



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette

No. 10231

Regulasiekoerant

Vol. 589

**Pretoria, 8 July
Julie 2014**

No. 37816

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



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

IMPORTANT NOTICE

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an "OK" slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender's responsibility to phone and confirm that the documents were received in good order.

Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

CONTENTS • INHOUD

No.

Page
No. Gazette
No.**GOVERNMENT NOTICE****Health, Department of***Government Notice*

| | | |
|---|---|-------|
| R. 536 Medicines and Related Substances Act (101/1965): Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances: Comment notice on the annual adjustment of the single exit price of medicines and scheduled substances for the year 2015 | 3 | 37816 |
|---|---|-------|

CORRECTION NOTICE

National Extraordinary Gazette No. **37796** of **3 July 2014** is hereby withdrawn and replaced with the following:

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH**No. R. 536****8 July 2014****MEDICINES AND RELATED SUBSTANCES ACT 1965 (No. 101 of 1965)****REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: COMMENT NOTICE ON THE ANNUAL ADJUSTMENT OF THE SINGLE EXIT PRICE OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2015**

In terms of Regulation 8 (1) of the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances of the Medicines and Related Substances Act, 1965 (No. 101 of 1965), the Minister of Health is required to determine on an annual basis, the extent to which medicine prices may be adjusted. In making this determination the Minister considers the following provisions of Regulation 8 (1)-

- (a) the average CPI for the preceding year;
- (b) the average PPI for the preceding year;
- (c) changes in the rates of foreign exchange and purchasing power parity;
- (d) international pricing information relating to medicines and scheduled substances;
- (e) comments received from interested persons in terms of regulation 8(2); and
- (f) the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic.

In 2014, the following formula was used as a guide in the review of the SEP adjustment-

$$\begin{aligned} &70\% \text{ (South African CPI)} + 15\% \text{ (Euro Rand exchange rate)} + \\ &15\% \text{ (Dollar Rand exchange rate)} = \% \text{ adjustment} \end{aligned}$$

The official data used in the formula with respect to the Consumer Price Index (CPI) for south Africa and the foreign exchange rates were obtained from official publications by

the Statistics South Africa at www.statssa.gov.za and the South African Reserve Bank at www.resbank.co.za respectively. The official period considered for determining the SEP adjustment was specified.

The extent to which medicine prices has been adjusted annually is not acceptable to all stakeholders due to a range of factors. On the other hand the Minister has an obligation to ensure that price adjustments take account of the availability, affordability, and quality of medicines and scheduled substances for use by the people of the Republic. The Minister of Health on recommendation of the Pricing Committee would like to review the use of the current formula as a reference guide for making a recommendation on the determination of the extent to which medicines prices may be adjusted on an annual basis. Interested parties are therefore invited to provide comments on alternative methodologies for adjusting medicines prices for 2015 in the following areas:

1. Investigate the feasibility of establishing an SEP inflator for-
 - (a) Fully imported generic products
 - (b) Locally produced generic products
 - (c) Originator medicines

2. Review the formula used as a reference guide in making a recommendation of the extent to which medicines prices may be adjusted on an annual basis.

The cost pressure for each category of these products is different and the annual price adjustment for each category should be different. The determination of the final price of a medicine takes account of the costs of producing the final pharmaceutical product and the desired margin or profit. The extent to which the product cost is influenced by inflation and exchange rate is determined by where the cost of producing the final pharmaceutical product is conducted.

Interested persons are invited to submit any substantiated comments and representations on the Minister's intended review, on a compact disc and a hard copy within three months from the date of publication of this notice to:

**The Director-General: Health
For Attention: Director (PharmaceuticalEconomicEvaluations)
Room2610SouthTower
Civitas Building
Corner Thabo Sehume & Struben Streets
PRETORIA, 0001**

For any further enquires please contact Mr. S Mngadi
Telephone: 012 395 8185; e-mail: mngads@health.gov.za



**Dr A MOTSOLEDI, MP
MINISTER OF HEALTH**

DATE: 23/6/2014

NOTICE – CHANGE OF TELEPHONE NUMBERS: GOVERNMENT PRINTING WORKS

As the mandated government security printer, providing world class security products and services, Government Printing Works has adopted some of the highly innovative technologies to best serve its customers and stakeholders. In line with this task, Government Printing Works has implemented a new telephony system to ensure most effective communication and accessibility. As a result of this development, our telephone numbers will change with effect from 3 February 2014, starting with the Pretoria offices.

The new numbers are as follows:

- Switchboard : 012 748 6001/6002
- Advertising : 012 748 6205/6206/6207/6208/6209/6210/6211/6212
- Publications Enquiries : 012 748 6052/6053/6058 GeneralEnquiries@gpw.gov.za
 - Maps : 012 748 6061/6065 BookShop@gpw.gov.za
 - Debtors : 012 748 6060/6056/6064 PublicationsDebtors@gpw.gov.za
 - Subscription : 012 748 6054/6055/6057 Subscriptions@gpw.gov.za
- SCM : 012 748 6380/6373/6218
- Debtors : 012 748 6236/6242
- Creditors : 012 748 6246/6274

Please consult our website at www.gpwnline.co.za for more contact details.

The numbers for our provincial offices in Polokwane, East London and Mmabatho will not change at this stage.

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 748 6052, 748 6053, 748 6058

Advertisements: Tel: (012) 748 6205, 748 6208, 748 6209, 748 6210, 748 6211

Subscriptions: Tel: (012) 748 6054, 748 6055, 748 6057

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001

Publikasies: Tel: (012) 748 6052, 748 6053, 748 6058

Advertensies: Tel: (012) 748 6205, 748 6208, 748 6209, 748 6210, 748 6211

Subskripsies: Tel: (012) 748 6054, 748 6055, 748 6057