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

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Closing times for **ORDINARY WEEKLY** **REGULATION GAZETTE** **2018**

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

- **28 December 2017**, Thursday for the issue of Friday **05 January 2018**
- **05 January**, Friday for the issue of Friday **12 January 2018**
- **12 January**, Friday for the issue of Friday **19 January 2018**
- **19 January**, Friday for the issue of Friday **26 January 2018**
- **26 January**, Friday for the issue of Friday **02 February 2018**
- **02 February**, Friday for the issue of Friday **09 February 2018**
- **09 February**, Friday for the issue of Friday **16 February 2018**
- **16 February**, Friday for the issue of Friday **23 February 2018**
- **23 February**, Friday for the issue of Friday **02 March 2018**
- **02 March**, Friday for the issue of Friday **09 March 2018**
- **09 March**, Friday for the issue of Friday **16 March 2018**
- **15 March**, Thursday for the issue of Friday **23 March 2018**
- **22 March**, Thursday for the issue of Thursday **29 March 2018**
- **28 March**, Wednesday for the issue of Friday **06 April 2018**
- **06 April**, Friday for the issue of Friday **13 April 2018**
- **13 April**, Friday for the issue of Friday **20 April 2018**
- **19 April**, Thursday for the issue of Thursday **26 April 2018**
- **25 April**, Wednesday for the issue of Friday **04 May 2018**
- **04 May**, Friday for the issue of Friday **11 May 2018**
- **11 May**, Friday for the issue of Friday **18 May 2018**
- **18 May**, Friday for the issue of Friday **25 May 2018**
- **25 May**, Friday for the issue of Friday **01 June 2018**
- **01 June**, Friday for the issue of Friday **08 June 2018**
- **08 June**, Friday for the issue of Friday **15 June 2018**
- **15 June**, Friday for the issue of Friday **22 June 2018**
- **22 June**, Friday for the issue of Friday **29 June 2018**
- **29 June**, Friday for the issue of Friday **06 July 2018**
- **06 July**, Friday for the issue of Friday **13 July 2018**
- **13 July**, Friday for the issue of Friday **20 July 2018**
- **20 July**, Friday for the issue of Friday **27 July 2018**
- **27 July**, Friday for the issue of Friday **03 August 2018**
- **02 August**, Thursday for the issue of Friday **10 August 2018**
- **10 August**, Friday for the issue of Friday **17 August 2018**
- **17 August**, Friday for the issue of Friday **24 August 2018**
- **24 August**, Friday for the issue of Friday **31 August 2018**
- **31 August**, Friday for the issue of Friday **07 September 2018**
- **07 September**, Friday for the issue of Friday **14 September 2018**
- **14 September**, Friday for the issue of Friday **21 September 2018**
- **20 September**, Thursday for the issue of Friday **28 September 2018**
- **28 September**, Friday for the issue of Friday **05 October 2018**
- **05 October**, Friday for the issue of Friday **12 October 2018**
- **12 October**, Friday for the issue of Friday **19 October 2018**
- **19 October**, Friday for the issue of Friday **26 October 2018**
- **26 October**, Friday for the issue of Friday **02 November 2018**
- **02 November**, Friday for the issue of Friday **09 November 2018**
- **09 November**, Friday for the issue of Friday **16 November 2018**
- **16 November**, Friday for the issue of Friday **23 November 2018**
- **23 November**, Friday for the issue of Friday **30 November 2018**
- **30 November**, Friday for the issue of Friday **07 December 2018**
- **07 December**, Friday for the issue of Friday **14 December 2018**
- **13 December**, Thursday for the issue of Friday **21 December 2018**
- **19 December**, Wednesday for the issue of Friday **28 December 2018**

LIST OF TARIFF RATES FOR PUBLICATION OF NOTICES

COMMENCEMENT: 1 APRIL 2018

NATIONAL AND PROVINCIAL

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

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

EXTRA-ORDINARY

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

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

GOVERNMENT PRINTING WORKS - BUSINESS RULES

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

CLOSING TIMES FOR ACCEPTANCE OF NOTICES

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

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

All notices received after the closing time will be rejected.

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

GOVERNMENT PRINTING WORKS - BUSINESS RULES

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

EXTRAORDINARY GAZETTES

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

NOTICE SUBMISSION PROCESS

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

GOVERNMENT PRINTING WORKS - BUSINESS RULES

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

QUOTATIONS

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

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

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

CANCELLATIONS

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

AMENDMENTS TO NOTICES

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

REJECTIONS

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

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

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

GOVERNMENT PRINTER INDEMNIFIED AGAINST LIABILITY

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

LIABILITY OF ADVERTISER

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

CUSTOMER INQUIRIES

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

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

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

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

GOVERNMENT PRINTING WORKS - BUSINESS RULES

PAYMENT OF COST

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

PROOF OF PUBLICATION

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

GOVERNMENT PRINTING WORKS CONTACT INFORMATION

Physical Address:

Government Printing Works
149 Bosman Street
Pretoria

Postal Address:

Private Bag X85
Pretoria
0001

GPW Banking Details:

Bank: ABSA Bosman Street
Account No.: 405 7114 016
Branch Code: 632-005

For Gazette and Notice submissions: Gazette Submissions:

For queries and quotations, contact: Gazette Contact Centre:

E-mail: submit.egazette@gpw.gov.za

E-mail: info.egazette@gpw.gov.za

Tel: 012-748 6200

Contact person for subscribers: Mrs M. Toka:

E-mail: subscriptions@gpw.gov.za

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Fax: 012-323-9574

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 1098

12 OCTOBER 2018

**MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)
SCHEDULES**

The Minister of Health has, in terms of section 22A(2) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the Medicines Control Council, made and updated the Schedules in the Schedule.

This Schedule amends the Schedules as inserted by Government Notice R.509 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 24727, 10 April 2003; substituted by Government Notice R.935 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 31387, 5 September 2008; and amended by Government Notice R.1230 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 32838, 31 December 2009; Government Notice R.227 (Medicines and Related Substances Act: Schedules) in Government *Gazette* 35149, 15 March 2012; Government Notice R.674 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 36827, 13 September 2013; Government Notice R.690 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 36850, 20 September 2013; Government Notice R.104 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 37318, 11 February 2014; Government Notice R.352 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 37622, 8 May 2014; Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 38586, 20 March 2015; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 39815, 15 March 2016; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 40041, 03 June 2016; Government Notice No.748 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41009, 28 July 2017; and Government Notice No.1261 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41256, 17 November 2017 using the following convention:

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]** in Schedule 1), indicate omission from a Schedule
- Words underlined with a solid line (e.g. Gamma benzene hexachloride), indicate insertions in a Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No.101 of 1965)

Note: Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided to indicate one or more alternative scheduling designation/s. This is for information only and shall not be used in the interpretation of such inscription.

SCHEDULE 1

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
 - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
 - (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(4)(a)(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care,

Schedule 2

SCHEDULE 2

- a. All substances referred to in this Schedule are excluded when specifically packed, labeled, sold and used for –
 - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
 - (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within their scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.
 - (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

Atovaquone,

- a. when co-formulated with proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S4)

Dulaglutide,

Ibuprofen,

SCHEDULE 3

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
- (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

Ibuprofen, except

- a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
- b. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over

Schedule 4

SCHEDULE 4

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
- (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (ii) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (iii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

[Atovaquine] Atovaquone, except

- a. when co-formulated with proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S2)

Bazedoxifene.

Daratumumab.

Deoxycholic acid.

Schedule 4

Dupilumab.Eftrenonacog alfa (Human coagulation Factor IX).Human Plasma Proteins.

Ibuprofen,

- a. when intended for the treatment of a haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age;
- b. except when contained in preparations intended for application to the skin; containing 5 % m/m or less of ibuprofen; (S0, S1)
- c. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
- d. except when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- e. except when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- f. except for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)
- g. except when intended for veterinary use. (S3)

Ixazomib.

Schedule 4

Lubiprostone.

Mepolizumab.

Midostaurin.

Oclacitinib.

Orphenadrine, except when contained in preparations intended for use as a muscle relaxant. (S2)

Proguanil, except

- a. when co-formulated with atovaquone and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S2)

Ramucirumab.

Siltuximab.

Tetanus toxoid.

Tipiracil.

Tofacitinib.

Vedolizumab.

– END SCHEDULE 4 –

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

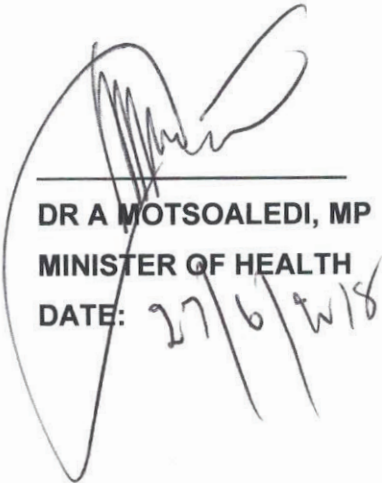
- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following:
- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
 - (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).
- c. Specified Schedule 5 substances listed in this schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by **

Schedule 5

Brexiprazole.

– END SCHEDULE 5 –

These Schedules as amended com into operation on the date of publication in the Government Gazette.



DR A MOTSOLEDI, MP
MINISTER OF HEALTH
DATE: 27/6/2018

DEPARTMENT OF HEALTH

NO. R. 1099

12 OCTOBER 2018

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

The Medicines Control Council, by virtue vested in it by Section 14(2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), has by resolution approved by the Minister of Health, determined that, with effect from the date of publication of this notice, all oral preparations which-

- (1) contain a bacterial strain(s) as listed in the Schedule hereto, either as such or in combination with any other pharmacologically active ingredient(s); and
- (2) make a medicinal claim other than the general health claim provided for their use as a Schedule 0 substance.

shall be subject to registration as medicines falling under Category A referred to in regulation 9(1) of the regulations promulgated in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and more particularly, as medicines falling under Class 30.4 of Category A of Appendix 1 of the Regulations.

It is hereby further notified that, under section 14(2)(b) of Act 101 of 1965, the above-mentioned resolution shall relate to preparations that are available for sale in the Republic on or before the date on which this notice comes into operation and shall relate also to preparations that become available after the said date.

Bacterial Strains

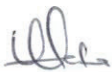
Bifidobacterium adolescentis,

Bifidobacterium animalis subsp. animalis,

Bifidobacterium animalis subsp. lactis,

Bifidobacterium bifidum,

Bifidobacterium breve,
Bifidobacterium lactis,
Bifidobacterium longum *subsp.* infantis,
Bifidobacterium longum *subsp.* longum,
Lactobacillus acidophilus,
Lactobacillus brevis,
Lactobacillus caucasicus,
Lactobacillus casei,
Lactobacillus delbrueckii (including Lactobacillus delbrueckii *subsp.* bulgaricus & Lactobacillus delbrueckii *subsp.* delbrueckii),
Lactobacillus fermentum,
Lactobacillus gasseri,
Lactobacillus helveticus,
Lactobacillus johnsonii,
Lactobacillus paracasei,
Lactobacillus plantarum,
Lactobacillus reuteri,
Lactobacillus rhamnosus,
Lactobacillus salivarius,



MS P NKAMBULE

ACTING CEO OF SAHPRA

DATE: 25/04/2018

DEPARTMENT OF LABOUR

NO. R. 1100

12 OCTOBER 2018

LABOUR RELATIONS ACT, 1995
REGISTRATION OF AN EMPLOYERS' ORGANISATION

I, **Lehlohonolo Daniel Molefe**, Registrar of Labour Relations, hereby notify, in terms of section 109(2) of the Labour Relations Act, 1995, that **Hospitality & Allied Services Employers' Association (HASEA)**, LR 2/6/3/1033, has been registered as an employers' organisation with

effect from 01 October 2018

**REGISTRAR OF LABOUR RELATIONS****DATE** 01 October 2018

DEPARTMENT OF LABOUR

NO. R. 1101

12 OCTOBER 2018

LABOUR RELATIONS ACT, 1995

CHANGE OF NAME OF A TRADE UNION

I, **LEHLOHONOLO DANIEL MOLEFE**, Registrar of Labour Relations, hereby notify, in terms of section 109(2) of the Labour Relations Act, 1995 that **Electronic, Allied and Metal Workers' Union of South Africa (LR 2/6/2/111)** resolved to change its name. With effect from 21 September 2018 the trade union is registered as **Electronic Allied Metal Workers' Union of South Africa (EAMWUSA)**


REGISTRAR OF LABOUR RELATIONSDATE: 21 September 2018

DEPARTMENT OF TRANSPORT

NO. R. 1102

12 OCTOBER 2018

CIVIL AVIATION ACT, 2009 (ACT NO. 13 OF 2009)

CIVIL AVIATION REGULATIONS, 2011

The Minister of Transport intends, in terms of section 155(1) of the Civil Aviation Act, 2009

(Act No. 13 of 2009) and on the recommendation of the Civil Aviation Regulations Committee (CARCom), to amend the Civil Aviation Regulations, 2011, by the amendment of the following Parts set out in Schedules below:

Schedule 1:	Part 1	(Definitions and Abbreviations)
Schedule 2:	Part 12	(Aviation Accidents and Incidents)
Schedule 3:	Part 61	(Pilot Licensing)
Schedule 4:	Part 172	(Airspace and Air Traffic Services)
Schedule 5:	Part 175	(Aeronautical Information Services)

The Director of Civil Aviation intends, in terms of section 163 of the Civil Aviation Act and on

Recommendation of CARCom, to amend the Technical Standards by the amendment of the

Following parts set out in the Schedules below:

Schedule 6:	SA CATS 24	(Airworthiness: Non-type Certification aircraft)
Schedule 7:	SA CATS 64	(Cabin Crew Licensing)
Schedule 8:	SA CATS 67	(Medical Certification)
Schedule 9:	SA CATS 172	(Airspace and Air Traffic Services)

Electronic copies of the draft Amendments are available in the South African Civil Aviation Authority website at www.caa.co.za and may also be requested from Josephine Freese at freesej@caa.co.za

Interested persons are hereby invited to submit written comments on these draft amendments on or before the **12 November 2018** to the Chairperson: CARCom, for the attention of.

Sipho Skosana
Private Bag X73
Halfway house
1685
Email: skosanas@caa.co.za
Tel: 011 545 - 1095

or

Noluthando Nkosi
Private Bag X73
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Email: nkosino@caa.co.za
Tel: 011 545 - 1231

WARNING!!!

To all suppliers and potential suppliers of goods to the Government Printing Works

The Government Printing Works would like to warn members of the public against an organised syndicate(s) scamming unsuspecting members of the public and claiming to act on behalf of the Government Printing Works.

One of the ways in which the syndicate operates is by requesting quotations for various goods and services on a quotation form with the logo of the Government Printing Works. Once the official order is placed the syndicate requesting upfront payment before delivery will take place. Once the upfront payment is done the syndicate do not deliver the goods and service provider then expect payment from Government Printing Works.

Government Printing Works condemns such illegal activities and encourages service providers to confirm the legitimacy of purchase orders with GPW SCM, prior to processing and delivery of goods.

To confirm the legitimacy of purchase orders, please contact:

Renny Chetty (012) 748-6375 (Renny.Chetty@gpw.gov.za),

Anna-Marie du Toit (012) 748-6292 (Anna-Marie.DuToit@gpw.gov.za) and

Siraj Rizvi (012) 748-6380 (Siraj.Rizvi@gpw.gov.za)

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