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