



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Vol. 611

25 May
Mei 2016

No. 40015

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ISSN 1682-5843



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Government Printing Works

Notice submission deadlines

Government Printing Works has over the last few months implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submit your notice request.

In line with these business rules, GPW has revised the notice submission deadlines for all gazettes. Please refer to the GPW website www.gpwonline.co.za to familiarise yourself with the new deadlines.

CANCELLATIONS

Don't forget!

Cancellation of notice submissions are accepted by GPW according to the deadlines stated in the table above.

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.

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

take note!

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

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.

PROOF OF PAYMENTS



GPW reminds you that all notice submissions **MUST** be submitted with an accompanying proof of payment (PoP) or purchase order (PO). If any PoP's or PO's are received without a notice submission, it will be failed and your notice will not be processed.

When submitting your notice request to submit.egazette@gpw.gov.za, please ensure that a purchase order (GPW Account customer) or proof of payment (non-GPW Account customer) is included with your notice submission. All documentation relating to the notice submission must be in a single email.

A reminder that documents must be attached separately in your email to GPW. (In other words, your email should have an Adobe Form plus proof of payment/purchase order – 2 separate attachments – where notice content is applicable, it should also be a 3rd separate attachment).

REMINDER OF THE GPW BUSINESS RULES

- Single notice, single email – with proof of payment or purchase order.
- All documents must be attached separately in your email to GPW.
- 1 notice = 1 form, i.e. each notice must be on a separate form
- Please submit your notice **ONLY ONCE**.
- Requests for information, quotations and inquiries must be sent to the Contact Centre **ONLY**.
- The notice information that you send us on the form is what we publish. Please do not put any instructions in the email body.

IMPORTANT NOTICE:

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

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

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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 565

25 MAY 2016

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCE ACT, 1965 (ACT 101 OF 1965)

I, **Joey Gouws, Registrar of Medicines**, acting by virtue of a delegation in terms of section 34A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), hereby exclude in terms of Section 36 of Act 101 of 1965, on the unanimous recommendation of the members present at a meeting of the Medicines Control Council held on **22 April 2016** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No R. 510 of 10 April 2003.



.....
JOEY GOUWS
REGISTRAR OF MEDICINES


DEPARTEMENT VAN GESONDHEID

NO. 565

25 MEI 2016

**UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKER
BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE
MIDDELS 1965 (WET 101 VAN 1965)**

Ek, **Joey Gouws, Registrateur van Medisyne**, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Middels, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op **22 April 2016** sluit hierby uit, kragtens Artikel 36 van die Wet 101 van 1965, die medisyne in die bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing Nr. R. 510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.



.....
JOEY GOUWS
REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATIO N/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING	APPLICANT/ APPLIKANT
45/B.3/0948	Ferinject	injection	<p>Regulation 8: Labeling of medicines: Regulation 8 (1) Bilingualism Regulation 8(1)(a) Scheduling status Regulation 8(1)(c) Registration number Regulation 8(1)(p) Name of the Holder of Registration</p> <p>Regulation 9: Package Insert Regulation 9(1) Bilingualism Regulation 9(1)(a) Scheduling status Regulation 9(1)(q) Registration number Regulation 9(1)(r) Name of the holder of the certificate of registration</p> <p>Regulation 10: Patient Information Leaflet Regulation 10(1) Bilingualism Regulation 10(1)(a) Scheduling status Regulation 10(1)(k) Registration number Regulation 10(1)(l) Name of the holder of the certificate of registration Regulation 10(1)(m) The date of publication of the patient information leaflet</p>	<p>Provided that the authorization is only for 5000 units of Batch 522011.</p>	Takeda (Pty) Ltd
43/20.2.8/0226	Aptivus 250 mg	tablet	<p>Regulation 8: Labeling of medicines: Regulation 8(1): Bilingualism Regulation 8 (1) (a) Scheduling status Regulation 8(1) (c) Registration number</p> <p>Regulation 9 Package Insert: Regulation 9(1) Bilingualism Regulation 9(1)(a) Scheduling Regulation 9(1)(q) Registration number Regulation 9(1)(r) Name of the Holder of the Certificate of Registration.</p> <p>Regulation 10 Patient Information Leaflet: Regulation 10(1)(a) Scheduling Regulation 10(1)(k) Registration number Regulation 10(1)(l) Name of the Holder of Certificate of Registration</p>	<p>A period of twelve months from the date of Government Gazette publication</p>	Ingelheim Pharmaceuticals

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATIO N/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING	APPLICANT/ APPLIKANT
Various	SCHEDULE 0 Human medicines	Various	Regulation 10(1)(m) date of publication of the patient information leaflet Section 22G(3) and Section 18A relating to the supply of the medicine according to a bonus system and a transparent pricing system which includes a single exit price	A period of three years from the date of Government Gazette publication.	Various

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
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Publications: Tel: (012) 748 6053, 748 6061, 748 6065