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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 184

4 March 2011

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 of 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, intends to publish the logistics fee as in the Schedule.

Interested persons are requested to submit substantiated comments or representations on the proposed logistics fee in writing, on a compact disc **and** hard copy within two 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 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) charges to produce a medicine or scheduled substance for consumption and includes costs incurred in releasing the medicine or scheduled substance to persons authorized in terms of section 22H to purchase medicines or any duly authorized purchaser and is a VAT exclusive component of the single exit price of that medicine;

“logistics fee” means the fee that is paid directly by manufacturers to logistics service providers exclusively for the provision of logistical services to manufacturers in respect of medicines or scheduled substances and may be paid by manufacturers to their in-house logistics-service-provider division;

“logistical services” means those services provided by logistics service providers, to manufacturers, for the distribution of medicines or scheduled substances to end-dispensers and include 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 from end dispensers;
- (e) Delivery of orders to end dispensers;
- (f) Provision of emergency services to end dispensers where required;
- (g) Proper record keeping;
- (h) Batch tracking and tracing;
- (i) Maintenance of cold chain requirements 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;

“logistics service provider” means a person, licensed in terms of section 22C (1) (b) of the Act that performs all 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;

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 (VAT exclusive) of a medicine or scheduled substance is less than one hundred rands, the logistics fee must not exceed 6% of the ex-manufacturer price (VAT exclusive) in respect of that medicine or scheduled substance;
 - (b) Where the ex-manufacturer price (VAT exclusive) 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 4% of the ex-manufacturer price (VAT exclusive) plus R2 in respect of that medicine or scheduled substance;
 - (c) Where the ex-manufacturer price (VAT exclusive) 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 3% of the ex-manufacturer price (VAT exclusive) plus R5 in respect of that medicine or scheduled substance;
 - (d) Where the ex-manufacturer price (VAT exclusive) of a medicine or scheduled substance is equal to or greater than one thousand rands, the logistics fee must not exceed 2% of the ex-manufacturer price (VAT exclusive) plus R10 in respect of that medicine or scheduled substance.
3. (a) The logistics fee actually paid by the manufacturer for a medicine or scheduled substance must be disclosed by the manufacturer, using addendum A, to the Director-General separately from the ex-manufacturer price. The total logistics fee paid by a manufacturer shall be published by the Director-General;

(b) Where a manufacturer 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) 1 X (estimated units to be distributed by LSP 1 in 12 months divided by total estimated units to be sold in the same 12 months) + logistics fee negotiated with logistics service provider (LSP) 2 X (estimated units to be distributed by LSP 2 in 12 months divided by total estimated units to be sold in the same 12 months). The final logistics fee as calculated must not exceed the maximum logistics fee contemplated in sub-regulation 2;

(c) At the end of a 12 month period a manufacturer must reconcile total units distributed per supplier with the estimates at the beginning of the year 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 then be factored into the calculation of logistics fees for the next 12 months;

(d) The logistics fee may only 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 Addendum B and A respectively, to the Director-General in terms of Regulation 14 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.



DR A MOTSOLEDI, MP

MINISTER OF HEALTH

DATE: 28/2/2011

ADDENDUM A: LOGISTICS FEE TEMPLATE FOR MANUFACTURERS OR IMPORTERS (APPLICANTS)			
QUESTIONS FOR THE APPLICANT			
APPLICANTS' ANSWERS TO QUESTIONS			
Name of applicant (As it appears on MCC license):			
Trade name of applicant (i.e. trading as):			
Name of contact person:			
E-mail address and telephone number of contact person:			
What is the total number of Logistics Service Providers (LSPs) used by the applicant?			
What is the total volume (units) of products supplied by the applicant to all listed LSPs per annum (specify period)?			
What is the budget (RANDBS) allocated for payment of Logistics Fees to LSPs in relation to the applicants' total business budget. (This is the total budget that the applicant is prepared to spend on Logistics Fees per annum) ?			
How is the overall LF of items in your portfolio determined (i.e. How is the LF as a component of SEP arrived at)?			
Name of Logistics Service Provider (LSP)	Category of products (Category: group of products that attract the same Logistics Fee)	Logistics Fee (RANDBS) budget for the agreed upon period	Provide explanation of how the % Logistics Fee in preceding column is arrived at.
1. LSP 1	Category 1		
	Category 2		
	Category 3		
	Category 4		
2. LSP 2	Category 1		
	Category 2		
	Category 3		
	Category 4		
3. LSP 3	Category 1		
	Category 2		
	Category 3		
	Category 4		

QUESTIONS FOR THE LOGISTICS SERVICE PROVIDER ADDENDUM B: LOGISTICS SERVICE PROVIDER ANSWERS TO QUESTIONS					
Name of logistics service provider (As it appears on MCC license):					
Trade name of logistics service provider (i.e. trading as):					
Name of contact person:					
E-mail address and telephone number of contact person:					
What is the total number of manufacturers or importers that you will be distributing for in the stipulated agreement period?					
What is the total volume (units) of products anticipated for distribution by yourself for all listed manufacturers/importers per annum (specify period)?					
What is the budget allocated for operational costs for logistics-related activities of schedule 1 and above products in relation to your total business budget (RANDS)?					
Name of Manufacturer or Importer	Names of category of products	Volumes anticipated for the agreement period as stipulated in the provided signed contract	Logistics Fee (RANDS) budget for the agreed upon period	Agreement period as stipulated in the signed agreement e.g. 02 January 2010 to 31 December 2010 i.e. latest 12 month period	Provide explanation of how the % Logistics Fee in preceding column is arrived at
1. Manufacturer/Importer 1	Category 1				Agreed upon average Logistics Fee (%)
	Category 2				
	Category 3				
	Category 4				
	Category 5				
1. Manufacturer/Importer 2	Category 1				
	Category 2				
	Category 3				
	Category 4				
	Category 5				
1. Manufacturer/Importer 3	Category 1				
	Category 2				
	Category 3				
	Category 4				
	Category 5				