



All correspondence should be addressed to the Director General

DMS/7/9/22/PR/2012 case quote

No.:

PHARMACEUTICAL REGULATORY AUTHORITY

28th May, 2012

Pharmanova (Zambia) Ltd,
Plot No. 7329, Moobola Road,
P.O. Box 31458,
Lusaka.

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Attn : **A.L. Murugappan (Mr)**

Dear Sir,

RE: APPLICATION FOR AMENDMENTS TO A REGISTERED PRODUCT

We refer to your letter dated 2nd April, 2012 in which you applied for authorisation to make changes to the following registered product:

No.	Name of Product	Licence No.
1.	Novalyte Oral Rehydration Salts 20.6g (sodium chloride 2.6g + potassium chloride 1.5g + sodium citrate 2.9g + anhydrous glucose 13.5g)	077/019

It is understood that the proposed changes include the following:

- 1) Additional pack size of 4.12g for a product packed in the same material construction of the primary packaging container as the currently approved pack size of 20.6g;
- 2) Product name change and labelling.

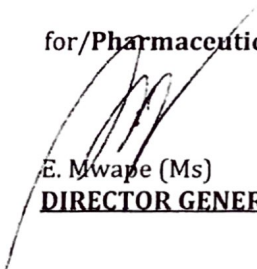
We wish to acknowledge receipt of a total sum of Zambian Kwacha five hundred thousand only (K 500,000-00) paid on cheque number 6737 as per our receipt number 1579 dated 3rd April 2012 being payment of amendment fees.

We wish to advise that we have completed our review of the submissions and, since all conditions of the amendments were fulfilled and the required supportive information and documentation was submitted and found satisfactory, then the proposed updates are considered acceptable and, accordingly, our records are being amended.

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

Yours faithfully,

for/Pharmaceutical Regulatory Authority


E. Mwape (Ms)
DIRECTOR GENERAL