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GUIDELINE DOCUMENT FOR DATABASE OF MEDICINE PRICES (DOP) CORRECTIONS: 12 OCTOBER 2012 TO 26 OCTOBER 2012

INTRODUCTION

This document addresses DOP corrections requirements from licensed manufacturers and or importers of medicines or scheduled substances (applicants). Applicants are required to provide information that will address any errors, omissions or discrepancies that might have occurred in the description of the items that are part of their portfolio. To make such corrections the National Department of Health (NDoH) has published the DOP schedule named "Database of Medicine Prices 12 October 2012" on www.mpr.gov.za. Applicants should note that the format of the latest DOP schedule and template G to be used for DOP correction purposes have been amended as discussed in the last two industry workshop held on 05 July 2012 and 04 October 2012 at NDoH premises. Applicants must note that two columns have been added on the DOP schedule and on template G. The effected changes affect the following areas;

1) The "originator/generic" column and
2) The "quantity" column.

A detailed description of these added columns is outlined in section 2(xxv) and 2(xxvi) of this document. Applicants must note that some of their product description

in the DOP schedule for either added columns maybe or may not be completely filled and this process is an opportunity for all applicants to correctly and completely fill all fields that represent each applicant's portfolio on the DOP schedule.

1. SUBMISSION PROCESS FOR THE DOP CORRECTION APPLICATIONS

Only the applicant as per MCC registration and Pharmaceutical Economic Evaluations (PEE) records is entitled to apply for the DOP corrections. Any notification from a person other than the applicant e.g. a marketing or distribution company will not be accepted. Applicants must use template G: Existing medicine detail amendment (of SEP update templates) when making DOP corrections. **Only those products with discrepancies should be submitted in template G as part of the Database of Medicine Prices correction process.**

Your submission will be considered complete if the following documents are part of the submission:

i. Signed Declaration document see for SEP updates. (www.mpr.gov.za) All the persons that appear in the declaration form should sign;
ii. A hard copy of the Excel spreadsheet template G. The latest version of template G as published on 12 October 2012 (www.mpr.gov.za).

Documents required to be submitted for each product that is amended;

iii. A dated covering letter on the company letter head signed by the person responsible pharmacist and CEO;
iv. Certified copy of the MCC Licence to Manufacturer;
v. Certified copy of the MCC Medicine Registration Certificate(s) of the product;
vi. The original MCC approved package insert (PI) that is part of the packaging of the registered product or certified copy of the MCC approved document.

2. TEMPLATE G (EXISTING MEDICINE DETAILS AMENDMENTS) REQUIREMENTS:

For the purposes of the DOP correction process the following must be noted;

i. All amended products must be submitted on the same template;
ii. When completing the template all fields must be filled before submission;
iii. The original details should be on the first line followed by the new details or specific amendment(s) of the product already on the market that is being changed on subsequent lines in order for the application to be considered.
iv. Failure to provide all pack sizes that currently exists implies that the submission is incomplete.
v. The cell that contains the incorrect description of the product must be highlighted in yellow (Note that the template requires that the incorrect complete product details description be on top and the corrected version to be immediately below it.

The following details are required when completing template G:

vi. Detailed description of the update (including reasons ;
vii. The applicant's full name as registered with MCC as it appears in the MCC licence;
viii. Contact details of the person responsible for a price update (name, surname, telephone, fax and e-mail).
ix. Date of the submission
x. The applicant's MCC licence numbers, i.e. a full ten digits number per applicant as appearing in the MCC certificate.
xi. A certified copy of the applicant's licence from MCC is required for **all** products.
xii. An appropriate licence number should be expressed as follows: 0000000123. The following examples are not acceptable : 1234567-890; 123

xiii. The applicant's full name as registered with MCC as it appears in the MCC licence (mentioned above) should match the applicant's name as it appears in the MCC medicine registration certificate.

xiv. The medicine registration number as it appears in the medicine registration certificate issued by the MCC.

xv. A certified copy of the medicine registration certificate is required for **all** products.

xvi. A nine-digit medicine specific Nappi code. This is a nine digit numeric field that should not contain any characters between numbers and therefore should not be hyphenated. Example of an appropriate and acceptable description of a Nappi code on the templates: 123456789. The following examples are not acceptable: 123456-001, 123456/001 and 123456.

xvii. ATC4code (5 characters) as prescribed by World Health Organization (WHO) website address (www.whocc.no). The following expression of the ATC 4 code is the only acceptable expression: R03CC. The following examples are not acceptable: R03C, R03CCXB.

xviii. Medicine schedule as registered with MCC (2 characters – a capital letter "S" followed by the schedule number; e.g. S3). This information should be in line with the package insert.

xix. A full medicine proprietary name as registered with MCC and the name should be exactly as it appears in the medicine registration certificate.

xx. A full description of the active ingredient [International non proprietary name (INN)] per medicine. Where a medicine contains more than one active ingredient, each active ingredient must be provided separately on a new line.

xxi. The strength of each active ingredient per medicine shall be furnished as a unit on each line.

xxii. The unit describing the quantum of the active ingredient per medicine must be furnished per active ingredient e.g. mg, ml, mg/5ml, g, IU, %, %/100ml etc on a new line. The unit should not be combined in a single cell with the strength mentioned above.

xxiii. The dosage form as it appears on the package insert approved by MCC should be in a 3 letter abbreviated format. See reference document named "Dosage Form Abbreviation List" on www.mpr.gov.za.

xxiv. The approved pack size, which is the amount of medicine within the MCC approved packaging (Note: this is a numeric field); For parenteral dosage forms where the reconstitution volume is less than the size of a container, the pack size would be the total reconstitution volume, this would be the maximum volume of liquid. For liquid, solutions, suspensions, infusion and injection dosage forms, the pack size is the actual volume to be ingested/used by the patient; For powder for injection the pack size is the reconstituted volume (see examples below);;

For liquid dosage forms, the pack size of a 75ml amoxicillin 125 mg suspension packed in a 100ml bottle is 75ml. The pack size of a single bottle of 100ml cough mixture packed in a box is 100ml.

For solid dosage form, the pack size is the number of tables or capsules contained in a pack. The pack size of 30 tablets contained in a blister pack is 30.

For liquid injections, the pack size of a 5ml injection packed in a 10ml vial is 5.

For creams, the pack size a tube containing 20g cream is 20.

xxv. The "quantity" column representing the multiples in which the medicine is packed/the number of pack sizes. Applicants would need the package insert and MCC registration certificate to complete this column

a. For solid dosage forms, the "quantity" for 10 packs of 30 tablets contained in a securitainer is 10.
b. For liquid injections, the "quantity" for 20 ampoules packed in a box, each containing 5ml of liquid injection is 20.
c. For liquid dosage forms, the "quantity" for 24 bottles containing 75ml of suspension is 24. The "quantity" of a single bottle of 100ml cough mixture packed in a box is 1.

d. For injections, the "quantity" for 50 vials containing 500mg powder for injection packed in 20ml vial to be reconstituted with 10ml of diluents is 50.
e. For creams, the "quantity" for 10 tubes of 20g cream packed in a box is 10.

xxvi. The "Originator / Generic" column represents a descriptor column to clarify whether a product is an originator or generic.

3. COLUMNS CHANGES ON THE DOP SCHEDULE AND TEMPLATE G:

Applicants are requested to note the new added columns on the DOP schedule and template- G;

1) Originator / Generic column
2) Quantity column

Applicants should verify the correctness of the new descriptor column "Originator / Generic". This should be in line with the definitions provided below for generic and originator medicines;

Originator: 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

Generic: Means a medicine, 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. Any medicine that does not fall into category originator as described above is regarded as a generic

The "quantity" column representing the multiples in which the medicine is packed/the number of pack sizes. Applicants would need the package insert and MCC registration certificate to complete this column.

Examples:

a) For solid dosage forms, the "quantity" for 10 packs of 30 tablets contained in a securitainer is 10.
b) For liquid injections, the "quantity" for 20 ampoules packed in a box, each containing 5ml of liquid injection is 20.
c) For liquid dosage forms, the "quantity" for 24 bottles containing 75ml of suspension is 24. The "quantity" of a single bottle of 100ml cough mixture packed in a box is 1.
d) For injections, the "quantity" for 50 vials containing 500mg powder for injection packed in 20ml vial to be reconstituted with 10ml of diluents is 50.
e) For creams, the "quantity" for 10 tubes of 20g cream packed in a box is 10.

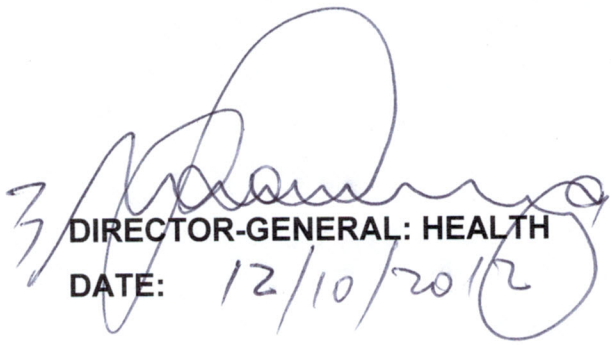
The submissions must be addressed and hand delivered between 09:00 am and 12:00 noon on weekdays to:

RE: DOP Corrections
The Director
Pharmaceutical Economic Evaluation (PEE)
Department of Health
Room S2611
Civitas Building
Cnr Struben and Andries Street
Pretoria
0001

An official of the DPEE unit, i.e. Mr Stanley Muthaphi or Ms Matshidiso Marokane will sign for receipt of submissions at the reception of the NDoH. The NDOH will not be held responsible for submissions that were not received and signed for by the above mentioned DPEE unit officials.

For any further enquiries on this process, contact Mr S Mngadi at:
Tel: 012 395 8184/7
Fax: 0865900113
E-mail: sepupdates@health.gov.za; Subject "DOP corrections and Applicant name"

Yours Sincerely



DIRECTOR-GENERAL: HEALTH
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