



# Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA  
REPUBLIEK VAN SUID-AFRIKA

*Regulation Gazette*

**No. 10251**

*Regulasiekoerant*

**Vol. 590**

**Pretoria, 22 August  
Augustus 2014**

**No. 37936**

*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. 642 Medicines and Related Substances Act (101/1965): General Regulations relating to bonusing and sampling ..... 3 37936

---

---

## GOVERNMENT NOTICE

---

### DEPARTMENT OF HEALTH

No. R. 642

22 August 2014

#### MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965) GENERAL REGULATIONS RELATING TO BONUSING AND SAMPLING

The Minister of Health, in consultation with the Pricing Committee, in terms of Section 35(1) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) intends to make the Regulations set out in the Schedule.

Interested persons are invited to submit, within three months of publication of this notice, comments on the proposed regulations to the Director-General of the Department of Health, for the attention of the Director: Pharmaceutical Economic Evaluations Directorate, Corner Thabo Sehume and Bloed Street, Pretoria, 0001.

#### SCHEDULE

##### 1. DEFINITIONS

In these regulations any word or expression defined in the Act and not defined below bears the same meaning as in the Act, unless the context otherwise indicates -

"**the Act**" means the Medicines and Related Substances, 1965 (Act No. 101 of 1965), as amended;

"**bonus system**" means an agreement or arrangement that rewards a purchaser, HCP, hospital, or funder with an inducement for purchasing or prescribing a particular medicine, or purchasing or prescribing a certain volume of a medicine in prejudice to another medicine;

"**discounts**" means a type of incentive scheme, which includes, but is not limited to-

- (a) volume or 'bulk purchase' discounts and other trade discounts including discounts given to customers off the manufacturer or importer's published selling price at the date of the sale, due to purchase of large quantities, as 'favoured' customers or for any other reason;
- (b) bonus deals in terms of which additional product units are supplied to customers below the list price or free of charge;
- (c) settlement discounts and rebates including payments made to purchasers after the date of sale for timeous payment of accounts, for achieving certain sales targets, or for any other reason;
- (d) formulary listing payments including payments made to-
  - (i) private hospitals, dispensing doctors, independent practitioner associations, provider networks; or
  - (ii) medical schemes, managed health care organisations and administrators of medical schemes as defined or contemplated in the Medical Schemes Act, 1998 (Act No. 131 of 1998) including the regulations thereto; or
  - (iii) any other person or organisation with the purpose of ensuring that a particular medicine or scheduled substance is included on the relevant formulary used by that funder or provider;
- (e) other allowances and fees including advertising fees and fees for shelf space;
- (f) free services rendered by manufacturers and importers or their agents to other persons selling medicines or Scheduled substances;
- (g) the purchase or the provision of any equipment by manufacturers or importers or their agents at a reduced cost or for free to other persons selling medicines

or Scheduled substances; and

- (h) contributions by manufacturers or importers to salaries or other recurrent expenditure or any other form of payment or inducement to any person or organisation selling medicines;

**"funder"** means any medical scheme as regulated by the Medical Schemes Act, 1998 (Act No. 131 of 1998), or any other person who arranges for payment for medical services and medicines, including a medical scheme administrator;

**"HCP"** means a Health Care Practitioner registered as such under the Allied Health Professions Act, 1982 (Act No.63 of 1982);

**"inducement"** means any material payment in cash, cash equivalent, reduction, rebate, offer, transfer of value gift in excess of an accumulative value of R750.00 (seven hundred and fifty rand) made or offered with the purpose of influencing a decision of a purchaser, HCP, hospital or funder;

**"incentive scheme"** means the supply of a medicine on terms or conditions, which include, but are not limited to any of the following:

- (a) Discounts;
- (b) rebates;
- (c) unacceptable advertising fees,
- (d) unacceptable credit payments;
- (e) unacceptable data fees, but excluding data fees paid to an independent firm that specialises in the provision of data to the health care industry;
- (f) unacceptable fees paid to induce and / or encourage biased sale of a particular medicine or scheduled product;
- (g) unacceptable marketing fees or co-marketing fees;
- (h) formulary listing payments;
- (i) inducements;
- (j) loyalty fees or similar fees, enrichment or benefit for purchasing or prescribing a particular medicine, or purchasing or prescribing a certain volume of a

- medicine;
- (k) shelf space fees;
  - (l) directors fees, honoraria and similar compensation paid to a HCP or any person who is in a position to potentially influence medicine choice, where such professional or other person actually do not perform any services or work for which he or she is purportedly being remunerated, or which are in excess of a reasonable fee, honoraria or compensation which would be negotiated on an arm's length commercial basis; and
  - (m) fees, enrichment of or benefit provided to a HCP, administrative staff or any business enterprise or health care establishment in the health care sector which fee, enrichment or benefit is provided on the understanding that the health establishment or professional will give preference to, or encourage the purchase, sale, prescription, dispensing, use or recommendation of a particular medicine or medicines in return for such fee, enrichment or benefit;

**"purchaser"** means any person that purchases a medicine;

**"rebate"** means a payment made to a purchaser of medicines as a reward for purchasing a particular medicine, or purchasing a certain volume of a medicine. A rebate is a type of incentive scheme;

**"supplier"** means a manufacturer or importer of medicines;

**"supply"** includes supply or offer to supply, sale, lease, loan, or donation;

**"unacceptable"** in relation to any incentive scheme means any amount in excess of a reasonable consideration, which would be negotiated, on an arm's length commercial basis as fair value for the relevant product or service.

## 2. PROHIBITED CONDUCT

- 2.1 This Regulation clarifies the operation of Section 18A of the Act, which prohibits the supply of any medicine according to a bonus system, rebate system or any other incentive scheme.

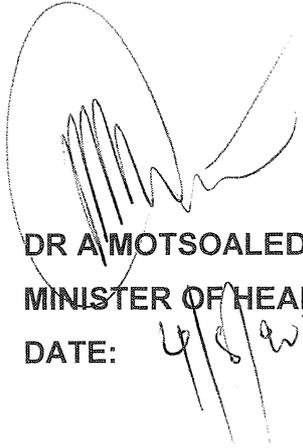
- 2.2 This prohibition applies to any incentive scheme, regardless of whether it is applied to a HCP, to a funder, to a purchaser or directly to the end user.
- 2.3 An incentive scheme is prohibited whether it applies directly, or whether it is achieved through indirect or disguised means, such as payment for a product or service in excess of the true value of that product or service, or through providing samples of a medicine as contemplated in Section 18B of the Act.
- 2.4 Where a Single Exit Price is applicable to a medicine, any discount, rebate, or inducement will constitute a contravention of Section 22G(3)(a) of the Act.

### 3. PENALTIES

- 3.1 Contraventions of Section 18A, Section 18B, or of the provisions of this Regulation shall give rise to liability for a fine or imprisonment or both, as contemplated by Section 35(7) and Section 30 of the Act.
- 3.2 An applicable fine may be up to 10% of the offending firm's turnover in its most recent financial year.
- 3.3 The amount of the fine will be determined having regard to the nature, duration and extent of the contravention.

### 4. COMMENCEMENT

These Regulations shall come into operation on the date of publication.



**DR A MOTSOALEDI, MP**  
**MINISTER OF HEALTH**  
DATE: 4/8/2014

**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](mailto:GeneralEnquiries@gpw.gov.za)
- Maps : 012 748 6061/6065 [BookShop@gpw.gov.za](mailto:BookShop@gpw.gov.za)
- Debtors : 012 748 6060/6056/6064 [PublicationsDebtors@gpw.gov.za](mailto:PublicationsDebtors@gpw.gov.za)
- Subscription : 012 748 6054/6055/6057 [Subscriptions@gpw.gov.za](mailto: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](http://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