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Review Article

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Regulatory requirements for Dossier submission in African Countries (Kenya, Uganda, and Tanzania) - A Review

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ABSTRACT

Africa is world's second fastest growing pharmaceutical market. The CGAR of African Pharmaceutical market is 10.6%. African people suffer from numerous diseases. The local pharmaceutical market is weak and insufficient to meet the demand of such diseased condition and so Africa relies heavily on externally developed and procured drugs. This combination of economic strength and prevalence of diseases is already driving a demand for medicines across Africa. The objective of this study is to delve in various parameters required for registration for externally developed pharmaceutical product African countries. A dossier containing detailed information about the drug and results of the studies carried out in its development process has to be submitted to the regulating bodies for getting market authorization. CTD is critical for dossier submissions. A comparative study will help the sponsor to file the dossier in many countries simultaneously; which can save time and money. Thus knowledge of guideline specific for individual country becomes important to determine the most stringent member, which shall ease approval process in other target countries in the region.

Keywords: African Countries, Dossier, Registration, CTD, Market Authorization.

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1. Introduction

Drug Regulatory Affairs is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession. Global harmonization in standards has led to consistent approach in regulatory submissions and hence its review. Systematic formulation development acts as a back bone for any dossier preparation in export registration.

There are different requirements in different countries for registration It is difficult for any company to develop product for each region Therefore; we need to consider majority of requirements during technical data submission which will help in export registration.

1.1. Semi regulated Market: (ROW Countries)

African countries: (Algeria, Zambia, Ghana, Kenya, Uganda, Namibia, Nigeria, Sierra Leone, Tanzania, Zimbabwe etc)

1.2. Recent Queries raised by various ROW markets

- Computation of batch size
- Chromatograms during method validation for assay and impurities
- Complete supporting data for process validation
- Cleaning validation report
- Reconstitution Stability (For oral suspensions)
- Preservative content and microbial limits
- Redispersibility and rheological properties
- Particle size distribution (1)

1.3. Over View of African Region

The African pharmaceuticals market has been growing at a fast pace. The continent has a population close to a billion. The pharmaceutical market in Africa is set to grow between \$8bn and \$10bn a year, with pharmaceutical spending in Africa expected to increase to about \$30bn by 2016. Africa's healthcare market is growing at an annual rate of 10.6%. Industry growth is attributed to the extensive surge of middle-class spending on diseases, and rapid urbanization. The industry has been growing fast

despite the infrastructural shortcomings in many of the African countries (2).

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation (3).

1.4. General Description of Registration Processes

Drug regulation generally covers the following areas:

- Pre-marketing assessment and evaluation of the quality, safety and efficacy of a medicine, including compliance of manufacturing sites and processes with Good Manufacturing Practice (GMP) standards.
- Assessment and inspection of all components of the pharmaceutical supply chain. Maintenance of a register of available products, and post-marketing surveillance activities, including random sampling of registered medicines for quality control And Pharmacovigilance.
- Promotion, advertising and provision of medicines information (3).

1.5. Current Weaknesses of the Africa's Healthcare System

- High infectious disease burden
- Limited local production
- Inadequate supply chain
- Weak procurement systems
- Counterfeited or substandard pharmaceutical products
- Lack of clinical research organizations and bioequivalence centers
- Lack of specialized skills
- Lack of technology
- Lack of affordability
- Lack of reimbursement and public funding
- Lack of IP protection
- Compliance challenges
- Weak regulatory framework

1.6. Range of Products Manufactured in Africa

The republic of South Africa and North African countries have well developed industries with participants producing a board range of products. The majority of manufacturers in the rest of sub-Saharan Africa produce a limited range generally covering neutraceuticals, cough and cold preparations, simple analgesics and sedatives, anti-malarial, older generations' antibiotics, anti-helminthic and first generation anti-hypertensive, anti-diabetics and neuro-psychiatric drugs (4).

Introduction to Pharmaceutical in African Countries

For many years, African medicine regulatory authorities (MRAs) have managed a broad range of responsibilities, often with limited resources. Their focus has generally been providing their population with access to wide range of affordable essential medicines. The role of an MRA is to ensure the quality, safety and efficacy of all medicines in circulation in their country, including regulating and monitoring their clinical development, manufacture, approval for marketing, distribution, procurement, import, export, supply, sale and promotion. One of the primary challenges facing an MRA is to ensure that the pharmaceutical products they need are registered in their country, this process is called "registration", "marketing approval", "marketing authorization" or "product licensing" and involves assessment of product information submitted by the manufacturer (product dossier) to make sure this safe and effective for use by local patients. Assessment of regulatory dossier for novel products is highly complex, even for well-resourced and experienced western regulators. Dossiers can extend to thousands of pages of data and information that must be sifted through and analysed by MRAs seeking evidence that the product meet their quality, safety and efficacy requirements (5).

2. Introduction of regulatory requirements

2.1. Requirements for Product Registration

In Administrative Requirements:

1. Manufacturing License

Any company who wishes to manufacture, import and/or wholesale any registered products needs to have Manufacturer's License, Import License and/or Wholesaler's License.

2. Good Manufacturing Practice (GMP) Certificate

Compliance to Good Manufacturing Practice (GMP) is prerequisite to application of a manufacturing license, as well as product registration/ cosmetic notification. GMP is a standard which shall be followed by the manufacturers to ensure that the products manufactured are safe, efficacious and of quality.

Upon complete application, a GMP certificate will be issued. If a manufacturer who wishes to build a new manufacturing premise, the manufacturer may submit a proposed premise layout plan to the Centre for Compliance and Licensing authority.

3. Certificate of Pharmaceutical Product (CPP)

A CPP which follows the format recommended by WHO shall be issued to locally manufactured products that are to be exported. Upon receipt of complete application, the certificate shall be issued within fifteen working days (2).

2.2. General Requirements

Common Technical Document: A process by which an organization/ sponsor/ innovator gets authorization to introduce a drug in the market is known as drug approval process. Drug approval is the long process of drug development. A drug approval process undergoes various stages: conducting clinical trials, filing of NDA and post marketing studies. Every country has its own regulatory authority which is responsible to enforce the rules and

regulations and issue the guidelines to regulate the marketing of drugs.

Common Technical Document is divided into five modules:

- 1) Administrative and Prescribing information
- 2) Overview and summary of module 3 to 5
- 3) Quality (pharmaceutical documentation)
- 4) Safety (toxicology studies)
- 5) Efficacy (clinical studies)

Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Module 1: Administrative Information & Prescribing Information

Module 2: Common Technical Document Summaries

Module 3: Quality

Module 4: Nonclinical Study Reports

Module 5: Clinical Study Reports (6)

2.3. Chemistry, Manufacturing & control documents:

API DMF Open part

Following data should be available in Open Part:

- Nomenclature
- General Properties
- Name of the Manufacturer and Site of manufacture
- Route of Synthesis, flow diagram in brief
- Structural Elucidation
- Impurities
- Specifications and Method of Analysis
- Container Closure System
- Stability testing – Retest period & Storage
- API Specification and Method of Analysis & COA of API by the Applicant

Justification for Impurity Limits

The following factors to be considered while fixing the specification limits

- API impurity limits data (COA), check ICH requirements, check pharmacopoeial limits, if any, API stability data, finished product stability data etc.

Manufacturing Formula & Process

- Manufacturing Formula
- Description of manufacturing/packaging
- Description of in process controls/test
- Flow Diagram- Indicate critical steps, In-process controls
- Master formula

- Batch manufacturing Record – Copy of the Master BMR or Completed BMR
- Process Validation Protocols and /or reports-3 batches process validation reports and /or protocol is to be submitted. 3 Batches should be of the same size and should be similar to the batch size mentioned above in the manufacturing formula.
- Formulation & Development is required for some countries like Russia, Ukraine, Algeria and Kenya.

Batch Analysis

- Results of at least one batch should be given. It should be preferably of the batch of which the samples will be submitted for registration. OR It can be of the latest batch, as required by the agency in the respective country. It should be given as certificate of analysis.

Excipients

- For Excipients of natural origin microbial limits should be specified.
- For Human or Animal origin TSE/BSE certificates from the manufacture should be incorporated.
- For Excipients described in compendia, copy of Monograph along with copies of the methods referred to in monograph but not appearing in monograph should be provided.
- Current Pharmacopoeial monograph is always applicable. Details of any specifications additional to monograph should be provided.(e.g. particle size, residual solvents)
- Excipients Certificate of Analysis tested against the full set of specifications.

Finished product Specification and Method of Analysis

- If not as per Pharmacopoeia specifications should be prepared as per ICH Q6A. Methods of Analysis should be described in details.
- If based on Pharmacopoeia additional product related specifications should be included as in-house specifications (e.g. Description, Hardness, Friability, Average weight, Dimensions, Identification of colorants, MLT). Copy of the Monograph is acceptable in some countries. Methods of the additional tests should be given.
- If a test is based on a compendia monograph, a copy of the monograph + any methods referenced in the monograph must be submitted.
- Details of any specifications and test methods additional to those in the Pharmacopoeia must be submitted.

Stability Data and Stability Protocol

- Ability of pharmaceutical product to retain its property within specified limits throughout shelf-life.

- The stability programme includes sample size, test interval, storage conditions, specific methods and container closure system.
- Stability studies should include testing of those attributes of the finished product that are susceptible to change during storage and are likely to influence quality, safety and efficacy.
- Testing should cover the physical, chemical, biological and microbiological attributes, preservative content and functionality tests (e.g. Nebulizer).
- Microbial limits at release and end of shelf life. Dissolution limit should be same as for release.
- API used shall preferably be of different batches.
- Stability to be performed on each individual strength & container size of drug product, unless bracketing or matrixing is applied.
- In conclusion Shelf life should be proposed / concluded including the storage condition.

- Generally 3 batches (2 pilots, 1 smaller) data is required to be submitted.
- A pilot scale batch is generally, one tenth of a full production scale or 100,000 units, whichever is larger.

Bioequivalence

- Compares the systemic exposure profile of a test product (Generic) to that of a reference product (Innovator Brand)
- For the test product to be bioequivalent it should exhibit the same rate and extent of absorption as the reference product. Required for Tablets, Capsules and Oral Suspensions etc. If Bioequivalence study is not available then multimedia, multipoint comparative dissolution profile data of the product with innovator product should be submitted. (1)

3. Discussion

3.1. General Regulatory Filing Procedure

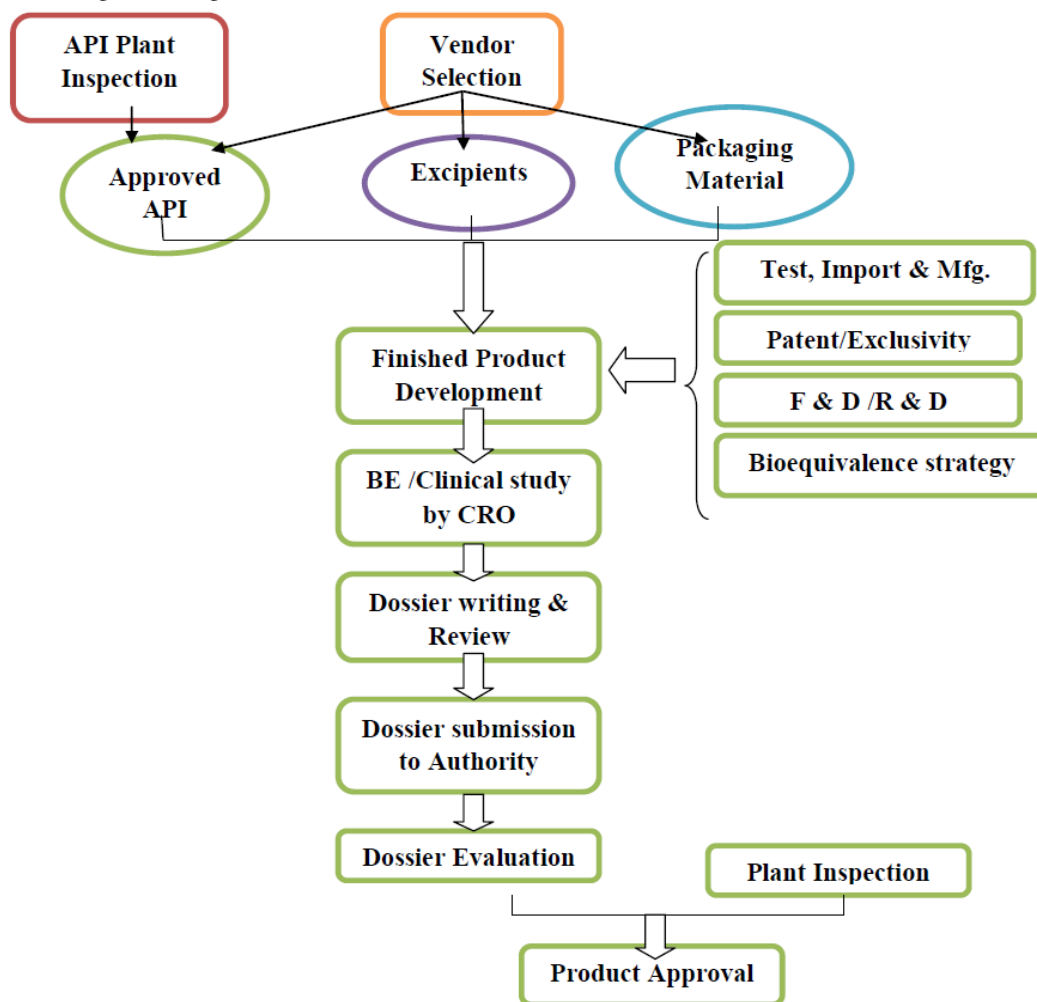


Figure 1. General Regulatory approval process (1)

3.2. Filing Strategy of Regulatory Requirements:

Table 1 Filing Strategy of Regulatory Requirements of African Countries (2, 7-12)

Filing Strategy of Regulatory Requirements of African Countries			
Requirements	Kenya	Tanzania	Uganda
MOH	PPB: Pharmacy and poisons board	TFDA: Tanzania and food and drug	NDA: National drug authority

	Dossier Format	CTD	administration CTD-Country specific	CTD	
Plant	cGMP Inspection	Required	Required	Required	
	cGMP Inspection Fee	Required	Required	Required	
Product	Validity period	3	5	3	
	Admin documents	Mf.lic, GMP(Notarized), CPP(Notarized)	Mf.lic, GMP, FSC, CPP	Mf.lic(Notarized), FSC, CPP(Notarized)	
	Artworks	English/ French	Anglo- French	English/ French	Anglo- French
	Sample requirements	8packs	6packs	5packs	
	Stability data	30/65(6Months)	30/65(6Months)	30/65(6Months)	
	Registration fee	USD 1000.00	USD 750.00	USD 1250.00	
	Registration lead time	12-18 Months	6-9 M (Fast track), 9-18M (Normal)	12-18 Months	
	Registration validity	1(Every year retention fee should be submitted)	5	1(Every year retention fee should be submitted)	
	Retention fee	USD 300.00	USD 100.00	USD 300.00	

Kenya

1. *Drug Regulatory Agency:* Pharmacy and Poisons Board
2. *Language:* English
3. *Format Followed:* CTD
4. *Type of Registration:*

a. *New Application for Registration:*

A new application for registration shall include submission of:

4. Two dully filled application forms (Original and duplicate) and an electronic copy (a summary of the dossier contents) in MS Word on a CD-ROM of modules 1 and 2 only including their supporting documents.
 5. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.
 6. An original Certificate of Pharmaceutical Product (WHO Format) on official papers of the issuing competent drug regulatory authority.
 7. A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.
 8. Non refundable application fee for registration of medicines in Kenya and GMP inspection fees for facilities not yet inspected by PPB.
- b. *Applications for Renewal of Registration:* Applications for renewal of registration shall be made at least 3 months before the expiry of existing registration by submitting the following:
- Dully filled in application form for renewal of registration.

- Batch Manufacturing Record (BMR) of a real batch manufactured within at most six months before the submission of the application.
- Submit Periodic Safety Update Reports (PSUR).
- Proof of interchange ability for generics as explained in Module 5.
- Any other requirements that the Board may determine.
- Three (3) samples of the smallest commercial pack(s) from the same batch along with batch certificates of analysis.
- A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.
- Non refundable application fee for registration of medicines in Kenya and GMP inspection fees for facilities not inspected and approved by PPB, GMP department.

c. *Application for Variation of a registered medicinal product:*

All applications for variation to a registered product shall be made according to requirements stipulated in the PPB Application Guideline for Variation of Registered Medicinal Products also available the PPB offices.

d. *Drug Approval process in Kenya:*

The drug regulatory agency in Kenya is the Pharmacy and Poisons Board, which was established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. It takes approximately 90 working days for fast-tracked drug registration. Fast-tracked applications include locally-manufactured and priority medicines only. The drug application is considered withdrawn if queries are not adequately responded to within 6 months of the request. If a drug is declined, the applicant may appeal that decision

within 2 months from the date of notification. Drug registration is valid for 5 years unless otherwise suspended or revoked (7).

Table 2 Cost of Drug Application in Kenya(7)

Imported into Kenya	\$1000
Fully manufactured in Kenya	\$500
Renewal of application(local)	\$300
Renewal of application (imports)	\$500

e. *Stability Conditions :*

Zone II, IVa

General Requirements:

Table 3 Storage requirement for Stability (7)

Study	Storage Conditions	Minimum time Period covered(months)
Long term	30±2°C / 65±5% RH	12
Accelerated	40±2°C / NMT 75±5% RH	6

Uganda

1. *Drug Regulatory Agency:* National Drug Authority
2. *Language:* English
3. *Format Followed:* CTD
4. *Requirement for dossier registration*
 - The appropriate application fees shall accompany each complete application form. (as per Annex I). Subsequent applications to amend any part of the application shall also be accompanied by appropriate fees per change. The guidelines on submission of amendment applications (Annex II) shall be followed.
 - Registration procedures shall commence only if Form NDA: R1 with its appendices has been properly completed.
 - Information Leaflet in case of prescription medicines, or a patient information leaflet in case of non prescription medicines.

Table 4 Storage requirement for Stability (8)

Table 5 Fees For Registration Of Drugs, Retention, Notification And Amendment (9)

Sr. No.	Registration /Retention/Notification/Amendments	Fees In Us \$ Except Where Indicated In Shillings
1.	First registration:	
	(a) Registration of imported human and veterinary drugs and preparations	US \$1250
	(b) Registration of locally manufactured drugs by a large scale manufacturer	US \$ 200
	(c) Registration of locally manufactured drugs by a small scale manufacturer	150,000/=
	(d) Registration of imported drugs and preparations which are repackaged in Uganda	US \$ 300
2.	Annual retention of registration of drugs and preparations on register:	
	(a) Retention of human and veterinary drugs and preparations on the register	US \$500
	(b) Retention of locally manufactured drugs by a large scale manufacturer	US \$100
	(c) Retention of locally manufactured drugs by small scale manufacturer	US \$100
3.	Fees for amendment of application for registration of drugs (human and veterinary)	

Sr. No.	Study	Storage Conditions	Minimum time Period covered (months)
1	Long term	30±2°C / 65±5% RH	12
2	Long term (product intended to storage in a refrigerator)	5 °C ± 3°C	12
3	Accelerated	40±2°C / NMT 75±5% RH	6
4	Accelerated (product intended to storage in a refrigerator)	40±2°C / NMT 25±5% RH	6

- In case the product is manufactured outside Uganda, a body corporate (company), licensed to handle pharmaceuticals, shall be the applicant's local representative in Uganda with legal authorisation to take full responsibility for the product on behalf of the patent/license holder or manufacturer, and will be answerable to NDA (8).
 - Another requirement as per prescribed in introduction of regulatory requirements.
5. *Stability Conditions :* Zone IVa
General Requirements:
 6. *Fee Requirement:* The National Drug Policy and Authority (Fees) Regulations, 2014. (Under section 64 of the National Drug Policy and Authority Act, Cap. 206) In exercise of the powers conferred upon the Minister responsible for Health by section 64 of the National Drug Policy and Authority Act, and on the advice of the National Drug Authority, these Regulations are made this 24th day of March, 2014. The fees paid under these Regulations to the Authority, in respect of any activity or function is non-refundable whether an application is successful or not. The prescribed fee is payable at the time of making the application to the Authority (9).

(a) Major amendment of application	US\$ 700
(b) Minor amendment of application	US\$ 400

Tanzania

1. *Drug Regulatory Agency:* Tanzania and Food and Drug Administration
2. *Language:* English
3. *Format Followed:* CTD
4. *General Information on format used:* The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and

effectiveness of food, drugs, cosmetics and medical devices.

The "Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products' First Edition, January 2015" is the TFDA publication which sets out procedures and requirements for the implementation of Pharmaceutical Products Registration through Common Technical Document (CTD). The CTD has five Modules. Another requirement as per prescribed in introduction of regulatory requirements (10).

5. *Stability Requirements:* zone II, IVb General Requirements

Table 6 Storage requirement for Stability (11).

Sr. No.	Study	Storage Conditions	Minimum time Period covered (months)
1	Long term	30±2°C / 65±5% RH or 30±2°C / 75±5% RH	12
2	Long term (product intended to storage in a refrigerator)	5 °C ± 3°C	12
3	Accelerated	40±2°C / NMT 75±5% RH	6
4	Accelerated((product intended to storage in a refrigerator)	25±2°C / NMT 60±5% RH or 30±2°C / NMT 65±5% RH or 30±2°C / NMT 75±5% RH	6

6. *Fee Requirements:* person shall pay a fee prescribed in the Schedules in respect of the products and services regulated under the Tanzania Food, Drugs and Cosmetics Act. Fees and charges paid under the Regulations shall be paid in Tanzanian shillings or US\$ equal to the amount of Tanzania shillings or any convertible shilling equal the amount payable in Tanzania Shillings. Fees and charges paid under the Regulations shall be collected and

appropriated by the Authority. The Authority may appoint an agent or any local Authority within the area the fees paid and charges operates to be a collecting agent. Fees and charges payable under the Regulations shall not be refundable or transferable. Failure to pay in time the fees and charges in force shall, in addition to the due charge, pay a penalty of 25% of the total amount payable.(12)

Table 7 TFDA Fees and Charges Structure for Registration/Retention/Notification/Variation (12)

Human and Veterinary medicines (Domestic)		
Sr. No.	Service	Fee
1.	Registration	USD 500
2.	Variation –Major	USD 100
3.	Variation –Minor	USD 50
4.	Retention	USD 150
5.	Duplicate Certificate	USD 50
Human, Veterinary Medicines and Biologicals (Imported)		
6.	Registration	USD 2000
7.	Registration – biological	USD 3500
8.	Retention	USD 300
9.	Variation – major	USD 1000
10.	Variation – minor	USD 300
11.	Duplicate certificate	USD 100
12.	Fast track registration-Pharmaceuticals	Double the respective fee

4. Conclusion

- A dossier containing detailed information about the drug and results of the studies carried out in its development process has to be submitted to the regulating bodies for getting market authorization. CTD is critical for dossier submissions.
- Any export market demands good quality dossier which can be generated through systematic Formulation Development.
- The proper planning and execution of Formulation development will help in quality dossier & in answering queries from Regulatory authorities.

- Since the world is divided in the drug approval procedures with technical data as described above, it is important especially for the generic manufacturers, to carefully judge the market need, Development Cost, target regions, & regulatory requirements before the development of drugs. Hence it is critical to plan and co-ordinate all the activities for successful launch of product in the market on time.
- As the regulatory requirements of various countries vary from each other, it is challenging for pharmaceutical companies to develop a drug formation which can be simultaneously submitted in numerous countries for approval at the same time. Therefore continuous process of harmonization is taking place all over the world, still we can see a huge challenge, which is yet to be overcome by the pharmaceutical industry in case of generic drug development and filing as it involves strategic planning.
- Hence, one should carefully understand and define the clear regulatory strategy by looking at the target regions, different patent terms and its extension, various application possibilities, data requirements, potential timeline for marketing launch in different regions. This eliminates unnecessary studies, minimizes the delay in drug approvals and subsequent launch, and reduces overall cost of development.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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