GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 770 **18 September 2012**

NATIONAL DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES ACT (101 OF 1965)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES:

LOGISTICS FEE COMPONENT OF A TRANSPARENT PRICING SYSTEM

The Minister of Health, on recommendation from the Pricing Committee, in terms of section 22G (2) (c) of the Medicines and Related Substances Act (No. 101 of 1965), read together with Regulation 5 (2) (g) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, in tends to conclude the logistics fee component of a transparent pricing system as in the Schedule.

Interested persons are requested to submit substantiated comments or representations on the reflected logistics fee in writing, on a compact disc **and** hard copy within 1 months of publication of this notice to:

The Director-General: Health (Attention to the Director: Pharmaceutical Economic Evaluations)

Room 2610 South Tower

Civitas Building

Cnr Andries and Bloed Streets

Pretoria

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SCHEDULE

DEFINITIONS

1. In this Notice any word or expression to which a meaning has been assigned in the Medicines and Related Substances Act (No. 101 of 1965) ("the Act") or the Regulations shall have such meaning and the Regulations means the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances;

"**end dispensers**" means all pharmacists and persons licensed in terms of section 22C (1) (a) of the Medicines and Related Substances Act (No. 101 of 1965) that dispense medicines or scheduled substances to end users as defined herein;

"**end user**" means all patients and related persons who are the ultimate consumers of the medicine or scheduled substance;

"**ex-manufacturer price**"; means the price that a manufacturer, licensed in terms of section 22C (1) (b) of the Act sets to produce a medicine or scheduled substance for consumption and includes costs incurred before release of a final pack of a medicine or scheduled substance for distribution by persons registered in terms of section 22H of the Act and who are logistics service providers. The Ex-Manufacturer Price is a VAT exclusive component of the Single Exit Price of a medicine or scheduled substance;

"logistics fee" is one of the three components that form the Single Exit Price, which are: (i) the ex-manufacturer price, which is determined by the manufacturer, (ii) the logistics fee, which is determined through negotiation between the manufacturer or importer and the logistics service provider of their medicines or scheduled substances and (iii) VAT. The logistics fee means the fee that is paid directly by manufacturers to logistics service providers exclusively for the provision of logistical services in respect of medicines or scheduled substances distributed from the

manufacturer or importer's premises to end dispensers. In the case of an in-house logistics service, the "fee" relates to the cost of performing the logistics service.

logistical services" means those services provided by logistics service providers (including in-house services), for the distribution of medicines or scheduled substances from the manufacturer and or importer to end-dispensers and comprises of the following activities in relation to medicines or scheduled substances:

(a) Receiving of medicines or scheduled substances;

(b) Warehousing of medicines or scheduled substances;

(c) Proper inventory control and rotation;

(d) Taking orders;

(e) Delivery of orders;

(f) Provision of emergency deliveries where required;

(g) Proper record keeping;

(h) Batch tracking and tracing;

(i) Ability to maintain cold chain storage and distribution where necessary;

(j) Returning products to manufacturers when required; and

(k) Having and operating a debtor's control system which conforms to accepted accounting norms;

(l) The logistics services include "bulk" (pre-wholesaling) and fine distribution services.

"logistics services provider" means a person, licensed in terms of section 22C (1) (b) of the Act that performs Logistical Services as defined herein;

"logistics fee cap" means the maximum logistics fee determined for medicines or scheduled substances, above which no logistics fee shall be allowed (unless authorized);

"Single Exit Price (SEP)" means the ex-manufacturer price, determined by the manufacturer or importer of a medicine or scheduled substance in terms of these Regulations, combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or scheduled substance within a pack multiplied by the number of units in the pack. The Director- General must confirm the correctness of the SEP calculation prior to communication to the public.

2. LOGISTICS FEE:

The maximum logistics fee as contemplated in section 22G (2) (c) of the Act and Regulation 5(2)(g) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, to be charged by logistics service providers, who may be distributors or wholesalers, for logistical services as defined herein, must be calculated, exclusive of VAT, as follows:

(a) Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is less than one hundred rands, the logistics fee must not exceed 8% of the ex-manufacturer price (ex VAT) plus 3 rand in respect of that medicine or scheduled substance;

(b) Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than one hundred rands but less than five hundred rands, the logistics fee must not exceed 6% of the ex-manufacturer price (ex VAT) plus 4 rand in respect of that medicine or scheduled substance;

(c) Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than five hundred rands but less than one

thousand rands, the logistics fee must not exceed 4% of the ex-

manufacturer price (ex VAT) plus 5 rand in respect of that medicine or scheduled substance;

(d) Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than one thousand rands, the logistics fee must not exceed 54 rand in respect of that medicine or scheduled substance.

3.

(a) The logistics fee to be paid and implemented by a manufacturer and/or importer to logistical service providers shall be a negotiated fee that is equal to or less than the logistics fee cap as reflected in regulation 2 of this schedule for that medicine or schedule substance;

(b) Following negotiations of the Logistics Fee to be paid for specified Logistical Services to be rendered, the agreeing manufacturer and/or importer and Logistics Services Providers must sign a contract that reflects this agreement for the specified period (s) prior to any Logistical Services being rendered;

(c) Where a manufacturer and/or importer has negotiated logistics fees for the same medicine or scheduled substance with several logistics service providers across the country, the final logistics fee shall be calculated as follows: final logistics fee = logistics fee negotiated with logistics service provider (LSP) A X (estimated units to be distributed by LSP A in 12 months divided by total estimated units to be sold in the same 12 months) + logistics fee negotiated with logistics service provider (LSP) B X (estimated units to be distributed by LSP B in 12 months divided by total estimated units to be sold in the same 12 months);

(d) At the time of implementation of these Regulations, where an existing negotiated logistics fee exceeds the regulated logistics fee cap of a medicine or scheduled substance, the manufacturer and/or importer of

that medicine or scheduled substance must negotiate with the relevant logistics service provider (s) a reduced logistics fee to be less than or equal to the regulated logistics fee cap of that medicine or scheduled substance within 60 working days of publication of the final Logistics Fee cap;

(e) The amount by which the logistics fee is reduced should be the same amount the Single Exit Price of the same medicine or scheduled substance is decreased by;

(f) The manufacturer and/or importer of affected medicines or scheduled substances must communicate the logistics fee that is in accordance with regulation 2 of this schedule to the Director-General within 30 working days of finalization of the negotiation contemplated in regulation 3 (e) (by a signed contract between the agreeing manufacturer and/or importer and logistics service provider) in a manner and format to be published by the Director-General.

(g) The logistics fee to be paid by manufacturers and/or importers to respective logistics service providers must be confirmed by manufacturers and/or importers by the use of templates to be published by the Director-General in terms of Regulation 14 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances;

(h) At the implementation of these regulations, manufacturers and importers should have exhausted provisions made in terms of the most recent Regulation 8 publication, of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, before the implementation of the Logistics Fee as in regulation 2 of this schedule.

4.

(a) At the end of the 12 month period from the date of implementation of the regulated logistics fee as reflected in regulation 2 of this schedule, the

logistics fee actually paid by the manufacturer of a medicine or scheduled substance must be disclosed by the manufacturer, using templates to be published by the National Department of Health, to the Director-General separately from the ex-manufacturer price of that medicine;

(b) At the end of the each 12 month period after implementation of the regulated logistics fee a manufacturer must reconcile total units distributed per logistics service provider with the estimates, as at the commencement of these regulations, used to calculate the final logistics fee. This reconciliation must be certified by an independent auditor. The extent of the over or under recovery of the logistics fee for a medicine or scheduled substance must be factored into the calculation of logistics fees for the next 12 months. The total logistics fee paid by a manufacturer shall be published by the Director-General in a manner and format to be determined by the Director-General;

(c) The final reconciled logistics fee must be implemented 30 working days after the date on which logistics service providers and manufactures of medicines or scheduled substances have communicated the required information, using templates to be published by the Director-General in terms of Regulation 14 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.

5. The Minister may, in exceptional circumstances, and on the recommendation of the Pricing Committee, authorise a manufacturer or importer, on written application by the manufacturer or importer, in the manner specified by the Director-General, to increase the logistics fee of a medicine or scheduled substance by a specified amount.

In considering an application as contemplated in regulation 5 of this schedule the Minister must take into account:

(a) the nature and extent of any adverse financial, operational and other circumstances for the manufacturer or importer if the application made in terms of regulation 5 of this schedule is not approved. The effect, if any, on the availability of the medicine or scheduled substance within the Republic if the application made in terms of regulation 5 of this schedule is not approved;

(b) the nature of the health condition for which the medicine or scheduled substance is a registered indication within the Republic and the extent to which public health would be adversely affected should the medicine or scheduled substance become unavailable or unaffordable within the Republic;

(c) the extent to which the rights contemplated in section 27 (1) (a) and 27 (3) of the Constitution may be adversely affected or limited—

(i) should the logistics fee not be increased by the amount requested in the application; and

(ii) should the medicine or scheduled substance become unavailable or unaffordable within the Republic.

(d) The provisions of regulation 2 and subsequent regulations of this schedule may be reviewed at intervals as determined by the Minister with regard to the CPI, PPI, or any other appropriate or relevant indicator and the need to ensure:

(i) That there is reasonable access to affordable medicines;

(ii) The realization of the constitutional right of access to health care services contemplated in section 27 of the constitution;

(iii) That there is effective and efficient distribution of relevant products throughout the Republic;

(iv) The nature of the medicine (s) and or scheduled substance (s) and distribution requirements for which the application is made.

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 1/9/2012