GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR

Ministry of Health and Sports

Department of Food and Drug Administration

A Guideline on Drug Registration Application

(February, 2018)

Ref : FDA/ (D)2018/149.

Date :15-2-2018

Initial application for Registration

1. An application for registration of drug must be submitted to the Department of Food and Drug Administration in the original prescribed form (Form I Registration). As of 26 February 2018 applications for new drug products and for renewals will have to be submitted using the online facility at https://user.dcdfdamm.online. **Applications that have not been submitted through the online facility will no longer be accepted.** In case of online applications, Form I will have to be printed by applicants using the appropriate system facility. Guidance to the use of the online application facility is provided in annex VIII.

2. A separate registration application has to be submitted for pharmaceutical preparations of different strength, different dosage form or different pack size. Provisions have been made to avoid duplications in printing physical dossiers (see annex X).

3. Steps to be followed in submitting an application are outlined in Annex IX.

4. Online submissions are first screened by FDA and, if found to be receivable, applicants will be requested to submit a physical dossier consisting of Form (I) accompanied by one set of documentation. See Annex I for type of documentation required. One additional copy of the dossier must be kept at company premises. Documents have to be submitted in file in an order as listed in "Documents Required for Registration of Drugs". A list of documents submitted should be shown on the first sheet of the file. Physical dossiers must be submitted within 60 days of being notified by FDA that application is receivable. Failure to meet the 60-day deadline will constitute forgoing of an application by an applicant. If so happens, neither the Registration Assessment Fees remitted nor any documents and drug samples will be returned.

5. A dossier with incomplete documentation or documentation that does not bear the printed security makings cannot be received. Submission of non-receivable dossiers does not affect the 60-day deadline. As a result, an application will be assumed to be forgone by the applicant if no receivable dossier is submitted within the 60-day deadline.

6. (a) An application must be submitted in person by an authorised representative of product owner[1]. Any application made by mail or any means other than in person, will not be accepted. An authorised representative has to be a resident of Myanmar.

(b) Should an authorisation for representation be granted to a local company, the representative shall be a company employee technical competent person authorised to act as a contact person.

7. Registration assessment fees; 300000 Kyats must have been remitted to Department of Food & Drug Administration's bank account MD-012456 at MEB before submission of the application form. The submission must be made within 183 days from the date of payment. **A new payment will** have to be made in order to submit an application after the payment validity deadline is passed.

8. Applications containing active substances or fixed-dose combinations never marketed in Myanmar can be received only if they have been already authorized for marketing in at least two the following regulatory authorities: TGA, Australia: Health Canada; European Medicines Agency; MHRA, United Kingdom; FDA, United States. Alternatively, they should have been prequalified by WHO or concern indications that are of specific relevance to Myanmar.

9. (a) If it is an application for registration of drugs manufactured outside Myanmar, the Food and Drug Administration will issue "Approval for importation of Drug Samples" (Annex II) after receiving an application for it. The drug samples as specified in the approval letter shall then be imported into the country. The holder of the approval letter shall comply not only with the conditions stipulated in the letter but also with the regulations of Trade and Customs Department.

(b) As per Ministry of Health Notification 3/93 dated 5-8-93 paragraph 5, prior approval shall be obtained from Food and Drug Administration for the importation of drug registration samples. The FDA will not issue approval letters for samples imported without prior approval of the FDA.

10. (a) The following kinds of drug samples are normally required:

- Samples for laboratory analysis
- Samples for retention
- Samples for clinical trials, only for new products of Myanmar that need to undergo clinical trial.

(b) For the total numbers of sample drugs to be submitted, please refer to "Required quantities of samples for registration" (Annex III).

(c) All drug samples must be accompanied by the information described in annex VII as well as their respective analytical report (certificate of analysis). The name and designation of an official who signs the report must be stated. A photocopy of the analytical report is not acceptable.

11. The evaluation process for registration will be started only when all the requirements for registration application have been met; viz.:

(a) remittance of Registration Assessment Fees,

(b) complete set of documents,

(c) sufficient quantity of good shelf-life (at least two thirds of shelf-life at lot release) drug samples.

12. (a) When the drug is approved for registration, the applicant will be notified to remit 500,000 Kyats as Registration Fee. The notification will be made only on the notice board of FDA or through the online system, where applicable.

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[1] Product marketing authorisation holder at country of origin

(b) Failure to remit Registration Fees within 90 days from the date of intimation will constitute forgoing of an application by an applicant. If so happens, neither the Registration Assessment Fees remitted nor registration documents and drug samples will be returned.

13. Failure to make a follow-up of an application by an applicant for more than six months from the date of remittance of assessment fees, will be taken as forgoing of an application. See also point 7 above.

14. The Drug Registration Certificate will be issued only after the acknowledgement of receipt of payments issued to FDA is submitted.

15. The submitted dossiers and fees are not reclaimable in case of rejection or forgoing of application.

Updating Changes to Registered Drugs (Variations)

1. Updating changes to registered drugs shall be made only with the approval of Department of Food and Drug Administration.

2. For this purpose, the holder of Registration Certificate shall apply for variation of Registration to FDA, stating

(a) reason for change.
(b) relevant data or findings from studies on which is based the justification of change.
(c) significant effect of changes to the specifications of the drug product.

3. The following shall be submitted together with the application:

(a) An attestation by the country's drug regulatory authority approving such changes. If the regulatory authority's attestation cannot be provided, explain the reason for it.
(b) A photocopy of the Drug Registration Certificate.

4. (a) When it is decided to approve the variation, 100,000 Kyats (per each variation) fee will be levied on an applicant. The Drug Advisory Committee may waive the fee requirement if it believes that the variation is of benefit to public as regards quality, safety and efficacy of drugs.

(b) An original Registration Certificate must then be submitted to make approved amendments on the certificate or print a new one.

Renewal of Registration

1. Application for renewal of registration shall be submitted **90days** before the validity of the registration terminates. Failure to adhere to the 90 days requirement may result in disruption of continued **validity of registration.**

2. Application shall be submitted in the same manner as prescribed for application for new registration of a drug product.

3. The drug samples for clinical trial are normally not required. The samples for laboratory analysis and for retention are still required. Please refer to "Required quantities of sample drug for analysis and retention". (Annex III)

4. For renewal of validity of marketing authorisations issued **after 31 December 2014**, the documentary requirement is the same as that of an initial application (See Type of documents required for registration Annex I). Information provided, however, has to be

updated. For renewal of validity of marketing authorisations issued **before 1 January 2015** the documentary requirement is provided in Annex V. New findings which had not been submitted in an initial application have to be submitted too, especially concerning drug safety profile.

5. Registration Assessment fees must have been remitted to FDA at the time of application of renewal of registration. When the renewal of registration is approved of, 500,000 Kyats must be remitted as Registration Fees.

6. Upon approval of renewal, a new Registration Number will be designated, which shall make the Old Registration Number null and void.

7. **Failure to apply for renewal of registration shall result in invalidation of registration with effect from the date of expiry of the certificate.**

Fees Levied

1. Registration Assessment Fees 300,000Kyats + Fees for Laboratory analysis

2. Registration Fees 500,000 Kyats

3. Variation of Registration 100,000 Kyats for each variation

Note: (1) & (2) are levied either for new registration or renewal of registration.

Annex I

THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

PART I: ADMINISTRATIVE DATA AND PRODUCT INFORMATION

1. Application Form
2. Letter of Authorisation
3. Certification

3.1 For contract manufacturing

(a) License of pharmaceutical industries and contract manufacturer
(b) Contract manufacturing agreement
(c) GMP certificate of contract manufacturer

3.2 For manufacturing "under- licence" (country specific)

(a) License of pharmaceutical industries
(b) GMP certificate of manufacturer
(c) Copy of" under-license" agreement

3.3 For imported products

(a) Licence of pharmaceutical industries/importer/wholesaler (country specific)
(b) Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format.
(c) Site master file of manufacturer (unless previously submitted within the last 2years) (country specific)

4. Labelling

4.1 Unit Carton
4.2 Inner Label
4.3 Blister/Strips

5. Product Information

5 .1 Package insert (package insert is required for generic products)

5.2 Summary of Product Characteristic (Product Data Sheet) (required for NCE & Biotechnology products)

5.2. l Name of the Medicinal Product

(a) Product Name
(b), Strength
(c) Pharmaceutical Dosage Form

5.2.2 Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.
(b) Quantitative Declaration The quantity of the active substance must be expressed per dosage unit

5.2.3 Pharmaceutical Form Image clearly showing colour, markings, etc.

5.2.4 Clinical Particulars

(a) Therapeutic indications
(b) Posology and method of administration
(c) Contraindications
(d) Special warning and precautions for use
(e) Interaction with other medicinal products and other forms of interactions
(f) Pregnancy and lactation
(g) Effects on ability to drive and use machine
(h) Undesirable effects
(i) Management of overdose

5.2.5 Pharmacological Properties.

(a) Pharmacodynamic Properties

(b) Pharmacokinetic Properties

(c) Preclinical safety Data

5.2.6 Phannaceutical Particulars

(a) List of excipients

(b) Incompatibilities

(c) Shelf-life. Shelf-life of the medicinal product as packaged for sale. Shelf-life after dilution or reconstitution according to directions. Shelf-life after first opening of the container

(d) Special precautions for storage

(e) Nature and contents of container

5.2.7 Marketing Authorization Holder

5.2.8 Marketing Authorization Numbers

5.2.9 Date of first authorization/ renewal of the authorization

5.2.10 Date of revision of the text

5.3 Patient Information Leaflet (PIL)

Part II: QUALITY

S Drug Substance

S1 General Information

S1.1 Nomenclature

- Information from the SI

S1.2 Structure

- Structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass.

S1.3 General Properties

- Physico-chemical characteristics and other relevant properties including biological activity for biotech.
- Schematic amino acid sequence indicating glycosylation sites or the post-translational modifications and relative molecular mass, as appropriate.

S2 Manufacture

S2.1 Manufacturer (s)

- Name and address of the manufacturer (s).

S2.2 Description of Manufacturing Process and Process Controls.*

S2.3 Control of Materials. *

- Starting materials, solvents, reagents, catalysts and any other materials used in the manufacture of the drugs substance indicating where each material is used in the process, Tests and acceptance criteria of these materials.
- Control of source and starting materials of biological origin.
- Source, history and generation of the cell substrate
- Cell banking system, characterization and testing.
- Viral safety evaluation.

S2.4 Controls of Critical Steps and Intermediates

- Critical steps: Test and acceptance criteria, with justification including experimental data, performed at critical steps of the manufacturing process to ensure that the process is controlled. *
- Intermediates: Specifications and analytical procedure, if any, for intermediates isolated during the process. *
- Stability data supporting storage conditions. *

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* required for NCE (New Chemical Entity)/New product for Myanmar.

S2.5 Process Validation and/or Evaluation. *

- process validation and/or evaluation studies for aseptic processing and sterilization.

S2.6 Manufacturing Process Development. *

- Description and discussion of significant changes made to the manufacturing process and/or manufacturing site of the drug substance used in producing non-clinical, clinical, scale-up pilot and if available, production scale batches.
- The development history of the manufacturing process as described in S2.2

S3 Characterisation. *

S3.1 Elucidation of Structure and other characteristics

- Confirmation of structure based on e.g. synthetic route and spectral analyses.
- Compendial requirement or appropriate information from the manufacturer.
- Details on primary, secondary and higher-order structure and information on biological activity, purity and immunochemical properties (when relevant).

S3.2 Impurities *

- Summary of impurities monitored or tested for during and after manufacture of drug substance.
- Compendial requirements or appropriate information from the manufacturer.

S4. Control of Drug Substance

S4. l Specification *

- Detailed specification, test and acceptance criteria.
- Compendial specification or appropriate information from the manufacturer
- Specify source, including as appropriate species of animal, type of microorganism etc.

S4.2 Analytical Procedures*

- The analytical procedures used for testing of drug substance.
- Compendial methods or appropriate information from the manufacturer.

S4.3 Validation of Analytical Procedures *

- The analytical information, including experimental data for the analytical procedures used for testing the drug substance.
- Non-compendial methods.

S4.4 Batch Analyses *

- Description of batches and results of the analysis to establish the specification.

S4.5 Justification of Specification *

- Justification for drug substance specification. *

S5 Reference Standard or Materials. *

- Information on the reference standards of reference materials used for testing the drug substance. *
- Compendial reference standards.

S6 Container Closure System *

- Descriptions of the container closure systems.

S7 Stability

- Stability report. *
- Literature data

P - DRUG PRODUCT

P1 - Description and Composition

Description

- Dosage form and characteristics
- Accompanying reconstitution diluent (s) if any.
- Type of container and closure used for the dosage form and reconstitution diluent, if applicable.

Composition

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* required for NCE (New Chemical Entity)/New product for Myanmar.

- Name quantity stated in metric weight or measures, function and quality

P2.1 Information on Development Studies. *

- Data on the development studies conducted to establish dosage form, formulation, manufacturing process, container closure system.

P2.2 Components of the Drug Product

P2.2.1 Active ingredient

- Justification of the compatibility of the active ingredient with excipients listed in Pl. In case of combination products, justification of the compatibility of active ingredients with each other. *
- Literature data.

P2.2.2 Excipients *

Justification of the choice of excipients mentioned in Pl. which may influence the drug product performance.

P2.3 Finished Product

P2.3.1 Formulation Development

- A brief summary describing the development of the finished product (taking into consideration the proposed route of administration and usage for NCE and Biotech)

P2.3.2 Overages

- Justification of any overage in the formulation(s) described in Pl.
- Physicochemical and Biological Properties.

Parameters relevant to the performance of the finished product e.g. pH, dissolution.

P2.4 Manufacturing Process Development

- Selection and optimisation of the manufacturing process.
- Differences between the manufacturing process(es) used to produce pivotal clinical batches and the process described in P.3.2, if applicable. *

P2.5 - Container Closure System

- Suitability of the container closure system used for the storage, transportation (shipping) and use of the finished product.

P2.6 - Microbiological Attributes

- Microbiological attributes of the dosage form, where appropriate.

P2.7 - Compatibility

- Compatibility of the finished product with reconstitution diluent(s) or dosage devices.

Literature data. *

P3 Manufacture

P3.1 Batch Formula

- Name and quantities of all ingredients.

P3.2 Manufacturing Process and Process Control.

- Description of manufacturing process and process control.

P3.3 Control of Critical Steps and Intermediates

- Tests and acceptance criteria

P3.4 Process Validation and/or Evaluation

- Description documentation and results of the validation and evaluation studies for critical steps or critical assays used in the manufacturing process.

P4 Control of excipients

P4.1- Specifications for excipients *

- Compendial requirement or appropriate information from the manufacturer.

P4.2 Analytical Procedures used for testing excipients where appropriate.

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* required for NCE (New Chemical Entity)/New product for Myanmar.

- Compendial requirements or appropriate information from the manufacturer

P4.3 Excipient of Human or Animal Origin: information regarding sources and or adventitious agents*.

- Compendial requirements or appropriate information from the manufacturer.

P4.4 Novel Excipients *

- For excipient(s) used for the first time in a finished product or by a new route of administration, full details of manufacture, characterization.

P5 Control of Finished Product

P5. 1. Specification

- The specification(s) for the finished product.

P5.2. Analytical Procedures

- Analytical procedures used for testing the finished product.

P5.3. Validation of Analytical Procedures

- Information including experimental data for the analytical procedure used for testing the finished product. *
- Non compendial method(s).

- Verification of compendial method applicability - precision & accuracy.

P5.4 Batch Analyses

- Description and test results of all relevant batches.

P5.5 Characterisation of Impurities

- Information on the characterisation of impurities. *
- Compendial requirements or appropriate information from the manufacturer

P5.6 Justification of Specification(s)

- Justification of the Proposed finished product specification.

P6. Container Closure System

- Specification and control of primary and secondary packaging material, type of packaging & the package size, details of packaging inclusion (e. g. desiccant, etc.)

P8. Stability

- Stability report: data demonstrating that product is stable through its proposed shelf life.
- Commitment on post approval stability monitoring.

P9 Product Interchangeability (Generic only)

Equivalence evidence

- In Vitro

Comparative dissolution study as required.

- In Vivo

Bioequivalence study as required.

Part III: NON CLINICAL (for NCE/ New products for Myanmar).

l. General Aspect

2. Content and structural format

1. Nonclinical Written Summaries

1.1 Pharmacology

1.1. l Primary Pharmacodynamics

1.1.2 Secondary Pharmacodynamics

1.1.3 Safety Pharmacology

1.1.4 Pharmacodynamics Drug Interactions.

1.2 Pharmacokinetics

1.2.1 Absorption

1.2.2 Distribution

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* required for NCE (New Chemical Entity)/New product for Myanmar.

1.2.3 Metabolism
1.2.4 Excretion
1.2.5 Pharmacokinetics Drug Interaction (non-clinical)
1.2.6 Other Pharmacokinetics Studies
1.3 Toxicology
1.3. l Single dose toxicity
1.3.2 Repeat dose toxicity
1.3 .3 Genotoxicity
1.3.4 Carcinogenicity
1.3.5 Reproductive and developmental toxicity
1.3.5. l Fertility & early embryonic development
1.3.5.2 Embryo- foetal development
1.3.5.3 Prenatal and postnatal development
1.3.6 Local tolerance
1.3.7 Other toxicity studies, if available

- Antigenicity
- Immunotoxicity
- Dependence
- Metabolites
- Impurities

Part IV: CLINICAL (for NCE/ New Product for Myanmar)
" Clinical Overview "
1. Product Development Rationale
2. Overview of Biopharmaceutics
3. Overview of Clinical Pharmacology
4. Overview of Efficacy
5. Overview of Safety
6. Benefits and Risk Conclusions
" Clinical Summary "
1. Summary of Biopharmaceutic Studies and Associated Analytical Method
1.1 Background and Overview
1.2 Summary of Results of Individual Studies
1.3 Comparison and Analyses of Result Across Studies
2. Summary of Clinical Pharmacology Studies
2. 1 Background and Overview
2.2 Summary of Results of Individual Studies
2.3 Comparison and Analyses of Results Across Studies
2.4 Special Studies
3. Summary of Clinical Efficacy
3 .1 Background and Overview of Clinical Efficacy
3 .2 Summary of Results of Individual Studies
3.3 Comparison and Analyses of Results Across Studies
3 .4 Analysis of Clinical Information Relevant to Dosing Recommendations
3 .5 Persistence of Efficacy and/or Tolerance Effects.
4. Summary of Clinical Safety
4. 1 Exposure to the Drug
4.2 Adverse Events
4.3 Clinical Laboratory Evaluations
4.4 Vital Sign, Physical Findings, and Other Observations Related to Safety
4.5 Safety in Special Groups and Situations
4.6 Post- marketing Data

5. Synopses of Individual Studies
"Clinical Study Reports " (if applicable)
1. Reports of Biopharmaceutic Studies
1.1 BA study Reports
1.2 Comparative BA or BE Study Reports
1.3 In vitro - In vivo Correlation Study Reports
1.4 Reports of Bioanalytical and Analytical Methods for Human Studies
2. Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials
2.1 Plasma Protein Binding Study Reports
2.2 Reports of Hepatic Metabolism and Drug Interaction Study
2.3 Reports of Studies Using Other Human Biomaterials
3. Report of Human Pharmacokinetic (PK) Studies
3.1 Healthy Subject PK and Initial Tolerability Study Reports
3.2 Patient PK and Initial Tolerability Study Reports
3.3 Population PK Study Reports
4. Reports of Human Pharmacodynamic (PD) Studies
4.1 Healthy Subject & PD and PK/PD Study Reports.
4.2 Patient PD and PK/PD Study Reports.
5. Reports of Efficacy and Safety studies
5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication
5.2 Study Reports of Uncontrolled Clinical Studies
5.3 Reports of Analyses of Data from More Than One Study, Including Any Formal integrated Analyses, Meta- analyses & Bridging Analyses
5.4 Other Clinical Study Reports
6. Reports of Post- Marketing Experience
7. Case Report Forms and Individual Patient Listing
8. List of Key Literature References

Well - established Drug Products. (WHO and ASEAN CTD Glossary)
Pharmaceutical Products that contain well established drugs & which:

- ☐ have been marketed for at least five years that undertake active post marketing monitoring;
- ☐ have been widely used in sufficiently large number of patients to permit the assumption that safety & efficacy are well known, have the same route of administration & strength & the same or similar indication as in those countries.

Department of Food & Drug Administration

Registration of Food Supplement/ Over The Counter Medicine

Definition: Whether a product should be regulated as a drug or a food supplement depends on the claims the manufacturer makes for the product on the product labels, leaflet or promotion materials. Claims that relate to the mitigation or treatment of disease entail that the product be regulated as a drug.

1. The Procedure of registration for Food Supplement is the same as Pharmaceuticals

2. The documents required for Food Supplement are the following:

Administrative data
(a) Letter of Authorisation
(b) Free Sale Certificate (original) issued by the competent authority in country of origin
(c) Properly endorsed/Legalization of Manufacturing Licence copy
(d) ISO Certificate (Standard)

Quality
(a) Raw Material Specification, Source of raw material
(b) Raw Material quality control
(c) Master Formula
(d) Manufacturing process
(e) Finished product specification
(f) Reference Text
(g) Certificate of Analysis (Finished product)
(i) Stability test of finished product

Safety & efficacy data
(a) Action of Active Ingredient, if any; (Reference Text) ·
(b) Safety data of finish Product
(c) Research Paper/Literature of Food Supplement (endorsed by a DFDA-Recognized Research Institute)

Documents required for Registration of Vaccines

In addition to all requirements as indicated for Pharmaceuticals:

I. Administrative data and product information
- Batch release certificate of regulatory authority
- WHO prequalification certificate
- Summary of product characteristic

II. Manufacturing and Quality
- Detailed composition of the product (Description, Characterization, Biological activity test)
- Description of manufacturing facility (Identification, Manufacture of other products, Layout, Precaution against contamination)
- Method of Manufacture (Description of the seed lot and cell substrate systems used, synthesis pathway and flow chart of manufacturing process)
- Detailed description of source of raw materials (e.g. virus sources, animal sources, DNA recombinant products, host cell, gene construct, vector etc., cell bank system, cell growth and harvesting, purification and inactivation processing)
- Process Controls (In process controls, Process validation)
- Manufacturing consistency (minimum of 3 consecutive batches)
- Immunogenic substance specifications
- Reprocessing (In event of rejection of the lot or batch by the Manufacturer's QA/ QC)
- Stability of the active ingredient and finished product (Real time and accelerated)
- Microbiological attributes
- Containers and closure system
- Documentation used in the manufacturing and control procedures including SOPs and protocols containing details of production and Quality Control testing carried out in all stages and production.
- Composition and characterization of final product including recipients, adjuvant and preservatives.

III. Report on pre-clinical studies

IV. Report on Clinical Trials

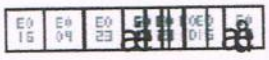
* For Established Biological Product only
  - Phase IV clinical trial
* For Live vaccine
  - Transmission to contact studies
  - Vaccine induced disease studies
  - Effect on large scale vaccination on the natural history of the disease
*For Combination of Biological Product
  - Clinical data on Efficacy
  - Clinical data on Safety

Annex II

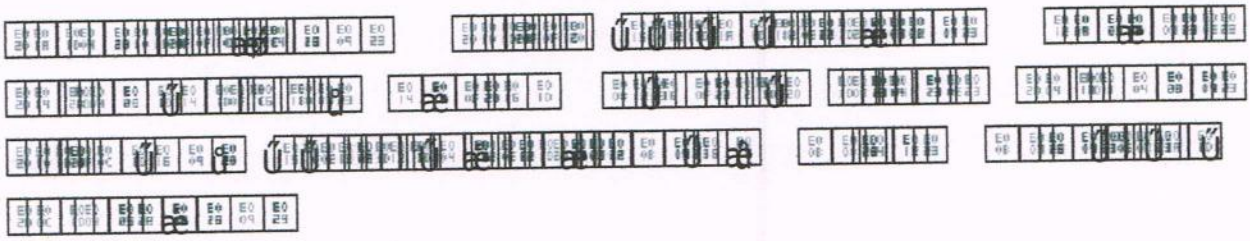
Ministry of Health and Sports

DEPARTMENT OF FOOD & DRUG ADMINISTRATION

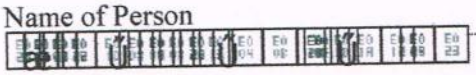
Approval No.



To whom it may concern



In order to carry out necessary tests on drugs which have been applied for registration in Myanmar, approval is hereby granted to under mentioned person to import one consignment of drug samples as specified in the attached schedule overleaf.

Name of Person  .....

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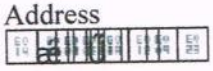
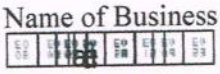
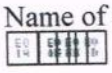
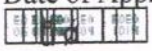
Address  .....

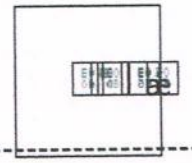
Name of Business  .....

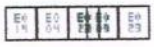
Name of Consignor  .....

Address .....

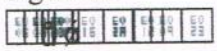
Date of Approval 

Valid up to



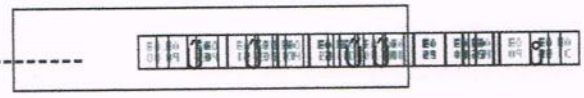


Signature



Name

Designation



See conditions attached

နမူနာတင်သွင်းမည့်ဆေးဝါးများ

စဉ် Sr No.	ဆေးဝါးအမည် (အမှတ်တံဆိပ်အမည်/ ဓါတုအမည်) Name of Drugs (trade name/ generic name)	ဆေးဝါးပုံသဏ္ဌာန် ပါဝင်မှုပမာဏ Dosage Form/ Strength	ထုပ်ပိုးပုံ Packing & Presentation	ရေတွက်ပုံ A/U	တင်သွင်းမည့် ဆေးဝါးပမာဏ	ထုတ်လုပ်စက်ရုံ/ နိုင်ငံ Name of Manufacturer/ Country

စည်းကမ်းချက်များ
Conditions

၁။ ဤတင်သွင်းခြင်းထောက်ခံချက်(မူရင်း)သာ တရားဝင်ဖြစ်သည်၊ မည်သည့်ပုံစံမျိုးဖြင့်ဖြစ်စေ၊ မိတ္တူသည် တရားဝင်ထောက်ခံချက်မဟုတ်

This approval shall official only with use of original Approval Certificate. Copy in any from shall be void.

၂။ ဤဆေးဝါးနမူနာတင်သွင်းခြင်းထောက်ခံချက်သည် တစ်ကြိမ်တင်သွင်းခြင်းကို ထောက်ခံခြင်းဖြစ်ပြီးဖော်ပြထားသော သတ်မှတ်ကာလအတွင်းတွင်သာအကျိုးသက်ရောက်စေရမည်၊

This approval shall be applicable for only consignment and shall be invalidated from the date stated on it.

၃၊ ဤတင်သွင်းခြင်းထောက်ခံချက်သည် လက်မှတ်တွင် ဖော်ပြထားသည့်ပုဂ္ဂိုလ်အား ခွင့်ပြုခြင်းသာဖြစ်ပြီးအခြားတစ်ဦးတစ်ယောက်အား လွှဲပြောင်းခြင်းမပြုရ၊

The approval is granted to a person as stated in the permit. This permit is not transferable to another person.

၄။ အသုံးမပြုသည့် တင်သွင်းခြင်းထောက်ခံစာအား တင်သွင်းခွင့် သက်တမ်းကုန်သည့်နေ့မှစ၍ (၁)ပတ်အတွင်း အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဦးစီးဌာနသို့ ပြန်လည်အပ်နှံရမည်၊

The unused approval must be returned to the Department of Food & Drug Administration within two days from date of expiry of the approval.

၅၊ တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲပါဇယားပေါ်ပါ ဖော်ပြထားသော အချက်အလက်များအားပြင်ဆင်ခြင်း၊ ဖျောက်ဖျက်ခြင်း မပြုလုပ်ရ၊

No Change or deletion shall be made to any expression of the approval and of the attached schedule.

၆၊ ဤတင်သွင်းခြင်းထောက်ခံစာအရ တင်သွင်းခဲ့သော ဆေးဝါးနမူနာများနှင့် တင်သွင်းခွင့် ထောက်ခံစာအား အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဦးစီးဌာနသို့ ဆိုက်ရောက်ရာဌာနမှ ထုတ်ယူပြီးသည့်နေ့မှစ၍ (၁)ပတ်အတွင်း အတွင်းပေးပို့ရမည်၊

The imported drug samples and the approval must be submitted to the Department to Food & Drug Administration within one week from the date of clearance from port of entry.

၇။ ပေးပို့သည့် ဆေးဝါးနမူနာသည် တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲဇယားပါသတ်မှတ်ချက်များအတိုင်းဖြစ်စေရမည်။ကွဲလွဲချက်များဖြစ်ပေါ်ပါကတင်သွင်းခွင့်ရရှိသူမှ လုံးဝတာဝန်ယူရမည်၊

Submitted drug samples must be totally in compliance with specifications stated in the schedule.
The holder of the approval shall bear the responsibilities of any discrepancies.

၈။ အထက်ပါစည်းကမ်းချက်များအားလိုက်နာရန် ပျက်ကွက်ပါကတည်ဆဲဥပဒေများအရအရေးယူခြင်းခံရမည်။

Failure to comply with above mentioned conditions, is liable to actions in accordance with existing rules and regulation laws.

၉။ ဤတင်သွင်းခြင်းထောက်ခံစာကိုင်ဆောင်သူသည် မှတ်ပုံတင်လျှောက်ထားရန်အတွက် ဆေးဝါးများတင်သွင်းရာတွင် တည်ဆဲအကောက်ခွန်စည်းမျဉ်းစည်းကမ်းလုပ်ထုံးလုပ်နည်းများကိုလိုက်နာရမည်။

In importing sample drugs, holder of the approval shall comply with existing rules and regulations of Commerce and Customs departments.

Annex III

DEPARTMENT OF FOOD & DRUG ADMINISTRATION

Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Dose	Syrup/ Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/Bot.)
1	Anti-bacterial	500	50	50	50	50
2	Anti-fungal	500		50		50
3	Anti-viral	500		50		50
4	Anti-malarial	500		50		
5	Anti-tuberculous	500		50		
6	Anti-amoebic	500	50	50	50	
7	Anthelmintic					
	(a) Single dose	150 doses	50			
	(b) Multiple doses	500 doses	50			
8	Anti-inflammatory Drugs(Non-steroidal)	500	50	50		50
9	Anti-depressant	500		50		
10	Anti-psychotic	500		50		
11	Anti-convulsant	500	50	50		
12	Anti-parkinsonism	500				
13	Anxiolytic	500		50		
14	Anti-diabetic	500		50		
15	Anti-thyroid	500				
16	Anti-emetic	500	50	50		
17	Anti-diarrhoeal	500				
18	Antispasmodic	500		50		
19	Antacid	500	50			
20	Anti-ulcer	500	50	50		
21	Anti-asthmatic	500	50	50		
22	Antitussive	500	50			
23	Antihistamine	500	50	50		
24	Mucolytic	500	50	50		50
25	Anti-anginal	500		50		
26	Anti-hypertensive	500		50		
27	Anti-arrhythmic	500		50		
28	Beta adrenergic blockers	500		50		
29	Calcium Antagonnist	500		50		
30	Diuretic	500		50		
31	Anti-hyperlipidaemic	500				
32	Anti-heamorrhoidal	500				
*33	Ant-neoplastic	200		30	30	
34	Anti-migraine	500	50	50		
35	Anaesthetics*			50	50	50

* Antineoplastic from India must be submitted with own COA and Lab analysis Report from Accredited Laboratories.

*Antineoplastic from other Countries must be submitted with own COA and Test result from accredited Analytical Laboratory.

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Dose	Syrup/ Suspension/ Ellixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/Bot.)
36	Amino Acids	500	50	50	50 (LVP) 50 (SVP)	
37	Antianaemic	500	50	50		
38	Contraceptive	150 cycles				
39	Corticosteroids	500		50		50
40	Intravenous Replacement Fluids				50 (LVP) 50 (SVP)	
41	Plasma Expander					
42	I/V Glucose (10% 25% 50%)			50		
43	Multivitamin	500	50	50		
44	Nootropic	500		50		
45	(a)Oral Rehydration Salt tablets	500				
	(b)Oral Rahydration Salt Powder	200 Sachets (one liter pack) 400 Sachets (less than one liter pack)				
46	Uricosurics	500				
47	Vaccines			50		
48	Dermatologicals					50
49	Eye/ Ear Drops					100

LVP = Large Volume Parenteral, (500 ml & above)

SVP = Small Volume Parenteral. (Less than 500 ml)

Note: (1) All the submitted sample drug must have a minimum of two years' shelf-life(or ¾ of * total shelf life)

(2) In case of large sized packs (e.g. 500's, liter pack or jar) the required amounts are 3 bottles.

(3) If more than one type of packaging or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remaining have to be submitted in a minimum of four unit-pack each if it is a small sized pack and one unit-pack each if it is a large sized pack.

Annex IV

Required quantities of sample drugs for renewal

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ United Dose	Syrup/ Suspension/ Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/Bot.)
1	Anti-bacterial	300	20	30	20	15
2	Anti-fungal	300	20	30		15
3	Anti-viral	300	20	30		15
4	Anti-malarial	300		30		
5	Anti-tuberculous	300		30		
6	Anti-amoebic	300	20	30	20	
7	Anthelmintic					
	(a) Single dose	50	20			
	(b) Multiple doses	50	20			
8	Anti-inflammatory Drugs(Non-steroidal)	300	20	30		15
9	Anti-depressant	300	20	30		
10	Anti-psychotic	300	20	30		
11	Anti-convulsant	300	20	30		
12	Anti-parkinsonism	300	20	30		
13	Anxiolytic	300	20	30		
14	Anti-diabetic	300		30		
15	Anti-thyroid	300				
16	Anti-emetic	300	20	30		
17	Anti-diarrhoeal	300	20			
18	Antispasmodic	300	20	30		
19	Antacid	300	20			
20	Anti-ulcer	300	20	30		
21	Anti-asthmatic	300	20	30		
22	Antitussive	300	20			
23	Antihistamine	300	20	30		
24	Mucolytic	300	20			
25	Anti-anginal	300		30		
26	Anti-hypertensive	300		30		
27	Anti-arrhythmic	300		30		
28	Beta adrenergic blockers	300		30		
29	Calcium Antagonist	300		30		
30	Diuretic	300		30		
31	Anti-hyperlipidaemic	300				
32	Anti-heamorrhoidal	300				
* 33	Ant-neoplastic	100		10		

* Antineoplastic from India must be submitted with own COA and Lab analysis Report from accredited laboratories.

*Antineoplastic from other Countries must be submitted with own COA and Test result from accredited Analytical Laboratory.

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ United Dose	Syrup/ Suspension/ Ellixir (Up to 120ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/Bot.)
34	Anti-migraine	300	20	30		
35	Anaesthetics*			30	20	
36	Amino Acids	300			10(LVP)20 (SVP)	15
37	Antianaemic	300	20	50		
38	Cold Remedy	300	20			
39	Contraceptive	30 cycles				
40	Corticosteroids	300		30		
41	Intravenous Replacement Fluids				10 (LVP) 20 (SVP)	
42	Multivitamin	300	20	50		
43	Nootropic	300	20	30		
44	(a)Oral Rehydration Salt tablets	100				
	(b)Oral Rahydration Salt Powder	30 Sachets (1 L pack) 50 Sachets (< one L pack)				
45	Uricosurics	300				
46	* Vaccines			30		
47	Dermatologicals					15
48	Eye/ Ear Drops					15

LVP = Large Volume Parenteral, (500 ml & above)

SVP = Small Volume Parenteral. (Less than 500 ml)

Note: (1) All the submitted sample drug must have a minimum **one year of** shelf-life

(2) In case of large sized packs (e.g. 500's, 1000's liter pack or jar) the required amounts are 2 bottles or boxes.

(3) If more than one type of packaging or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remainings have to be submitted in a minimum of one unit-pack.

Annex V

DOCUMENTS REQUIRED FOR RENEWAL OF REGISTRATION
OF PRODUCTS AUTHORIZED BEFORE 1 JANUARY 2015

(I) Administrative Documents

(1) Letter of Authorisation
(2) Company Profile
(3) Certificate of Pharmaceutical product
(4) G.M.P Certificate
(5) Manufacturing licence
(6) Proforma statement (Annex VI of Drug registration guideline)
(7) Summary Drug Information Sheet
(8) Form I

Remarks on administrative documents _____

_____

_____

(II) Pharmaceutical Documents

(1) Name of Drug, its composition and physical, chemical properties of active substances and excipients
(2) Analytical method for active substances and excipients
(3) Standard control procedure on raw material
(4) Raw material specifications
(5) Specimen Q.C report on raw material
(6) Manufacturing process
(7) Specimen in-process Q.C report
(8) Finished product specifications
(9) Disintegration and dissolution profile
(10) Analytical method for finished product
(11)
(12) A sample copy of certificate of analysis
(13) Stability test report
(14) Packaging specifications
(15) Images of product, package, label, & package insert
(16) Q.C procedure & report on label, and packaging

Remarks on pharmaceutical documents _____

_____

_____

(III) Pharmacovigilance & Safety updated information

Remarks _____

_____

_____

_____

Annex VI

PROFORMA STATEMENT

SN	TRADE NAME	GENERIC NAME OR FORMULA	INDICATION	REMARKS

PACKING :

SHELF LIFE :

FOB PRICE :

MANUFACTURER :

Annex VII

DRUG SAMPLE	
Batch No. **Manufacture Date** **Exp. Date** **Certificate of Analysis**	**Type of Packing** **Presentation (Pack Size)** **Submitted Quality**

Finished Product Specifications	
Physical Specifications (colour, shape, size, weight, hardness, disintegration etc.)	**Chemical & Microbiological specifications**

Packaging Specifications (primary packaging, secondary packaging)

Shelf life & recommended **Storage conditions**

*** Submission for consideration**	*** Approval/** **Rejection**

*** For official Use**

ANNEX VIII

DFDA ONLINE DRUG REGISTRATION

APPLICATION INSTRUCTIONS

DFDA is introducing a computer-assisted drug registration system. When fully functional the system will enable applicants to submit applications online as described in the diagram in attachment 1.

First step: obtain username and password for applicant company staff.

Applicant companies should submit a request to DFDA Drug Control Section in writing asking for the assignment of username and password for their staff. Requests should include the following information:

- Company full name and address;
- Name, mobile telephone, and email of contact person (contact person is only one per company and does not need to be the same as the person for which username and password are requested);
- Number, issue date and expiry date of company business registration;
- Full name, ID number, address, and email for each person for which access is requested;
- A copy of the following: a) company business registration; b) national ID or passport of the person for which access is requested; c) signature of the person accessing the online registration system; d) national ID or passport of the contact person.

Companies may register up to five users under each company name. Each request should include only one user. When written requests include more than one user, only the first user will be taken into account.

DFDA-DCS (Drug Control Section) will enter company data into the online system. After entering company data, DFDA-DCS will respond by email inviting companies to instruct their staff who will become users to submit a request for username and password to DFDA Drug Control Section using the "Sign up now" option that appears at URL https://user.dcdfdamm.online/

To request a username and password users should provide the information requested by the system, such as:

- Company name (the system will display address of company if already recorded in the system; if no data has been recorded password assignment will be delayed until data is recorded).
- Full name, ID number, address, email, mobile number, proposed username (a different username must be created for each company person for which access is requested).
- A scanned copy of the following: a) company letter authorizing user to submit applications on company's behalf; b) national ID or passport; c) signature of the person accessing the online registration system.

After accessing the system, users will be able to change password, contact email, address, and names of alternates. For each user, up to two alternates can be registered to act on a user's behalf.

Please note:

1. The same person may act as user on behalf of more than one applicant-company. However, a different username and password will have to be used for different applicant-companies.
2. Companies should notify DFDA-DCS as soon as possible when new situations arise and users should no longer be allowed to act on behalf of a given applicant-company. DFDA-DCS cannot be held responsible for any misuse of system access rights by any user under any circumstances.

How to cancel a username/password.

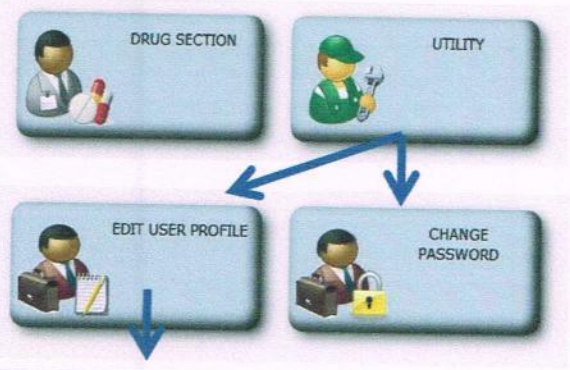
Companies may occasionally need to cancel the authorisation given to a user to act on company's behalf. In these cases please follow this procedure:

1. Notify DFDA-DCS in writing the name of the person who is no longer authorized to access the system. DFDA-DCS will inactivate that user's account. All draft and pending applications related to that username will temporarily cease to be accessible to the company.
2. Decide if another user already registered in the system can inherit the pending applications related to the discontinued account. If no active user is identified, companies should proceed to requesting the authorization for a new user as described above.
3. After identifying the user who will inherit access rights of the discontinued user, companies should request DFDA-DCS in writing to switch access rights from the discontinued user to the new one. After receiving this request, DFDA-DCS will change access rights as appropriate and the requesting company will recover full access to the pending applications that were originally related to the discontinued user.

Second step: access system.

Reach URL https://user.dcdfdamm.online/ and enter username and password to log in.

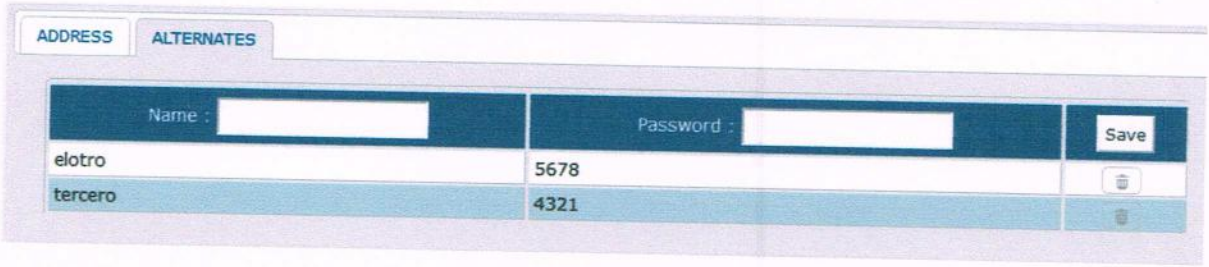
Two options will appear



The UTILITY option will permit to update user's profile and change password.

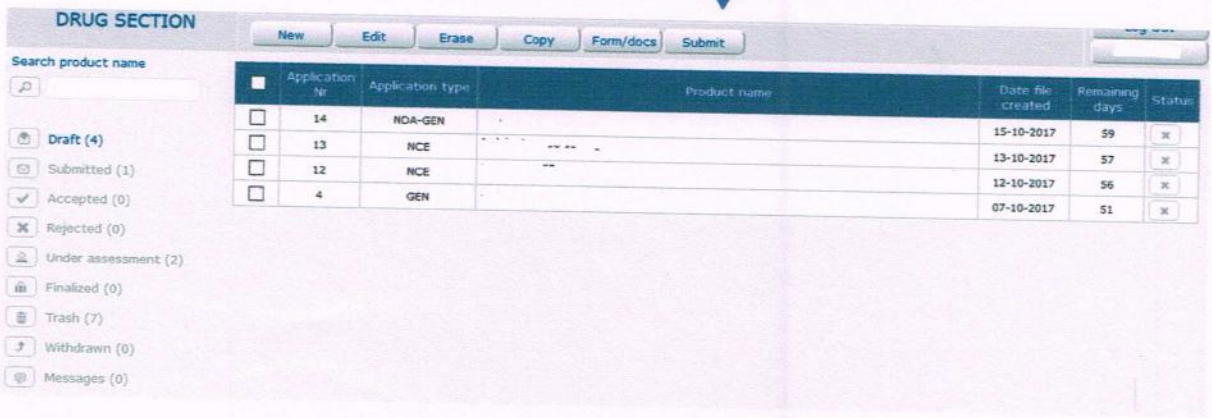
Updating the user profile permits creating/editing alternates to assist a user to perform data entry work. To create/edit an alternate, a user will enter a

name and a password for each alternate. The alternate will access the system using the same username as the user but will have a separate password.



Users will be able to monitor the work of their alternates.

The DRUG SECTION option gives access to the main data entry facility.



Third step: start a new application.

Applicants use the system facility to generate and submit new applications.

A separate application must be generated for each strength, dosage form, and pack size of a product. The system has a "copy" facility to enable users to "replicate" similar applications without typing the same information again.

A new application is generated by users in draft form. Users can edit, add or remove data, and make any kind of change until they decide to submit the application. After submission, users will no longer be able to make any change to the data submitted, unless requested to do so by DFDA-DCS. Applications can be kept in draft status for up to 20 calendar days. Past such time, applications will be automatically removed from the system, disk space will be freed and data will be lost. The maximum number of draft applications simultaneously open is 50 for each company.

To start a new application, press the "New" button at the top of the screen shown above. A new application will be generated and new screens will appear for users to enter application data.

The Edit button permits to access existing draft application to change/add/remove data as required.

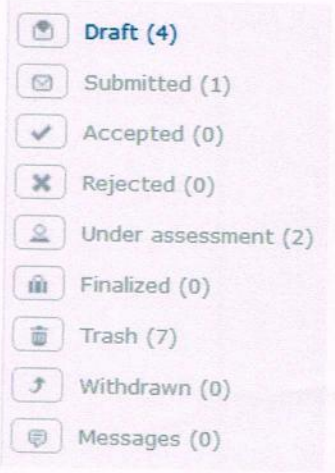
The Erase button fully removes a draft application.

The Copy button generates a new application copying data from an existing application regardless of its status (i.e. copies data from draft, submitted, verified, or approved applications). This facility saves user's data entry time when preparing applications for different strengths, dosage forms or pack sizes of the same product.

The Form/Docs button permit to print the content of an application.

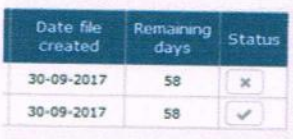
The Submit button 'seals' application data and 'sends' the application to DFDA-DCS. After submission users will not be able to change any data of the submitted application.

Some buttons will change label and function depending on the type of applications being shown in the list.



These options are used to filter the applications that will appear in the list at the centre of the screen. Statuses are as follows:

Draft: applications in draft form. Can be edited.
Submitted: submitted to DFDA-DCS. Cannot be edited.
Accepted: accepted by DFDA-DCS for assessment. Cannot be edited.
Rejected: rejected by DFDA-DCS. Will not be assessed.
Under assessment: samples and physical dossier have been accepted by DFDA-DCS and assessment phase started.
Finalized: assessment completed and final decision taken.
Trash: draft applications deleted by the user or by the system (no uploaded documents can be restored).
Withdrawn: applicants can withdraw an application after it has been submitted
Messages: messages to the applicant from DFDA-DCS.



Date file created	Remaining days	Status
30-09-2017	58	×
30-09-2017	58	✓

These columns indicate: the date on which the draft application has been created, the number of days remaining available for editing and an icon indicating whether all the minimum required information has been entered and the application is therefore ready for submission ✓.

× Incomplete applications cannot be submitted.

Fourth step: enter new application data.

The system will ask applicants to select the type of application among these options:

- BIO: biological products such as vaccines and biotechnological products.

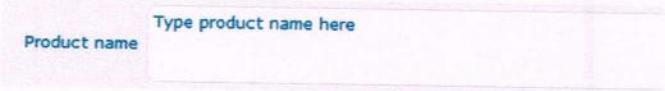
- GEN: generic. It concerns pharmaceutical equivalents of products already approved for marketing in Myanmar.
- FSU: food supplements.
- NPM: product new to Myanmar. It concerns products containing active substances or fixed-dose combinations never marketed in Myanmar before. NPM applications are accepted only for products that have already been approved for marketing by a reference[2] national authority in a foreign country.
- REN: renewal. It permits to enter an application to renew the validity of a drug registration certificate. See below specific advice on entering data for renewals.
- SPE: special access products. It concerns donations and products for specific disease control programmes.

Depending on the type of application, the system will require different types of information and documents to be submitted.

An application number is automatically generated by the system. Data entry is carried out in three different ways:

1. Some data must be entered directly by the applicant (e.g. product name, packaging description) by typing in the spaces made available for the purpose.
2. Some data will be selected from look-up tables (e.g. dosage forms, ingredient names). This will ensure consistency of terminology. If a specific term is not found in the look-up tables, applicants should first make sure that a synonym is not already included in the tables and, if no synonym is found, request DFDA-DCS to consider adding the new term by writing to contact@dcdfdamm.online.
3. Some data will be uploaded by applicants as PDF or product images. Images should be in JPG or PNG format. Each image size must not exceed 500KB and the maximum number of images that can be uploaded is 10. All files in other formats, such as .DOC or .XLS, will have to be converted by applicants to the PDF format before uploading. Applicants should ensure that no individual PDF file size is greater than 3MB. Occasionally, DFDA-DCS may request applicants to submit specific documents in other formats, but this will be done outside the online application system.

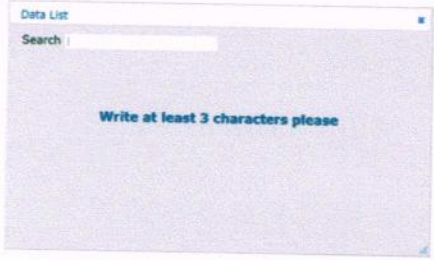
An example of data to be typed directly is the product name



[2] The list of reference countries is regularly updated; applicants should enquire at DFDA-DCS.

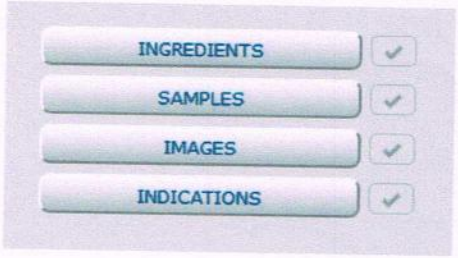
An example of data to be selected from a look-up table is the dosage form. Press this icon

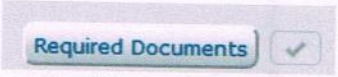
This window will appear

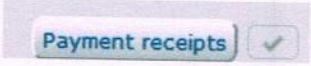


Type 3 characters and select from the list.

To be able to save a draft, applicants must enter at lest the basic product information appearing on the first screen (product name, generic name, strength, dosage form, etc.). Additional information, such as manufacturers, ingredients and other data (see the six buttons below) can be added later, on condition of remaining within the limit of 20 days.



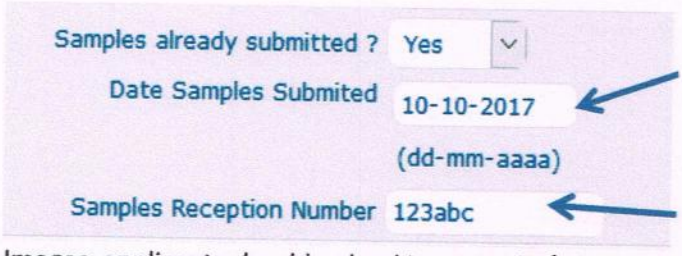




These six 'buttons' will lead to new windows where specific data can be entered/uploaded.

Ingredients: will open a window where detailed qualitative and quantitative information about active and inactive ingredients must be entered.

Samples: will open a window where applicants will describe the samples submitted. Samples must have been submitted before an application can be submitted. Applicants will provide date of submission and reception number. For applications that do not require submitting samples, applicants should first obtain a sample exemption number from DFDA-DCS. At data entry applicants shall put zero as sample quantity, type "not applicable" in the other fields. They will then enter information as if samples had already been submitted, type the exemption number and date where the computer asks for sample reception number and date (see image below).



Images: applicants should upload images of: a) the outer packaging showing all sides and including marks indicating sizes; b) the primary container showing all printed/engraved information; c) the

actual dosage form clearly showing colour(s) and details of markings (e.g. logos, numbers, grooves), if any. As stated earlier, these images should be in JPG or PNG format. Each image size must not exceed 500KB and the maximum number of images that can be uploaded is 10.

Indications: will open a window where applicants can type (or paste) free text mentioning the proposed product indications with related dosage and administration information.

Required documents and payment receipts: will open a window where applicants can upload all the documentation that is required depending on the type of application. When originals are required, applicants should keep them for later submission to DFDA-DCS together with the full dossier (see below). Again, only PDF format and maximum 3MB per file.

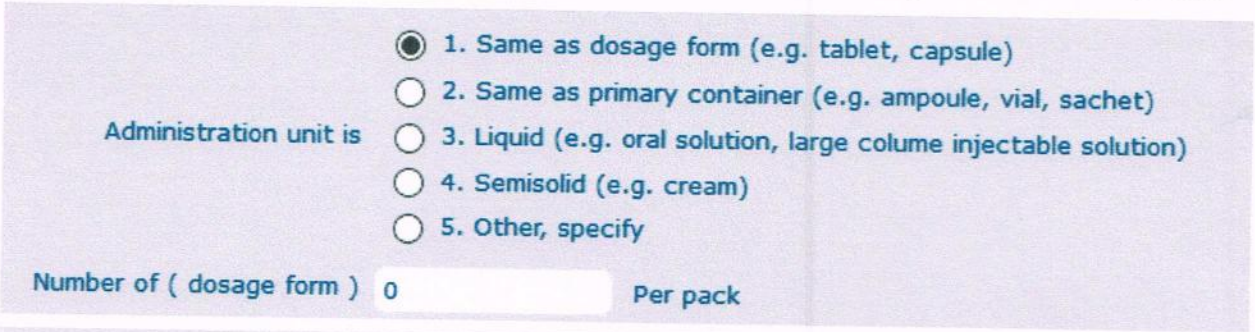
Naming files: applicants are expected to use the following rule to name the files that they intend to upload. Files names should be a string including: a document name as it appears in the Guideline on Drug Registration Application (this will also appear on the screen for easy reference)+product name+strength+dosage form. Examples: PI3.3-CPP.Aspirin.5mg.capsule.pdf; PIIP8-Drug Product-Stability.Aspirin.5mg.capsule.pdf. PI3.3 corresponds to Part I point 3.3 of the ASEAN Common Technical Dossier (ACTD), PIIP8 corresponds to Part II, point P8 of the ACTD. The ACTD can be downloaded from http://asean.org/storage/2017/03/68.-December-2016-ACTD.pdf and the ASEAN Common Technical Requirements http://asean.org/storage/2017/03/67.-December-2016-ACTR.pdf.

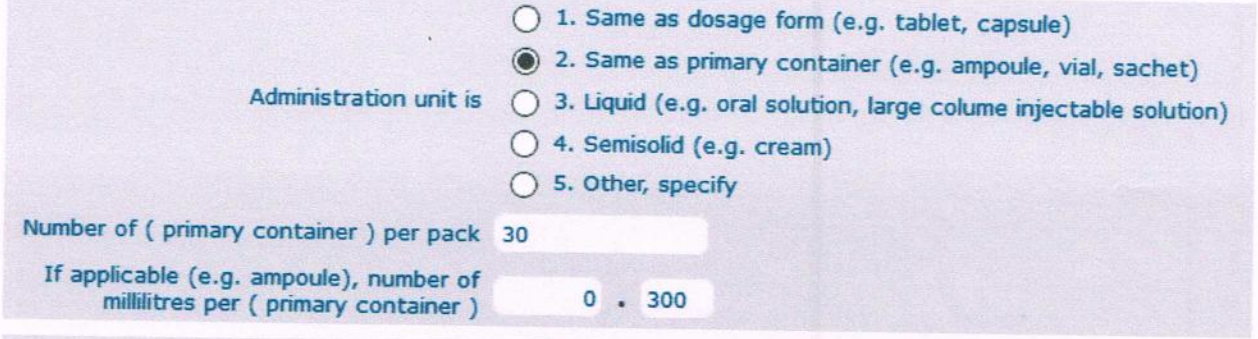
Special data entry requirements for quantitative data

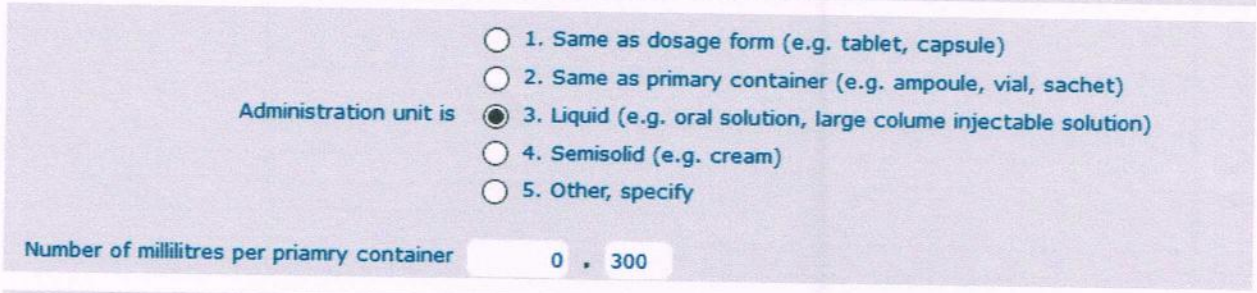
Quantitative data are required when describing the number of units in a product package and the quantities of active ingredients in an administration unit. Accuracy of information is crucial to ensure effectiveness of electronic management of information.

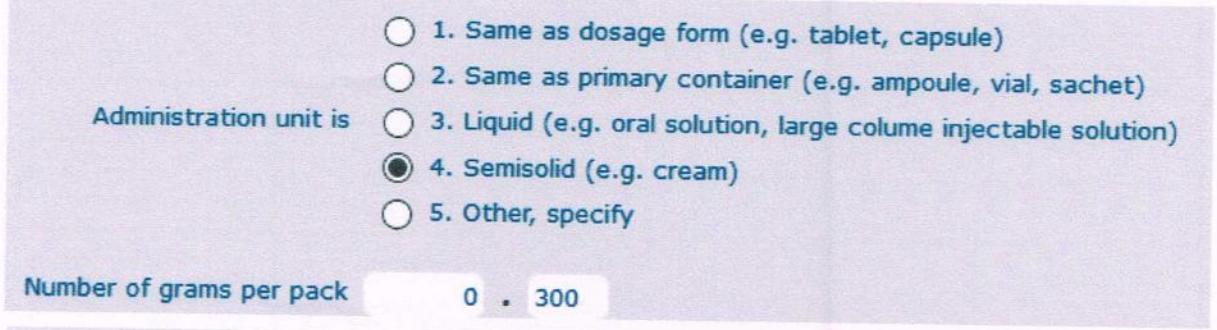
1. Enter dosage form and primary container first. The primary container (e.g. bottles, vials, closures, blisters) is in direct physical contact with the dosage form, whereas the secondary, or outer, containers are not (e.g. aluminium caps, cardboard boxes). Applicants will not be able to enter ingredients data if they have not entered dosage form and primary container.
2. Check that dosage form and primary container are correct. These can be changed later, however number of units per pack and quantity of active ingredients per administration unit may have to be re-entered if either form or primary container information is changed.
3. Applicants should now identify the administration unit. This can be the same as the dosage form (e.g. tablet, capsule), the same as the primary container (e.g. ampoule, vial, sachet), a reference to a volume of a liquid (e.g. oral solution, large volume injectable solution), a reference to the weight of a semisolid (e.g. cream, ointment), or be a special case, e.g. a device such as a metered-dose dispenser.
4. Next step, state number of administration units contained in the outer package or primary container, as applicable (e.g. 20 tablets, 12 ampoules, 60ml, 20grams, 10 syringes, etc.).
5. Mention, if applicable, the volume of the primary container (e.g. 2ml ampoule).

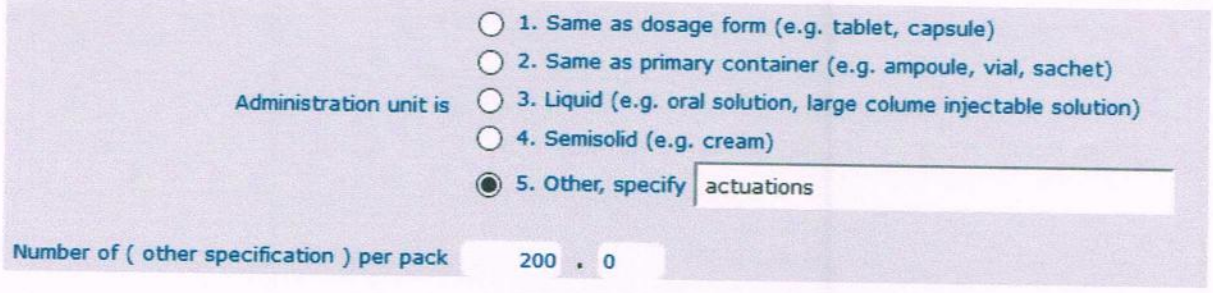
These images show how the data entry changes depending on the type of administration unit.







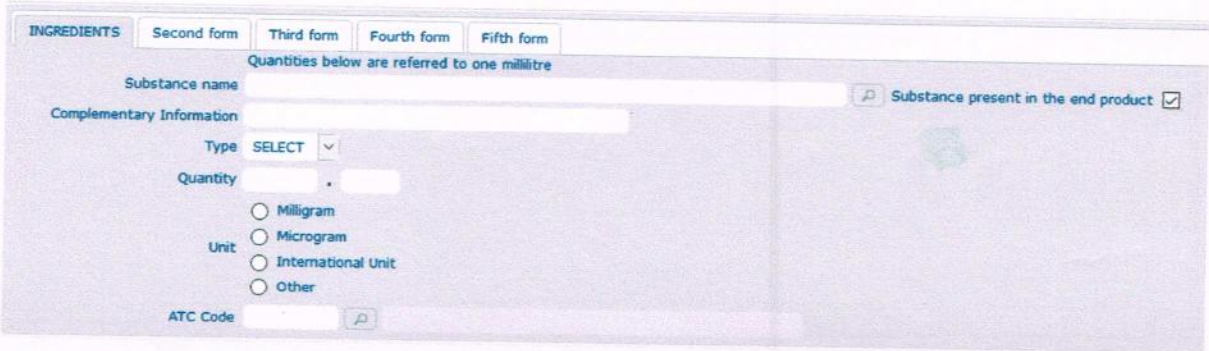




Entering ingredients data

At this stage applicants are ready to enter ingredients information. The system will use the information already entered and will propose the appropriate reference unit (e.g. composition referred to one tablet, one gram, one ml, one ampoule, etc.).

Ingredients data are entered in the screen shown below.



Substance names must be selected from a look-up table. For active substances, INNs must be used if available. The look-up table includes all INNs plus a number of other substance names for which INNs have not been assigned. An inactive substance look-up table including almost 14 thousand substance names is also available. If a substance name is not found, applicants should first make sure that a synonym is not already included in the tables and, if no synonym is found, request DFDA-DCS to consider adding the new term writing to contact@dcdfdamm.online. Such request should include literature reference indicating the source of the substance name.

Selecting the type of ingredient (active/inactive) will direct the system to seek data in the correct database and, in the case of inactives, will not make entry of quantity data compulsory.

When a salt or other specification is not included in the INN or in the table, applicants will be able to enter additional information about the active substance in the 'Complementary information' field.

Quantities and related measurement unit are then entered. A blank field is available to enter units that are not the milligram, the microgram or the international units.

Entered ingredients appear in a table like the one show here below.

		Substance name	Type	Quantity	Unit	ATC Code
		AMOXICILLIN	Active	500.000	Milligram	J01CA4
		LACTOSE MONOHYDRATE - CELLULOSE, MICROCRYSTALLINE	Inactive			

The two icons on the left permit to edit or delete entered data. There is no limit to the number of ingredients that can be entered.

The tags that appear at the top of the ingredient data entry screen (Second form, Third form, etc.) are meant to enable applicants to enter data referred to complex products, such as certain oral contraceptives, where the same blister pack (or other package unit) includes different dosage forms

with different compositions (e.g. yellow tablets contain AAA 3mg; red tablets contain AAA 2mg and BBB 5mg; orange tablets contain AAA 2mg; white tablets contain only inactives).

Fifth step: manage submitted applications.

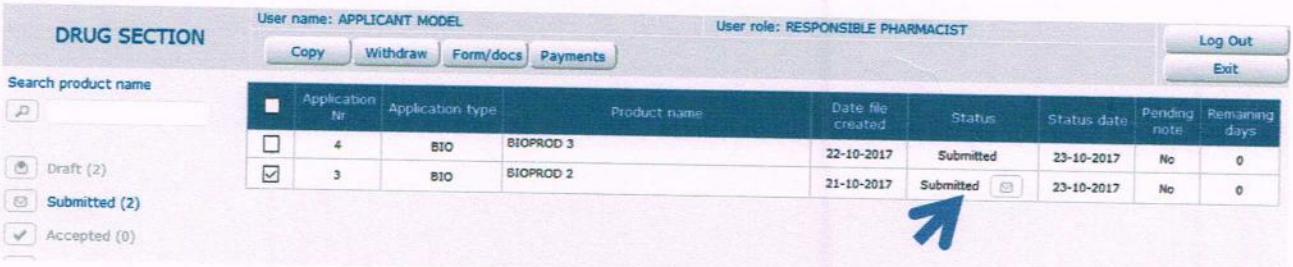
Completed applications can be submitted to DFDA. The system will not allow to submit incomplete applications and will mark with different signs those ready for submission ✓ and those still incomplete.

Date file created	Remaining days	Status
30-09-2017	58	×
30-09-2017	58	✓

Submission is done simply by pressing the submit button that appears on the bar over the grid showing draft applications.

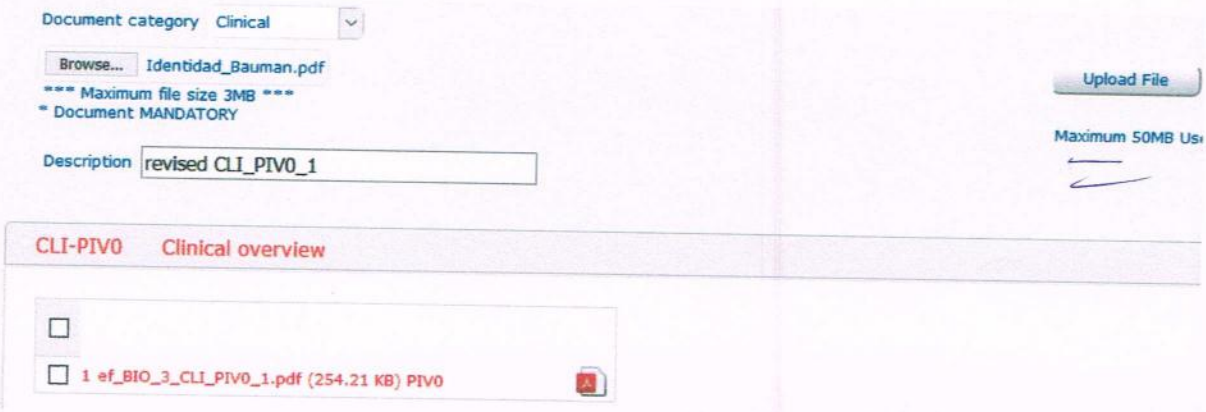
After submission, applicants will receive an automatic email message confirming that the submitted application has been received by DFDA-DCS. This submission enables DFDA-DCS to verify the content of the application. The verification has two possible outcomes: a) the content of submitted application is readable and meets the required formal aspects (e.g., a pdf file uploaded with the file name mentioning stability study does indeed include a stability study document; this does not mean the study has been assessed and found satisfactory), or b) there is a problem with one or more elements of the information submitted. In the first case, submission is conforming, applicants will receive an email message mentioning this outcome and asking to print the physical dossier and submit it to DFDA-DCS. Applicants must use the system facility to print the physical dossier to ensure that computer-generated secure markings appear on all printed pages for DFDA-DCS verification that electronic and printed versions are exactly the same.

In the second case (there is a problem with some aspects of the application), applicants will receive an email mentioning the problem(s) and inviting to make the necessary amendments. The graphic below shows two types of submitted applications.



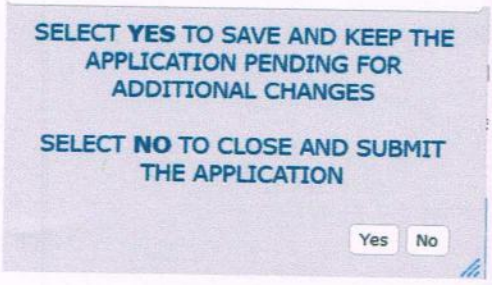
The applications that appear in the grid and have no icon are those submitted but still under DFDA-DCS review.

Those with an envelope icon are applications that require applicant's attention. Clicking on the icon, applicants can see the content of DFDA-DCS's email mentioning application shortcomings. Clicking elsewhere on the raw of that application will enable applicant to access selected content of the application and make the necessary amendments. In the example shown in the image, the 'clinical overview' pdf should be replaced or complemented by a new one.



Applicants can replace the uploaded document with a new one by selecting the check box of the file to replace.

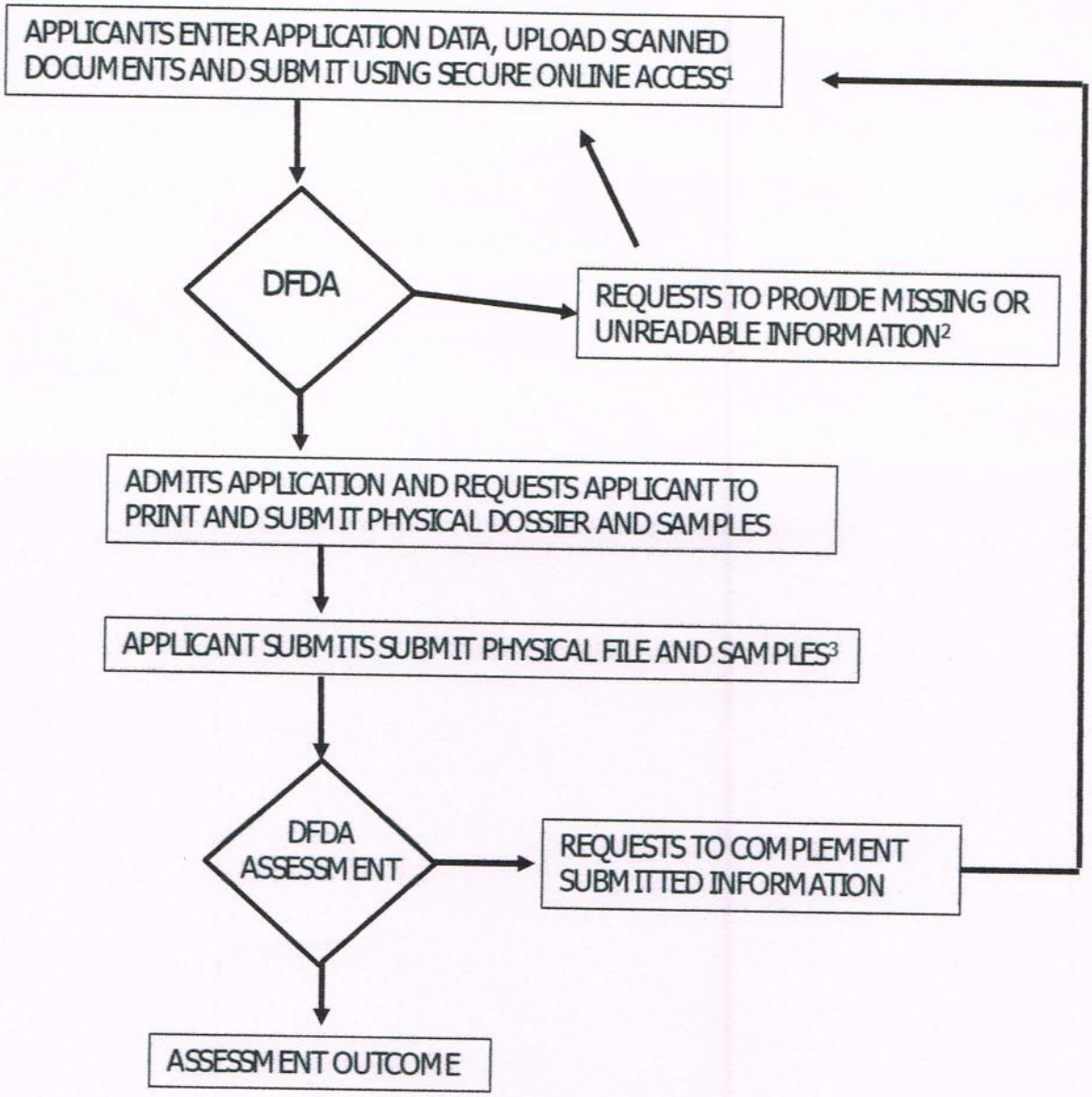
After editing part of an application, applicants will be asked if other changes are needed or the amended application is ready for re-submission.



Renewal applications

Data entry for renewal applications requires entering the existing drug registration certificate number. The system retrieves any information already available and data is provided for the applicant to update information as necessary. In the first years of the online registration system, information on previously authorized products is not available. This means that applicants will have to provide the missing information (generic name, dosage form, ingredients, etc.) in a way that is similar to that used for entering new drug applications.

ATTACHMENT 1



NOTES:

1 - For each application, the system will allow data entry and document upload for up to 20 days from the date on which data entry is started. During this time data can be modified as needed. However, after submitting an application, applicants will no longer be able to modify anything.

2 - If DFDA requests additional data to be uploaded, applicants will only have access to the specific part of the application where data is required. The rest of the application will be fully visible but not editable.

3 - The physical file must be an exact copy of the electronic submission. To ensure this, the entire file must be printed using a specific facility of the online system. The resulting printout will be marked with a security code which will also appear on the electronic version. Printed documents that do not carry the proper verification code will not be accepted by DFDA.

Annex IX

Steps to be followed in submitting dossier and samples for new drug registration

Step	Applicant action	FDA action
1	Carefully study Guideline for Submission of Application for Drug Registration	
2	Submit list of drug products for which applicant intends to apply for drug registration.	
3	Obtain FDA letter to remit assessment fees.	Issue letter for remittance of assessment fees.
4	Pay assessment fees to FDA's account MD-012456 at MEB.	
5	Request DFDA approval for importation of samples. The following shall be submitted to Drug Control Section: - Receipt issued by MEB upon remittance of assessment fees; - letter, in a format prescribed by DFDA, informing DFDA that payment for the drugs has been made; - List of sample drugs to be imported, specifying name of drug (trade name, generic name), dosage form, presentations, contents of each unit dose, pack size (accounting unit), quantities. (For the convenience sake, a form has been prepared by DFDA); - For samples already at port/airport, in addition to the above, airway bill, signed invoice and packing list of samples. No approval for importation will be issued for samples shipped before obtaining FDA letter for remittance of fees (Step3). Ensure to comply with Trade and Customs Departments regulations for importation procedures.	Check documents. Verify and then return originals. Issue approval for importation of samples.
6	Submit samples to FDA within one week from the date of clearance from point of entry.	Check and accept (or reject) samples. Issue receipt with reception number and date.

7	Start entering data in online application system https://user.dcdfdamm.online System will not permit to submit applications with incomplete information and without correct sample reception number. Submit complete application online. Application number is generated by computer.	Issue receipt of online application. Check application. Request applicant to correct inaccuracies, if any. Request applicant to print and submit physical dossier, if application meets completion requirements. Reject application if inaccuracies are not addressed by applicant with specified deadline.
8	Submit, in person, computer-generated form I plus all accompanying documentation as required for each type of application within 60 days of being notified by FDA to submit physical dossier. All documentation must be printed using the online application facility. Documentation that does not carry the printed security markings will not be accepted.	Receive and check physical dossier. Issue note acknowledging receipt of physical dossier, if all documentation carried security markings. Reject dossier if documentation does not carry security markings. Assign dossier to specific assessment procedure and determine estimated duration.
9		Request applicant to submit complementary information if found necessary during assessment.
10	Provide requested complementary information through online system within established deadlines.	Acknowledge receipt of complementary information and continue assessment.
11		Complete assessment. If outcome entails issuance of drug registration certificate, issue letter for applicant to remit registration fees. If outcome is denial of approval, issue letter informing of denial. All communications are sent via the online system using the email address provided by the applicant.
12	Remit registration fees within 90 days from the date of intimation. Upload payment receipt using online facility. Original to be submitted when visiting FDA to collect drug registration certificate.	
13	Within 60 days of payment, request appointment for collecting drug registration certificate at FDA premises.	Issue drug registration certificate. Certificate will be delivered in person only to duly authorized company representative.

Annex X

In case of multiple pack size

CASE 1 – Products never registered before.

If applicant intends to submit simultaneously for more than one pack size

a) Applicant creates first application with one pack size. In the comment space applicant mentions that applications for additional pack sizes are simultaneously being submitted.
b) Applicant uses the copy facility and creates new application with next pack size. In the comment space applicant mentions that this application concerns an additional pack size related to application number XXX.
c) Applicant finalizes applications ensuring that all dossier information is exactly the same for all pack sizes.
d) Applicant submits all applications simultaneously.
e) When requested to print and submit physical dossier, applicant prints and submits only one physical dossier for all pack sizes and the specific application form for each pack size.
f) FDA assesses application and reaches final decisions that may be different for different pack sizes.

If applicant submits new pack size after having submitted application for first pack size but before final decision is reached

a) Applicant uses the copy facility and creates new application with next pack size. In the comment space applicant mentions that this application concerns an additional pack size related to application number XXX.
b) Applicant finalizes application ensuring that all dossier information is exactly the same for all pack sizes.
c) Applicant submits new application.
d) When requested to print and submit physical dossier, applicant prints and submits only the application form.
e) FDA assesses application and reaches final decisions that may be different for different pack sizes.

CASE 2 – Products with a valid registration number.

If applicant submits application for additional pack size for product with information already entered in the online database

a) Applicant uses "additional pack size" procedure to create a new application for the additional pack size. Applicant enter valid drug registration number and system will display existing product information.
b) Applicant can edit pack-size related information and, in the comment space applicant mentions that this application concerns an additional pack size related to DRC number XXX.
c) Applicant finalizes and submits new application.
d) When requested to print and submit physical dossier, applicant prints and submits only the application form.

If applicant submits application for additional pack size for product with information not present in the online database

a) Applicant uses "additional pack size" procedure to create a new application for the additional pack size. Applicant enter valid drug registration number and system will display existing product name. Applicant will enter all missing product information.
b) In the comment space applicant mentions that this application concerns an additional pack size related to DRC number XXX.
c) Applicant finalizes and submits new application.

When requested to print and submit physical dossier, applicant prints and submits both the physical dossier and the application form.

CASE 3 – Renewal procedure.

If applicant submits renewal application for product with information already entered in the online database

a) Applicant creates a first renewal application by entering a valid drug registration number. The system will display existing product information.
b) Applicant edits pack-size related information and, in the comment space applicant mentions that this application concerns one of N pack sizes related to old DRC number XXX.
c) Applicant finalizes application and uses system Copy facility to generate as many additional renewal applications as necessary for all pack sizes.
d) Applicant submits renewal applications.
e) When requested to print and submit physical dossier, applicant prints and submits only the application form.

If applicant submits renewal application for product with information not present in the online database

a) Applicant creates a first renewal application by entering a valid drug registration number.
b) The system will display existing product name. Applicant will enter all missing product information.
c) In the comment space applicant mentions that this application concerns one of N pack sizes related to old DRC number XXX.
d) Applicant finalizes application and uses system Copy facility to generate as many additional renewal applications as necessary for all pack sizes.
e) Applicant submits renewal applications.
f) When requested to print and submit physical dossier, applicant prints and submits the application form for all pack sizes and only one physical dossier.

Requirement Checklist For New Registration of Generic, POM products

Brand Name & Dosage form :
Generic Name & Strength :
Owner Name :
Manufacturer Name :

Reg. Process : New/ Initial
Received Date :

All documents must be with valid update data.

Part I Admin:	No.	Dossiers Description	√ / ×	Remark
1.Form I	1	Application Form		
2.LOA	PI.2	Letter of Authorisation to represent product owner		Original
3.Admin Doc.	3.3	For imported products		
	A7	Manufacturing License with condition		Country specific
	PI.3A	CPP		Original
	PI.3B	GMP		Original or legalized copy
	A3	Attestation by product owner on compliance of manufacturing procedure		
	A4	Product owner's company profile		
	A5	Statement describing duties and responsibilities of each manufacturer		
	A6	Certificate of NRA of country of origin showing acceptance of more than one manufacturer		If more than one manufacturer.
	A8/ PI.3D	Site Master File of manufacturer		
	A9	List of countries where product is authorized for marketing with date of authorization or last renewal and brand name if different than Myanmar		
4.Labelling	PI.4	Unit Carton, Label, primary container & dosage form		
5.Product Information	PI.5.1	Package insert (for generic)		
	PI.5.2	Summary of Product Characteristic (SMPC)		
	PI.5.2.5	Pharmacological Properties SMPC		
	PI.5.2.6	Pharmaceutical Particulars SMPC / Package insert		
	PI.5.3	Patient Information Leaflet (PIL) Package Insert		Required for OTC.

Part II Quality	No.	Dossiers Description	√ / ×	Remark
S- Drug substance				
1. General information	S1.1	Nomenclature		
	S1.2	Structure		
	S1.3	General properties		
2. Manufacturer	S2.1	Manufacturer		
P- Drug product				
1. Composition	P1	DP Description & composition		
2. Pharmaceutical Development	P2.2	Component of the drug product		
	P2.3.1	Formulation development of Finished Product		
	P2.3.2	Overage of Finished Product		
	P2.5	Container closure stystem		
	P2.6	Microbiological attributes		
3. Manufacture	P3.1	Batch formula		
	P3.2	Manufacturing process & process control		
	P3.3	Ctrl of critical steps and intermediate		
	P3.4	Process validation & Evaluation		
4. Control of DS	P4.2	Analytical procedure (AP) of excipients		
5. Control of FP	P5.1	Specification		
	P5.2	Analytical procedure (AP)		
	P5.4	Batch analysis		
	P5.6	Justification of specification		
7. Packaging	P7	Container closure stystem & Details		
8. Stability	P8	Stability (Both Long term & accelerated data)		
9. BA/ BE	P9	Product interchangeability (Generic only)		