

Government Gazette Staatskoerant REPUBLIC OF SOUTH AFRICA

REPUBLIEK VAN SUID AFRIKA

Regulation Gazette No. 11350 Regulasiekoerant

Vol. 676 15 October 2021 No. 45314

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





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.

Contents

No.

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

Health, Department of / Gesondheid, Departement van

R. 1032 Medicines and Related Substances Act, 1965 (Act No. 101 of 1965): Publishing of Notice of Registrations in the Gazette 45314 13



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.

OB

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 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, Prov	incial - Variable Priced No	tices
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.

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
Extraordinary Gazettes	As required	Any day of the week	Before 10h00 on publication date	Before 10h00 on publication date
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 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.
- 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.

- 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.
- 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.

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 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.

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.

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.
- 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:Postal Address:GPW Banking Details:Government Printing WorksPrivate Bag X85Bank: ABSA Bosman Street149 Bosman StreetPretoriaAccount No.: 405 7114 016Pretoria0001Branch Code: 632-005

For Gazette and Notice submissions: Gazette Submissions: E-mail: submit.egazette@gpw.gov.za
For queries and quotations, contact: Gazette Contact Centre: 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

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 1032 15 October 2021

200	Product name	Dosage form	Applicant	API	Conditions of Registrations
2021/04/06	CONVULEX IV	INJECTION	TAKEDA (PTY) LTD	EACH 1,0 ml CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
2021/04/13	RUMATOR 30 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
2021/04/13	RUMATOR 60 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
2021/04/13	RUMATOR 90 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
2021/04/13	RUMATOR 120 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
2021/04/13	REPOFEM 30	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
2021/04/13	REPOFEM 60	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
2021/04/13	REPOFEM 90	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
2021/04/13	REPOFEM 120	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
2021/04/13	OSTEORIX 30 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
2021/04/13	OSTEORIX 60 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
2021/04/13	OSTEORIX 90 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
2021/04/13	OSTEORIX 120 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
2021/04/06	VIDALTA 10 mg	TABLET	INTERVET SA (PTY) LTD	EACH TABLET CONTAINS CARBIMAZOLE 10,0 mg	Annexure A
2021/04/06	VIDALTA 15 mg	TABLET	INTERVET SA (PTY) LTD	EACH TABLET CONTAINS CARBIMAZOLE 15,0 mg	Annexure A
2021/04/06	KIENDRA 0,25	TABLET	SANDOZ SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS SIPONIMOD 0,25 mg	Annexure A
2021/04/06	KIENDRA 2	TABLET	SANDOZ SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS SIPONIMOD 2,0 mg	Annexure A
2021/04/20	ERADIA	ORAL	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS METRONIDAZOLE 125,0 mg	Annexure A
2021/04/20	CUROCEF DUO	INJECTION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SUSPENSION CONTAINS CEFTIOFUR 50,0 mg KETOPROFEN 150,0 mg	Annexure A
2021/04/28	TILOMIA 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
2021/04/28	TASICAP 150	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 150,0 mg	Annexure A
2021/04/28	TASICAP 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
2021/04/28	TASILEUK 150	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 150,0 mg	Annexure A
2021/04/28	TASILEUK 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
2021/04/28	VALOMA 1	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 1,0 mg	Annexure A
2021/04/28	VALOMA 2,5	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 2,5 mg	Annexure A
2021/04/28	VALOMA 3,5	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
2021/05/04	STAQUIS	OINTMENT	PFIZER LABORATORIES (PTY) LTD	EACH 1,0 g OINTMENT CONTAINS CRISABOROLE 20,0 mg	Annexure A
2021/05/04	ALKOZID	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
2021/05/04	LINOKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
2021/05/04	LINEZOLID ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
2021/05/11	SEDOLAM 50	INJECTION	WILDLIFE PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS MIDAZOLAM 50,0 mg	Annexure A
2021/05/11	ENERZAIR BREEZHALER 150/50/80	INHALER	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 80,0 ug	Annexure A
	ENERZAIR BREEZHALER		ATT LYMM AND A THE LOCAL PROPERTY.	EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug	Accessor

Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A
EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM SO,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 80,0 ug	EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM SO,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 160,0 ug	EACH TABLETS CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 100,0 mg	EACH TABLETS CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 400,0 mg	EACH TABLET CONTAINS DEXKETOPROFEN 25,0 mg TRAMADOL HYDROCHLORIDE 75,0 mg	EACH TABLET CONTAINS DEXKETOPROFEN 25,0 mg TRAMADOL HYDROCHLORIDE 75,0 mg	EACH TABLET CONTAINS LINEZOLID 600,0 mg	EACH TABLET CONTAINS LINEZOLID 600,0 mg	EACH TABLET CONTAINS LINEZOLID 600,0 mg	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg	EACH 0,5 ml SOLUTION CONTAINS OMALIZUMAB 75,0 mg	EACH 1,0 mI SOLUTION CONTAINS OMALIZUMAB 150,0 mg	EACH CAPSULE CONTAINS VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 20,0 mg	EACH CAPSULE CONTAINS VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 30,0 mg	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	EACH TABLET CONTAINS DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 50,0 mg	EACH TABLET CONTAINS DESVENIAFAXINE SUCCINATE EQUIVALENT TO DESVENIAFAXINE 100,0 mg	EACH 2,0 ml SOLUTION CONTAINS DEXKETOPROFEN 50,0 mg	EACH 2,0 ml SOLUTION CONTAINS DEXKETOPROFEN 50,0 mg	EACH CAPSULE CONTAINS DUTASTERIDE 0,5 mg	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE 5,0 mg	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE 10,0 mg	EACH TABLET CONTAINS RUPATADINE 10.0 mg
NOVARTIS SOUTH AFRICA (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD	ADCOCK INGRAM CRITICAL CARE (PTY) LTD	ADCOCK INGRAM CRITICAL CARE (PTY) LTD	LEBASI PHARMACEUTICALS CC	LEBASI PHARMACEUTICALS CC	MYLAN (PTY) LTD	MYLAN (PTY) LTD	MYLAN (PTY) LTD	CIPLA MEDPRO (PTY) LTD	CIPLA MEDPRO (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD	EUROLAB (PTY) LTD	EUROLAB (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	CIPLA MEDPRO (PTY) LTD	CIPLA MEDPRO (PTY) LTD	LEBASI PHARMACEUTICALS CC	LEBASI PHARMACEUTICALS CC	ZYDUS HEALTHCARE S.A. (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	IPHARMA (PTY) LTD	IPHARMA (PTY) LTD	DHARMA-O (PTI (VTG) O-DHARMA-O			
INHALER	INHALER	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	INJECTION	INJECTION	CAPSULES	CAPSULES	TABLET	TABLET	TABLET	TABLET	TABLET	INJECTION	INJECTION	CAPSULES	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	TARIFT
ZIMBUS BREEZHALER 150/50/80	ZIMBUS BREEZHALER 150/50/160	IMATINIB 100 mg ADCO	IMATINIB 400 mg ADCO	SKUDEXA	LENIZAK	LISOLVID	LINEZOLID MYLAN 600 mg	LIDOMYL	DALVUTIN	LOMIDA	XOLAIR 75 mg/0,5 ml	XOLAIR 150 mg/1,0 ml	NAVILIN 20	NAVILIN 30	RIVAROXABAN TEVA 10	RIVAROXABAN TEVA 15	RIVAROXABAN TEVA 20	DEPVEN 50 XL	DEPVEN 100 XL	KETESSE 50 mg/2 ml	KERAL 50 mg/2 ml	ZEDRAST	COXETORI 30	COXETORI 60	COXETORI 90	COXETORI 120	SOLIREST 5	SOLIREST 10	7FALARGY
2021/05/11	2021/05/11	2021/05/18	2021/05/18	2021/05/18	2021/05/18	2021/05/18	2021/05/18	2021/05/18	2021/05/25	2021/05/25	2021/05/25	2021/05/25	2021/06/08	2021/06/08	2021/06/15	2021/06/15	2021/06/15	2021/06/15	2021/06/15	2021/06/15	2021/06/15	2021/06/15	2021/06/22	2021/06/22	2021/06/22	2021/06/22	2021/06/22	2021/06/22	2021/06/22
54/10.2.1/0875.873	54/10.2.1/0876.874	53/34/0187	53/34/0188	54/2.8/0538	54/2.8/0539.538	54/20.1.1/0754	54/20.1.1/0755.754	54/20.1.1/0756.754	54/20.2.8/0641	54/20.2.8/0642.641	-	55/34/0714	53/26/0743	53/26/0744	54/8.2/0417	54/8.2/0418	54/8.2/0419	53/1.2/0048	53/1.2/0049	54/2.7/0534	54/2.7/0535.534	54/21.12/0491	50/3.1/0756	50/3.1/0757	50/3.1/0758	50/3.1/0759	55/5.4/0028	55/5.4/0029	54/5.7.1/0789

SYNGLUTRA 5/500	TABLET CIP	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 500,0 mg FACH TARIFT CONTAINS DAPAGLIFLOZIN PROPRANEDIOL	Annexure A
TABLET	CIP	CIPLA MEDPRO (PTY) LTD	EACH TABLET CON AINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
TABLET	CIPI	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
TABLET	CIPI	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
TABLET	CIPI	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
TABLET	CIPI	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 500.0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
TABLET	AUF	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2.5 mg	Annexure A
TABLET	AUF	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2,5 mg	Annexure A
TABLET	AUF	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2,5 mg	Annexure A
CAPSULES		AUSTELL PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250,0 mg	Annexure A
CAPSULES		AUSTELL PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250.0 mg	Annexure A
TABLET	PHA	PHARMA DYNAMICS (PTY) LTD	EACH TABLET CONTAINS VENLAFAXINE 300,0 mg	Annexure A
TABLET	TEV	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ABIRATERONE 250,0 mg	Annexure A
TABLET		CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
TABLET	CIPL	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
TABLET		CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10.0 mg	Annexure A
			EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE	

	LA 20	VORTIOXETINE CIPLA 20 KETESSE 25 mg KERAL 25 mg
GILEAD SCIENCES SOUTH AFRICA (PTY)	IABLE	POWDER FOR INFUSION
Z	Z	INFUSION
TABLET MYLAN (PTY) LTD		
TABLET MYLAN (PTY) LTD	TABLET MYLAN (PTY) I	
TABLET MYLAN (PTY) LTD		
TABLET MYLAN (PTY) LTD		
TABLET MSD (PTY) LTD		
TABLET CIPLA MEDPRO (PTY) LTD		
TABLET CIPLA MEDPRO (PTY) LTD		
TABLET CIPLA MEDPRO (PTY) LTD	TABLET	
TABLET CIPLA MEDPRO (PTY) LTD	TABLET	IN CIPLA 10 TABLET
		INJECTION
INJECTION SANDOZ SOUTH AFRICA (PTY) LTD	INJECTION	INJECTION
ORAL SOLUTION HUVEPHARMA SOUTH AFRICA (PTY) LTD	ORAL SOLUTION	NOI
TABLET AUSTELL PHARMACEUTICALS (PTY) LTD		
TABLET RANBAXY PHARMACEUTICALS (PTY) LTD		CO TABLET
TABLET CIPLA MEDPRO (PTY) LTD		D TABLET
TABLET CIPLA MEDPRO (PTY) LTD		
EYEDROPS PHARMACARE LIMITED		
POWDER CIPLA MEDPRO (PTY) LTD		
POWDER CIPLA MEDPRO (PTY) LTD		
INJECTION GE HEALTHCARE (PTY) LTD		

Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A	Annexure A
EACH 1,0 ml SOLUTION CONTAINS ENROFLOXACIN 50,0 mg	EACH 1,0 ml SOLUTION CONTAINS ENROFLOXACIN 100,0 mg	EACH VIAL CONTAINS AVIBACTAM SODIUM EQUIVALENT TO AVIBACTAM 0,5 g CETTAZIDIME 2,0 g	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 5,0 mg	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg	EACH PRE-FILLED SYRINGE CONTAINS OFATUMUMAB 20,0 mg	EACH TABLET CONTAINS RASAGLINE TARTRATE 1,0 mg	EACH 1,0 ml SOLUTION CONTAINS CICLOSPORIN 100,0 mg
AFRIVET BUSINESS MANAGEMENT (PTY) LTD	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	PFIZER LABORATORIES (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	TEVA PHARMACEUTICALS (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD	ADCOCK INGRAM LIMITED	VIRBAC RSA (PTY) LTD
INJECTION	INJECTION	INFUSION	TABLET	TABLET	TABLET	TABLET	INJECTION	TABLET	SOLUTION
AFROXIN 5 %	AFROXIN 10 %	ZAVICEFTA 2 g/0,5 g	CRUVOR 5	CRUVOR 10	CRUVOR 20	2021/09/21 CRUVOR 40	BONSPRI	RASAPAR	2021/09/28 CYCLAVANCE
2021/09/21	2021/09/21	2021/09/21	2021/09/21	2021/09/21	2021/09/21	2021/09/21	2021/09/28 BONSPRI	2021/09/28	2021/09/28
14/17.1.6/12	14/17.1.6/13	53/20.1.1/0060	53/7.5/0268	53/7.5/0269	53/7.5/0270	53/7.5/0271	55/32.16/0368	54/5.4.1/0701	20/21/05

ANNEXURE A

CONDITIONS OF REGISTRATIONS

- The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
- 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. 5
 - The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA. 'n
- The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended.

4.

- 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 5
- 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 9
- 7. The product may be advertised to the professions only.

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001 Contact Centre Tel: 012-748 6200. eMail: info.egazette@gpw.gov.za Publications: Tel: (012) 748 6053, 748 6061, 748 6065