No. R. 1211 **1 December *2006***

MEDICINES AND RELATED SUBSTNACES ACT, 1965

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

METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF THE PRICES OF MEDICINES AND SCHEDULED SUBSTANCES IN SOUTH AFRICA

The Minister of Health intends in terms of regulation 5(2)(e) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances as published in Government Gazette Number 28214 of 11 November 2005, to publish the Methodology for International Benchmarking of the Prices of Medicines and Scheduled Substances in South Africa reflected in the Schedule.

Interested persons are invited to make written comments by no later than 19 February 2007 to:

The Director-General: Health (Attention: Dr A Pillay)
Private Bag X828
PRETORIA
0001

SCHEDULE

Draft Methodology for International Benchmarking of Medicine Prices in South Africa

BACKGROUND

The Government of South Africa wishes to ensure that citizens obtain value for money when purchasing pharmaceutical products, whether this is in the public or private health sector. Modem drugs are expensive to develop and it is accepted that countries should contribute to the costs of research and development, so long as these costs are accurately estimated and according to their ability to pay. The principle of differential pricing of essential medicines is accepted by the World Health Organization and World Trade Organization, and is practised by some pharmaceutical manufacturers.

The Pricing Committee's view is that the purchase prices of medicines in the private sector should relate to their therapeutic performance and take account of national socio-economic factors. In the last decade several countries have instituted programs that involve evaluation of the cost-effectiveness of pharmaceutical products, and these countries have negotiated drug prices using a range of techniques that involve evidence-based comparisons with standard treatments. The Pricing Committee and Department of Health wish to establish such a program in South Africa. As a first step the Committee wishes to ensure that South African citizens do not pay higher prices than their counterparts in other countries. To achieve this initial aim the Pricing Committee has recommended the introduction of international price benchmarking. This document outlines the methodology proposed by the Pricing Committee.

DEFINITIONS

"originator medicine"

means a medicine, registered in South Africa, where such medicine is currently protected by a patent or had been protected by a patent previously. Such medicine may be marketed either by the original patent holder or another entity.

"independent multisource medicines (generics)"
means medicines, registered in South Africa, where such a medicine has never been protected by patent legislation. Such medicines are being manufactured by companies other than the company that originally held the patent.

"benchmark product for originator medicines"
means an originator medicine in the benchmark countries, with the same International Non-proprietary Name (INN), strength and dosage form. Where the pack size varies, a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre or capsule). If there is no identical strength available then the lowest available common denominator e.g. mg/mg price comparisons of the active ingredients will be used.

"benchmark product for generic medicines"
means generic medicine/s with the same INN, route of administration and strength. Where the pack size varies, a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre or capsule). If there is no identical strength available then the lowest available common denominator e.g. mg/mg price comparisons of the active ingredients will be used.

"benchmark price"
In South Africa: means the Rand equivalent of the ex-manufacturer price, i.e. the SEP less (or nett of) the Logistics Fee and VAT, for the same branded or generic product.
In Australia, Canada, New Zealand and Spain: means the Rand equivalent of the ex-manufacturer price, i.e. the list price less the Logistics Fee (or wholesaler fee), taxes, discounts and/or rebates, for the same originator product. There may be several selling prices in benchmark countries, in which case the price used in the largest ambulatory sector will be used.

"benchmark country"
means any of the countries from the basket of comparator countries selected below (i.e. Australia, Canada, New Zealand, South Africa or Spain).

"INN"
means International Non-proprietary Name.