa molao;
- (ii) mokopi wa thuso ya molao a le dilemo tse ka hodimo ho dilemo tse 60 kapa a na le boqhwala.”.

Tokiso ya molao 14 ho Melao

5. Molao 14 ya Melao e fetotswe ka phetolo ho molawana (1) bakeng la temana (c) ka temana e latelang:

- “(c) thuso bakeng la ho kenya tshebetsong sephetho sa Khomishene ya Poelano le Bonamodi e theuweng ho latela Molao wa Basebetsi wa 1995, moo Khomishene ya Poelano le Bonamodi e seng e laetse sherifi ka ditjeho tsa yona mme sherifi e sa kgona ho ka atleha tshebetsong ya hae, ntle le moo ho senang kgonahalo ya phumaneho.”.

Tokiso ya molao 15 ho Melao

6. Molao 15 ho Melao e lokisitswe ka phetolo bakeng la molawana (2) wa molawana o latelang:

- “(2) Thuso ya Molao Afrika Borwa e ka se nehelane ka thuso ya molao bakeng la dintlha tse latelang:
 - (a) boipiletso tlhalanong;
 - (b) nyewe ya tlhalano e bang mokopi wa thuso ya molao a nyalane le molata hore molata eo a fumane boahi ba Afrika Borwa; le
 - (c) tlhalano moo—
 - (i) ho senang tlhekefetso ya ka lapeng;
 - (ii) ho senang ngwana, ho akga ngwana wa seqhwalwa kapa ya nang le bothata ba kelelle;
 - (iii) ho senang thepa e sa sutheng e le karolo ya thepa ya kopanelo;
 - (iv) ho senang kgahleho ya phenshene e le karolo ya kopanelo ya thepa; kapa
 - (v) kuno e nngwe le enngwe e kgolo kopanelong ya thepa.”.

Tokiso ya molao 23 ho Melao

7. Molao 23 ho Melao o lokisitswe ka phetolo bakeng la molawana (8) ho molawana o latelang:

- “(8) Thuso ya molao e ka nehelwa ho ngwana bakeng la tleleimi ya tjelete e welang ka tlasa matla a tjelete a lekgotla la dinyewe la ditleleimi tse nyane moo ho hlokalang ho sireletsa dikgahleho tsa ngwana eo mme toka e ka be e sa phethahala.”.

Tokiso ya molao 27 ho Melao

8. Molao 27 o lokisitswe ka ho kenngwa ha molawana o latelang ka mora molawana (6):
 “(7) Palo e hlalositse molawaneng (2), (3), (4), (5) le (6) e tla eketseha selemo le selemo ka la 1 Mmesa ka lebaka la Tshupane ya Theko ya Bareki, e akareditsweng ho 100 le latelang.”.

Tokiso ya molao 31 ho Melao

9. Molao 31 ho Melao e lokisitswe—

- (a) ka phetolo bakeng la molawana (1) wa molawana o latelang:
 - “(1) E bang mokopi wa thuso ya molao a sa dumellesehe ho ka thuswa ho latela teko e etswang, Thuso ya Molao Afrika Borwa e ka nehelana ka thuso e sa fellang ya molao mme e kope mokopi wa thuso ya molao ho kaba le seabo ditjehong tsa thuso ya molao.”;
- (b) ka phetolo ho molawana (2) bakeng la kgutlo qetellong ya temana (c) ho polelwana “; le”; le
- (c) ka ho kenngwa ha molawana (2) ka mora temana (c) ka temana e latelang:
 - “(d) hore na ditlhoko tsa molao 9(1) di fihletswe, dinyeweng tsa baahi.”.

Tokiso ya molao 32 ho Melao

10. Molao 32 ho Melao e lokisitswe—

- (a) ka phetolo ho molawana (1) bakeng la temana (b) le (c) tsa ditemana tse latelang:
 - “(b) ho fediswa ha nyewe ya tlolo ya molao;
 - (c) moqosuwa o ahlotswe aba a kwallwa; kapa”; le
- (b) ka ho kenngwa ka mora temana (c) ya temana e latelang:
 - “(d) phethelo nyeweng tsa baahi.”.

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