MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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MULTIPLE SUBMISSIONS OF THE SAME APPLICATION FOR REGISTRATION WITH DIFFERENT PROPRIETARY NAMES

This document describes the process for the submission and ~~of~~ handling of multiple submissions of the same application for registration of a medicine which are identical but have ~~with~~ different proprietary names.

~~For the purpose of this process the following definitions apply:~~

1 Definitions

1.1 Duplicate or multiple ~~or duplicate~~ applications are defined as ~~duplicates of an~~ two or more applications submitted simultaneously by the same applicant ~~or a subsidiary company of the same applicant~~, which are identical in every respect except for the proposed proprietary name(s) ~~(~~ and includes duplicate or multiple applications of innovator and generic products~~)~~.

1.2 A clone is defined as an application submitted by the innovator as a copy of its own product under a different proprietary name at any stage during the product life cycle.

~~NCEs (submitted without duplicates) and Biological medicines are excluded from this process.~~

2 Background

Applicants ~~may~~ often submit multiple applications for the same product under different proprietary names.

Generally, in practice the first application is compiled by the applicant and then additional applications for the additional product names are prepared by replacing the proprietary name of the first, or master application, with each of the additional proprietary names.

These types of submissions are generally referred to as ‘duplicates’ / ‘refer to’ or in Europe as ‘clones’ and should not be confused with the applications of the same molecule from different Applicants, final product (FP) and active pharmaceutical ingredient (API) manufacturers.

Sometimes the additional applications are not submitted together with the first or master application but even many years later.

3 Principles

3.1 A duplicate application may be for an innovator or a generic product.

3.2 The process outlined in this document will not apply to application for registration of clones.

3.3 A duplicate application must be submitted at the same time as the master application. If for example an application is submitted days, months or years after the master, it is regarded as **not** being linked to a master and would follow the normal evaluation process.

4 Process

4.1 A single "master" dossier for an application for registration ~~application~~ is ~~submitted~~ required with a module 1.2.1 for each proprietary name. The application must be accompanied by~~, together with~~ *a single* sample and *a single ~~PI/PIL~~* package insert and patient information leaflet where the product name is indicated as [PRODUCT NAME]. ~~, including a~~ A list of all the proposed proprietary names must be included in module 1.5.3. ~~, and the~~ The application must be accompanied by the applicable ~~relevant~~ screening and application fees for each application ~~duplicate applied for~~.

4.2 The applicant must indicate~~s~~ which proprietary name should be regarded as the "master"; if not indicated the invented name will usually be regarded as the master.

~~2.3 For more than three of the same applications the applicant has to submit a motivation as to why the further applications are required. Council reserves the right not to accept the additional applications.~~

4.3 Additional product applications (same API and source, same indications, same FP manufacturer) not linked to the master will not be handled as a duplicate~~s~~ application. ~~The applicant has to submit a motivation as to why these products are required.~~ In this case, each application will stand on its own, and be evaluated on its own, and a committee recommendation on one product may not be applied and responded to for the other applications.

4.4 An application number is allocated to the master dossier, and a linking application number to the master for the additional proprietary names, e.g. 500010 for the master and the additional proprietary names 500013.10, 5090016.10 – the ".10" indicates the link to the master application.

Example of application numbers for three copies of an application with three strengths:

	Master	*Duplicate 1*	*Duplicate 2*	*Duplicate 3*
5 mg	**500010**	500013.10	500016.10	500019.10
10 mg	**500011**	500014.11	500017.11	500020.11
20 mg	**500012**	500015.12	500018.12	500021.12

~~2.5 Duplicates are *not accepted* as such if they are not submitted at the same time as the master application, e.g. if an application is submitted two months or two years after the master, it is regarded as not being linked to a master and would follow the normal process.~~

4.5 The single master dossier is fully evaluated by all the relevant Committees and all the proposed proprietary names are reviewed by the Names and Scheduling Committee.

4.6 When approved by all Committees the master product and all the duplicates are registered.

4.7 A registration certificate is issued for each approved proprietary name linked to the master dossier (~~including~~ reflecting the application number indicating the link e.g. 50/2.5/0013.10).

4.8 Pre- and Post-registration changes (refer to the Amendments guideline) are effected to and reviewed only for the single master dossier.

4.8.1 The declaration provided with submission of amendments ~~has to~~ must include a clause in which the Responsible Pharmacist confirms that the change will be made ~~unilaterally across the range of~~ for all the linked dossiers.

4.8.2 If an application is made for an amendment, ~~is applied for~~ which is *not intended* to be implemented ~~unilaterally~~ across all the ~~range of~~ linked dossiers, ~~then~~ the affected dossier will be automatically

delinked and will be considered to be a stand-alone dossier. Such an application requires submission of a complete dossier and the relevant amendment fee(s) to amend the registration certificate because of the amendment(s) to the entry in the register in terms of section 15A and/or 15B of Act 101 of 1965. A certified copy of the original registration certificate may be submitted on submission of the amendment, in which case the amended certificate will only be issued on approval of the amendment and submission of the original certificate.

4.8.3 If the master dossier has not been updated within the past ~~two~~ five years, a full update ~~has to~~ must be submitted with the amendment applied for. If the dossier is up-to-date, a full update ~~has to~~ must be submitted within one year of the delinking. ~~The registration certificate will also be amended and the relevant amendment fee be submitted because of the change in registration number.~~

~~2.9.3 In cases where the amendment affects the registration certificate (e.g. a transfer of applicant), the relevant dossier will be delinked from the master application, and the new certificate will not be issued until a full update in current regulatory format and complying with current regulatory standards is submitted, evaluated and approved.~~

4.8.4 Upon approval of a stand-alone dossier the linking number is removed (e.g. 500013.10 becomes 500013) and this application then stands on its own.

5 Fees payable

The application fee for ~~duplicates, clones and additional~~ multiple applications will be ~~adjusted~~ as follows:

5.1 The fee for the master application will remain t~~he same~~ as published.

5.2 The fee ~~of~~ for the duplicates will ~~escalate with each additional application~~ be the same as for the master.

~~3.3 The fee for more than one clone application will also escalate.~~

~~3.4 The fee for any additional application at any stage for the same API and with the same indications and same FP manufacturer as that already in the process or registered will also escalate.~~

6 ~~Submissions~~ Applications already in the system

6.1 The system will be ~~retrospectively~~ implemented in four phases. The phases are as follows:

6.1.2 Phase I: Applications currently in the process of evaluation where one or more committee recommendation letters have been issued.

- ~~Phase I: Applications where screening has been complete and final application sets have been submitted but not distributed for evaluation~~

6.1.2 Phase II: Applications currently in the process of evaluation but where the evaluation has not been completed (i.e. no recommendation letters have been received).

6.1.3 Phase III: Applications where screening has been completed and final application sets have been submitted but not distributed for evaluation and applications where the screening outcome has yet to be communicated to the applicant.

- ~~III: Applications currently in the process of evaluation where one or more committee recommendation letters have been issued.~~

6.1.4 Phase IV: Post-registration of multiple applications.
Applications that are still registered by the same applicant that meet the criteria of a multiple application and where the status of the master dossier will be applicable to all duplicates post-registration.

6.2 In order to proceed with Phase I, applicants are requested to submit the following information to the Registrar, under the working code AGC, by *a date to be communicated*.

- A letter signed by the Responsible Pharmacist on the company letterhead, identifying the relevant applications and indicating the master dossier.
- Module 1.2.1 of each application reflecting the unique proprietary name.

6.3 Applicants will be notified when the duplicate dossiers can be uplifted.

6.4 Applicants will also be notified when Phases II, ~~and~~ III and IV will commence~~, and when the new fees have been approved~~.

The process will be implemented with immediate effect for all new applications for registration.

DR JC GOUWS
REGISTRAR OF MEDICINES