P.o Box 31890
Lusaka, Zambia

Telephone: +260-21-1 220429
Telefax: +260-21-1 238458
E-mail: pharmacy@pra.gov.zm

In reply, please quote
No. DMS/7/9/22/PR/373

All correspondence should be addressed to the Director General

PHARMACEUTICAL REGULATORY AUTHORITY

ZAMBIA MEDICINES REGULATORY AUTHORITY (MINISTRY OF HEALTH)
15 FEB 2009
P. O. BOX 31890, LUSAKA, ZAMBIA.

cONSIDER THIS DATE

17th April, 2009

NAZIR-MOHME

**India.**

Dear Sir/Madam,

**RE: APPLICATION FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS**

Reference is made to your applications for registration of pharmaceutical products, submitted under Section 37 of the Pharmaceutical Act (No. 14) of 2004.

We wish to inform you that we have completed our review of the submissions and are pleased to inform you that the Pharmaceutical Regulatory Authority at its meeting of 26th March, 2009 considered your product applications and the corresponding evaluation reports and, based on the submitted information, **approved** the registration of the following products with their licence numbers and methods of sale indicated below:

| No. | Name of Product | Application no. | Method of sale | Licence No. |
|---|---|---|---|---|
| 1. | **COMPOUND MAGNESIUM TRISILICATE**tablets (Magnesium Trisilicate BP 250mg+ Dried Aluminium Hydroxide BP 120mg) | 4991/08 | P | 022/015 |
| 2. | **CIPROZ- 500** tablets(Ciprofloxacin hydrochloride USP 500mg) | 4989/08 | POM | 022/016 |
| 3. | **INDOMIN**-25 capsules(Indomethacin BP 25mg) | 4993/08 | P | O22/017 |

**Abbreviation:** POM– Prescription Only Medicine; P– Pharmacy Medicine.

Please note that approval is granted subject to your submission to the Authority as soon as possible, but not later than sixty days from the date of this letter, information and documents which were noted missing from your submissions on at least the following:

**Certificates:** - original copy of WHO-type certificate of Pharmaceutical product on each of the above products specifically addressed to Zambia and 2 certificates of analysis. In addition, documentary evidence of registration in the declared countries; Specific storage conditions on the package material

**Therapeutic equivalence:-** reports on at least comparative dissolution profiles in respect of all oral solid dosage forms of the above products with their respective innovator products to demonstrate interchangeability;

**Labelling information:** product samples should be submitted to demonstrate compliance with labelling requirements- Labels and packaging materials should have sufficient labelling information including among others; method of sale, specific storage conditions, product license number and physical address of manufacturing site;

In addition, your attention is drawn to the requirements of Statutory Instrument No. 7 of 2008 on product retention fees for pharmaceutical products to be imported into Zambia. You are therefore requested to pay annual retention fees of ZMK 2,530,000-00 per product on each of the above products effective 1st January 2010. The amount due may be paid into the following bank account:

| | |
|---|---|
| **Name of Account holder:** | Pharmaceutical Regulatory Authority |
| **Name of Bank:** | Standard Chartered Bank,<br>North-End Branch, Cairo Road, Lusaka, Zambia |
| **ZMKBank Account No.** | 0100122033800 |
| **US Dollar Account No.** | 8700211468100 |

Please note that registration of the above products does not imply final approval as all products are subject to review at a later date and this decision to register the above products is subject to change on the basis of new information that may be available to the Authority.

In view of this, you are advised to put in place an appropriate pharmacovigilance system for monitoring, detecting and reporting adverse drug reactions and the performance of registered products in general.

We remind you that you must comply with labeling requirements as prescribed in the Statutory Instrument No 47 of 1993 by ensuring that products including labels and packaging materials have sufficient labelling information including among others; method of sale, specific storage conditions, and product licence number and physical address of manufacturing site.

If you have any questions, please do not hesitate to contact our Secretariat.

Yours faithfully,
for/**Pharmaceutical Regulatory Authority**

B.C Mwale (Mrs)
**A/DIRECTOR GENERAL**

c.c. ChaChaCha Healthcare Ltd of Lusaka, Zambia