GUIDELINE DOCUMENT FOR SINGLE EXIT PRICE (SEP) UPDATES

1. Purpose of this document

This document addresses requirements from applicants with respect to the introduction of new medicines and changes to existing medicines SEP or their description. It also provides a step-by-step guidance on how to complete different templates used for different SEP submissions.

2. SEP Submission Process

Only the applicant as per MCC registration and Pharmaceutical Economic Evaluations (PEE) records is entitled to supply the SEP update. Any notification to update an SEP from a person other than the applicant e.g. a marketing or distribution company will not be accepted.

An applicant may only make one submission at any point in time. Simultaneous submission of a Regulation 9 application or an SEP adjustment whilst an SEP update is still in process is not allowed.

All submissions with respect to SEP updates must be furnished both in electronic format (Excel) on a workable compact disc and in a hard copy document format, and delivered to Department of Health (NDoH) at the address provided below. The excel spreadsheet must not be locked, protected or submitted in pdf format. Deliveries of submissions will only be accepted between 09h00 and 12h00 Monday to Friday, excluding public holidays. Submissions sent by e-mail will not be accepted. The notification of price updates to all stakeholders e.g. price file vendors, remains the responsibility of NDoH.

All correspondence should be addressed to:

Single Exit Price Updates

The Director: Pharmaceutical Economic Evaluations (PEE)
ATT: Ms Ntobeko Mpanza
Room S0419 Civitas Building
Corner of Thabo Sehume Street and Struben Street
0001

For queries:

Telephone: 012 395 8184/8181
E-mail: sepupdates@health.gov.za
Queries are only taken on Mondays to Fridays between 13:00 and 15h00.

NDoH will **not** be held responsible for submissions that were not received and signed for by an official of the PEE unit. An acknowledgement notice signed by applicant representative and NDoH representative shall be issued upon delivery of submissions.

For meetings: (Between NDoH and Industry if necessary)
Thursdays between 09:00 and 12:00

3. Mandatory Submission Documents

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

- A dated covering letter on the company letterhead signed by the person responsible for the submission.
- Certified copy of the MCC License to Manufacture.
- Certified copy of the MCC medicine registration certificate(s) of the medicine applied for.
- The original MCC approved package insert (PI) that is part of the packaging of the registered medicine.

- Excel spreadsheet of the template.
- A completed New Medicine Launch Regulation 19 for (word document) if the template to be submitted is template D.
- A completed and signed Declaration Form for SEP Updates found on the website, www.mpr.gov.za.

ALL documentation provided must be clear and legible. The minimum allowable font size will be Arial font size 10.

If any of these documents are not accompanying the submission, the submission will be considered incomplete and will not be reviewed. All supporting documents with an expiry date should be valid (unexpired) for a period of 30 working days from the date of receipt.

For exceptional cases the applicant may be required to provide a sample of the packaged medicine applied for.

4. Templates and Timelines

Department of Health's Directorate: PEE has developed nine different excel templates and one word document template (specific to medicine launch) that must be used by all applicants for medicine update notification(s). It is mandatory to fill in all the fields in the templates. If a template is incomplete or if any required documentation or information is missing, the applicant will be considered as having submitted an incomplete submission. All incomplete submissions shall not be approved. The applicant may then make a complete and new submission should they deem necessary Submissions may not be updated. The applicant should ensure that the latest version of all templates and forms is used. Where uncertain, applicants are advised to seek clarity from the PEE directorate.

The format in which the information should be filled in is the same as that

used for the Database of Prices (formatting as can be found on www.doh.gov.za).

a.) Timelines for notifying NDoH regarding price updates are 2 working days prior to implementation date for Templates A and B:

- Template A : Permanent SEP Reduction
- Template B: SEP Reduction (non permanent)

b.) Timelines for notifying NDoH regarding price update is 30working days prior to implementation date for Templates E and I:

- Template E: New Pack Size
- Template I: Post Regulation 9 SEP Approval
- Template C: SEP Increase post SEP Reduction (non permanent)
- Template D: New Medicine Launch
- Template F: Medicine Discontinuation
- Template G: Existing Medicine detail(s)Amendments
- Template H: Re-introduction of a Medicine Previously available in the Market.

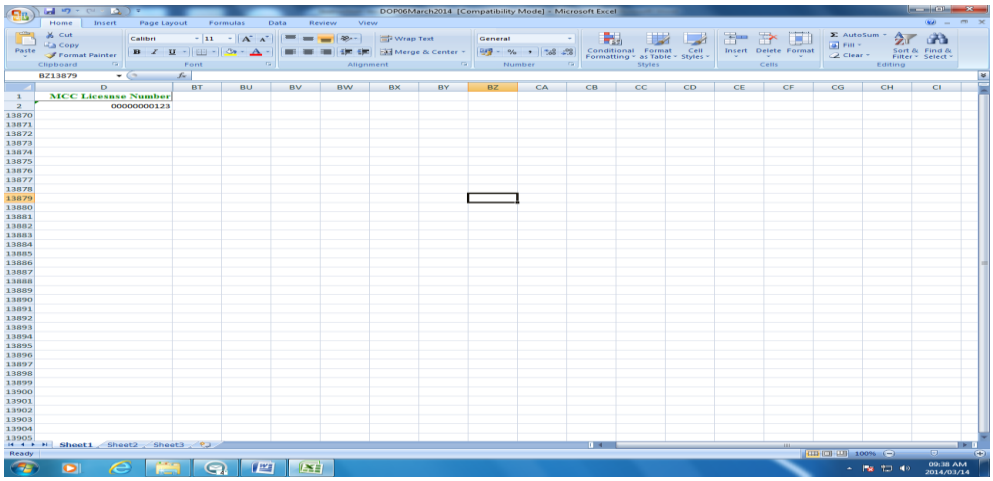
An incomplete submission will not be approved and the applicant will be informed of the reasons for the non-approval. The timelines will only commence one day after receipt of submission. Old submissions will not be updated.

The effective date will be determined and communicated by PEE in accordance with the date of receipt and the type of submission (as described above). An applicant cannot determine an effective date, even if the date is later than that officially determined by PEE.

5. The following details are required for the templates:

a) Detailed description of the submission.
b) The applicant's full name as registered with MCC as it appears in the MCC license.
c) Contact details of the person responsible for a price update (name, surname, telephone, fax and e-mail). It is the responsibility of the applicant to ensure that these contact details are up-to-date on the records of the Directorate: PEE. Queries will not be accepted from persons not listed as the contact person in an applicant's submission.
d) Date of the submission
e) All submissions require the applicant's MCC license numbers, i.e. a full ten digits number per applicant as appearing in the MCC certificate. A certified copy of the applicant's license from MCC is required for **all** submissions. An appropriate license number should be expressed as follows: 0000000123. The following examples are not acceptable : 0000000123.-.8; 123

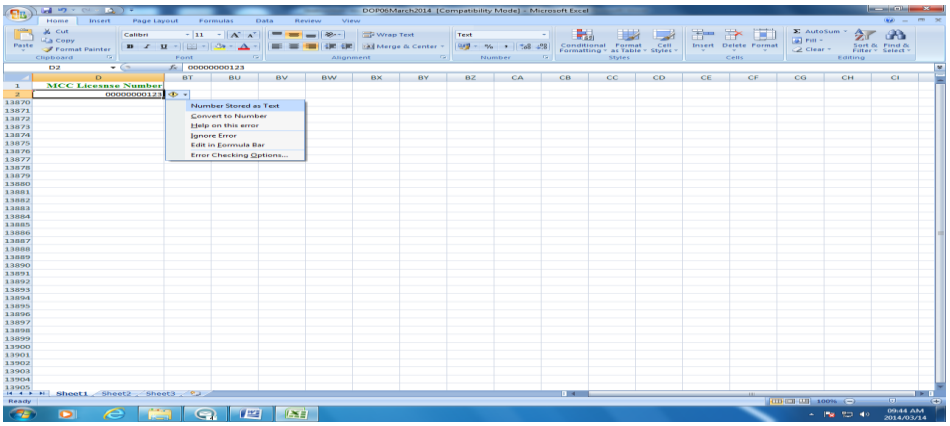
The screen below shows an example of an incorrect MCC License Number. The green flag on the left top corner of the cell confirms that this is not a numeric value as per the requirement.



To resolve this problem you have to follow the following steps.

i. Click on the cell then caution sign to scroll to convert the value to Number->select convert to number from the scroll

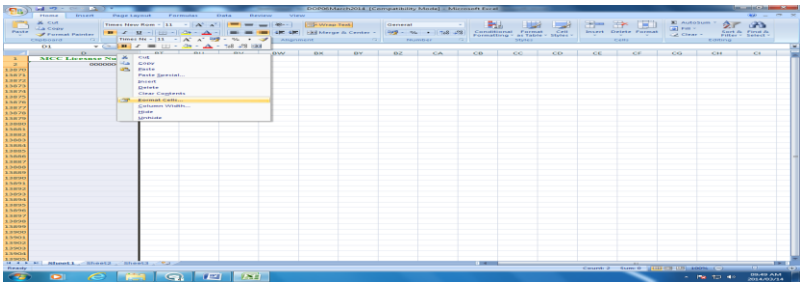
list. See below.



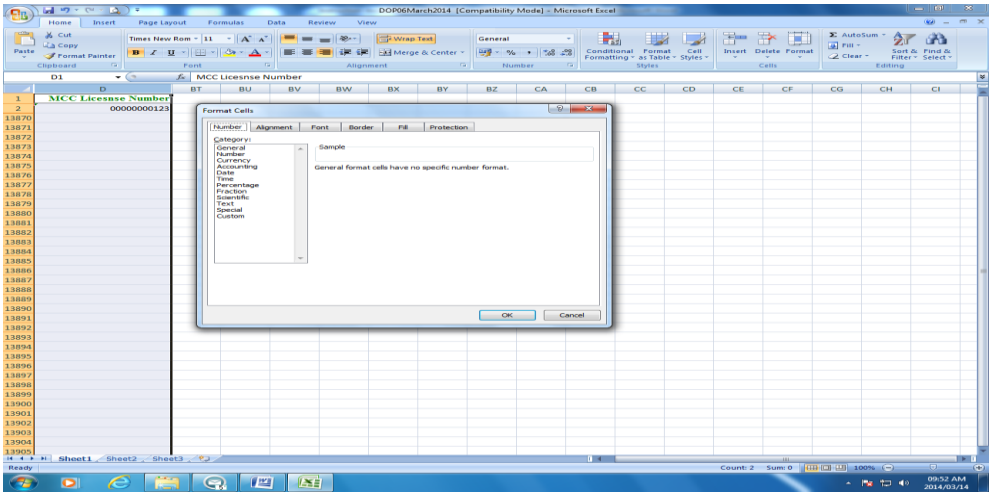
ii. To ensure that zeros are always in front of the MCC License Number, you have to follow the following steps

Steps to be followed for correct cell formatting

1. **Highlight** the column by clicking on the column heading; **right click** on the mouse**->**select **format cells** to format the column entries.



2. On the pop up dialogue box, under the tab **number**, select category **custom**->under **Type**, click on 0, Then in the text box where the cursor flashes, type in and add 9 or more zeros, resulting in 10 zeros “0000000000” .-> Go to the cell where the License number must be entered and type in the MCC License number -> tab enter . The MCC License number will now appear correctly. If the Category is in text format it will be regarded as incorrect, this will warrant a rejection.

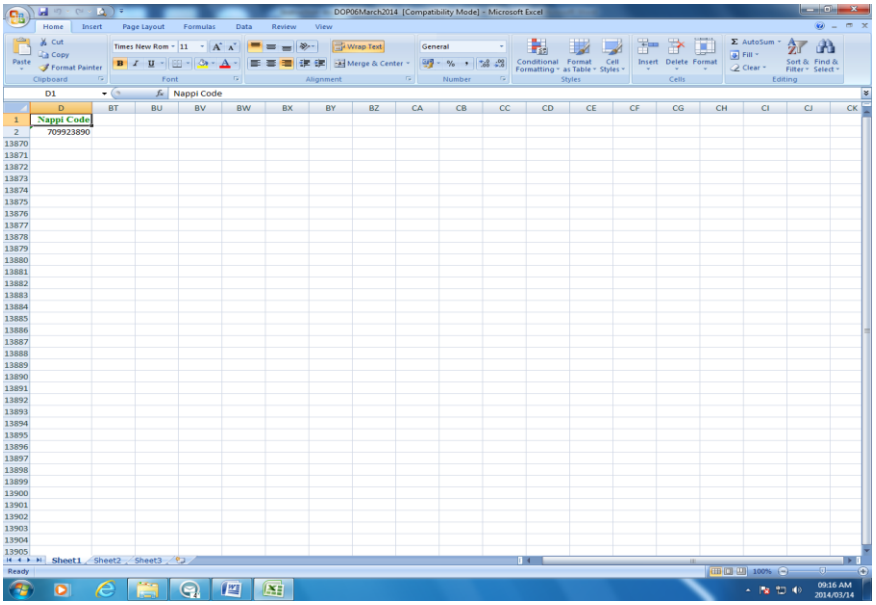


f) The applicant's full name as registered with MCC as it appears in the MCC license (mentioned above) should match the applicant's name as it appears in the MCC medicine registration certificate.

g) The medicine registration number as it appears in the medicine registration certificate issued by the MCC and a certified copy of the medicine registration certificate is required for **all** submissions.

h) A nine-digit medicine specific nappi code. This nine digit numeric field 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 123456 are not acceptable. Any expression of a nappi code that is not in line with the appropriate example shown above shall render the submission incomplete.

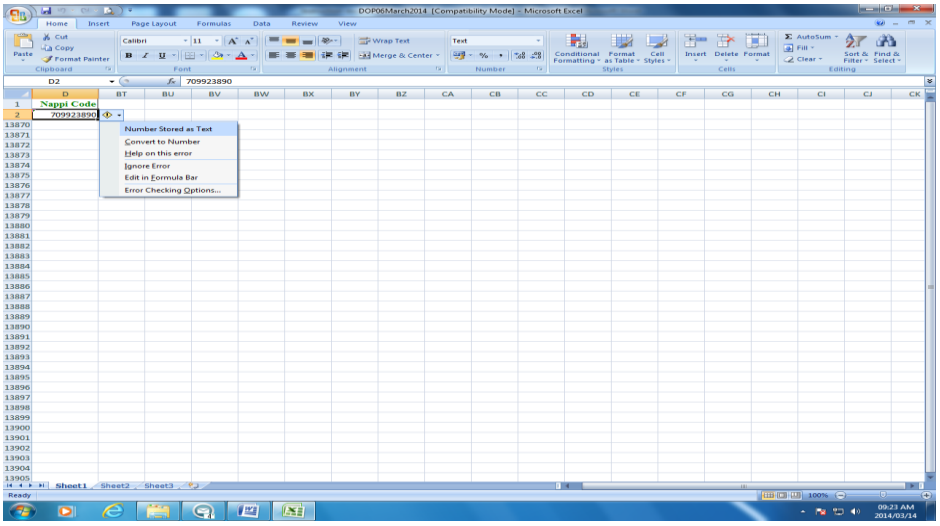
The following screen shows the example of an incorrect (sting value/ Numeric character) Nappi-Code format.



Here you can see that the nappi code has a green flag on the left top corner of the cell.

To resolve this problem you have to follow the following steps.

1. Click on the cell then caution sign to scroll to convert the value to Number->select convert to number from the scroll list.



i) 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.

j) 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 package insert.

k) A full medicine proprietary name as registered with MCC and the name should be exactly as it appears in the medicine registration certificate.Any medicine proprietary name that differs from the name reflected on the MCC certificate shall be considered incorrect and will render the submission incomplete.

l) 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.

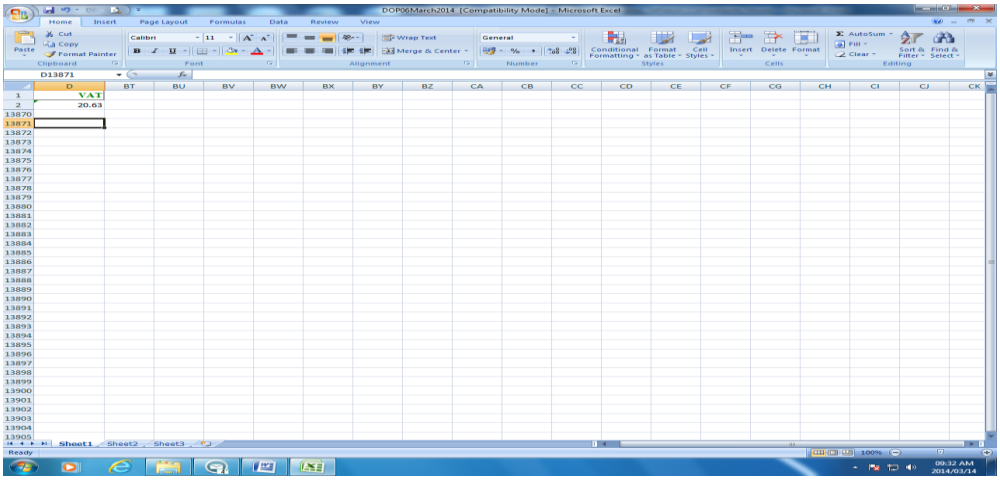
m) The quantity of each active ingredient per medicine shall be furnished as a unit on each line.

n) The character 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. This character should not be combined in a single cell with the quantum mentioned above.

o) The approved pack size, which is the quantity of medicine within the MCC approved packaging. Where the reconstitution volume is less than the size of a container the pack size would be the total reconstitution volume. For injections, this would be the maximum volume of liquid. (this is a numeric field).

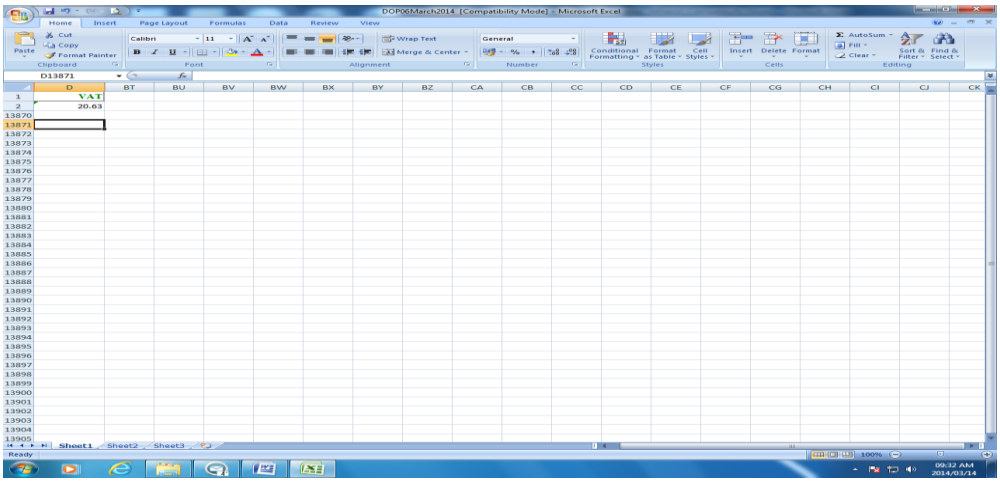
p) The dosage form as it appears on the package insert approved by MCC should be in a 3 letter abbreviated format. See reference document named "Dosage Form Abbreviation List"

q) The VAT exclusive ex-Manufacturer price as defined in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act).



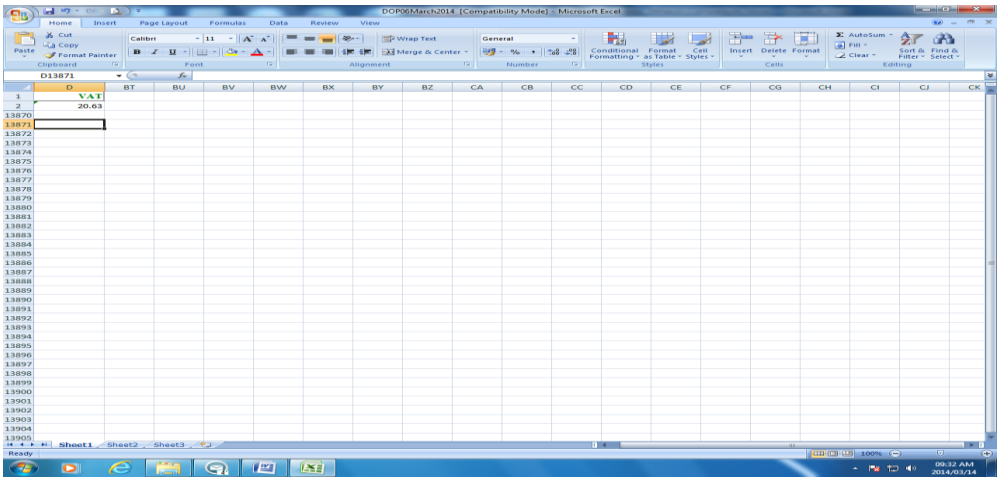
To resolve this problem you have to follow the steps in (h)

r) The VAT exclusive logistics fee as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act).



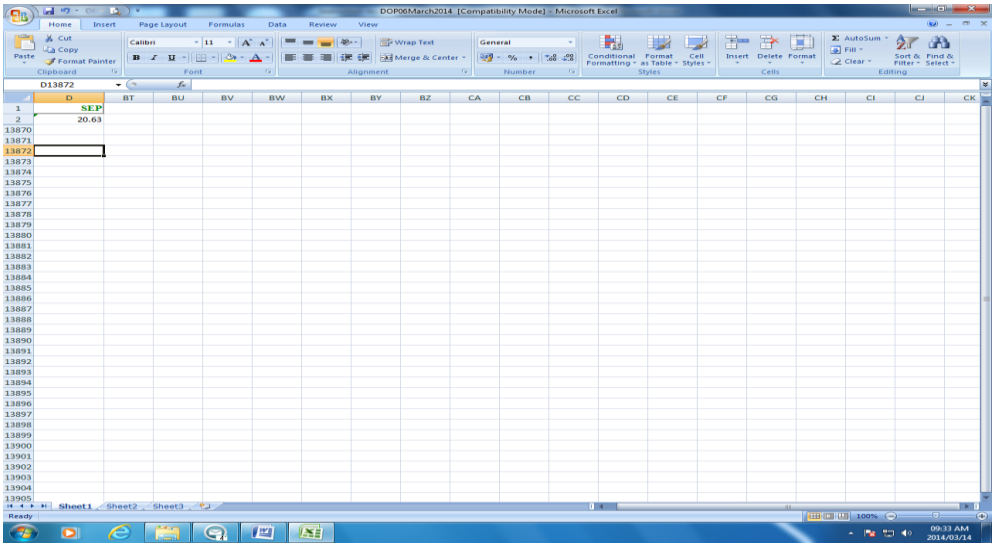
To resolve this problem you have to follow the steps in (h)

s) Value Added Tax (VAT)



To resolve this problem you have to follow the steps in (h)

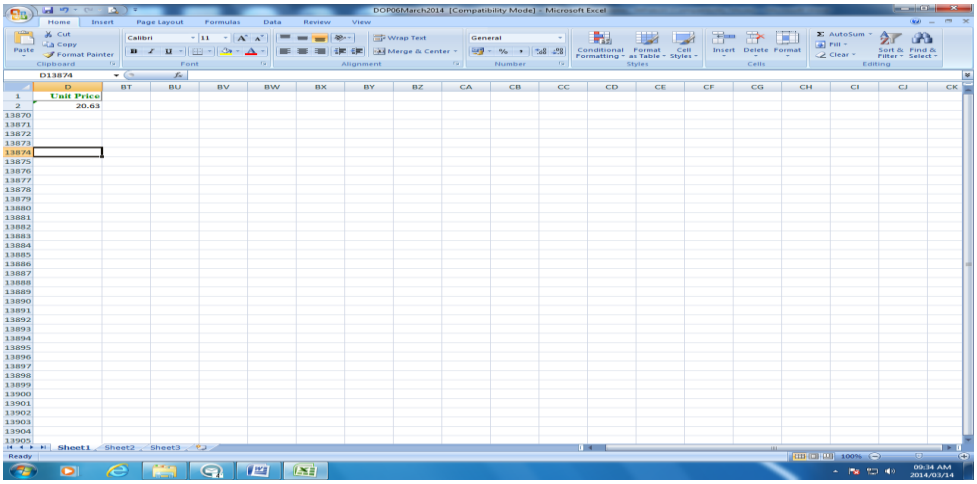
t) SEP as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act), i.e. the sum of the manufacturer price (VAT excl) + logistics fee (VAT excl) + VAT.



To resolve this problem you have to follow the steps in (h)

u) Unit price as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act), must always be displayed next to the SEP per medicine. Note that unit pricing applies to all medicines with the same proprietary name,

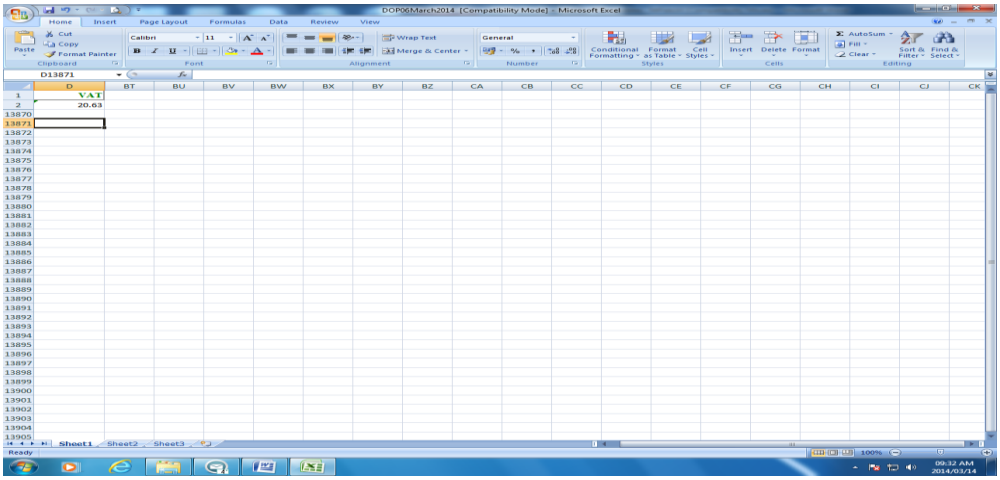
v) Strength and dosage form. For injections the unit price shall be calculated per ml even where the total volume of the medicine administered to a single patient is less than 1 ml.



To resolve this problem you have to follow the steps in (h)

w) The VAT exclusive ex-Manufacturer price, VAT exclusive logistics

fee, Value Added Tax (VAT), SEP and unit price will always be assumed to be in Rands. These should all be numeric fields to two decimal places. No currency should be depicted in these columns.



To resolve this problem you have to follow the steps in (h)

x) Columns relating to status and effective date are for official use, by NDoH only.

y) The Originator or Generic column must be completed according to the definitions below:

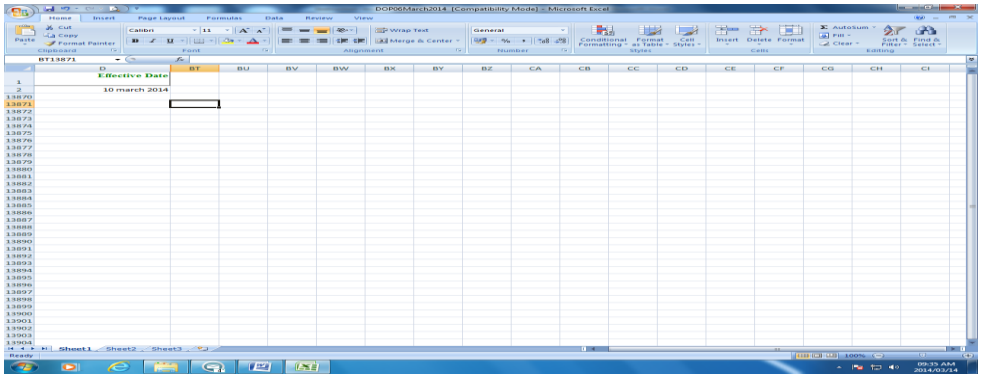
"originator medicine"

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.

"Generics (independent multi-source medicines)"

means medicines, registered in South Africa, where such a medicine has never been protected by patent legislation. Usually such medicines are being manufactured by companies other than the company that originally held the patent. The company would have not needed to provide a clinical trial showing efficacy upon registration of the medicine, but rather pharmaceutical equivalence.

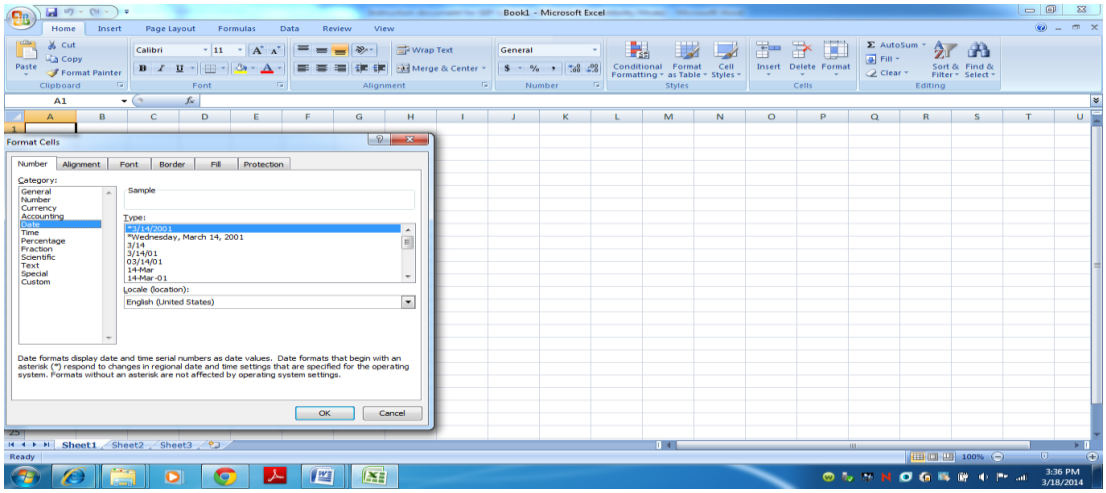
z) The Volume of Sales must be completed for the preceding full year, i.e. 01 January 2014 to 31 December 2014.



To insert the date in correct format you need to follow the following steps

1. Ensure that you have entered a date in this format: 10/03/2014.

2. Then highlight Effective Date columns-> right click on mouse->select-> format cells->category on the format cells dialogue box->click on date



Then change location to (English South Africa) -> select type as 10 march 2014. Click OK

Attached, see templates A-I that must be used to communicate all SEP updates notifications to the Directorate: PEE. All templates are to be completed in full in order for a submission to be considered. Note that the

templates are locked to prevent tampering. However, all templates can be copied and pasted for usage.

6. Specific template requirements

Templates must not be altered, edited or tampered with before submitting in order to be considered valid. Submissions on a format other than the valid template will not be reviewed.

Template A: Permanent SEP Reduction

The current, existing SEP and the new, requested SEP must be furnished at all times. A certified copy of the medicine's MCC registration certificate must be included in every submission.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

All pack sizes that are in the market and the corresponding details are to be provided for each medicine. Each pack size should be on a new line.

The effective date is within 2 working days from the date of receipt of the complete submission.

Template B: SEP Reduction (non permanent)

The current, existing single exit prices and the new, requested single exit prices must be furnished. A certified copy of the medicine's MCC registration certificate must be included in every submission.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

The batch number, expiry date, and the expected number of units to be sold per medicine must be supplied. All pack sizes that are in the market and the corresponding details are to be provided for each medicine. Each pack size should be on a new line.

NB! Non-permanent SEP reductions are allowed for a **minimum** period of six weeks.

The expected duration of the new SEP, based on historical sales, must be provided. If this period is less than 6 weeks, it must be noted that the minimum period for which an SEP reduction will be applicable will be 6 weeks.

Note that applicants requesting this price update are not exempt from unit pricing.

The effective date is within 2 working days from the date of receipt of the complete submission.

Template C: SEP increase post SEP Reduction(non permanent)

The SEP prior to the increase request and the requested increased single exit price must be furnished. A certified copy of the medicine's

MCC registration certificate must be included in every submission.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

Where deemed necessary the NDoH may request further details of the units sold. All pack sizes that are in the market and the corresponding details are to be provided for each medicine. Each pack size should be on a new line.

NB! SEP reductions are allowed for a **minimum** period of six weeks.
It must be further noted that applicants requesting this price update are not exempt from unit pricing.

The submission of this template is forfeited by any other price amendment after the related Template B (SEP reduction (non-permanent)) submission. Template C becomes not applicable at the end of each annual cycle. The last submission for the medicine must be a Template B, Non permanent Reduction.

The effective date is within 30 working days from the date of receipt of the complete submission.

Template D: New Medicine Launch

This is a submission that requires the applicant to fill in both the excel spreadsheet and the word document form (see Regulation 19 from attached).

The details on the calculations of the SEP for which the company is submitting should be described in the **New Medicine Launch Submission Form (Regulation 19)** (word document). The new single exit prices must also be furnished in **Template D** (the excel document).

This template should not be used for medicine re-introduction or for adding on additional pack sizes for medicines that already exist. It is for a completely new medicine.

All pack sizes being introduced into the market and their corresponding details are to be provided, with each medicine pack size on a new line.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

A certified copy of the medicine's MCC registration certificate must be included in every submission.

The launch date is within 30 working days from the date of the receipt of a **complete** submission.

Template E: New Pack Size

The details of the new pack size should be on the 1st line followed by the details for medicines already in the market on subsequent lines in

order for this submission to be considered. Failure to provide all pack sizes that currently exist implies an incomplete submission. The official prices must be furnished per medicine.

This template may also be used in the event of launching a different packaging for an already existing medicine.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

A certified copy of the medicine's MCC registration certificate must be included in every submission.

This template is not for the re-introduction of a pack size that previously existed but rather only for the introduction of a new pack size. Template H should be used for the re-introduction of a previously existing pack size.

The effective date is within 30 working days from the date of receipt of the complete submission.

Template F: Medicine Discontinuation

The notification of discontinuation should be at least 30 working days before the discontinuation date by the applicant. The last SEP at

which the medicine is to be traded, the expiry date, batch numbers of all remaining stock and the reason for the discontinuation must be furnished at all times. Details of all pack sizes including SEP of medicines remaining in the market must be provided.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

A certified copy of the medicine's MCC registration certificate must be included in every submission.

It must be further noted that applicants requesting this update are not exempt from unit pricing and this medicine will not be removed from the Department of Health (NDoH)'s Medicines Price List for at least 5 years. The unit price calculation of this medicine shall however be maintained.

Price File Managers shall be informed of the discontinuation of the medicine and the NDoH's files shall be updated accordingly.

Template G: Existing Medicine Detail(s) Amendments

It is compulsory to notify the Directorate: PEE of every change to details of medicines and scheduled substances with a registered SEP. Template G will be used to furnish NDoH with the original details and the specific amendments of a medicine already on the DoP.

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

A certified copy of the medicine's MCC registration certificate must be included in every submission.

A reason for the change in the submission must be provided and supporting documentation must accompany it.

Depending on the type of amendment, there are instances where relevant evidence of the change must be attached.
Where there is a change in the medicine MCC registration certificate or the company MCC license, both the old and new documentation must be provided.

Where there is a change to the Applicant Name of a medicine both the old and new medicine MCC registration certificate, package insert and the company MCC license must be provided. These should be certified copies of the original. This requires the new applicant of the medicine to be in possession of both the previous applicant's registration documents as well as theirs. Absence of certified copies of these documents as part of the submission will render the submission incomplete.

Where there is a change to the scheduling status of the medicine, the relevant MCC documentation authorizing the change must be submitted including any MCC conditions. In addition both the old and

new MCC approved PI must be submitted.

NB: Note that the correctness of a nappi code is the responsibility of the applicant and the relevant service provider. The nappi code is recorded at the time the medicine is launched and cannot be changed thereafter.

The effective date is within 30 working days from the date of receipt of the complete submission.

Template H: Re-introduction of a Medicine Previously Available in the Market

It is mandatory that the original MCC approved package insert (PI) that is part of the packaging of the registered medicine be included with every submission. This should not be a printed copy on an A4 page as submitted by the applicant to MCC but the actual MCC approved version that goes into the packaging material. Where such a package insert is not available MCC approved package insert accompanied by an affidavit must be provided.

A certified copy of the medicine's MCC registration certificate must be included in every submission.

Failure to provide this implies an incomplete submission. This template should be used for medicine re-introduction for medicines that already exist. It is not for a completely new medicine.

All pack sizes being introduced into the market and pack sizes that may already exist, and their corresponding details are to be provided, with each medicine on a new line.

The re-launch effective date is within 30 working days from the date of the receipt of a **complete** submission.

The SEP must be same as the last SEP at which the medicine was available. In the event where a medicine has related pack sizes and the unit price of such pack sizes was maintained, the pack size that is being re-introduced shall assume the same unit price.

Template I: Post Regulation 9 SEP Approval

It is compulsory that the applicant notify the Directorate: PEE of the breakdown of their Regulation 9 approved SEP. Template I will be used to furnish NDoH with the breakdown of the Regulation 9 approved SEP into manufacturer price, logistic fee and VAT. Failure to provide this information within 14 days of the Ministerial notification of an approved Regulation 9 increase may result in the Regulation 9 SEP approval being revoked.

The effective date is within 30 working days from the date of receipt of the **complete** submission.

The certified copy of the Regulation 9 SEP approval letter signed by the Minister of Health must always accompany template I submission.

All the relevant SEP templates can be accessed on this link: www.doh.gov.za .