



# Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA  
REPUBLIEK VAN SUID AFRIKA

*Regulation Gazette*

**No. 11617**

*Regulasiekoerant*

Vol. 699

1

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

**IMPORTANT NOTICE:**

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

**Contents**

<i>No.</i>		<i>Gazette No.</i>	<i>Page No.</i>
<b>GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS</b>			
<b>Health, Department of / Gesondheid, Departement van</b>			
R. 3829	Medicines and Related Substance Act, 1965 (Act No. 101 of 1965), as amended: Notification of registration of medicines in terms of section 17 of the Act, as amended.....	49217	13
<b>PROCLAMATIONS • PROKLAMASIES</b>			
<b>Justice and Constitutional Development, Department of / Justisie en Staatkundige Ontwikkeling, Departement van</b>			
R. 136	Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of 1996): Referral of matters to existing Special Investigating Unit: Gauteng Department of Health and its Provincial Hospital in Tembisa.....	49217	24
R. 136	Wet op Spesiale Ondersoekenhede en Spesiale Tribunale, 1996 (Wet No. 74 van 1996): Verwysing van aangeleenthede na bestaande Spesiale Ondersoekenhede: Gauteng Departement van Gesondheid en sy Provinsiale Hospitaal in Tembisa.....	49217	26



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](mailto: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](mailto:@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](http://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](mailto:Annamarie.DuToit@gpw.gov.za)

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

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

# Closing times for **ORDINARY WEEKLY** **REGULATION GAZETTE** **2023**

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

- **29 December**, Thursday for the issue of Friday **06 January 2023**
- **06 January**, Friday for the issue of Friday **13 January 2023**
- **13 January**, Friday for the issue of Friday **20 January 2023**
- **20 January**, Friday for the issue of Friday **27 January 2023**
- **27 January**, Friday for the issue of Friday **03 February 2023**
- **03 February**, Friday for the issue of Friday **10 February 2023**
- **10 February**, Friday for the issue of Friday **17 February 2023**
- **17 February**, Friday for the issue of Friday **24 February 2023**
- **24 February**, Friday for the issue of Friday **03 March 2023**
- **03 March**, Friday for the issue of Friday **10 March 2023**
- **10 March**, Friday for the issue of Friday **17 March 2023**
- **16 March**, Thursday for the issue of Friday **24 March 2023**
- **24 March**, Friday for the issue of Friday **31 March 2023**
- **30 March**, Thursday for the issue of Thursday **06 April 2023**
- **05 April**, Wednesday for the issue of Friday **14 April 2023**
- **14 April**, Friday for the issue of Friday **21 April 2023**
- **20 April**, Thursday for the issue of Friday **28 April 2023**
- **26 April**, Wednesday for the issue of Friday **05 May 2023**
- **05 May**, Friday for the issue of Friday **12 May 2023**
- **12 May**, Friday for the issue of Friday **19 May 2023**
- **19 May**, Friday for the issue of Friday **26 May 2023**
- **26 May**, Friday for the issue of Friday **02 June 2023**
- **02 June**, Friday for the issue of Friday **09 June 2023**
- **08 June**, Thursday for the issue of Thursday **15 June 2023**
- **15 June**, Thursday for the issue of Friday **23 June 2023**
- **23 June**, Friday for the issue of Friday **30 June 2023**
- **30 June**, Friday for the issue of Friday **07 July 2023**
- **07 July**, Friday for the issue of Friday **14 July 2023**
- **14 July**, Friday for the issue of Friday **21 July 2023**
- **21 July**, Friday for the issue of Friday **28 July 2023**
- **28 July**, Friday for the issue of Friday **04 August 2023**
- **03 August**, Thursday for the issue of Friday **11 August 2023**
- **11 August**, Friday for the issue of Friday **18 August 2023**
- **18 August**, Friday for the issue of Friday **25 August 2023**
- **25 August**, Friday for the issue of Friday **01 September 2023**
- **01 September**, Friday for the issue of Friday **08 September 2023**
- **08 September**, Friday for the issue of Friday **15 September 2023**
- **15 September**, Friday for the issue of Friday **22 September 2023**
- **21 September**, Thursday for the issue of Friday **29 September 2023**
- **29 September**, Friday for the issue of Friday **06 October 2023**
- **06 October**, Friday for the issue of Friday **13 October 2023**
- **13 October**, Friday for the issue of Friday **20 October 2023**
- **20 October**, Friday for the issue of Friday **27 October 2023**
- **27 October**, Friday for the issue of Friday **03 November 2023**
- **03 November**, Friday for the issue of Friday **10 November 2023**
- **10 November**, Friday for the issue of Friday **17 November 2023**
- **17 November**, Friday for the issue of Friday **24 November 2023**
- **24 November**, Friday for the issue of Friday **01 December 2023**
- **01 December**, Friday for the issue of Friday **08 December 2023**
- **08 December**, Friday for the issue of Friday **15 December 2023**
- **15 December**, Friday for the issue of Friday **22 December 2023**
- **20 December**, Wednesday for the issue of Friday **29 December 2023**

# 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](http://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 <b>after</b> 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 <b>after</b> submission deadline
Northern Cape Liquor License Gazette	Monthly	First Friday of the month	Two weeks before publication	3 working days <b>after</b> submission deadline
National Liquor License Gazette	Monthly	First Friday of the month	Two weeks before publication	3 working days <b>after</b> 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](http://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](mailto: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](mailto: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](mailto: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](http://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](mailto:submit.egazette@gpw.gov.za)
**E-mail:** [info.egazette@gpw.gov.za](mailto:info.egazette@gpw.gov.za)
**Tel:** 012-748 6200

**Contact person for subscribers:** Mrs M. Toka:

**E-mail:** [subscriptions@gpw.gov.za](mailto:subscriptions@gpw.gov.za)
**Tel:** 012-748-6066 / 6060 / 6058

**Fax:** 012-323-9574

## GOVERNMENT NOTICES • GOEWERMENSKENNISGEWINGS

## DEPARTMENT OF HEALTH

NO. R. 3829

1 September 2023

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

Registration Number	Registration Date	Product Name	Dosage Form	Applicant Name	Ingredients	Conditions for Registration
55/8.2/0143.140	2023/04/04	AXOLTA 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0144.141	2023/04/04	AXOLTA 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0145.142	2023/04/04	AXOLTA 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/3.3/0784	2023/04/04	COLNOVA 0,5	Tablet	Novagen Pharma (Pty) Ltd	EACH TABLET CONTAINS COLCHICINE 0,5 mg	Annexure A
56/7.1.3/1177	2023/04/04	COVENAP 10 mg	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 10,0 mg	Annexure A
56/7.1.3/1176	2023/04/04	COVENAP 5 mg	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 5,0 mg	Annexure A
55/21.1/0514.513	2023/04/04	INSULIN ASPART 100 units/ml SAMOFI	Injection	Sanofi-Aventis South Africa (Pty) Ltd	EACCH 1,0 ml SOLUTION CONTAINS INSULIN ASPART 100,0 units	Annexure A
54/10.2.1/0627	2023/04/04	LEVAlBUTEROL 0,31 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,31 mg	Annexure A
54/10.2.1/0628	2023/04/04	LEVAlBUTEROL 0,63 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,63 mg	Annexure A
54/10.2.1/0629	2023/04/04	LEVAlBUTEROL 1,25 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 1,25 mg	Annexure A
55/8.2/0716.715	2023/04/04	RABOVIX 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0715	2023/04/04	REXARAV 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
54/10.2.1/0630.627	2023/04/04	SILEA 0,31 mg/3ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,31 mg	Annexure A
54/10.2.1/0631.628	2023/04/04	SILEA 0,63 mg/3 ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,63 mg	Annexure A
54/10.2.1/0632.629	2023/04/04	SILEA 1,25 mg/3ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 1,25 mg	Annexure A
54/15.3/0408	2023/04/04	TOBROFT	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS DEXAMETHASONE 1,0 mg, TOBRAMYCIN 3,0 mg	Annexure A

55/21.1/0513	2023/04/04	TRUVELOG	Injection	Sanofi-Aventis South Africa (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS INSULIN ASPART 100,0 units	Annexure A
54/1.2/0557	2023/04/04	VORTIOXETINE 10 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
54/1.2/0558	2023/04/04	VORTIOXETINE 20 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
54/1.2/0556	2023/04/04	VORTIOXETINE 5 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
54/15.3/0409.408	2023/04/04	XAMFLAM	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1.0 ml SUSPENSION CONTAINS DEXAMETHASONE 1,0 mg TOBRAMYCIN 3,0 mg	Annexure A
55/8.2/0140	2023/04/04	XAROBAN 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0141	2023/04/04	XAROBAN 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0142	2023/04/04	XAROBAN 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/8.2/0717.715	2023/04/04	XAVIAT 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/11.10/0503	2023/04/11	ACEMISO	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 ug	Annexure A
54/21.2/0465	2023/04/11	FORTESE XR 500	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
54/21.2/0466	2023/04/11	FORTESE XR 750	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg	Annexure A
54/15.4/0388	2023/04/11	LOBIMOPT	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
54/21.2/0467.465	2023/04/11	METFORMIN XR 500 ALKEM	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0mg	Annexure A
54/21.2/0468.466	2023/04/11	METFORMIN XR 750 ALKEM	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg	Annexure A
54/15.4/0390.388	2023/04/11	TIMATEAR	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
54/15.4/0389.388	2023/04/11	TIMPROMAT	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
56/2.6.5/0059	2023/04/18	AMPERI 5 mg/ml	Injection	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS HALOPERIDOL 5,0 mg	Annexure A
55/8.2/0492.489	2023/04/18	AZIRIV 10	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0493.490	2023/04/18	AZIRIV 15	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0494.491	2023/04/18	AZIRIV 20	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A

55/32.16/0351	2023/04/18	BYDUREON BCISE	Injection	AstraZeneca Pharmaceuticals (Pty) Ltd	EACH DOSE CONTAINS EXENATIDE 2,0 mg	Annexure A
56/21.8.2/0340	2023/04/18	DIENOGEST 2 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure A
55/26/0558	2023/04/18	MELPISPAL 50	Injection	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS MELPHALAN HYDROCHLORIDE 50,0 mg	Annexure A
56/34/0213	2023/04/18	MODLIFIN 0,5 mg	Capsule	Accord Healthcare (Pty) Ltd	EACH CAPSULE CONTAINS FINGOLIMOD HYDROCHLORIDE EQUIVALENT TO FINGOLIMOD 0,5 mg	Annexure A
55/7.2/0361	2023/04/18	PHENPRESSOR 10 mg/ml	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 10,0 mg	Annexure A
55/8.2/0489	2023/04/18	RUBAROX 10	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0490	2023/04/18	RUBAROX 15	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0491	2023/04/18	RUBAROX 20	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/21.5.1/0730	2023/04/18	SERHALE 50/100	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 100,0 ug	Annexure A
55/21.5.1/0731	2023/04/18	SERHALE 50/250	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 250,0 ug	Annexure A
55/21.5.1/0732	2023/04/18	SERHALE 50/500	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 500,0 ug	Annexure A
57/20.2.3/0155	2023/04/18	UKUZID 300 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ISONIAZID 300,0 mg	Annexure A
55/2.6.5/0263	2023/04/18	QLANTRIS XR 50 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 50,0 mg	Annexure A
55/2.6.5/0264	2023/04/18	QLANTRIS XR 150 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg	Annexure A
55/2.6.5/0265	2023/04/18	QLANTRIS XR 200 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg	Annexure A
55/2.6.5/0266	2023/04/18	QLANTRIS XR 300 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg	Annexure A
55/2.6.5/0267	2023/04/18	QLANTRIS XR 400 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 400,0 mg	Annexure A
56/26/0040	2023/04/25	BORTEZOMIB EQUITY	Injection	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
54/20.2.3/0237	2023/04/25	CLOFAZIMINE TABLETS 100 mg MACLEODS	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 100,0 mg	Annexure A
54/20.2.3/0236	2023/04/25	CLOFAZIMINE TABLETS 50 mg MACLEODS	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 50,0 mg	Annexure A
55/26/0171	2023/04/25	COCITRED	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECITABINE 50,0 mg	Annexure A
53/20.1.1/0715	2023/04/25	CYTAGIL IV	Infusion	Pharma Dynamics (Pty) Ltd	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A

55/26/0173.171	2023/04/25	DARBECT	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECTABINE 50,0 mg	Annexure A
55/21.8.2/0725	2023/04/25	DIENOGEST 2 mg PHARMC	Tablet	Pharmacorp (Pty) Ltd	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure A
53/20.1.1/0716.715	2023/04/25	GATICIL IV	Infusion	Pharma Dynamics (Pty) Ltd	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A
53/7.1.3/0156	2023/04/25	LOSARTAN CO 100/12,5 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Annexure A
53/7.1.3/0157	2023/04/25	LOSARTAN CO 100/25 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Annexure A
53/7.1.3/0155	2023/04/25	LOSARTAN CO 50/12,5 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Annexure A
54/7.1.5/0035	2023/04/25	STENDRIL 100	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg	Annexure A
54/7.1.5/0826	2023/04/25	STENDRIL 25	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25,0 mg	Annexure A
54/7.1.5/0034	2023/04/25	STENDRIL 50	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 50,0 mg	Annexure A
55/26/0172.171	2023/04/25	TOCENAR	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECTABINE 50,0 mg	Annexure A
54/20.2.3/0239.237	2023/04/25	TUBRAMAK 100 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 100,0 mg	Annexure A
54/20.2.3/0238.236	2023/04/25	TUBRAMAK 50 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 50,0 mg	Annexure A
53/20.2.8/0106	2023/04/25	VIRONETO	Tablet	Strides Pharma (SA) (Pty) Ltd	EACH TABLET CONTAINS TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
55/21.12/0112	2023/05/02	ABIZISTA 250 mg	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 250,0 mg	Annexure A
55/21.12/0113	2023/05/02	ABIZISTA 500 mg	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 500,0 mg	Annexure A
53/5.7.1/0331.330	2023/05/02	ALLERBAS ALLERGY 10 mg TABLETS	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS EBASTINE 10,0 mg	Annexure A
53/5.7.1/0330	2023/05/02	EBASTINE 10 mg ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS EBASTINE 10,0 mg	Annexure A
57/20.2.3/0157	2023/05/02	FRIPNIT PLUS	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIFAPENTINE 300,0 mg ISONIAZID 300,0 mg	Annexure A
55/2.5/0553	2023/05/02	NAVILIZE 100 mg/ml (10 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
55/2.5/0551	2023/05/02	NAVILIZE 100 mg/ml (3 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
55/2.5/0552	2023/05/02	NAVILIZE 100 mg/ml (4 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
53/11.5/0673	2023/05/02	PHOLIPEG	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 13,125 g POTASSIUM CHLORIDE 0,0466 g SODIUM BICARBONATE 0,1785 g SODIUM CHLORIDE 0,3507 g	Annexure A



53/11.5/0674.673	2023/05/02	PHYGLETON	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 13,125 g POTASSIUM CHLORIDE 0,0466 g SODIUM BICARBONATE 0,1785 g SODIUM CHLORIDE 0,3507 g	Annexure A
56/26/0453	2023/05/02	RIBEND 100	Infusion	Innovata Pharmaceuticals	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100,0 mg	Annexure A
56/26/0452	2023/05/02	RIBEND 25	Infusion	Innovata Pharmaceuticals	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25,0 mg	Annexure A
56/20.2.8/0482	2023/05/02	TRIETA	Tablet	Cipla Medpro (Pty) Ltd	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL EQUIVALENT TO TENOFOVIR DISOPROXIL 245,0 mg	Annexure A
56/20.2.8/0483.482	2023/05/02	TRILEF	Tablet	Cipla Medpro (Pty) Ltd	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL EQUIVALENT TO TENOFOVIR DISOPROXIL 245,0 mg	Annexure A
55/7.5/0453	2023/05/02	CREVAS 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 15,0 mg	Annexure A
55/7.5/0454	2023/05/02	CREVAS 30 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 30,0 mg	Annexure A
56/26/0923	2023/05/09	CYCLOCORD 1 g	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS CYCLOPHOSPHAMIDE MONOHYDRATE 1,0 g	Annexure A
56/26/0922	2023/05/09	CYCLOCORD 500 mg	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS CYCLOPHOSPHAMIDE MONOHYDRATE 500,0 mg	Annexure A
55/7.5/0407	2023/05/09	LIPOCOMB 10 mg/10 mg	Capsule	Servier Laboratories South Africa (Pty) Ltd	EACH CAPSULE CONTAINS ROSUVASTATIN ZINC 10,0 mg EZETIMIBE 10,0 mg	Annexure A
55/7.5/0408	2023/05/09	LIPOCOMB 20 mg/10 mg	Capsule	Servier Laboratories South Africa (Pty) Ltd	EACH CAPSULE CONTAINS ROSUVASTATIN ZINC 20,0 mg EZETIMIBE 10,0 mg	Annexure A
55/34/0899	2023/05/09	TEMADEX 200	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 2,0 ml VIAL CONTAINS SUGAMMADEX SODIUM EQUIVALENT TO SUGAMMADEX 200,0 mg	Annexure A
55/34/0900	2023/05/09	TEMADEX 500	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 2,0 ml VIAL CONTAINS SUGAMMADEX SODIUM EQUIVALENT TO SUGAMMADEX 500,0 mg	Annexure A
55/20.1.1/0750	2023/05/09	TIGECYCLINE ADCO	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A
53/20.1.2/0153	2023/05/16	AMOXICILLIN 250 PORTFOLIO	Capsule	Portfolio Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 mg	Annexure A
53/20.1.2/0154	2023/05/16	AMOXICILLIN 500 PORTFOLIO	Capsule	Portfolio Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 500,0 mg	Annexure A
54/15.1/0202	2023/05/16	AVOXA EYE DROPS	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 5,0 mg	Annexure A
55/1.2/0106	2023/05/16	BRIVOR 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A

55/1.2/0107	2023/05/16	BRIVOR 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
55/1.2/0105	2023/05/16	BRIVOR 5 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
57/5.7.1/0264	2023/05/16	DAZIT SYRUP	Oral Solution	Ranbaxy Pharmaceutical (Pty) Ltd	EACH 5,0 ml SOLUTION CONTAINS DESLORATADINE 2,5 mg	Annexure A
56/20.2.8/0886.883	2023/05/16	DUNARID 400	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 400,0 mg	Annexure A
56/20.2.8/0888.885	2023/05/16	DUNARID 800	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 800,0 mg	Annexure A
53/20.1.1/0575.574	2023/05/16	FORURI	Oral Solution	Abex Pharmaceutica (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/3.1/0039	2023/05/16	LEXIB 100	Capsule	Ruby Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS CELECOXIB 100,0 mg	Annexure A
54/3.1/0040	2023/05/16	LEXIB 200	Capsule	Ruby Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS CELECOXIB 200,0 mg	Annexure A
53/20.1.1/0574	2023/05/16	UTICIDE	Oral Solution	Abex Pharmaceutica (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
55/34/0103	2023/05/16	VERSUDEX	Injection	Pharmcare Limited ù Woodmead	EACH 1,0 ml SOLUTION CONTAINS SUGAMMADEX OCTASODIUM 100,0 mg	Annexure A
55/1.2/0109.106	2023/05/16	VORTIOXETINE 10 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
55/1.2/0110.107	2023/05/16	VORTIOXETINE 20 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
55/1.2/0108.105	2023/05/16	VORTIOXETINE 5 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
56/20.2.8/0883	2023/05/16	VUNAD 400	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 400,0 mg	Annexure A
56/20.2.8/0885	2023/05/16	VUNAD 800	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 800,0 mg	Annexure A
55/19/0705	2023/05/16	OXYTOCIN 10 IU/ml COSPHARM	Injection	Cospharm Investments (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS OXYTOCIN 10,0 IU	Annexure A
55/5.4/0554	2023/05/16	SOLIFENACIN 5 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE EQUIVALENT TO SOLIFENACIN 5,0 mg	Annexure A
55/5.4/0555	2023/05/16	SOLIFENACIN 10 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE EQUIVALENT TO SOLIFENACIN 10,0 mg	Annexure A
55/5.7.1/0712	2023/05/23	ALLERWAY MELTAWAY 5	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS LEVOCETIRIZINE DIHYDROCHLORIDE 0,5 mg	Annexure A

55/2-11/0517.515	2023/05/23	CABREXXA 0,5	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 0,5 mg	Annexure A
55/2-11/0518.516	2023/05/23	CABREXXA 1	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 1,0 mg	Annexure A
56/20.1.1/0105	2023/05/23	CLINDAMYCIN EQUITY	Capsule	Equity Pharmaceutical (Pty) Ltd	EACH CAPSULE CONTAINS CLINDAMYCIN HYDROCHLORIDE EQUIVALENT TO CLINDAMYCIN 150,0 mg	Annexure A
55/7-1.3/0413	2023/05/23	ENPRESIL CO	Tablet	Unicorn Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 20,0 mg HYDROCHLOROTHAZIDE 12,5 mg	Annexure A
54/20.1.1/0076	2023/05/23	EURINIC 3 g	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/20.1.1/0078.076	2023/05/23	FOSFOMYCIN 3 g AUSTELL	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/20.1.1/0077.076	2023/05/23	FOSFOMYCIN 3 g CAMOX	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
55/30.2/0426	2023/05/23	MEASLES RUBELLA CIPLA	Injection	Cipla Medpro (Pty) Ltd	EACH 0,5 ml DOSE CONTAINS MEASLES VIRUS (EDMONSTON ZAGREB STRAIN) NLT 1.000,0 CCID50 RUBELLA VIRUS (WISTAR RA27/3) NLT 1.000,0 CCID50	Annexure A
55/20.2.2/0667	2023/05/23	MICAFUNGIN 100 mg ADCO	Infusion	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 100,0 mg	Annexure A
55/20.2.2/0666	2023/05/23	MICAFUNGIN 50mg ADCO	Infusion	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 50,0 mg	Annexure A
55/2-11/0515	2023/05/23	NIKABEX 0,5	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 0,5 mg	Annexure A
55/2-11/0516	2023/05/23	NIKABEX 1	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 1,0 mg	Annexure A
56/26/0575	2023/05/23	ROZLYTREK 100 mg	Capsule	Roche Products (Pty) Ltd	EACH CAPSULE CONTAINS ENTRECTINIB 100,0 mg	Annexure A
56/26/0576	2023/05/23	ROZLYTREK 200 mg	Capsule	Roche Products (Pty) Ltd	EACH CAPSULE CONTAINS ENTRECTINIB 200,0 mg	Annexure A
54/20.1.2/0009	2023/05/30	ACTIMENTIN 600 BD	Suspension	Activo Health (Pty) Ltd	EACH 5,0 ml SUSPENSION CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILIN 600,0 mg CLAVULANATE TRIHYDRATE EQUIVALENT TO CALVULANIC ACID 42,9 mg	Annexure A
54/1-2/0431	2023/05/30	ATEROCON LA 10 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE METHYLPHENIDATE HYDROCHLORIDE 10,0 mg	Annexure A
54/1-2/0432	2023/05/30	ATEROCON LA 20 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 20,0 mg	Annexure A
54/1-2/0433	2023/05/30	ATEROCON LA 30 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 30,0 mg	Annexure A
54/1-2/0434	2023/05/30	ATEROCON LA 40 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 40,0 mg	Annexure A

54/1.2/0435	2023/05/30	ATEROCON LA 60 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 60,0 mg	Annexure A
56/2.2/0389	2023/05/30	CADIATEV	Tablet	Teva Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MELATONIN 2,0 mg	Annexure A
53/32.2/0386	2023/05/30	DEPROL 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0387	2023/05/30	DEPROL 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
56/21.12/0699.699	2023/05/30	FENDEXAM	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS TAMOXIFEN CITRATE EQUIVALENT TO TAMOXIFEN 20,0 mg	Annexure A
53/32.2/0388.386	2023/05/30	LESOR 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0389.387	2023/05/30	LESOR 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 360,0 mg	Annexure A
55/26/0846	2023/05/30	MERCAPTOPURINE EQUITY	Tablet	Equity Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS MERCAPTOPURINE 50,0 mg	Annexure A
55/21.7/0727	2023/05/30	TESTAFORTE	Cream	Pharmacorp (Pty) Ltd	EACH 1,0 ml CREAM CONTAINS TESTOSTERONE 50,0 mg	Annexure A
53/32.2/0390.386	2023/05/30	TRANSWELL 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0391.387	2023/05/30	TRANSWELL 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 360,0 mg	Annexure A
56/21.12/0698	2023/05/30	TREMOFID	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS TAMOXIFEN CITRATE EQUIVALENT TO TAMOXIFEN 20,0 mg	Annexure A
55/21.12/0760	2023/06/06	ACEGYNE	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 mg	Annexure A
55/21.12/0761.760	2023/06/06	ACEMIFE	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 mg	Annexure A
55/6.2/0465	2023/06/06	AMIODARONE 30 mg/ml PREFILLED SYRINGE ACCORD	Injection	Accord Healthcare (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS AMIODARONE 30,0 mg	Annexure A
55/13.1/0755	2023/06/06	CHLORHEXIDINE GLUCONATE HANDRUB ADCO	Solution	Adcock Ingram Critical Care (Pty) Ltd	EACH SOLUTION CONTAINS CHLORHEXIDINE GLUCONATE 0,5% w/v	Annexure A
53/26/0177	2023/06/06	PROTECADE 1 mg	Injection	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 1,0 mg	Annexure A
53/26/0178	2023/06/06	PROTECADE 3,5 mg	Injection	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
56/7.2/0060	2023/06/06	RUSAIN 10 mg/ml	Injection	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 10,0 mg	Annexure A
56/26/0386	2023/06/06	VIZIMPRO 15 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 15,0 mg	Annexure A
56/26/0387	2023/06/06	VIZIMPRO 30 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 30,0 mg	Annexure A
56/26/0388	2023/06/06	VIZIMPRO 45 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 45,0 mg	Annexure A
55/10.3/0685	2023/06/13	ACC 200 POWDER FOR ORAL SOLUTION	Solution	Sandoz South Africa (Pty) Ltd	EACH SACHET CONTAINS ACETYLCYSTEINE 200,0 mg	Annexure A

55/15.4/0346.345	2023/06/13	DORZOPRES		Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg	Annexure A
55/15.4/0345	2023/06/13	DORZOPT		Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg	Annexure A
55/20.2.2/0496	2023/06/13	MICAFUNGIN 100 SANDOZ		Infusion	Sandoz South Africa (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 100,0 mg	Annexure A
55/20.2.2/0495	2023/06/13	MICAFUNGIN 50 SANDOZ		Infusion	Sandoz South Africa (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 50,0 mg	Annexure A
55/34/0851	2023/06/13	PHINMO 0,5		Capsule	Dr Reddy's Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS FINGOLIMOD HYDROCHLORIDE 0,5 mg	Annexure A
53/5.7.2/0449.446	2023/06/13	PREPIX 125		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 125,0 mg	Annexure A
53/5.7.2/0448.445	2023/06/13	PREPIX 80		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 80,0 mg	Annexure A
53/5.7.2/0450.447	2023/06/13	PREPIX COMBI PACK		Capsule	Adcock Ingram Limited	EACH BLISTER PACK CONTAINS TWO CAPSULES EACH CONTAINING APREPITANT 80,0 mg ONE CAPSULE CONTAINING APREPITANT 125,0 mg	Annexure A
20/17.1.11/01	2023/06/13	SHOTAPEN LA		Injection	Virbac RSA (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BENZYL PENICILLIN BEZATHINE 73,58 mg, BENZYL PENICILLIN PROCAINE MONOHYDRATE 56,80 & DIHYDROSTREPTOMYCIN SULPHATE 164,0 mg	Annexure A
56/8.5/0108	2023/06/13	STROPEG		Injection	KAHMA BIOTECH (Pty) Ltd	EACH 0,6 ml SOLUTION CONTAINS PEGFILGRASTIM 6,0 mg	Annexure A
55/32.16/0245.244	2023/06/13	TERIFLUNOMIDE ADCO		Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
55/32.16/0244	2023/06/13	TERITEMSO		Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
53/5.7.2/0446	2023/06/13	VOMEND 125		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 125,0 mg	Annexure A
53/5.7.2/0445	2023/06/13	VOMEND 80		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 80,0 mg	Annexure A
53/5.7.2/0447	2023/06/13	VOMEND COMBI PACK		Capsule	Adcock Ingram Limited	EACH BLISTER PACK CONTAINS TWO CAPSULES EACH CONTAINING APREPITANT 80,0 mg ONE CAPSULE CONTAINING APREPITANT 125,0 mg	Annexure A
56/26/0129	2023/06/20	EGROTIB 100		Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 100,0 mg	Annexure A
56/26/0130	2023/06/20	EGROTIB 150		Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 150,0 mg	Annexure A
56/26/0128	2023/06/20	EGROTIB 25		Gel	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 25,0 mg	Annexure A

56/3-1/0376	2023/06/20	FLAMUGO 100 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3-1/0377	2023/06/20	FLAMUGO 120 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3-1/0378	2023/06/20	FLAMUGO 150 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3-1/0373	2023/06/20	FLAMUGO 30 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3-1/0374	2023/06/20	FLAMUGO 50 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3-1/0375	2023/06/20	FLAMUGO 60 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
53/10.2.2/0068	2023/06/20	MONTASCEND	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
53/10.2.2/0070.068	2023/06/20	MONTELUKAST 10 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
56/26/0055	2023/06/20	NATPEM 1 000	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 1 000,0 mg	Annexure A
56/26/0053	2023/06/20	NATPEM 100	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 100,0 mg	Annexure A
56/26/0054	2023/06/20	NATPEM 500	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 500,0 mg	Annexure A
53/10.2.2/0069.068	2023/06/20	TELUKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
53/3-1/0017	2023/06/20	ASCEPRIB IV 400	Infusion	Ascendis Pharma (Pty) Ltd	EACH 100,0 ml SOLUTION CONTAINS IBUPROFEN 400,0 mg	Annexure A
53/3-1/0018	2023/06/20	ASCEPRIB IV 600	Infusion	Ascendis Pharma (Pty) Ltd	EACH 100,0 ml SOLUTION CONTAINS IBUPROFEN 600,0 mg	Annexure A
54/26/0081	2023/06/20	BETANUJZ	Injection	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
54/26/0082.081	2023/06/20	DEVACAD	Injection	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
56/20.2.2/1125	2023/06/20	TERISOM	Infusion	Ranbaxy Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS AMPHOTERICIN B LIPOSOME 50,0 mg	Annexure A
54/1.2/0183.181	2023/06/27	BUPROPION 150 mg XR DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 150,0 mg	Annexure A
54/1.2/0184.182	2023/06/27	BUPROPION 300 mg XR DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 300,0 mg	Annexure A
56/26/0827	2023/06/27	CABXEL 60 mg/1,5 ml IV	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH 1,5 ml SOLUTION CONTAINS CABAZITAXEL 60,0 mg	Annexure A

56/26/0828.827	2023/06/27	CAPHET 60 mg/1.5 ml IV	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH 1.5 ml SOLUTION CONTAINS CABAZITAXEL 60,0 mg	Annexure A
56/32.2/0193.189	2023/06/27	POMALIDOMIDE 1 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 1,0 mg	Annexure A
56/32.2/0194.190	2023/06/27	POMALIDOMIDE 2 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 2,0 mg	Annexure A
56/32.2/0195.191	2023/06/27	POMALIDOMIDE 3 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 3,0 mg	Annexure A
56/32.2/0196.192	2023/06/27	POMALIDOMIDE 4 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 4,0 mg	Annexure A
56/32.2/0189	2023/06/27	POMYLO 1 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 1,0 mg	Annexure A
56/32.2/0190	2023/06/27	POMYLO 2 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 2,0 mg	Annexure A
56/32.2/0191	2023/06/27	POMYLO 3 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 3,0 mg	Annexure A
56/32.2/0192	2023/06/27	POMYLO 4 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 4,0 mg	Annexure A
54/1.2/0181	2023/06/27	PRODYNA 150 mg XR	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 150,0 mg	Annexure A
54/1.2/0182	2023/06/27	PRODYNA 300 mg XR	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 300,0 mg	Annexure A
55/2.6/0546	2023/06/27	CLOBAZAM 10 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS CLOBAZAM 10,0 mg	Annexure A
55/2.6/0547	2023/06/27	CLOBAZAM 20 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS CLOBAZAM 20,0 mg	Annexure A

#### Annexure A

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.
54. The SCoRE/QOS/QIS document must be maintained and must be consistent with the current approved information.

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**PROCLAMATIONS • PROKLAMASIES**

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**PROCLAMATION 136 OF 2023**

**by the  
PRESIDENT of the REPUBLIC of SOUTH AFRICA**

**SPECIAL INVESTIGATING UNITS AND SPECIAL TRIBUNALS ACT, 1996 (ACT NO. 74 OF 1996): REFERRAL OF MATTERS TO EXISTING SPECIAL INVESTIGATING UNIT: GAUTENG DEPARTMENT OF HEALTH AND ITS PROVINCIAL HOSPITAL IN TEMBISA**

WHEREAS allegations as contemplated in section 2(2) of the Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of 1996) (hereinafter referred to as “the Act”), have been made in respect of the affairs of the Gauteng Department of Health (hereinafter referred to as “the Department”) and its Provincial Hospital in Tembisa (hereinafter referred to as “Tembisa Hospital”);

AND WHEREAS the Department and Tembisa Hospital may have suffered losses that may be recovered;

AND WHEREAS I deem it necessary that the said allegations should be investigated and civil proceedings emanating from such investigation should be adjudicated upon;

NOW, THEREFORE, I hereby, under section 2(1) of the Act, refer the matters mentioned in the Schedule, in respect of the Department and the Tembisa Hospital, for investigation to the Special Investigating Unit established by Proclamation No. R. 118 of 31 July 2001 and determine that, for the purposes of the investigation of the matters, the terms of reference of the Special Investigating Unit are to investigate as contemplated in the Act, any alleged—

- (a) serious maladministration in connection with the affairs of the Department and the Tembisa Hospital;
  - (b) improper or unlawful conduct by officials or employees of the Department and the Tembisa Hospital;
  - (c) unlawful appropriation or expenditure of public money or property;
  - (d) unlawful, irregular or unapproved acquisitive act, transaction, measure or practice having a bearing upon State property;
  - (e) intentional or negligent loss of public money or damage to public property;
  - (f) offence referred to in Parts 1 to 4, or section 17, 20 or 21 (in so far as it relates to the aforementioned offences) of Chapter 2 of the Prevention and Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004), and which offences were committed in connection with the affairs of the Department or the Tembisa Hospital; or
  - (g) unlawful or improper conduct by any person, which has caused or may cause serious harm to the interests of the public or any category thereof,
- which took place between 1 January 2020 and the date of publication of this



Proclamation or which took place prior to 1 January 2020 or after the date of publication of this Proclamation, but is relevant to, connected with, incidental or ancillary to the matters mentioned in the Schedule or involve the same persons, entities or contracts investigated under authority of this Proclamation, and to exercise or perform all the functions and powers assigned to or conferred upon the said Special Investigating Unit by the Act, including the recovery of any losses suffered by the Department or Tembisa Hospital or the State, in relation to the said matters in the Schedule.

Given under my Hand and the Seal of the Republic of South Africa at Pretoria this Ninth day of August Two thousand and twenty three.

**MC Ramaphosa**

**President**

By Order of the President-in-Cabinet:

**RO Lamola**

**Minister of the Cabinet**

## **SCHEDULE**

1. The procurement of, or contracting for goods and services by or on behalf of the Department for the Tembisa Hospital, or by the Tembisa Hospital, and payments made in respect thereof in a manner that was—

- (a) not fair, competitive, transparent, equitable or cost-effective;
- (b) contrary to applicable—
  - (i) legislation;
  - (ii) manuals, guidelines, circulars or instructions issued by the National Treasury or the relevant Provincial Treasury; or
  - (iii) manuals, policies, procedures, prescripts, instructions or practices of or applicable to the Department or the Tembisa Hospital,and any related unauthorised, irregular or fruitless and wasteful expenditure incurred by the Department or the Tembisa Hospital or the State or losses suffered by the aforementioned parties.

2. Any unlawful or improper conduct by officials or employees of the Department or the Tembisa Hospital, the applicable suppliers or service providers or any other person or entity, in relation to the allegations set out in paragraph 1 of this Schedule.

**PROKLAMASIE 136 VAN 2023**  
**van die**  
**PRESIDENT van die REPUBLIEK van SUID-AFRIKA**

**WET OP SPESIALE ONDERSOEKEENHEDE EN SPESIALE TRIBUNALE, 1996 (WET NO. 74 VAN 1996): VERWYSING VAN AANGELEENTHEDE NA BESTAANDE SPESIALE ONDERSOEKEENHEID: GAUTENG DEPARTEMENT VAN GESONDHEID EN SY PROVINSIALE HOSPITAAL IN TEMBISA**

AANGESIEN bewerings soos beoog in artikel 2(2) van die Wet op Spesiale Ondersoekeenhede en Spesiale Tribunale, 1996 (Wet No. 74 van 1996) (hierna na verwys as die "Wet"), gemaak is in verband met die aangeleentheid van die Gauteng Departement van Gesondheid (hierna na verwys as "die Departement") en sy Provinsiale Hospitaal in Tembisa (hierna na verwys as "Tembisa Hospitaal");

EN AANGESIEN die Staat of die Departement en die Tembisa Hospitaal verliese gelyk het wat moontlik verhaal kan word;

EN AANGESIEN ek dit nodig ag dat gemelde bewerings ondersoek en siviele geskille voortspruitend uit sodanige ondersoek bereg moet word;

DERHALWE verwys ek hierby, kragtens artikel 2(1) van die Wet, die aangeleentheid in die Bylae vermeld, ten opsigte van die Departement en die Tembisa Hospitaal vir ondersoek na die Spesiale Ondersoekeenheid ingestel by Proklamasie No. R. 118 van 31 Julie 2001 en bepaal dat, vir die doeleindes van die ondersoek van die aangeleentheid, dit die opdrag van die Spesiale Ondersoekeenheid is om soos beoog in gemelde Wet, ondersoek te doen na enige beweerde—

- (a) ernstige wanadministrasie in verband met die aangeleentheid van die Departement en die Tembisa Hospitaal;
- (b) onbehoorlike of onregmatige optrede deur beamptes of werknemers van die Departement en die Tembisa Hospitaal;
- (c) onregmatige bewilliging of besteding van openbare geld of eiendom;
- (d) onwettige, onreëlmatige of nie-goedgekeurde verkrygende handeling, transaksie, maatreël of praktyk wat op Staatseiendom betrekking het;
- (e) opsetlike of nalatige verlies van openbare geld of skade aan openbare eiendom;
- (f) misdryf bedoel in Dele 1 tot 4, van artikel 17, 20 of 21 (vir sover dit op voornoemde misdrywe betrekking het) van Hoofstuk 2 van die Wet op die Voorkoming en Bestryding van Korrupte Bedrywighede, 2004 (Wet No. 12 van 2004), en welke misdrywe in verband met die sake van die Departement en die Tembisa Hospitaal gepleeg is; of
- (g) onwettige of onbehoorlike optrede deur enige persoon wat ernstige benadeling vir die belange van die publiek of enige kategorie daarvan veroorsaak het of

kan veroorsaak, wat plaasgevind het tussen 1 Januarie 2020 en die datum van publikasie van hierdie Proklamasie of wat plaasgevind het voor 1 Januarie 2020 of na die datum van publikasie van hierdie Proklamasie, wat relevant is tot, verband hou met, insidenteel of bykomstig is tot die aangeleenthede vermeld in die Bylae of wat dieselfde persone, entiteite of kontrakte betrek wat ondersoek word kragtens die volmag verleen deur hierdie Proklamasie, en om al die werksaamhede en bevoegdhede wat deur die Wet aan die gemelde Spesiale Ondersoekenheid toegewys of opgedra is, uit te oefen of te verrig in verband met die genoemde aangeleenthede in die Bylae, insluitend die verhaal van enige verliese wat deur die Departement en die Tembisa Hospitaal gely is.

Gegee onder my Hand en die Seël van die Republiek van Suid-Afrika te Pretoria op hede die Negende dag van Augustus Twee duisend-en-drie- en twintig.

**MC Ramaphosa**

**President**

Op las van die President-in-Kabinet:

**RO Lamola**

**Minister van die Kabinet**

#### **BYLAE**

1. Die aanskaffing van of kontraktering vir produkte en dienste deur of namens die Departement vir die Tembisa Hospitaal, of deur die Tembisa Hospitaal en betalings wat in verband daarmee gemaak is op 'n wyse wat—

- (a) nie regverdig, mededingend, deursigtig, billik, of koste-effektief was nie;
- (b) strydig was met toepaslike—
  - (i) wetgewing;
  - (ii) handleidings, riglyne, praktyknotas, omsendbriewe of instruksies wat deur die Nasionale Tesourie of toepaslike Provinsiale Tesourie uitgevaardig is; of
  - (iii) handleidings, beleid, prosedures, voorskrifte, instruksies of praktyke van, of wat op die Departement of die Tembisa Hospitaal van toepassing is,

en enige verbandhoudende ongemagtigde, onreëlmatige of vrugtelose en verkwiste uitgawes wat deur die Departement of die Tembisa Hospitaal, of die Staat opgedoen was, of verliese wat deur die voormelde partye gely is.

2. Enige onwettige of onbehoorlike gedrag deur beamptes of werknemers van die Departement of die Tembisa Hospitaal, die verskaffers of diensverskaffers of enige ander persoon of entiteit, ten opsigte van die bewering uiteengesit in paragraaf 1 van hierdie Bylae.

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