



health

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DISCUSSION DOCUMENT

ANNUAL ADJUSTMENT TO THE SINGLE EXIT PRICE FOR MEDICINES

27 FEBRUARY 2014

TO: ALL INTERESTED STAKEHOLDERS

1. The pricing of medicines in South Africa is regulated in terms of the Pricing Regulations published by the Minister of Health on recommendation of the Pricing Committee by Notice in the Government Gazette. In terms of these regulations, the Minister is required to determine on an annual basis, the extent to which medicines prices may be adjusted.
2. The Pricing Committee has noted that the extent to which medicine prices has been adjusted annually is not acceptable to all stakeholders due to a range of factors. Additionally pharmaceutical companies have not benchmarked their prices against the basket of countries hence price adjustments for such products should not be applied. However, manufacturers continue to increase prices with the annual increase.
3. The Pricing Committee has, on the other hand, an obligation to ensure the recommendations of the committee take account of the availability, affordability, and quality of medicines and scheduled substances for use by the people of the Republic.

4. The annual single exit price adjustment is intended to provide for adjustments to the ex-manufacturer price and the logistics fee. Historically the Pricing Committee has recommended a composite adjustment that takes account of both the logistics fee adjustment and the ex-manufacturer price adjustment in a single calculation. The Pricing Committee has received complaints from the distributors of medicines wherein the SEP adjustment does not result in an adjustment in their logistics fee despite increases in labour and fuel.
5. The pricing committee is considering a differentiation of the single exit price adjustment to take account of cost pressures experienced by the different types of manufacturer and the logistics providers.
6. The Pricing Committee would like to review the use of the current formula as a reference guide for making a recommendation on the determination of the extent to which medicines prices may be adjusted on an annual basis. The Pricing Committee therefore, intends to engage interested parties on alternative methodologies for adjusting medicines prices for 2015 in the following areas-
 - 6.1 Investigate the feasibility of establishing an SEP inflator for-
 - (a) fully imported generic products
 - (b) locally produced generic products
 - (c) originator medicines
 - 6.2 Review the formula used as a reference guide in making a recommendation of the extent to which medicines prices may be adjusted on an annual basis.
 - 6.3 Engage interested stakeholders on the finalisation of the determination of an appropriate logistics fee to be charged by wholesalers and

distributors of medicines and the methodology to review the fee on an annual basis

7. Originator Medicines

- 7.1 These products are patent protected. The manufacturer attempts to recoup the cost of research and development on the product by adding this to the actual cost of production. Typically these product prices take account of cost of production, cost of R&D and profit. The contribution of the various cost components is usually not declared by companies hence it is difficult to accurately calculate adjustments based on exchange rate. Companies would therefore be required to declare a detailed cost structure for the purpose of the price adjustment.

8. Multi-source Medicines (Generics)

- 8.1 These medicines are not patent protected. The final price of the products is typically made up of the cost of production plus profit. There are no significant R&D costs for such medicines.
- 8.2 The extent to which the product is manufactured in South Africa will affect the cost pressures for such products. Products that are produced in another market may not experience as much currency volatility as that of locally manufactured medicines. Therefore generic medicines can be classified into those that are produced fully overseas and those that are partially produced in South Africa.
- 8.3 The cost pressures for each of these products is different, hence the price adjustment for each category is different. Where the manufacturer fails to provide information regarding the cost breakdown then the Pricing Committee will make a recommendation in this regard.

- 8.4 In terms of the cost of producing the final pharmaceutical product for sale these typically include the cost of the active pharmaceutical ingredients, formulation costs, packaging, warehousing costs, administrative and marketing costs. The determination of the final price takes account of all these costs plus the desired margin/profit for the product.
- 8.5 Some or all of the above activities / costs may be incurred in South Africa. The extent to which factors such as inflation and exchange rate influences a product cost is determined by where the activity is conducted.

9. Logistics Service Providers

- 9.1 In the case of logistics service providers the committee would like to provide an indication of the extent to which the fee should be adjusted taking account of cost inputs. The industry is invited to provide their cost information individually so that the committee can make an appropriate determination. The deadline for written submissions is 28 March 2014.