

## Government Gazette Staatskoerant REPUBLIC OF SOUTH AFRICA

**Regulation Gazette** 

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41871

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### **IMPORTANT NOTICE:**

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### Closing times for ORDINARY WEEKLY REGULATION GAZETTE

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
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- 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, Prov	incial - Variable Priced No	tices
Notice Type	Page Space	New Price (R)
Ordinary National, Provincial	1/4 - Quarter Page	252.20
Ordinary National, Provincial	2/4 - Half Page	504.40
Ordinary National, Provincial	3/4 - Three Quarter Page	756.60
Ordinary National, Provincial	4/4 - Full Page	1008.80

### **EXTRA-ORDINARY**

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

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

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

### CLOSING TIMES FOR ACCEPTANCE OF NOTICES

- 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 <a href="https://www.gpwonline.co.za">www.gpwonline.co.za</a>

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

All notices received after the closing time will be rejected.

Government Gazette Type	Publication Frequency	Publication Date	Submission Deadline	Cancellations Deadline
National Gazette	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Regulation Gazette	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Petrol Price Gazette	Monthly	Tuesday before 1st Wednesday of the month	One day before publication	1 working day prior to publication
Road Carrier Permits	Weekly	Friday	Thursday 15h00 for next Friday	3 working days prior to publication
Unclaimed Monies (Justice, Labour or Lawyers)	January / September 2 per year	Last Friday	One week before publication	3 working days prior to publication
Parliament (Acts, White Paper, Green Paper)	As required	Any day of the week	None	3 working days prior to publication
Manuals	Bi- Monthly	2nd and last Thursday of the month	One week before publication	3 working days prior to publication
State of Budget (National Treasury)	Monthly	30th or last Friday of the month	One week before publication	3 working days prior to publication
Extraordinary Gazettes	As required	Any day of the week	Before 10h00 on publication date	Before 10h00 on publication date
Legal Gazettes A, B and C	Weekly	Friday	One week before publication	Tuesday, 15h00 - 3 working days prior to publication
Tender Bulletin	Weekly	Friday	Friday 15h00 for next Friday	Tuesday, 15h00 - 3 working days prior to publication
Gauteng	Weekly	Wednesday	Two weeks before publication	3 days <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 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.
- 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 <a href="mailto:submit.egazette@gpw.gov.za">submit.egazette@gpw.gov.za</a>. The form needs to be submitted in its original electronic *Adobe* format to enable the system to extract the completed information from the form for placement in the publication.
- Every notice submitted must be accompanied by an official GPW quotation. This must be obtained from the eGazette Contact Centre.
- 8. Each notice submission should be sent as a single email. The email **must** contain **all documentation** relating to a particular notice submission.
  - 8.1. Each of the following documents must be attached to the email as a separate attachment:
    - 8.1.1. An electronically completed Adobe form, specific to the type of notice that is to be placed.
      - 8.1.1.1. For National *Government Gazette* or *Provincial Gazette* notices, the notices must be accompanied by an electronic Z95 or Z95Prov *Adobe* form
      - 8.1.1.2. The notice content (body copy) **MUST** be a separate attachment.
    - 8.1.2. A copy of the official **Government Printing Works** quotation you received for your notice. (*Please see Quotation section below for further details*)
    - 8.1.3. A valid and legible Proof of Payment / Purchase Order: **Government Printing Works** account customer must include a copy of their Purchase Order. **Non-Government Printing Works** account customer needs to submit the proof of payment for the notice
    - 8.1.4. Where separate notice content is applicable (Z95, Z95 Prov and TForm 3, it should **also** be attached as a separate attachment. (*Please see the Copy Section below, for the specifications*).
    - 8.1.5. Any additional notice information if applicable.

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

### **Q**UOTATIONS

- 13. Quotations are valid until the next tariff change.
  - 13.1. Take note: GPW's annual tariff increase takes place on 1 April therefore any quotations issued, accepted and submitted for publication up to 31 March will keep the old tariff. For notices to be published from 1 April, a quotation must be obtained from GPW with the new tariffs. Where a tariff increase is implemented during the year, GPW endeavours to provide customers with 30 days' notice of such changes.
- 14. Each quotation has a unique number.
- 15. Form Content notices must be emailed to the *eGazette* Contact Centre for a quotation.
  - 15.1. The *Adobe* form supplied is uploaded by the Contact Centre Agent and the system automatically calculates the cost of your notice based on the layout/format of the content supplied.
  - 15.2. It is critical that these *Adobe* Forms are completed correctly and adhere to the guidelines as stipulated by **GPW**.

### 16. APPLICABLE ONLY TO GPW ACCOUNT HOLDERS:

- 16.1. GPW Account Customers must provide a valid GPW account number to obtain a quotation.
- 16.2. Accounts for GPW account customers must be active with sufficient credit to transact with GPW to submit notices.
  - 16.2.1. If you are unsure about or need to resolve the status of your account, please contact the GPW Finance Department prior to submitting your notices. (If the account status is not resolved prior to submission of your notice, the notice will be failed during the process).

### 17. APPLICABLE ONLY TO CASH CUSTOMERS:

- 17.1. Cash customers doing **bulk payments** must use a **single email address** in order to use the **same proof of payment** for submitting multiple notices.
- 18. The responsibility lies with you, the customer, to ensure that the payment made for your notice(s) to be published is sufficient to cover the cost of the notice(s).
- 19. Each quotation will be associated with one proof of payment / purchase order / cash receipt.
  - 19.1. This means that the quotation number can only be used once to make a payment.

### COPY (SEPARATE NOTICE CONTENT DOCUMENT)

- 20. Where the copy is part of a separate attachment document for Z95, Z95Prov and TForm03
  - 20.1. Copy of notices must be supplied in a separate document and may not constitute part of any covering letter, purchase order, proof of payment or other attached documents.

The content document should contain only one notice. (You may include the different translations of the same notice in the same document).

20.2. The notice should be set on an A4 page, with margins and fonts set as follows:

Page size = A4 Portrait with page margins: Top = 40mm, LH/RH = 16mm, Bottom = 40mm; Use font size: Arial or Helvetica 10pt with 11pt line spacing;

Page size = A4 Landscape with page margins: Top = 16mm, LH/RH = 40mm, Bottom = 16mm; Use font size: Arial or Helvetica 10pt with 11pt line spacing;

### **C**ANCELLATIONS

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

### AMENDMENTS TO NOTICES

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

### REJECTIONS

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

### **APPROVAL OF NOTICES**

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

### GOVERNMENT PRINTER INDEMNIFIED AGAINST LIABILITY

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

### LIABILITY OF ADVERTISER

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

### **C**USTOMER INQUIRIES

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

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

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

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

### PAYMENT OF COST

- 31. The Request for Quotation for placement of the notice should be sent to the Gazette Contact Centre as indicated above, prior to submission of notice for advertising.
- 32. Payment should then be made, or Purchase Order prepared based on the received quotation, prior to the submission of the notice for advertising as these documents i.e. proof of payment or Purchase order will be required as part of the notice submission, as indicated earlier.
- 33. Every proof of payment must have a valid **GPW** quotation number as a reference on the proof of payment document.
- Where there is any doubt about the cost of publication of a notice, and in the case of copy, an enquiry, accompanied by the relevant copy, should be addressed to the Gazette Contact Centre, **Government Printing Works**, Private Bag X85, Pretoria, 0001 email: <a href="mailto:info.egazette@gpw.gov.za">info.egazette@gpw.gov.za</a> 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 <a href="https://www.gpwonline.co.za">www.gpwonline.co.za</a> free of charge, should a proof of publication be required.
- 39. Printed copies may be ordered from the Publications department at the ruling price. The **Government Printing Works** will assume no liability for any failure to post or for any delay in despatching of such *Government Gazette*(s)

### **GOVERNMENT PRINTING WORKS CONTACT INFORMATION**

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

For Gazette and Notice submissions: Gazette Submissions: E-mail: <a href="mailto:submit.egazette@gpw.gov.za">submit.egazette@gpw.gov.za</a>
For queries and quotations, contact: Gazette Contact Centre: E-mail: <a href="mailto:info.egazette@gpw.gov.za">info.egazette@gpw.gov.za</a>

Tel: 012-748 6200

Contact person for subscribers: Mrs M. Toka: E-mail: subscriptions@gpw.gov.za

Tel: 012-748-6066 / 6060 / 6058

Fax: 012-323-9574

### GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

### **DEPARTMENT OF HEALTH**

NO. R. 912

31 AUGUST 2018

### FEES PAYABLE IN TERMS OF THE PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

The Minister of Health, in consultation with the Minister of Finance and the South African Health Products Regulatory Authority, in terms of Section 35(1)(xxxi) and (xxxii) read together with Section 35(4) of the Medicines and Related Substances, intends to make the Regulations in the Schedule.

This Schedule intends to amend the Schedules as published in Government Notice Government Gazette No 39154 Notice R 784 (Medicines and Related Substances Act, 1965 (Act 101 of 1965) using the following convention:

- Words and figures in square brackets and bold print e.g. [R30 000], indicate an amendment from the Schedules:
- Words underlined with a solid line e.g. <u>Vaccines: R65 000</u>, indicate insertions and replacement of the current fee in the Schedule.

Interested persons are invited to submit, within three month of publication of this notice, comments on the proposed Regulations to the <u>South African Health-Products Regulatory</u> <u>Authority</u>, for the attention of the <u>Chief Executive Officer</u>, Private Bag X828, Pretoria, 0001

### **SCHEDULE**

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 1 of 1965). The following fees shall be payable to the <u>Chief Executive Officer</u> or the Director General as the case may be:

### 1 Category A medicines

Human medicines, including Biologicals, for which an application for registration <u>is</u> submitted as contemplated in Section 15 of the Act,

- (a) In respect of the submission of an application for registration of-
  - (i) New Chemical Entities, including highly technological products, and new biotherapeutics other than vaccines, which have been processed by the abbreviated registration process [AMRP] (first strength, first dosage form): [R49 000] R R53 900 per application;

- (ii) Strengths and dosage forms other than those referred to in subparagraph (i): **[R21 000]** R R23 100 per application;
- (iii) New Chemical Entities, including highly technological products, other than vaccines (first strength, first dosage form): [R54 000] R59 400 per application;
- (iv) Strengths and dosage forms other than those referred to in subparagraph (iii): **[R27 000]** R29 700 per application;
- (v) Biological products e.g. vaccines and biosimilars (excluding new biotherapeutics): [R43 000] R47 300 per application;
- (vi) Strengths and dosage forms other than those referred to in subparagraph (v): [R13 500] R14 850 per application;
- (vii) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products (first strength, first dosage form): [R27 000] R29 700 per application;
- (viii) Strengths and dosage forms other than those referred to in sub-paragraph (ix): [R9 500] R10 450;
- (ix) Generic products with clinical data: [R44 000] R48 400;
- (x) Strengths and dosage forms other than those referred to in subparagraph (xi): [R13 500] R14 850 per application;
- (xi) Screening fee on receipt of a <u>Common Technical Document (CTD)</u> format application: [R1 600] <u>R1 760;</u>
- (xii) Screening fee on receipt of an electronic Common Technical Document (eCTD) format application: R1 760 per sequence;
- (xiv) Evaluation of additional submitted clinical data (pre-registration): [R2 700] R2 970;
- (xv) An application in terms of Section 15C of the Act: [R32 700] \_R35 970;
- (b) An application for priority review: R25 000;
- (c) Any medicine, the registration of which has been approved by the Council in terms of Section 15(3) of the Act:
  - (i) In respect of registration of any medicine, the registration of which has been approved by the Council in terms of Section 15(3) of the Act (in the case of medicines in minute-dose form; the fee encompasses

- different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid: [R1 600] R1 760 for each registration;
- (ii) Evaluation of request for rescheduling of products: [R5 400] R15 000
- (iii) Evaluation of request to amend package insert and Patient Information Leaflets in respect of which data relating to safety must be evaluated (post registration): [R3 500] R3 850;
  - Evaluation of request to amend package insert and Patient Information Leaflets in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): **[R3 500]** R15 000;
- (iv) Evaluation of request to amend the Generic medicine package inserts and Patient Information Leaflet where clinical data are not required (post registration): R2 500;
- (v) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration): R15 000;
- (vi) Evaluation of requests for approval of once-off deviations from registered requirements: R5 000;
- (vii) Evaluation of requests for exemption from registered post-importation testing requirements per product: R5 000;
- (viii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Council in terms of Section 15(3): [R1 100] R5 000: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).
- (d) <u>In respect of the testing of a biological medicine for purposes of batch release</u> by the National Control Laboratory: R22 000 per batch;

### 2 Category C medicines

Veterinary medicines, including Biologicals, for which Council has determined by resolution that they are registerable:

- (a) In respect of the submission of an application for registration of-
  - (i) New Chemical Entities, including highly technological products, (first strength, first dosage form): [R12 000] R13 200 per application;
  - (ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): **[R11 000]** R12 100 per application;
  - (iii) Generic products with clinical data: [R12 000] R13 200;
  - (iv) Strengths and dosage forms other than those referred to in subparagraphs (i), (ii), (iii): **[R3 800]** R4 180;
  - (v) Screening fee on receipt of the application: **[R1 600]** R1 760;
  - (vi) Evaluation of additional submitted clinical data (pre-registration): [R2 400] \_R2 640.
- (b) Any medicine, the registration of which has been approved by the Council in terms of Section 15(3):
  - (i) In respect of the registration of any medicine, the registration of which has been approved by the Council in terms of Section 15(3) (in the case of medicines in minute-dose forms; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid: [R1 000] R 1 760 for each registration;
  - (ii) Evaluation of request for rescheduling of products: [R5 400] \_\_R5 940;
  - (iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: [R3 500]\_R3 850;
  - (iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Council in terms of Section 15(3): [R850] R2 300: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3): Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that

year, failing which the registration may be cancelled in terms of Section 16(4).

### 3 Category D medicines (Human medicines)

Human medicines\_for which an application for registration has been submitted as contemplated in Section 15 of the Act,

- (a) In respect of the submission of an application for registration of-
  - (i) Products submitted with clinical and or toxicological data (first strength, first dosage form): [R12 400] R13 640 per application;
  - (ii) Strengths and dosage forms other than those referred to in subparagraph (i): **[R3 900]** R4 290 per application;
  - (iii) Products submitted with no clinical or toxicology data (first strength, first dosage form): **[R5 500]** R6 050 per application;
  - (iv) Strengths and dosage forms other than those referred to in subparagraph (iii): [R1 800] R1 980;
  - (v) Screening fee on receipt of an application: [R1 600] R1 760;
  - (vi) Evaluation of additional submitted clinical data (pre-registration): [R2 500] R2 750;
  - (vii) An application in terms of Section 15C of the Act: **[R30 000]** R33 000;
- (b) Any medicine, the registration of which has been approved by the Council in terms of Section 15(3) of the Act:
  - (i) In respect of registration of any medicine, the registration of which has been approved by the Council in terms of Section 15(3) of the Act and in respect of which an application fee has been paid: [R950] R1 760 for each registration;
  - (ii) Evaluation of request for rescheduling of products: [R5 000] \_R5 500;
  - (iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated (post-registration): [R3 000] R3 300;
  - (iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Council in terms of

Section 15(3): **[R650]** R1 700: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

### 4 Category D medicines (Veterinary medicine)

Veterinary medicines for which Council has determined by resolution that they are registerable:

- (a) In respect of the submission of an application for registration of -
  - (i) Products submitted with clinical and or toxicological data, (first strength, first dosage form): [R3 400] R3 740 per application;
  - (ii) Products submitted with no clinical or toxicology data (first strength, first dosage form): [R2 400] R2 640 per application;
  - (iii) Strengths and dosage forms other than those referred to in subparagraphs (i), (ii): **[R1 400]** <u>R1 540</u>;
  - (iv) Screening fee on receipt of the application: [R1 600] R1 760;
  - (v) Evaluation of additional submitted clinical data (pre-registration): [R1 300] R1 430
- (b) Any medicine, the registration of which has been approved by the Council in terms of Section 15(3):
  - (i) In respect of the registration of any medicine, the registration of which has been approved by the Council in terms of Section 15(3) and in respect of which an application fee has been paid: R1 760 for each registration;
  - (ii) Evaluation of request for rescheduling of products: [R5 000] <u>R5 500</u>;
  - (iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: [R3 000]
     R3 300;
  - (iv) Annually, in respect of the retention of the registration of a medicine,

the registration of which has been approved by the Council in terms of Section 15(3): **[R430]** R1 200: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3): Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

### 5 Use of unregistered medicines

- (a) In respect of the submission of an application for the **authorisation of the use**of an unregistered medicine:
  - (i) Clinical trial application (Companies): [R9 000] R9 900;
  - (ii) Clinical trial application (Institutions): [R4 500] R4 950;
  - (iii) Any other clinical trial application: [R2 200] R2 420;
  - (iv) Any other application except for the purpose of performing a clinical trial: [R300] R330.
- (b) In respect of clinical trials amendments:
  - (i) Fees in respect of an application for technical amendments: [R2 100] R 2 310 per amendment;
  - (ii) Fees in respect of an application for administrative amendment: **[R650]**R715 per amendment.

### 6 In respect of licences

- (a) An application for a new licence in terms of Section 22C (1)(b) of the Act:
  - (i) Manufacture: **[R21 800]** R23 980;
  - (ii) Distribute: **[R13 000]** R14 300 [Holder of certificate of registration (HCR)];
  - (iii) Wholesale: [R13 000] R14 300;
  - (iv) Import: [R13 000] R14 300 (Holder of certificate of registration);
  - (v) Export: [R13 000] R14 300 (Holder of certificate of registration).

- (b) An application for the renewal of a licence in terms of Section 22D of the Act, the licensing of which has been approved by the Council in terms of Section 22C(1)(b) of the Act:
  - (i) Manufacture: [R19 000] R20 900
  - (ii) Distribute: **[R10 900]** R11 990 (Holder of certificate of registration);
  - (iii) Wholesale: [R10 900] R11 990;
  - (iv) Import: [R8 000] R8 800 (Holder of certificate of registration);
  - (v) Export: [R8 000] R8 800 (Holder of certificate of registration).
- (c) Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: [R3 000] R10 000, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled;
- (d) Licensing for any manufacture, distributor, wholesale, import or export, the license of which has been approved by the Council in terms of Section 22(1)(b) of the Act: [R2 900] R3 190;
- (e) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export: R5 000.

### 7 Inspections to assess the quality, <u>safety and efficacy</u> of medicines <u>or scheduled</u> substances

- (a) Local manufacturing site [R650/h] R715/h;
- (b) International manufacturing sites (excluding Southern Africa Development Community countries): [R4 000/h] R4 400/h
- (c) <u>International manufacturing sites in Southern Africa Development</u> Community countries: R2 000/h;
- (d) Wholesale sites **[R5 500]** R6 050;
- (e) Distributor sites **[R5 500]** R6 050;
- (f) Local clinical trial site: R715/h;
- (g) <u>International clinical trial site (excluding Southern Africa Development Community countries): R4 400/h;</u>
- (h) <u>International clinical trial sites in Southern Africa Development Community countries: R2 000/h;</u>
- (i) <u>Local pharmacovigilance inspection: R715/h;</u>
- (j) <u>International pharmacovigilance inspection (excluding Southern Africa</u>

  Development Community countries): R4 400/h;

(k) <u>International pharmacovigilance inspection in Southern Africa Development</u>
Community countries: R2 000/h.

### 8 <u>Desktop inspection to assess quality, safety and efficacy of medicines or</u> scheduled substances: R2 000

### 9 Permits and Certificates

In respect of the issuing of a permit or a certificate:

- (a) Certificate [Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale]: [R1 200] \_ R1 320;
- (b) Import permit (holder of certificate of registration): **[R800]** R880;
- (c) Export permit (holder of certificate of registration): [R790] R869;
- (d) Any other permit or certificate: [R820] R902;
- (e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: [R820] R902.

### 10 Amendment of entries in register

In respect of all applications for amendments in terms of Section 15A, the name of the medicine approved by the Council under Section 15(5), which shall be the proprietary name, the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine, the conditions of registration, the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility: **[R700]** R770 per application.

### 11 Transfer of certificates of registration

In respect of an application in terms of Section 15B: **[R900]** R990 per application.

### 12 Appeal against the decision of the Authority

In respect of an application in terms of Section 24 (3): R50 000 per application.

### 13 Withdrawal of Notice

Government Notice Government Gazette No 39154 Notice R 784 is hereby withdrawn.

DR A MOTSOALEDI, MP

MINISTER, OF HEALTH

DATE:

### **SOUTH AFRICAN REVENUE SERVICE**

### NO. R. 913

31 AUGUST 2018

## CUSTOMS AND EXCISE ACT, 1964. AMENDMENT OF SCHEDULE NO. 2 (NO. 2/3/23)

In terms of section 57 of the Customs and Excise Act, 1964, Part 3 of Schedule No. 2 to the said Act is hereby amended, up to and including 10 August 2019, to the extent set out in the Schedule hereto.

M GUNGUBELE
DEPUTY MINISTER OF FINANCE

SCHEDULE

By the sub	By the substitution of the following	following:					
ltem	Tariff Heading Code		9	Description	Rebate Items	Imported from or Originating in	Rate of Safeguard duty
7.03 7.09 7.09	72.08	01.04	74	Flat-rolled products of iron or non-alloy steel, of a width of 600 mm or more, hot-rolled, not clad, 301.00-399.00, plated or coated (excluding that imported from or originating in. Adpanistan, Albania. Algeria, 401.00-499.00 American Samoa, Angola Antigua and Barbuda, Argentina, American Republic and Excluding Belarus, Belize, Benin, Bhuthan, Bolivia (Purinational State of), Bosnia and Herzegovina, 460.15/7208.25 African Republic. Chad, Chile, Cohombia, Comoros, Congo (The Democrate Republic of the), 460.15/7208.37 Republic. Chad, Chile, Cohombia, Comoros, Congo (The Democrate Republic of the), 460.15/7208.37 Republic. Chad, Chile, Chodombia, Comoros, Congo (The Democrate Republic of the), 460.15/7208.37 Republic. Chad, Chile, Cohombia, Comoros, Congo (The Democrate Republic of the), 460.15/7208.37 Republic. Chad, Chile, Chodombia, Comoros, Congo (The Democrate Republic of the), 460.15/7208.37 Republic. Chad, Chile, Chodombia, Comoros, Chile, Chad, Alamaida, Joddan, 460.15/7208.37 Republic. Chad, Alamaida, Joddan, 460.15/7208.37 Republic. Lavia, Indiania, Republic of the), 460.15/7208.37 Republic. Lavia, Indiania, Republic. Lavia, Lebanon, Lesotho, Liberia, Libya, Lithuania, Mauritus, Mexico, Micronesia (Federated States of), Moldova (Republic of), Republic of), Madagascar, Malawi, Maldives, Mali, Marshall Islands, Montenegro, Morocco, Mozambique, Namar, Panay, Peru, Philippines, Romania, Russian Federation, Rwanda, Saint Kitts and News, Saint Lucia, Saint Vincent and the Genadines, Saura South Sudan, St. Litaka, Sudan, Suiran, Surian, Surian, Vincent and the Solomon Islands, South Sudan, St. Lucia, Saint Vincens, Saint Lucia,	301.00-399.00; 401.00-399.00 (excluding 460.15/7208.25/01.06; 460.15/7208.36/01.06; 460.15/7208.36/01.06 460.15/7208.36/01.06 and 460.15/7208.36/01.05 - 460.15/7208.5/1/01.06	All Countries	40%

By the substitution of the following:	f the followin	.g.				
Tariff Heading	Code	СО	CD Description	Rebate Items	Imported from or Originating in	mported from or Rate of Safeguard Originating in duty
7225.40	01.06	67	Other, not further worked than hot-rolled, not in coils (excluding that imported from or originating in: Afghanistan, Albania, Algeria, American Samoa, Angola, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia (Pluinational State of), Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Burkina Faso, Burundi, Cambodia, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Comoros, Congo (The Democratic Republic of the), Congo (Republic of the), Costa Roa, Other Roa, Other Dibouti, Dominica, Dominican Republic, Ecuador, Egypt (Arab Republic of), El Salvador, Eritrea, Ethiopia, Fiji, Gabon, Gambia (Republic of), Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran (Islamic Republic of), Iraq (Republic of), Jamaica, Jordan, Kazakhtan, Kenya, Krinbati, Korea (Democratic People's Republic of), Kosvov, Kyrgyzstan Republic, La People's Democratic Republic, Lativa, Lebanon, Lesoftho, Liberia, Lifthuaria, Mauritania, Mauritius, Mexico, Micronesia (Federated States of), Moldova (Republic of), Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Panama, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Romania, Russian Federation, Rwanda, Saint Kitts and Newis, Saint Lucia, Saint Vincent and the Grenadines, Somalia, South Sudan, Sri Lanka, Sudan, Suriname, Swaziland, Syrian Arab Republic, Taiwan (Province of China), Tajikistan, Tanzania (United Republic of), Thailand, Timor-Leste, Togo, Tonga, Tunisia, Turkey, Turkmenistan, Tanzania (United Republic of), Yemen, Venezuela (Bolivarian Republic of), Vietnam, West Bank and Gaza (State of Palestine), Yemen,	301.00-399.00; 401.00-499.00 (excluding 460.15/7225.40/19.06)	All Countries	10%

### **SUID-AFRIKAANSE INKOMSTEDIENS**

### NO. R. 913 **31 AUGUSTUS 2018**

# DOEANE- EN AKSYNSWET, 1964. WYSIGING VAN BYLAE NO. 2 (NO. 2/3/23)

Kragtens artikel 57 van die Doeane- en Aksynswet, 1964, word Deel 3 van Bylae No. 2 by bogenoemde Wet hiermee gewysig, tot en met 10 Augustus 2019, in die mate in die Bylae hierby aangetoon.

M GUNGUBELE ADJUNKMINISTER VAN FINANSIES

Deur die √	Deur die vervanging van die volgende:	e volgende:					
ltem	Tariefpos	Kode	TS TS	Beskrywing	Kortingitems	Ingevoer vanaf of Oorspronklik van	Skaal van Beskermende reg
260.03	72.08	01.04	74	Gewalste platprodukte van yster of nie-legeringstaal, met 'n wydte van minstens 600 mm, 301.00-399.00; warmgewals, nie bedek, geplateer of bestryk nie (uitgesonderd die van vlekvrye staal) (uitgesonderd die yan vlekvrye staal) (uitgesonderd die gevoer vanaf of afkonstig van. Afghanitë, Adbanië, Agerbeigh, 401.00-499.00 (uitgesonderd die nigevoer vanaf of afkonstig van. Afghanista, Amenië, Aserbeidjan, Amerikaans Samoa, Angola, Antigua en Barbuda, Argentinië, Amenië, Aserbeidjan, Bangladesj, Belarus, Belize, Benin, Bhoetan, Bolivia (Pluralistiese Staat van), Bosnië en 401.15/7208.37 Harcsgowina, Botswana, Brasilië, Bulganye, Burkina Faso, Burundi, Kambodia, Comoria, 601.15/7208.37 Kameroen, Kaap Verde, Sentraal-Afrikaanse Republiek, Ecuador, Egipte (Arabiese Republiek van), Georgië, Ghana, Grenada, Guatemala, Guinee, Guinee-Bissau, Guyana, Haiti, Honduras, Indië, Indonesië, Iran (Islamitiese Republiek van), Irak (Republiek van), Jamaika, Jordanië, Kasakstan, Kenia, Kiribati, Korea (Demokratiese Volksrepubliek van), Kosov, Kiribstisanse Republiek, Leiland, Libanon, Lesotho, Liberië, Libië, Litaue, Macedonië (voormalige Joego Slawiese Republiek van), Madagaskar, Malawi, Maldives, Mali, Marshall-eilande, Mauritanië, Mauritius, Mexiko, Mikronesië (Federale State van), Moldawië (Republiek van), Morgolië, Montenegro, Marokko, Mosambiek, Myanmar, Namibië, Nepal, Nicaragua, Niger, Solomon Ellande, Somalië, Suid-Soedan, Sri Lucia, Sint Lucia, Sint Vincert en die Grenadines, San Tome en Principe, Senegal, Soedan, Suriname, Swaziland, Siriese Republiek, Tawan (Povinisie van China), Tarzanië (Verenigde Republiek van), Thailand, Timor-Leste, Togo, Tonga, Tunisië, Turkye, Turkmenistan, Tuvawan, Uganda, Ukarine, Urganda, Usanda, Uganda, Usanda, Uganda, Usanda, Saz Tome, Saz Tome, Saz Tome, Saz Tome, Saz Tome, Saz Tome, Saz	301.00-399.00; (uitgesonderd 460.1677208.25/01.06, 460.1577208.35/01.06, 460.1577208.37/01.06 en 460.1577208.5/01.05 - 460.1577208.5/01.05 - 460.1577208.5/101.06)	Alle Lande	10%

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Deur die v	Deur die vervanging van die volgende:	e volgende:					
Item	Tariefpos	Kode	TS	Beskrywing	Kortingitems	Ingevoer vanaf of Oorspronklik van	Skaal van Beskermende reg
260.03	7225.40	01.06	29	Ander, nie verder bewerk as warmgewals nie, nie in rolle nie (uitgesonderd die ingevoer vanaf of afkomstig van: Afghanistan, Albanië, Agerië, Amerikaans Samoa, Angola, Antigua en Barbuda, Argentinië, Armenië, Aserbeidjan, Bangladesj, Belarus, Belize, Benin, Bhoetan, Bolivia (Pluralistiese Staat Aserbeidjan, Bangladesj, Belarus, Belize, Benin, Bhoetan, Bolivia (Pluralistiese Staat Aserbeidjan, Bangladesj, Belarus, Belize, Benin, Bhoetan, Bolivia (Pluralistiese Staat Kambodja, Kameroen, Kaap Verde, Sentraal-Afrikaanse Republiek, Tsjad, Chili, Colombia, Comore, Kongo, (Demokratiese Republiek van die), Kongo (Republiek van die), Kongo (Republiek van die), Costa Rica, Ivoorkus, Kuba, Dijboeti, Dominikanse Republiek, Ecuador, Egipte (Arabiese Republiek van), El Salvador, Eritrea, Ethiopië, Fidji, Gaboen, Gambië (Republiek van), Georgië, Ghana, Grenada, Guatemala, Guinee, Guinee-Bissau, Guyana, Haiti, Honduras, Indië, Indonesië, Iran (Islamitiese Republiek van), Irak (Republiek van), Asovov, Kirgisistanse Republiek, Laos Demokratiese Volksrepubliek van), Kosovo, Kirgisistanse Republiek, Laos Demokratiese Volksrepubliek, Lefland, Libanon, Lesotho, Liberië, Lifaue, Macedonië (voormalige Joego Slawiese Republiek, Annon, Macagaskar, Malawi, Maldives, Mali, Marshall-eilande, Mauritanië, Mauritius, Mexiko, Mikronesië (Federale State van), Moldawië (Republiek van), Mondenegro, Marokko, Mosambiek, Myanmar, Namibië, Nepal, Nicraqua, Niger, Nigerië, Pakistan, Palau, Panama, Papoea-Nieu-Guinee, Paraguay, Peru, Filippypur, Roemeneië, Russiese Federasie, Rwanda, Sint Kitts en Nevis, Sint Lucia, Sint Vincent en die Grenadines, Samoa, Sao Tome en Principe, Senegal, Serwië, Seychelle, Sierra Leone, Solomon Eilande, Somalië, Suirk-Soedan, Sri Lanka, Soedan, Suriname, Swaziland, Siriese Arabiese Republiek, Taiwan (Provinsie van China), Tadzjikistan, Tanzanië (Verenigde Republiek van), Tiadzjikistan, Tanzanië (Verenigde Republiek van), Viëtnam, Wesoewer en Gaza (Staat van Palestina), Jemen, Zambië, Zimbabwe)	301.00-399.00; 401.00-499.00 (uitgesonderd 460.15/7225.40/19.06)	Alle Lande	10%

### **SOUTH AFRICAN REVENUE SERVICE**

### NO. R. 914 31 AUGUST 2018

## CUSTOMS AND EXCISE ACT, 1964. AMENDMENT OF SCHEDULE NO. 2 (NO. 2/3/24)

In terms of section 57 of the Customs and Excise Act, 1964, Part 3 of Schedule No. 2 to the said Act is hereby amended, with effect from 11 August 2019 up to and including 10 August 2020, to the extent set out in the Schedule hereto.

DEPUTY MINISTER OF FINANCE

SCHEDULE

By the su	bstitution of	By the substitution of the following:	.: G				
Item	Tariff Heading	Code	CD	Description	Rebate Items	Imported from or Originating in	Rate of Safeguard duty
260.03	72.08	01.04	74	Flat-rolled products of iron or non-alloy steel, of a width of 600 mm or more, hot-rolled, not clad, claded products of iron or non-alloy steel, of a width of 600 mm or more, hot-rolled, not data, American Samoa, Angola, Antigua and Barbuda, Argentina, American Samoa, Angola, Antigua and Barbuda, Argentina, American Samoa, Angola, Antigua and Barbuda, Argentina, American Samoa, Angola, Angula, Angula, Angula, Angula, Stee of), Bosnia and Herzegovina, Botswana, Barzil, Bulgaria, Burkina Faso, Burundi, Cambordia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Comordia, Comordia, Comordia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Condrodia, Cameroon, Cape Verde, Dennica, Dominican Republic, Chad, Chile, Costa Rica, Cote Ilviourie, Cuba, Dilbouti, Dominica, Dominican Republic, Ecuador, Egypt (Arab Republic of), El Salvador, Errica, Ethiopa, Fiji, Gabon, Gambia (Republic of), Georgia, Ghara, Grenada, Guatemala, Guinea, Suinea, Bissau, Guyana, Haiti, Hondruras, India, Indonesia Iran (Islamic Republic, Of), Iraq (Republic of), Rosovo, Kyrgyszata Republic, La People's Bepublic, Larivia, Lebanon, Lesotho, Ukrigyastar, Republic, Of), Mongolia, Montenagor, Morcoco, Micronosia (Federated States of), Moldova (Republic of), Mongolia, Montenagor, Morcoco, Mozambique, Myammar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Romania, Russian Federation, Ramana, Papua New Saint Lucia, Saint Vincent and the Grenadines, Samoal, Souriella, Sunth Roden, Sonmola, Sonmalia, Chorne of China), Talikistan, Tanzania (United Republic of), Thalland, Timor-Leste, Togo, Tonga, Turkey, Turkmenistan, Tuwalu, Venezuela (Bolivarian Republic of), Weiman, West Bank and Gaza (State of Palestine), Yenne, Zandu (Palestine), Yenne, Zandu (Palestine), Wenne, Zandu (Palestine), Wenne, Zandu (Palestine), Wenne, Zandu (Palestine), Wenne, Landawa, Zandawa, Zanda (Palestine), Wenne, Zanda (Palestine), Wenne, Zanda (Palestine), Wenne, Zanda	301.00-399.00; 301.00-399.00; (excluding) 460.15/7208.25/01.06; 460.15/7208.35/01.06; 460.15/7208.35/01.06; 460.15/7208.51/1.05; 460.15/7208.51/1.06)	All Countries	%8

By the sul	By the substitution of the following:	he followii	ng:				
ltem	Tariff Heading	Code	9	CD Description	Rebate Items	Imported from or Rate of Originating in duty	Rate o
260.03	7225.40	01.06	29	Other, not further worked than hot-rolled, not in coils (excluding that imported from or originating in: Adahanisa, Albania, Barai, Bularia, Benin, Buturdi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Comoros, Congo (The Democratic Republic of the), Congo (Republic of the), Costa Rica, Cofte d'Voire, Cuba, Dijbouti, Dominica, Dominican Republic, Ecudor, Egytt (Arab Republic of), El Salvador, Eritrea, Ethiopia, Flij, Gabon, Gambia (Republic of), Georgia, Ghana, Grenada, Guaremala, Guinea, Guinea, Ethiopia, Flij, Gabon, Gambia (Republic of), Georgia, Chara, Grenada, Guaremala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Kora (Democratize People) Se Republic of), Jamaica, Jordan, Kazakhtsan, Kenya, Kiribati, Kora (Democratize People) Se Republic of), Jamaica, Jordan, Kazakhtsan, Kenya, Kiribati, Kora (Democratize People) Se Republic of), Jamaica, Jordan, Kazakhtsan, Kenya, Kiribati, Kora (Democratize People) Se Republic of), Madagascar, Malawi, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia (Federated States of), Moldova (Republic of), Mongola, Mongola, Mongola, Mongola, Mongola, Santa, Lucia, Santa (Virgania, Somalia, Somalia, South Sudan, Shiri Kitts and Nevis, Saint Lucia, Saint Urca, Saint Urca, Sama (Sulpipines, Romania, Russia), Tajikistan, Tanzania (United Republic of), Thailand, Timor-Leste, Tongo, Tonga, Tunisia, Turkey, Turkmenistan, Tuzadia, Uganda, Ukraine, Unugay, Uzbekistan, Amarut, Albania, Marenzula, Marenzula Republic, Tanwan (Pervulne), Vietnam, West Bank and Gaza (State of Palestine), Yemen,	301.00-399.00; 401.00-499.00 (excluding 460.15/7225.40/10.06 - 460.15/7225.40/19.06)	All Countries	%8

### **SUID-AFRIKAANSE INKOMSTEDIENS**

### NO. R. 914 **31 AUGUSTUS 2018**

# DOEANE- EN AKSYNSWET, 1964. WYSIGING VAN BYLAE NO. 2 (NO. 2/3/24)

Kragtens artikel 57 van die Doeane- en Aksynswet, 1964, word Deel 3 van Bylae No. 2 by bogenoemde Wet hiermee gewysig, met ingang vanaf 11 Augustus 2019 tot en met 10 Augustus 2020, in die mate in die Bylae hierby aangetoon.

		aal van Beskermende	
	•	Ingevoer Ska vanaf of reg Oorspronklik van	Alle Lande 8%
		Kortingitems	331.00-399.00; (uitgesonderd 480.15/7208.25/01.06, 480.15/7208.25/01.06, 480.15/7208.37/01.06 en 480.15/7208.37/01.06 en 480.15/7208.5/01.05, 480.15/7208.5/10.06,
BYLAE		Beskrywing	Gewalste platprodukte van yster of nie-legeringstaal, met 'n wydte van minstens 600 mm, 301.00-399.00 warmgewals, nie bedek, geptableer of bestryk nie (uitgesonderd die van viekryve staal) (uitgesonderd die bedek, geptableer of bestryk nie (uitgesonderd die van viekryve staal) (uitgesonderd die ingevoer vanaf of afkomstig van. Afghanistan, Albanië, Algerië, 401.00-499.00 (uitgesonderd die ingevoer vanaf of afkomstig van. Afghanistan, Albanië, Algerië, 401.00-700-82 (uitgesonderd die ingevoer vanaf of afkomstig van. Afghanistan, Albanië, Algerië, 401.01-702.82 (uitgesonderd) (uitgesonderd die van. Benderd, Antigue en Barbuda, Argertlinië, Ammerië, Aserbeidjan, 401.15/7208.31 (kameroen, Kaap Verde, Sentraal-Afrikaanse Republiek, Tsjad, Chili, Colombia, Comore, 401.15/7208.31 (kameroen, Kaap Verde, Sentraal-Afrikaanse Republiek, Ecuador, Egipte (Arabiese 401.15/7208.51 (koorkus, Kuba, Djiboeti, Dominikaanse Republiek, Ecuador, Egipte (Arabiese 401.15/7208.51 (koorkus, Kuba, Djiboeti, Dominikaanse Republiek, Malik, Malik, Kania, Kiribati, Korea (Demokratiese Volksrepubliek van.), Jamarika, Jordanië, Kasakstan, Kenia, Kiribati, Korea (Demokratiese Volksrepubliek van.), Madagaskar, Malik, Marshall-ellande, Mauritanië, Mauritus, Mexiko, Mikronesië, Tederderie State van.) Madagaskar, Malawi, Maldives, Mali, Marshall-ellande, Mauritanië, Noemeië, Pakkisan, Rabawi, Madives, Mosambiek, Nayammar, Namibië, Nepa, Nigerië, Pakkisan, Palau, Panama, Papoea-Nieu-Guinee, Paraguay, Peru, Filippyne, Roemenië, Rabakis, Tawan (Provinsie van China), Tadzikjkistan, Tarzanië (Verenigde Republiek, Tawan Provinsie van China), Tadzikjkistan, Tarzanië (Verenigde Republiek, Tawan Provinsie van China), Tadzikjkistan, Tarzanië (Verenigde Republiek, Tawan Provinsie van China), Tadzikjkistan, Tarzanië (Verenigde Republiek van), Thailand, Timor-Lesster, Pogo-Toma (Granda), Jamanis, Jamanis, Ukraine, Urganda, Ukraine, Urganda, Ukraine, Urganda, Ukraine, Urganda, Ukraine, Urganda, Ukraine, Urganda, Verenigde Republiek, Van.), Viëtinam, Wesoewer en
		TS	74
	e volgende	Kode	01.04
	ervanging van d	Tariefpos	72.08
	Deur die v	Item	260.03
	BYLAE	BYLAE  Deur die vervanging van die volgende:	die vervanging van die volgende:    Tariefpos   Kode   TS   Beskrywing   Kortingitems   Kortingitems

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2	200

1	oral die vervanging van die volgende	201361146					
Item	Tariefpos	Kode	ST	Beskrywing	Kortingitems	Ingevoer vanaf of Oorspronklik van	Skaal van Beskermende reg
260.03	7225.40	01.06	29	Ander, nie verder bewerk as warmgewals nie, nie in rolle nie (uitgesonderd die van Vekvrye staal) (uitgesonderd die ingevoer vanaf of afkomstig van. Afghanistan, Albanië, Aserbeidian, Bangaledes, Belaus, Beitze, Benin, Bhoetan, Bolivia (Pluralistiese Staat van), Bosnië en Herzegowina, Botswana, Brasilië, Bulgarye, Burkina Faso, Burundi, Rambodja, Kameroen, Kaap Verde, Sentraal-Afrikaanse Republiek, Tişad, Chili, Colombia, Comore, Kongo, (Demokratiese Republiek van die), Kongo (Republiek van die), Costa Rica, Ivoorkus, Kuba, Djiboeti, Dominika, Dominikaanse Republiek, Ecuador, Egipte (Arabiese Republiek van), Elashador, Eritraa, Ethiopië, Fidji, Gabben, Gambië (Republiek van), Georgië, Ghana, Grenada, Guatemala, Guinee, Guinee-Bissau, Guyana, Haiti, Hondruas, Indië, Indonessië, Iran (Islamitiese Republiek van), Irak (Republiek van), Jamaika, Jordanië, Kasakstan, Kenia, Kiribati, Kora (Demokratiese Volksrepubliek, Latlane, Maccedonië (voormalige Joego Slawiese Republiek van), Madagaskar, Malawi, Maldives, Mala, Marshall-eilande, Maurtanië, Murtunie, Marokko, Microresië (Federale State van), Moldawië (Republiek van), Morawië, Rosov, Kingististanse Republiek, Lashana, Papocea-Neu-Guinee, Paraguay, Peru, Filippyne, Roemenië, Russiese Federasie, Rwanda, Sint Kitts en Nevis, Sint Lucia, Sint Vincerte and ie Geraddines, Santoa, Sao Tome en Principe, Snervië, Servië, Seychelle, Sierra Leone, Solomon Ellande, Somalië, Suld-Soedan, Sri Lanka, Seedan, Suriname, Swaziland, Siriese Arabiese Republiek, Taiwan (Provinsie van China), Tadzikistan, Tanzanië (Verenigde Republiek van), Thaland, Timor-Leste, Togo, Tonga, Tunsië, Turkye, Turkmenistan, Tuvalu, Uganda, Ukraine, Uruguay, Uzbekistan, Vannuali, Jamen, Zambië, Zimbabwe)	301.00-399.00; 401.00-499.00 (uitgesonderd 460.15/7225.40/19.06)	Alle Lande	%8

### **SOUTH AFRICAN REVENUE SERVICE**

### NO. R. 915 31 AUGUST 2018

# CUSTOMS AND EXCISE ACT, 1964. AMENDMENT OF SCHEDULE NO. 4 (NO. 4/2/390)

In terms of section 75 of the Customs and Excise Act, 1964, Part 2 of Schedule No. 4 to the said Act is hereby amended to the extent set out in the Schedule hereto.

M GUNGUBELE DEPUTY MINISTER OF FINANCE

By the insertion of the following:

Rebate Item Tariff Headi	Tariff Heading	Rebate Code	СО	CD Description	Extent of Rebate
460.15	7208.51	01.06	63	Flat-rolled products of iron or non-alloy steel, of a width of 600 mm or more, not in coils, not further worked than hot-rolled, of a Full duty in Schedule No. tickness of 10 mm or more but not exceeding 100 mm, with a yield strength of 315 MPa or more but not exceeding 460 MPa and Schedule No. 2 and a tensile strength of 490 MPa or more but not exceeding 650 MPa, having an impact strength of 27 Joules or more but not exceeding 650 MPa, having an impact strength of 27 Joules or more but not exceeding 650 MPa or more but not exceeding 650 MPa, in such quantities, at such times and subject to such conditions as the international Trade Administration Commission may allow by specific permit, provided the products are not available in	Full duty in Schedule No. 1 and Schedule No. 2
460.15	7225.40	19.06	89	Flat-rolled products of other alloy steel, of a width of 600 mm or more, not in coils, not further worked than hot-rolled, of a Full duty in Schedule No. 1 thickness of 10 mm or more but not exceeding 100 mm, with a yield strength of 315 MPa or more but not exceeding 460 MPa and Schedule No. 2 and a tensile strength of 490 MPa or more but not exceeding 650 MPa, having an impact strength of 27 Joules or more but not exceeding 650 MPa, having an impact strength of 27 Joules or more but not exceeding 460 MPa and Schedule No. 2 exceeding 40 Joules at +20°C or less but not less than -20°C, in such quantities, at such times and subject to such conditions as the International Trade Administration Commission may allow by specific permit, provided the products are not available in the SAQU market	Full duty in Schedule No. 1 and Schedule No. 2

### **SUID-AFRIKAANSE INKOMSTEDIENS**

### NO. R. 915 **31 AUGUSTUS 2018**

# DOEANE- EN AKSYNSWET, 1964. WYSIGING VAN BYLAE NO. 4 (NO. 4/2/390)

Kragtens artikel 75 van die Doeane- en Aksynswet, 1964, word Deel 2 van Bylae No. 4 by bogenoemde Wet hiermee gewysig in die mate in die Bylae hierby aangetoon.

M GUNGUBELE ADJUNKMINISTER VAN FINANSIES

Deur die invoeging van die volgende:

Kortingitem	ortingitem Tariefpos Kortingkode	Kortingkode	TS	TS Beskrywing	Mate van Korting
460.15	7208.51	01.06	63	63 Gewalste platprodukte van yster of nie-legeringstaat, met 'n wydte van 600 mm of meer, nie in rolle, nie verder bewerk as volle reg in Bylae No. 1 en warmgewals nie, met 'n dikte van 10 mm of meer maar hoogstens 100 mm, met 'n meegee sterkte van 315 MPa of meer maar hoogstens 460 MPa, en met 'n riefkrag sterkte van A90 MPa of meer maar hoogstens 650 MPa, en met 'n trefkrag sterkte van mistens 22 Joules of meer maar hoogstens 40 Joules teen +20°C of minder maar nie minder as -20°C, in die hoeveelhede en op die tye en onderhewig aan sodanige voorwaardes wat die Internasionale Handelssadministrasiekommissie by bepaalde permit mag toelaat, met dien verstande dat die produkte nie in die SADU gebied beskikbaar is nie	Volle reg in Bylae No. 1 en Bylae No. 2
460.15	7225.40	19.06	89	68 Gewalste platprodukte van ander legeringstaal, met 'n wydte van 600 mm of meer, nie in rolle, nie verder bewerk as volle reg in Bylae No. 1 en warmgewals nie, met 'n dikte van 10 mm of meer maar hoogstens 100 mm, met 'n meegee sterkte van 315 MPa of meer maar hoogstens 400 MPa, en met 'n spankrag sterkte van 490 MPa of meer maar hoogstens 650 MPa, en met 'n trefkrag sterkte van 22 Joules steen +20° C of minder maar in em mider as -20° C, in dié hoeveelhede en op dié tye en onderhewig aan sodanige voonwaardes wat die Internasionale Handelsadministrasiekommissie by bepaalde permit mag toelaat, met dien verstande dat die produkte nie in die SADU gebied beskikbaar is nie	Volle reg in Bylae No. 1 en Bylae No. 2

### **SOUTH AFRICAN REVENUE SERVICE**

NO. R. 916 31 AUGUST 2018

## CUSTOMS AND EXCISE ACT, 1964. AMENDMENT OF SCHEDULE NO. 4 (NO. 4/2/391)

In terms of section 75 of the Customs and Excise Act, 1964, Part 2 of Schedule No. 4 to the said Act is hereby amended to the extent set out in the Schedule hereto.

M GUNGUBE

SCHEDULE

By the inserti	y the insertion of the following:	ing:			
Rebate Item	Tariff Heading	Rebate Code	CD	CD Description	Extent of Rebate
460.16	8523.52.10	01.08	87	Digital "smart cards" (excluding proximity cards or tags), in such quantities, at such times and subject to such conditions as the Full duty International Trade Administration Commission may allow by specific permit, provided the "smart cards" are not available in the SACU area	Full duty

### **SUID-AFRIKAANSE INKOMSTEDIENS**

NO. R. 916 **31 AUGUSTUS 2018** 

# DOEANE- EN AKSYNSWET, 1964. WYSIGING VAN BYLAE NO. 4 (NO. 4/2/391)

Kragtens artikel 75 van die Doeane- en Aksynswet, 1964, word Deel 2 van Bylae No. 4 by bogenoemde Wet hiermee gewysig in die mate in die Bylae hierby aangetoon.

M GUNGUBELE ADJUNKMINISTER VAN FINANSIES

	zoar are mroeging ran are reigenae:	on and			
Kortingitem	Tariefpos	Kortingkode	TS	Beskrywing	Mate van Korting
460.16	8523.52.10	01.08	87	Digitale "slimkaarte" (uitgesonderd "proximity" kaarte of etikette), in dié hoeveelhede en op dié tye en onderhewig aan sodanige voorwaardes wat die Internasionale Handelsadministrasiekommissie by bepaalde permit mag toelaat, met dien verstande dat die "slimkaarte" nie in die SADU gebied beskikbaar is nie	Volle reg

### **DEPARTMENT OF TRADE AND INDUSTRY**

NO. R. 917 31 AUGUST 2018

PROPOSED AMENDMENTS TO THE NATIONAL GAMBLING REGULATIONS, 2004, PUBLISHED IN GOVERNMENT GAZETTE NO. 26994 OF 12 NOVEMBER 2004

By virtue of the powers vested in me in terms of section 87 of the National Gambling Act, 2004 (Act No. 7 of 2004), I, Dr Rob Davies, the Minister of Trade and Industry, after consultation with the National Gambling Policy Council, intend to make amendments to the National Gambling Regulations 2004.

The proposed amendments are contained in the Schedule hereto. Interested persons are hereby invited to comment and to make written submissions in this regard within 45 (forty five) calendar days from the date of publication of this Notice to:

Director-General, Department of Trade and Industry Private Bag X 84 Pretoria 0001

Or hand deliver to:

77 Meintjies Street Block B, 1st Floor Sunnyside Pretoria, 0002

Or e-mail: TShale@thedti.gov.za For attention: Ms Tsholofelo Shale

Dr Rob Davies (MP)

Minister of Trade and Industry

1 August 2018

### **DEPARTMENT OF TRANSPORT**

NO. R. 918 31 AUGUST 2018

### **South African Civil Aviation Authority**

### APPLICATION FOR A HELIPORT LICENCE

- An application for a heliport licence relating to the proposed Ultimate Heliport has been received from Ultimate Heliport (Pty) Ltd in terms of regulation 139.03.11 of the South African Civil Aviation Regulations,
- 2. In terms of regulation 139.03.11(1) of the said regulations, the following particulars concerning the application are published for comment:
  - (a) Full name of the applicant: Ultimate Heliport (Pty) Ltd.
  - (b) Particulars of the location heliport coordinates: S26 ° 01' 42.12" and E028 ° 06' 38.54".
- 3. Written representations against or in favour of the said application should reach the Director of Civil Aviation at the following address: South African Civil Aviation Authority, Private Bag x 73, Halfway House, 1685.

Comments should be forwarded to: Mr Nelson Nkabiti at e-mail address: Nkabitin@caa.co.za, not later than **3 September 2018**.

### 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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