DEPARTMENT OF HEALTH

NO. 1321 01 DECEMBER 2017

# MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965) REQUEST FOR COMMENT ON THE GENERAL REGULATIONS RELATING TO BONUSING

The Minister of Health, in terms of Section 35(1) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) intends to make regulations set out in this 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 Struben Street, Pretoria, 0001.

## SCHEDULE

## PREAMBLE

These regulations are intended to support the attainment of affordable medicines, medical devices and in vitro [diagnostic medical device] diagnostic (IVD)'s and to give effect to the prohibition of activities which have the effect of undermining the transparent pricing system of medicines, medical devices and IVDs and more specifically the activities as envisaged in regulation 18A(1), namely the supply of medicine, medical devices and IVDs according to a **bonus system**, **rebate system** or any other **incentive scheme**.

## 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 Act 101 of 1965,(Act No. 101 of 1965), as amended;

"**customer**" means any person to whom a medicine, medical device or IVD is supplied or who purchases, prescribes, orders, reimburses or pays (directly or indirectly) for a medicine, medical device or IVD and includes:

i. Health care providers, a health establishment, a hospital and a health worker (as defined in the National Health Act) and any health care provider representative association, independent practitioner association, health care provider network and a veterinarian as defined in the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982);
ii. Health care funders which include 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 and Health Insurance Products as governed by the Long Term Insurance and Short Term Insurance Acts of 1998.;
iii. Health information and data collection companies, data switching entities, practice management companies, including healthcare software support and maintenance companies and health care provider claims administrators;
iv. Medical advisors, medical, pharmaceutical or related advisory committees, patient information service entities or any other related entities; and
v. Consumers, patient advocacy groups and patient representative groups.

"**discounts**" include, but are not limited to -

i. volume or 'bulk purchase' discounts and other trade discounts, including discounts given to customers off the supplier's published selling price at the date of sale;
ii. bonus deals in terms of which additional units of the same, related or unrelated medicines, medical devices or IVDs are supplied to customers below the published price or free of charge;
iii. settlement discounts and rebates, including payments made to customers after the date of sale for timeous payment of accounts or cash payment for achieving sales targets, or for any other reason;

"**formulary**" means a list of selected medicines, therapeutic classes, medical devices or IVDs.

"**Health Care Provider**" means any healthcare professional registered under the Allied Health Professions Act, 1982 (Act No. 63 of 1982), the Health Professions Act, 1974 (Act No. 56 of 1974), the Nursing Act, 2005 (Act No. 33 of 2005), the Pharmacy Act, 1974 (Act No. 53 of 1974) and the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).

"**inducement**" means any act, including but not limited to, the payment in cash, cash equivalent, reduction, rebate, offer, service, subsidy, contribution or gift made or offered with the purpose of influencing a customer by a supplier;

"**protocol**" means a set of guidelines in relation to the optimal sequence of diagnostic testing and treatments for specific conditions and includes, but is not limited to, clinical practice guidelines, standard treatment guidelines, disease management guidelines, treatment algorithms and clinical pathways;

"**purchase**" act of acquiring a medicine, medical device or IVD by paying for it and a person who so acquires a medicine, medical device or IVD is a purchaser;

"**supplier**" means a manufacturer, wholesaler, distributor or agent of medicines, medical devices or IVDs;

"**supply**" to make available, sell, lease, loan, or donate whether for gain or not for gain a medicine, medical device or IVD;

## 2. PROHIBITED ACTIVITY

2.1 This Regulation clarifies the operation of section 18A of the Act which prohibits the supply of any medicine, medical device or IVD that is subject to a, bonus system, rebate system or any other incentive scheme.

2.2 This prohibition applies to any prohibited activity between a supplier/s and any

customer/s

2.3 These Regulations apply to all prohibited activities whether achieved through direct or indirect means.

3. **BONUS SYSTEM**

Any practice which gives a customer a fee or a benefit over and above what is due and which has the effect of inducing the purchase, prescription or use of a particular medicine, medical device or IVD or the supply of a medicine, medical device or IVD.

4. **REBATE SYSTEM**

A practice which facilitates a payment to a customer in relation to the purchase of a medicine, medical device or IVD, usually after the sale has occurred, either directly to the customer or to a related entity, which has the effect of reducing the cost of the medicine, medical device or IVD.

5. **INCENTIVE SCHEME**

Means any practice which encourages or rewards a customer for the use, prescription, purchase, order or reimbursement of a medicine, medical device of IVD which may include but is not limited to:

a) a discount;
b) payment for marketing, promotion, and advertising;
c) fees for shelf space;
d) data fees and registry fees but excludes the purchase of health informatics supplied by an independent entity, which entity has no association with a customer and where such data is unrelated to the supply of a medicine, medical device or IVD; and also excludes fees payable for registered clinical trials;
e) loyalty fees or similar fees;
f) directors' fees or shareholder fees, honoraria and similar compensation paid to a customer, excluding a fee, honorarium or compensation which is for a legitimate educational activity and at fair value;
g) entertainment costs, meals and disbursements including congress and

conference attendance in excess of acceptable practices of any marketing code approved and or endorsed by the regulator;

h) payment or contribution by a supplier towards any recurring expenditure of a customer which includes salaries or any subsidy of staff costs of personnel or contractors of a customer;

i) free services rendered by suppliers or their agents to customers which has the effect of (h) above;

j) the placement or the provision of any equipment, medicine, medical device or IVDs by suppliers or their agents at a reduced cost, nominal cost or for free to customers whether directly or indirectly, related to or unrelated, to the supply of a medicine, medical device or IVD and includes consignment stock and loan sets;

k) unjustified credit payments which have the effect of an inducement;

l) formulary and protocol listing payments to any customer or any person who is able to influence such a listing

## 6. PENALTIES

6.1 Contraventions of these shall give rise to an offence and a penalty as contemplated in section 35(7) and/or section 30 of the Act, namely that the transgressor/s, if found guilty, may be fined or imprisoned for a period not exceeding 10 years.

6.2 When an offence has been committed, the fine or imprisonment applies to all parties that are involved in such an activity.

6.3 The amount of the fine will be determined having regard to the nature, duration and extent of the contravention.

6.4 A maximum penalty of 10% of the supplier's turnover in its most recent financial year may be imposed.

## 7. COMMENCEMENT

These Regulations are called Regulations relating to bonusing made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and will commence upon the date signed by the minister.

**DR A MOTSOALEDI, MP**
**MINISTER OF HEALTH**
**DATE:** 1/10/2017