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A Comparative Study of the Regulatory Landscape for Pre-filled Syringes (PFS) in the Philippines and Uganda

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Abstract

The regulatory approval of pharmaceutical products like Pre-filled Syringes (PFS) differs significantly among various international health authorities due to the format of the dossier, the time taken to evaluate the product, and the legal requirements that must be fulfilled. This paper seeks to compare the registration procedures of the National Drug Authority (NDA) of Uganda, which follows a five-module format of the Common Technical Document (CTD), and the Food and Drug Administration (FDA) of the Philippines, which follows the ASEAN format of the Asian Common Technical Dossier (CTD) comprising four parts. Unlike the NDA of Uganda, which regulates the Ugandan market, where 90% of the drugs used are imported, the FDA of the Philippines requires a Certificate of Product Registration (CPR) to market a product.

Conclusion: Regulatory approval for pre-filled syringes varies between Uganda and the Philippines in dossier format, timelines, and legal requirements. Uganda follows a five-module CTD, while the Philippines uses the ASEAN ACTD and requires a Certificate of Product Registration.

Keywords: Pre-filled Syringe (PFS), Uganda, Philippines, NDA, FDA Philippines, CTD, ACTD

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1. Introduction

Regulatory Affairs (RA) refers to the professional field responsible for ensuring that pharmaceutical products comply with the regulations established by authorities such as the U.S. Food and Drug Administration and other international regulatory agencies before a drug can be marketed. Professionals working in regulatory affairs act as a link among regulatory authorities, the pharmaceutical industry, and consumers. Their main responsibility is to ensure that medicines available in the market are safe, effective, and of high quality.

Within the pharmaceutical industry, regulatory affairs professionals collaborate with researchers, healthcare professionals, manufacturing teams, and marketing departments. Their role is to collect, organize, and submit the scientific and regulatory data required by government authorities for evaluating a medicine. At the same time, regulatory agencies interpret and enforce laws established by legislative bodies to protect public health. In simple terms, regulatory affairs connects pharmaceutical companies with regulatory authorities worldwide, particularly during drug registration before a product can be marketed in a specific country. (1)

The sections of a pharmaceutical dossier are known as modules. The number, name, and content of these modules may vary depending on the regulatory requirements of different regions. For example, the pharmaceutical dossier structure used in India and the United States typically includes five modules, while the dossier format followed by the Association of Southeast Asian Nations (ASEAN) is organized into four modules. This difference reflects variations in regulatory requirements and documentation structures among different regions. (2)

In the Common Technical Document (CTD) format, each document should normally start with page number 1, except for the literature reference section. According to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guideline M4, it is not mandatory to number every page as "1 of n," where n represents the total number of pages. However, each page should include a clear header or footer that identifies the document or section, such as a shortened

section title (for example, 2.7 Clinical Summary). The guidelines also allow simplified section numbering to avoid overly complex numbering systems. For instance, instead of very detailed numbering such as 2.6.6.3.2.1, shorter numbering formats like 1, 1.1, 2, 3, 3.1, and 3.2 can be used to maintain clarity and readability. (3)

2. Overview of Pre-filled Syringe

More than 20 pharmaceutical companies manufacture prefilled syringes (PFS) as a preferred delivery system for over 50 injectable drugs and vaccines. Taken together, these products generate an estimated global sales volume of about US$500 million. (4) Prefilled syringes offer several advantages, including a reduction in preparation steps and administration time, as the injection is supplied in a ready-to-use form.

The market offers different types of PFS that vary in needle design, plunger systems, and cartridge configurations. Moreover, a variety of prefilled injection devices are currently available, including insulin pens, growth hormone delivery pens, and choriogonadotropin alfa pen systems. These innovations improve patient convenience and treatment adherence, allowing patients to self-administer medications outside the hospital setting. (5)

In this approach, patients are less concerned about dosing errors associated with conventional vials, since preparing doses from vials can be a complex and time-consuming procedure. The following are the two types of PFS configurations based on the needle options:(6)

1) Staked needle PFS

2) Luer lock Luer tip

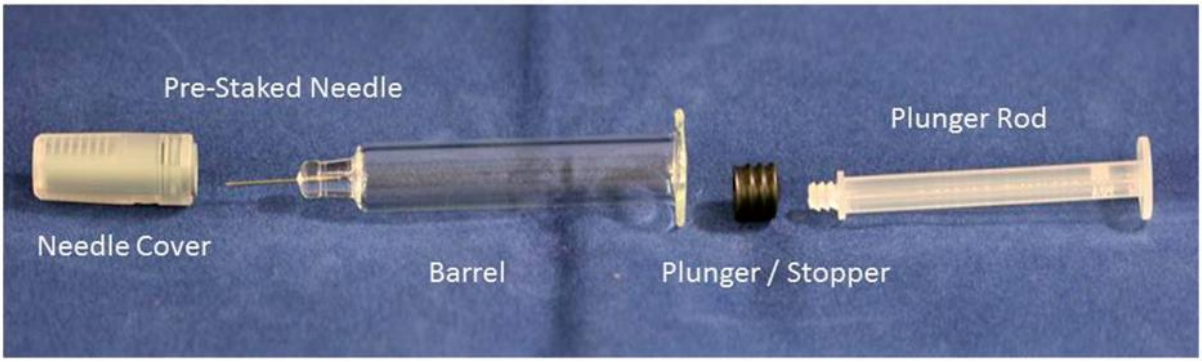

Figure 1. Prefilled syringe (7)

2.1 Growing Prefilled Syringe Market: -

The use of prefilled syringes has been steadily growing due to their convenience, sterility, and precise dosing capability. They help minimize drug wastage and can also improve the overall utilization and shelf life of the medication. Because these syringes are simple to handle and provide accurate dosing, they make drug administration easier for patients and healthcare providers. This convenience can reduce the need for frequent hospital visits, allowing patients to manage certain treatments more comfortably. (8)

2.2 Types of Prefilled Syringe: -

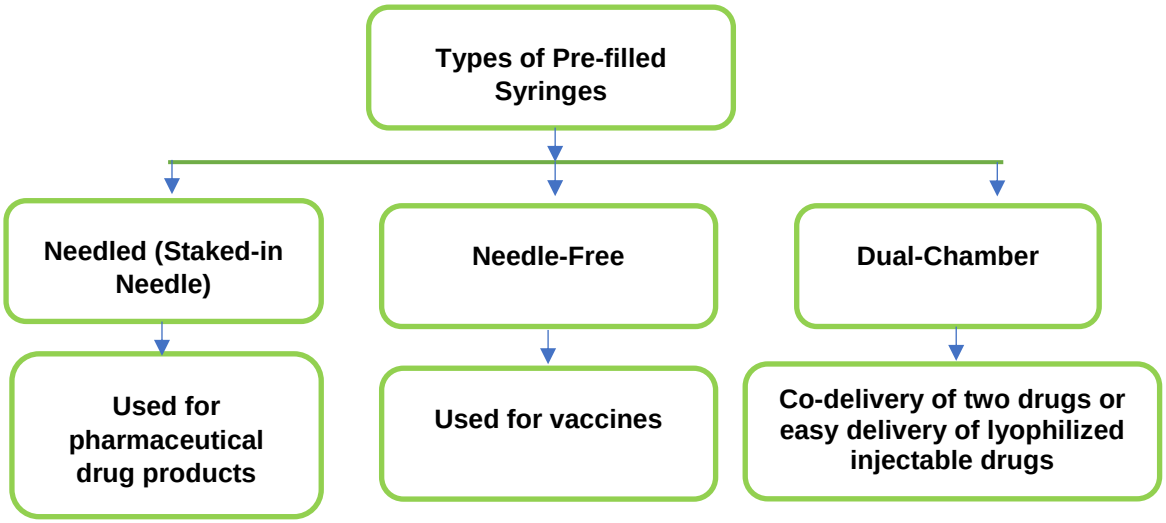

Figure 2. Types of Prefilled syringe (8)

3. Summary of the Regulatory Process of Uganda

In 2019, Uganda had 21 pharmaceutical manufacturing companies, most of which operated on a small scale. The country relies heavily on imported medicines, with approximately 90% of pharmaceuticals imported mainly from India and China. As a result, only about 10% of medicines are produced locally in Uganda.

The National Drug Policy of Uganda is implemented through the National Drug Authority (NDA), which operates under the National Drug Policy and Authority Act. This policy aims to maintain a consistent supply of medicines in Uganda that are safe, effective, and affordable, ensuring that the population has reliable access to essential healthcare treatments. (9,10)

Approved pharmaceutical products in the country are recorded in the National Drug Register (NDR), an official government database that provides detailed information about medicines permitted for use in Uganda. The NDA is responsible for regulating pharmaceutical products and maintaining this register (11)

NDA product regulated (12)

- Human and veterinary pharmaceuticals, including herbal medicines
- Human and veterinary biological products and vaccines
- Nutritional food supplements
- Medical devices
- Public health products

In Uganda, the Common Technical Document (CTD) dossier is organized into five main modules, each containing specific information required for regulatory review. These modules help ensure that all aspects of a pharmaceutical product are properly documented and evaluated. The structure follows internationally accepted guidelines, including those developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) under the M4 guideline.

This modular structure enables regulatory authorities to systematically evaluate comprehensive data on the quality, safety, and efficacy of a medicinal product before approving its use. (13)

The five modules of the CTD dossier include: (14)

- Module 1: Administrative and prescribing information
- Module 2: Overviews and summaries of Modules 3, 4, and 5
- Module 3: Quality information (pharmaceutical documentation)
- Module 4: Non-clinical study reports (pharmacology and toxicology)
- Module 5: Clinical study reports

3.1 Procedure for Submission of an Application in CTD Format (15)

a) The application should be typed in English. Supporting documents in other languages must be accompanied by an English translation.
b) The application should include an index of all appendices.
c) The following summaries should be submitted in Word format: Quality Information Summary (QIS), Quality Overall Summary (QOS), Bioequivalence Trial Information Form (BTIF), Biopharmaceutical Classification System (BCS) Biowaiver, and application forms. The main body data should be submitted in PDF format with bookmarks and optical character recognition (OCR).
d) Each page should include the application number and page numbering in the format "Page x of y."
e) The Marketing Authorization application fee must be paid before submission.
f) Fees should be paid to the National Drug Authority using the following bank details:
Account Number: 9030005759829 (UGX)
Account Number: 9030008068851 (USD)
Bank: Stanbic Bank Uganda Limited, Kampala Branch
g) The application should be submitted on CD-ROM to the Secretary to the Authority, National Drug Authority.
h) All submissions, including QIS/QOS, Package Insert (PI), Patient Information Leaflet (PIL), BTIF, and Summary of Product Characteristics (SmPC), should follow the format provided in the appendices of this guideline.
i) A separate application must be submitted for each product.

4. A Summary of the Regulatory Authority in the Philippines

The Association of Southeast Asian Nations (ASEAN) includes 10 member states: Singapore, Malaysia, Indonesia, Vietnam, Thailand, Cambodia, Myanmar, the Philippines, Brunei, and Laos. Pharmaceutical products in these countries are generally submitted for registration using the ASEAN Common Technical Dossier (ACTD) format.

The ACTD structure contains four main parts:

Part I: Administrative Data

Part II: Quality

Part III: Non-clinical Overview, Summary, and Study Reports

Part IV: Clinical Data

This format provides a standardized structure for submitting applications to regulatory authorities in ASEAN countries for the registration of pharmaceutical products intended for human use. (16,17) Typically, the registration process begins when the applicant submits an application to the relevant regulatory authority. The application is received by the document management unit, where it is registered, assigned an identification number, and stamped with the date of receipt. Afterward, the application is forwarded to the appropriate regulatory staff for initial screening and verification using a checklist. A filing review is usually conducted within a specified period after submission to confirm that the application is complete and ready for further evaluation. (18) The ACTD guideline provides a common format for preparing pharmaceutical registration dossiers in ASEAN countries. This initiative seeks to unify ASEAN regulatory standards to simplify the evaluation process and optimize resource allocation for both applicants and authorities. (19)

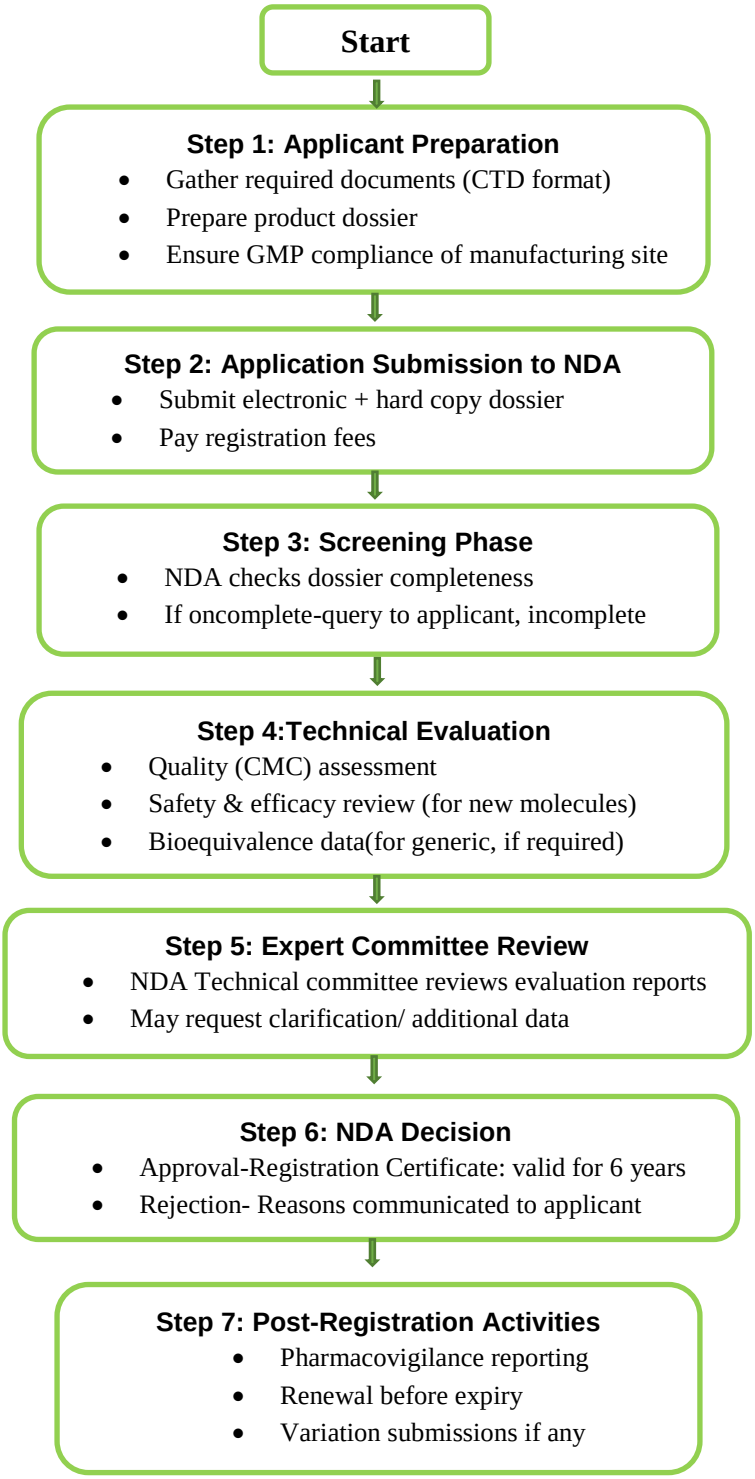

Figure 3. Drug registration process in Uganda

Part I – Administrative Data and Product Details

This section contains administrative and regulatory information related to the application. It includes the cover letter, table of contents, application forms, and product information. Integrated within the dossier are exhaustive overviews of both laboratory and human trial data, coupled with defined protocols for ongoing drug safety monitoring. Furthermore, it incorporates essential regulatory and logistical paperwork, including GMP certifications, drug substance analysis reports, patent filings, and pricing structures.

Part II – Quality Document

This section contains quality-related information about the drug substance and drug product. It includes details on the manufacturing process, control of drug substances, reference standards, formulation and composition, and product specifications. Technical documentation also covers stability studies, product description, and information on the preparation and quality control of the drug product.

Part III – Non-Clinical Document

This section provides non-clinical study data, including pharmacology, pharmacodynamics, pharmacokinetics, and toxicology. It describes how the drug is absorbed,

distributed, metabolized, and excreted in the body. In addition, it includes toxicity studies, both after single-dose and repeated-dose administration, to evaluate the safety profile of the drug.

Part IV – Clinical Document

This section includes reports of clinical studies conducted in humans. It covers biopharmaceutical studies, bioavailability and bioequivalence studies, and clinical trial reports. To substantiate the therapeutic's safety and effectiveness in humans, the documentation incorporates data from laboratory-based in vitro assays and animal in vivo models, alongside comprehensive bioanalytical evaluations. (20)

4.1 Drug Application and Registration

The CPR acts as official evidence that the registrant is authorized to market the specific drug product, provided that the company also holds a valid License to Operate (LTO).

The registration process begins when the applicant company such as a licensed manufacturer, trader, or distributor submits an electronic application along with the required documents through the Integrated Application Form in the regulatory system. After submission, the Centre for Drug Regulation and Research (CDRR) reviews and evaluates the documents to ensure that the product meets the required standards of safety, efficacy, and quality.

Upon verifying that the medicinal product meets all established criteria, the authorities grant a Certificate of Product Registration, which remains effective for a five-year period. Should the evaluation reveal significant shortcomings, the regulatory body reserves the right to issue a Letter of Disapproval (LOD) or a Notice of Deficiency (NOD), with the specific action dictated by the severity of the findings.

The FDA disapproves of products based on the following grounds:

- The requirements for the application presented indicate that the drug product does not meet the necessary technical requirements or standards.
- The applicant provided false information and misrepresentations
- Major inconsistencies were identified in the information presented in the registration dossier;
- Major queries were not clarified or satisfied by the applicant company on the compliance with NOD; and
- Major inconsistencies were identified in the compliance for NOD and the registration dossier itself.

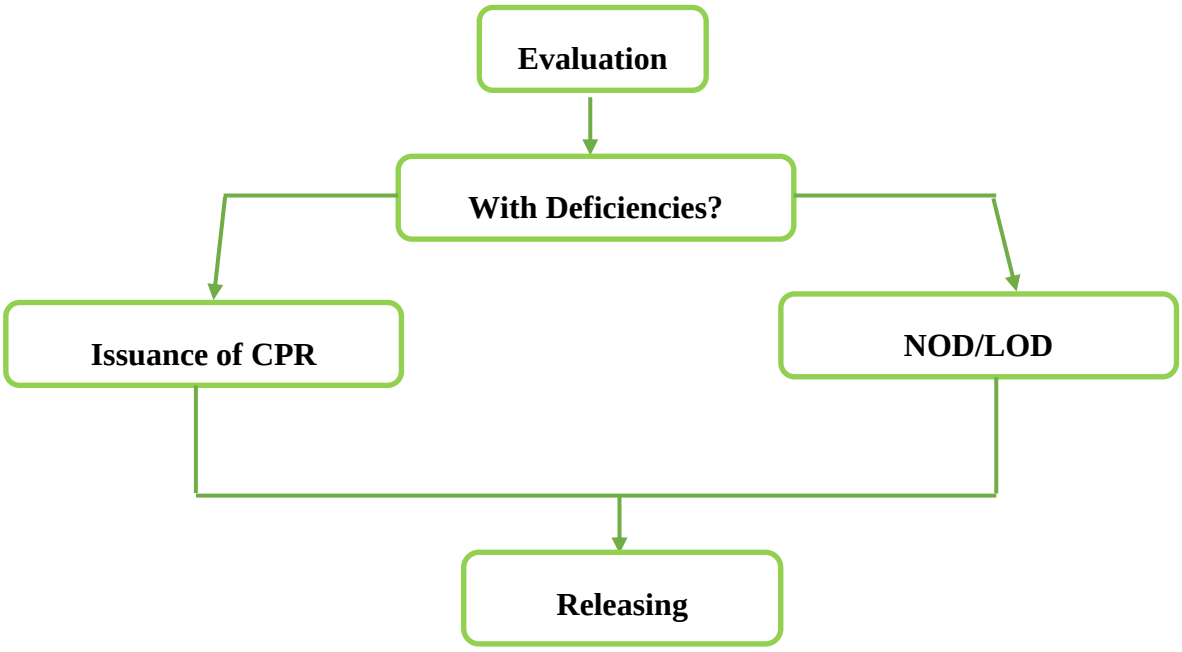

Figure 4. Drug Registration process in the Philippines

Table 1. Comparison study of regulatory authority and dossier in the Philippines & Uganda for PFS

Particular	Philippines	Uganda
National Authority	FDA Philippines	NDA
CTD/NCTD/ACTD	eACTD	CTD
Legal document	COPP with QnQ, LOA, WHO- GMP, GMP certificate form FDA Philippines, sample photo, SMP	Both the WHO COPP and Non WHO
Submission	Both hard copy and soft copy, in hard copy legal documents	Dossier submission in CD and application form, QIS, QOS

MOA evaluation time	6 to 9 months	1 to 2 years
GMP valid	2-year validity	3-year validity
Application form	Integrated FDA e-Application form	NDA drug registration form
Sample requirements	2 pack only	5 commercial pack
Registration validity	5 years	Lifetime
Fess	New reg.: - 40,000P Generic: -15.000P Import permit: -500P	Variation: -100 USD Retention: - 500 $ New reg.: - 3695 GMP inspection: - 6000 Dollars
Stability Condition	Zone IVa (30°C & 65% RH)	Zone IVb (30°C & 75% RH)

5. Conclusion: -

The comparative analysis indicates that, although the objectives of drug safety, quality, and efficacy are the same in Uganda and the Philippines, the methods to achieve these goals differ. In Uganda, the structure of the CTD is followed, and the drug enjoys a "lifetime" of valid registration, whereas in the Philippines, the ACTD structure is used, and the CPR remains valid for five years. It has been observed that there are significant differences in the evaluation periods, with the Philippines typically taking 6 to 9 months, compared to 1 to 2 years in Uganda. Additionally, there are differences in stability testing requirements: Uganda mandates Zone IVb conditions, while the Philippines requires Zone IVa. Reliance models and harmonized formats, including ACTD, are decreasing the workload for both regulators and applicants, thus facilitating quicker access to life-saving medicines, such as injectable prefilled syringes (PFS).

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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