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Review Article

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Regulatory Submission for Drug Approval in North East Asian countries: Hong Kong, South Korea and Taiwan

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Abstract

Asia is the third largest Pharmaceutical market in the world after North America & Western Europe. Based on the current scenario of the Pharmaceutical market in the developing countries of Asia& Asian countries emerging as strong market especially North & South East Asia. Due to increasing health care market & trends at global level , countries like china, South Korea, Taiwan, Japan, Hong Kong& many other North east Asian countries are consider as fastest growing & emerging Pharmaceutical market are emerging as fast growing Pharmaceutical market at global level. Looking at this increase in market trade this North East Asian countries have set up their own requirements for product to be places in their market. This topic while look out and mark the regulatory requirements which are necessary for the product to get marketed in developing north East Asia countries like Hong Kong, South Korea & Taiwan. It will provide relative guidance regarding regulatory framework & regulatory submission requirements, registration process, regulatory filing etc. in these three developing countries of North East Asia. The article is brief overview of registration process of NDA filing, Generic Filing & renewal process including dossier requirements & submission in Hong Kong, South Korea& Taiwan .It will provide the basic knowledge of Online registration via PRS 2.0, MFDS & TFDA.

Keywords: Emerging Pharmaceutical Market, regulatory filing, NDA, Generic filing, PRS 2.0, MFDS, TFDA.

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1. Introduction

Asian Pharmaceutical market is one of the leading & strong Emerging market across the globe. It is expected to overtake Europe in Pharmaceutical market during 2021 or 2023. Asian countries like China, Taiwan, South Korea, Japan, India, ASEAN countries are the major Pharmaceutical growing & emerging markets. For e.g. China is deemed to be the second largest Pharmaceutical market after the United States. In Asia more than half of population lives & migrate to this major growing & emerging market & so the economic growth of these markets increases rapidly. This promotes many Pharmaceutical companies to switch on the business to these emerging countries.

- The global Pharmaceutical market, whole was worth $935 billion in 2017 and will reach $1170 billion in 2021, growing at 5.8%, an accelerated pace compared to its 5.2% a year growth for the years before 2017.
- The Asia Pharmaceutical market for drugs will be worth $277 billion in 2021, having grown from $200 billion in 2017. (1, 2)

North East Asia Pharmaceutical Market

Northeast Asia specifically & Major countries constituting are:

a) Japan
b) Russia
c) Mongolia
d) China (including Hong Kong)
e) Taiwan
f) North & South Korea

The Growing & current Pharmaceutical market size of North East Asia was about USD 40.54 in 2019 which will reach upto more than USD 43.54 billion in 2020. This may lead to Asia as second largest Pharmaceutical

market after north america with the increasing growth in some major countries like:

- South Korea was having Pharmaceutical market size upto 23. 1 trillion in 2018 almost increased upto 17.2 trillion in last decade
- Japan is the world's second-largest Pharmaceutical market with a global market share of 11%.
- In 2018, China's Pharmaceutical market was valued at $134.6 billion & It is estimated to reach$161.8 billion by 2023 and take a 30% share of the global market.
- Taiwan's Pharmaceutical market is currently was valued at USD 3.3 billion in 2016

The major key trend behind increase in the North East Asia Pharmaceutical market is:

- Strengthening of primary care system through healthcare reform
- Variable reforms yielding fragmented market
- Generic medicines are the fastest growing segment in Pharmaceutical Industry
- Healthcare Coupons for geriatrics
- Public Healthcare Insurance under consultation due to ageing population
- Price controls to be extended to all reimbursed drugs, including patented brands
- Increasing role of Pharmaceuticalco-economics

Some of the major challenges in north east asia Pharmaceutical market affecting the growth factor of market.

- Lack of reimbursment and public funding.
- Lack of health care infrastructure.
- Price pressure.
- Local competition.
- Lack of affordability.
- Lengthy product registration process.
- Lack of proper regulatory requirement & compilance challenges. (1, 2)

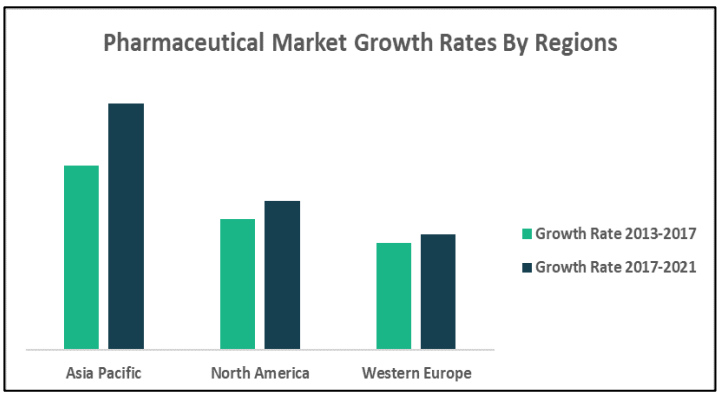

Figure1. Growth rate chart of NEA & Global (3)

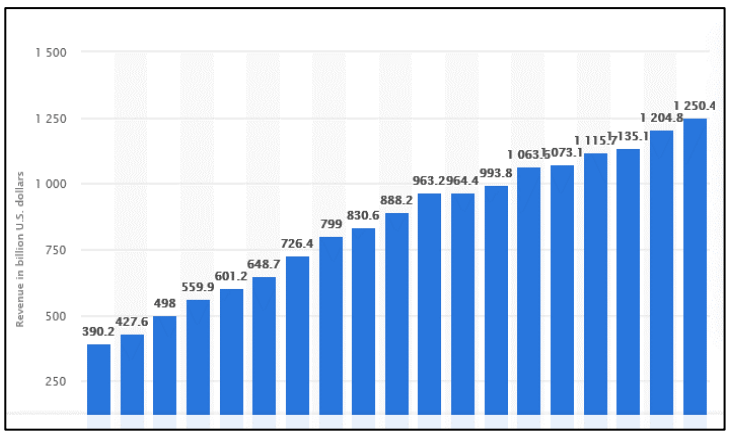

Figure2. shows the market size of Hong Kong

Due to increasing health care trends at global level &increase in market trade this North east Asian countries have set up their own requirements for product to be places in their market which provide relative guidance regarding regulatory framework & regulatory submission requirements (registration process, regulatory filing etc.) especially in emerging countries like Japan, Taiwan, Hong Kong , South Korea. (1-4)

2. Regulatory Framework & Pharmaceutical Market of Hong Kong

The Hong Kong Pharmaceutical market is attractive. It is the gateway to the world's fastest-growing economy. In 2017, Hong Kong's Pharmaceutical market is worth $1.8 billion, 2019 it was grown to over US$2 billion. Figure 1 shows the market size of Hong Kong

2.1. Drug Regulatory System of Hong Kong

The Department of Health (DH) is responsible for regulation of drugs & medical device in Hong Kong. Mostly Drugs are regulated under *Pharmacy & Poison Ordinance Cap-138* formed under DH. The purpose of DH is to ensure that medicines available for sale are safe, effective and of good quality. This is necessary for the protection of the health of members of the general public. (5)

The Drug Office **is the law enforcement agency over the legislations concerning with western medicines** under the Department of Health (DH) which is under the Food and Health Bureau.

Under *Pharmacy & Poison Ordinance(PPO)* There is established Pharmacy & Poison Board(PPB) which functions towards the licensing to Pharmacist , importers , manufacturer & regulate the marketing approval to drug product& other regulatory aspects.

2.2. Definition of Pharmaceutical Product as per Pharmacy & Poison Regulation (PPR) in Hong Kong

As per PPR the Pharmaceutical Product is categorized in 4 category:

a) **New Drug:** It means a medicine containing an active ingredient, or a substance, having a chemical formula which has not previously been marketed or registered in Hong Kong under some other name or description.

b) **Generic Drug :** Products whose originator products have been registered in Hong Kong for over 8 years. If a product meets the aforementioned criteria, the applicant could submit generic drug application for the product.

c) **Orphan Drug :** There is no special definition for orphan drug.

d) **Sales Control Drug :** Medicines are classified into three main categories of sales control according to the severity of diseases that they are intended for use, and the magnitude of side effects that they might cause.

   i. **CATEGORY 1** : Prescription Drug

   ii. **CATEGORY 2** :Drug under supervisied sales.

   iii. **CATEGORY 3** :Medicines in this category can be sold in Pharmaceuticalcies**.**

2.3. Drug Approval System in Hong Kong

➢ **Application For Registration Of Pharmaceutical Product**

As per the Pharmacy & Poisons Regulations, Pharmaceutical products manufactured inside or outside Hong Kong must be registered with the Pharmacy and Poisons Board before the sale & distribution of that Pharmaceutical product in Hong Kong market.

The Regulatory pathway for New drug approval, Generic Drug approval & Orphan Drug approval is same.

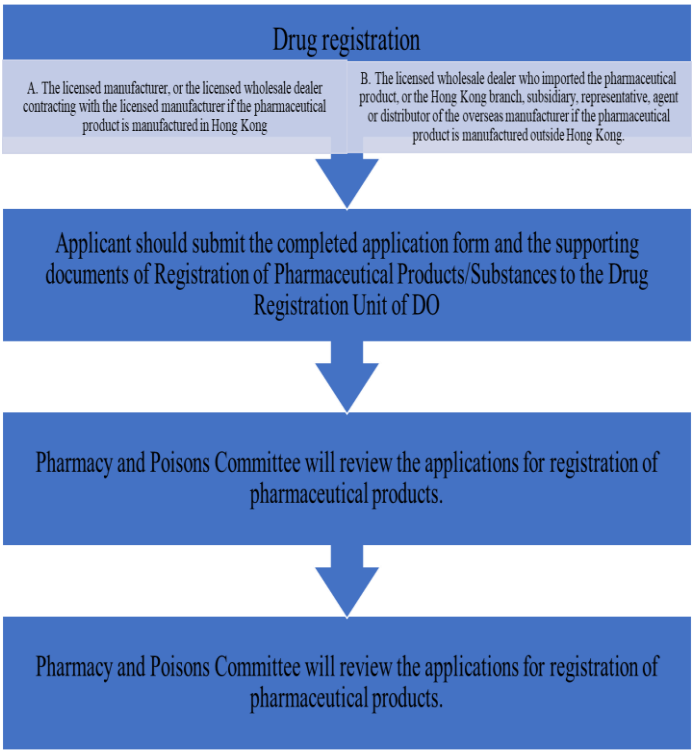

Figure 3. Registration pathway of drug marketing in Hong Kong (5)

2.4.Pharmaceutical Registration System – PRS 2.0

PRS 2.0 is online Pharmaceuticals Registration System for obtaining registration of Pharmaceutical drug product in Hong Kong market Operated under DH of Govt. of Hong Kong. You should submit your new application via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at (5-11):

https://www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp

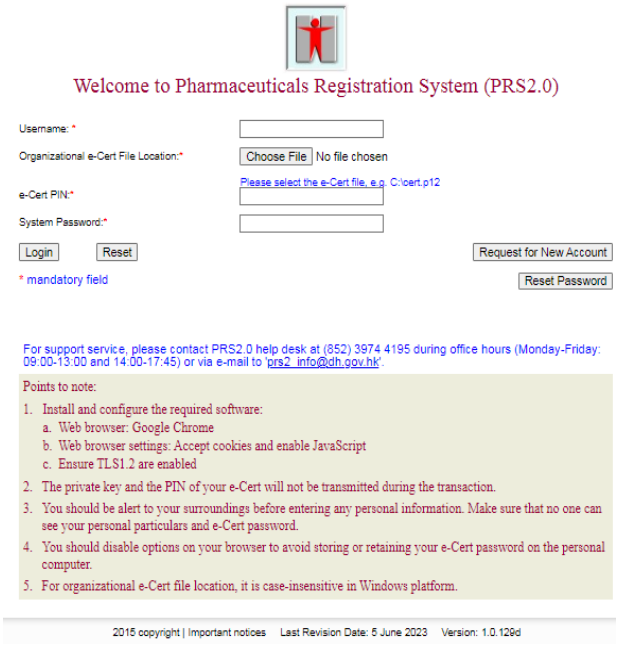

Figure 4. PRS 2.0 is online Pharmaceuticals Registration System

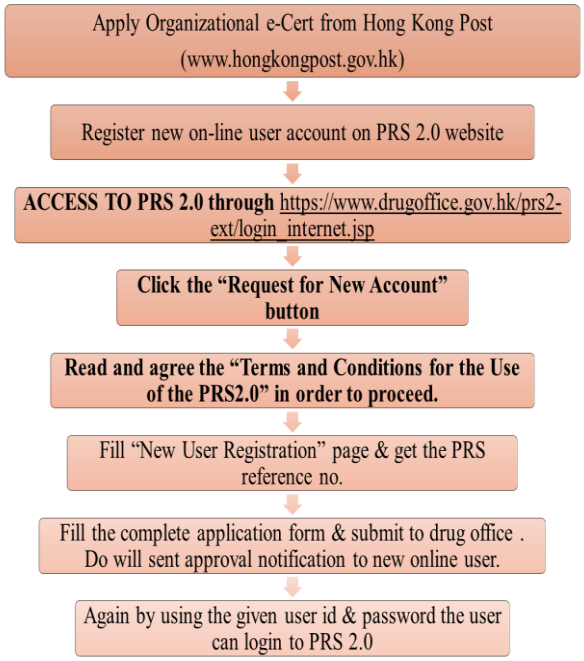

Figure 5. Registration for New On-Line User

Before applying to new user in PRS 2.0 the applicant has to obtain "e-certificate" or "e-cert" of organization or company. It can be obtain by filing "e-Cert (Organizational) application form" can be downloaded from the website & within 1-2 months the "e-cert" will be obtained by company. After obtaining the e-certificate the applicant can follow following steps to get user registration in PRS 2.0:

Basically The Whole PRS 2.0 is For:

A. Registration Of New Product ,

B. Change In Registered Product,

C. Renewal Of Certificate Of Product.

A. Registration of New Product (12,13)

This application submission & registration involves basic steps:

- Initiate New Product Registration Application by applying online for new product registration
- Filing of Product details as per CTD Format (Module 1 to Module 5)
- After Filing Module the system will generate application form so filing of application form.
- Reviewing of the documents & application form: Review the application, edit the application with necessary changes if required any by selecting "edit application" option & then submit the form.
- Payment of Application FEES: By selecting "Application status" option & select ACTION REQUIRED Option & than payment of Registration application can be done.
- Evaluation & Screening of Application
- Payment Of Certificate Fees : By selecting "PAYMENT POOL" OPTION payment for certificate can be done

B. For Registration of Change product particular

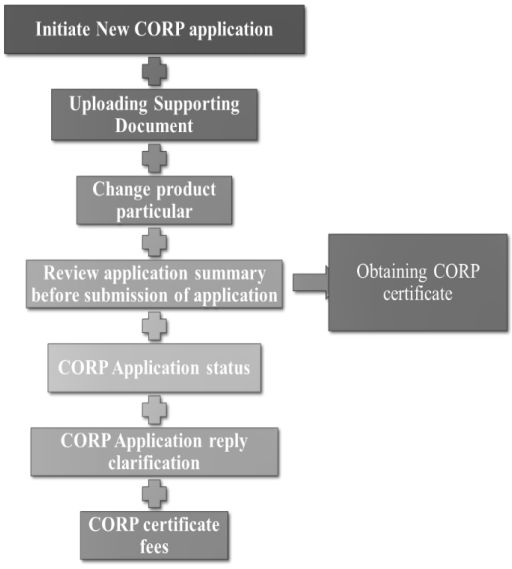

Figure 6. Registration for New On-Line User (13)

The change in registered product involves that if any necessary new changes related to product or manufacturer or any other relevant data is required to add than applicant has to apply online on PRS 2.0 for CORP. It involves above steps.

C. Renewal of Certificate of Product.

The procedure is for the renewal of registration of already existing drug product in Hong Kong Pharmaceutical market.

a. STEP 1: **Online Notification**: Select "online Notification" option. Click the "Open" link to read the notification. There are 4 types of notification:
   - *Renewal Notification: Given by system before 4 months*
   - *Renewal Reminder: Given by system before 3 months*
   - *Renewal Notice of Expiry : Given by system before 1 month*
   - *Expired Product Notice : Given by system on day of expiry*

b. STEP 2: Renewal application status: Filing up the changed or pending renewal form & data reports.

c. STEP 3: Payment of renewal fees online or by manually way (by person) & Approval of the renewal & generation of receipt of renewal. (12-14)

3. Regulatory Framework & Pharmaceutical Market of South Korea (2,3)

South Korea is the 13th largest Pharmaceutical market in the world Korea has emerged as a leading Pharmaceutical market and global hub in Asia over the last two decades. According to Pharmaceutical Sales are forecast to grow from $15.1 billion in 2015, in 2016, Korea's Pharmaceutical market was worth over $16 billion and it was estimated to reach $20 billion in 2020.

3.1. Drug Regulatory System of South Korea (12-19)

Ministry of Food and Drug Safety (MFDS, formerly known as the Korea Food & Drug Administration or KFDA) is the governmental agency that regulates food, Pharmaceuticals, medical devices, and cosmetics in South Korea.

MFDS has vision of "Safe Food and Drug, Healthy People, we are making utmost efforts to protect consumers and promote the public health by ensuring the safety of all foods, drugs, cosmetics, herbal medicines, and medical devices that we use in our daily lives"

There are six (6) Regional Offices: Seoul Regional Office, Busan Regional Office,

Gyeongin Regional Office, Daegu Regional Office, Gwangju Regional Office, and Daejeon Regional Office.Working under MFDS

Under MFDS there is an organisation NIFDS **National Institute of Food and Drug Safety Evaluation** which is responsible for conducting review, test, analysis, research, and risk assessment of food, drugs, cosmetics, and medical devices.

3.2. Definition & Classification of Pharmaceutical Products as per MFDS

According to the classification as per stated in "Pharmaceutical Affairs Act", the Pharmaceutical Product is classified in 4 types (13-16):

a) New Drug: It is a drug of novel materials with the new chemical structure or construction of substance, or a combination drug containing novel materials as active substance. And listed in Korean Pharmacopeia or foreign Pharmaceutical compendia/ Pharmacopeia, recognized by the MFDS like (USP, BP, Japanese Pharmacopeia, European Pharmacopeia)

b) Drug Requiring Data Submission: According to the Regulation on Pharmaceuticals Approval, Notification, and Review (MFDS Notification), "drug requiring the safety/efficacy review data submission referred to as "drug requiring data submission".

c) Generic Drug: Generic drug means Pharmaceutical drugs of which type of active substance, strength, dosage form, efficacy/effectiveness, administration/ dosage, and route of administration are identical to those of the previously approved drugs.

d) Orphan Drug: Orphan drug refers to a Pharmaceutical drug designated by the MFDS, for which introduction is urgently required since there is no alternative drug, and meets the unmeet medical demand.

3.3. Drug Approval System in South Korea

Basically the application is done for different categories of drug;

a) For IND application
b) For New Drug
c) For Generic Drug
d) For Orphan Drug
e) For Renewal of drug certificate

3.4. Application for Registration of Investigational New Drug Product (13)

"Investigational New Drug Application (IND)" shall refer to the process through which a person, who intends to execute a clinical trial using the relevant drugs in order to collect the safety and efficacy data on humans, requests the approval from the Minister of Ministry of Food and Drug Safety. The following drugs require IND application:

a) New drugs under development;

b) Drugs with new formulation, route of administration, indication, or administration/ dosage.

The review process for IND application shall follow five (5) steps:

a. STEP 1: Receipt of IND application dossiers;
b. STEP 2 :Request for consultation of the Drug Evaluation Department
c. STEP 3 :Review of submitted data (including safety data)
d. STEP 4 :Notification of review result
e. STEP 5 :Request for supplementation or final decision

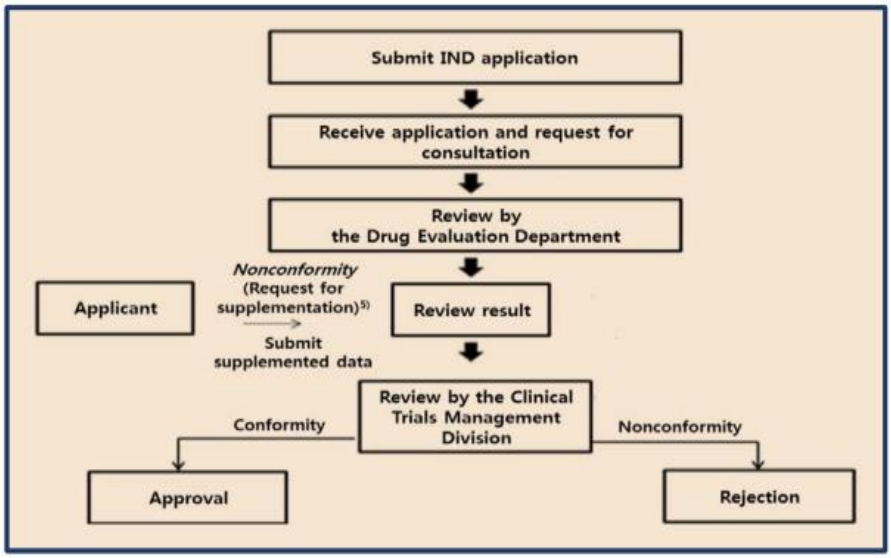

Figure 7. The review process for IND application

Table 1. Required Documents for dossier submission of IND:

Required Documents for Dossier Submission:
• An applicant for investigational new drug application shall submit the following data:
• IND application
• Development plan
• Investigator's Brochure (IB)
• Documentation or data that prove the investigational drug is manufactured in compliance with (Good Manufacturing Practice) or (Good Manufacturing Practice for investigational drug) of the Regulation on Safety of Medicinal Products, etc.
• Data on manufacturing and quality of the investigational drug: Data on drug substance and its quantity, manufacturing method, and manufacturer of the investigational drug
• Data of nonclinical test results: Toxicity, pharmacological, and ADME (Absorption, distribution, metabolism,and excretion) data
• Data on the prior clinical use of the investigational product (if available)
• Data on clinical trial institution, investigator, and contract research institute according to Article 34-2 (2) of the Act
• Rules on compensation for victims of clinical trial
• Trial subject's informed consent form
• Clinical trial protocol

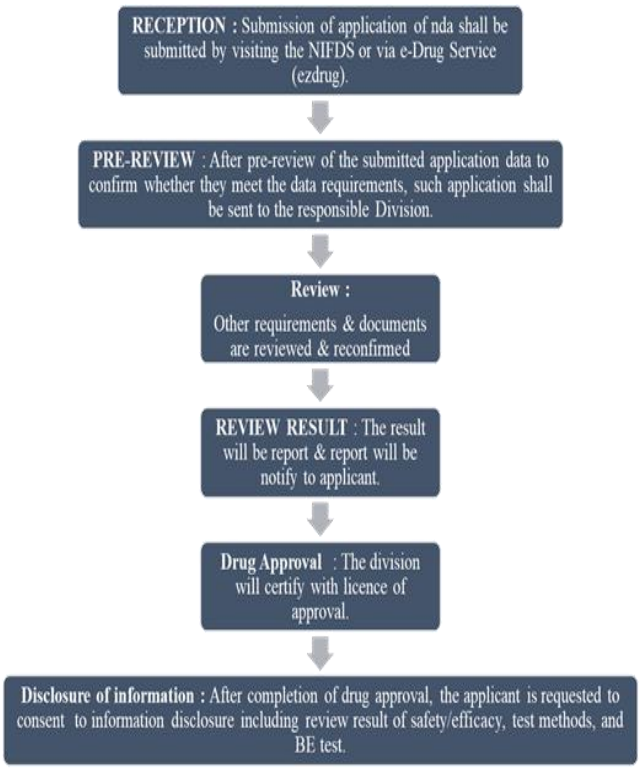

Figure 8. Registration New Drug Product

- **Application Submission for Registration New Drug Product:**
  Drug manufacturers, contract manufacturers/ distributors, and importers with legitimate facilities may apply for approval of new drug manufacturing/marketing (import) to the NIFDS according to the following process. A review of such application shall be conducted by the Drug Evaluation Department. The process is divided into 6 steps.

- **Application for Approval of Generic Drug Notification**

Drug manufacturers, contract manufacturers/distributors, and importers with legitimate facilities may apply for approval of Generic drug approval for marketing to NIFDS.

Before submission of the generic drug approval the company of applicant has to submit BE protocol to MFDS (NIFDS) after approval of the protocol the applicant will submit the application of the generic drug approval. The process for generic drug approval is divided in different steps:

Review Period: 90 Days

- **Application Submission for Registration Orphan Drug Product**

Orphan drugs are to meet urgent medical needs without an alternative treatment, time to review orphan drug designation may be reduced with high priority. To be designated as orphan drug (14):

a) The number of patients must be 20,000 or less in Korea; and drugs must be used to treat diseases, for which appropriate therapies and drugs have not developed; or

b) Drugs should demonstrate a significant improvement in safety or efficacy compared with the existing alternative drugs.

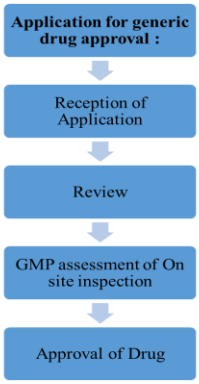

Figure 9. Approval of Generic Drug Notification

Figure 10. Registration Orphan Drug Product

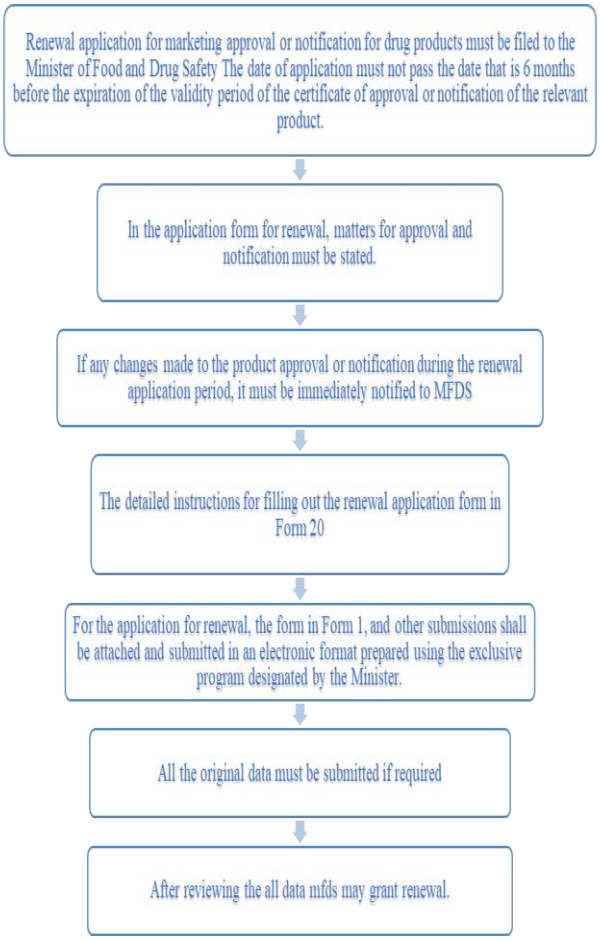

Figure 11. Steps for renewal application

➢ **Application For Renewal of Drug Product:**

The "validity period" means the first five years counting from the day following the date of product approval or notification with specific expiration date. After the validity is over the product can be applied for renewal.

Other than this application there are other 2 types of fast process:

1. Priority Review
2. Expedited Review

4. Regulatory Framework & Pharmaceutical Market of Taiwan (19-21)

Taiwan is among the top five Pharmaceutical markets in the Asian (6^{TH}). In starting Taiwan Pharmaceutical was NT$110 billion (US$ 3.19 billion) in 2002, in 2006 it was Compound Annual Growth Rate (CAGR) of 2.9% from 2006.In 2017 it was around US$5.6 billion with annual growth rate of 4% & lastly in 2018 it was US$5.5 billion & CAGR was 3.9%.

4.1. Drug Regulatory System of Taiwan

Taiwan Food & Drug Administration under Ministry of health & welfare is responsible for regulation Pharmaceutical drug products & medical device

Website of TFDA: http://www.fda.gov.tw/EN/

TFDA vision is to promote health &well-being of all citizens & to become most trustworthy administration.

With TFDA there is CDE (Center of Drug Evaluation) established by dept. of health which works with TFDA & Function to conduct technical review on the application of new drugs, medical devices, and clinical trials to fulfill regulatory requirements; and also provides health technology assessment (HTA), advisory services, researches on regulatory science and recommendations to health-related policies.

4.2. Definition of Pharmaceutical Product as Per TFDA

According to the classification as per stated in "Pharmaceutical Affairs Act", the Pharmaceutical Product is classified in 3 types:

1. **New drug:** According to the "Pharmaceutical Affairs Act(Chapter 1, Article 7)" in Chinese Taipei, the term "new drugs" refers to drugs which are of the preparations having new compositions, new therapeutic compounds or new method of administration as verified and recognized by the central competent health authority.
2. **Generic drug:** The "Regulations for Registration of Medical Products" defines Generic as Pharmaceutical preparations identical to a drug already approved in Chinese Taipei in the aspects of ingredients, dosage form, contents and efficacy.

3. **Orphan drug:** Orphan drugs refer to Pharmaceuticals with major indications for the prevention, diagnosis and treatment of rare diseases that have been duly submitted for application in accordance with the Rare Disease and Orphan Drug Act and have been publicly announced by the central competent authority.

4.3. Drug Approval System in Taiwan

Review Period

- Regular Review: 30 days
- Fast Track Review: 15 days

4.4. Application for Registration of Investigational New Drug (IND) Approval (12)

The sponsor of the clinical trial refers to an individual, company, institution, or organization which takes responsibility for the planning and management of a clinical trial. An investigator is also considered as a sponsor if he or she independently plans, conducts and is totally responsible for a clinical trial. The Whole process with steps is justified in below figure.

4.5. Application for Registration of New Drug Approval

The basic process of NDA is in 5-6 steps

According to the types of application, the procedure would differ as follows:

Table 2. Required documents for dossier (IND)

1.	Form of documentation
Chinese form is generally expected, but English is also acceptable.	
1.	Documentation
•	**Application for Import Certificate**
•	**Pharmaceutical Company License**
•	**IND letter or IRB approval letter from other participating countries (if available)**
•	**IRB approval letter**
•	**Clinical Trial Application Form**
•	**Protocol with principle investigator's signature**
•	**Informed Consent Form with principle investigator's signature (Chinese version)**
•	**Case Report Form (draft version is acceptable)**
•	**SAE Reporting Form**
•	**Investigators' CV**
•	**Insurance certificate or indemnity letter**
•	**Investigator's Brochure or product characteristics information**
•	**Certificate of Analysis and stability data**
•	**Registration fee for registration trial**
•	**Chinese/English synopsis**
•	**Questionnaire (if completed by patient, the questionnaire must be in Chinese and validated)**
•	**Amendment history**
•	

(1) New chemical entity (NCE) or new active substance (NAS)

(2) Non-NCE/NAS or NME :

- Submission → filing meeting → review meeting → notification for completion of review → approval/non-approval by TFDA.

The Whole process with steps is justified in below figure.

Review Period:

The review period of NDA applications differs according to each track:

A. FOR NCE :

(1) Standard Review (CPP): 360 days
(2) Standard Review (non-CPP): 360days
(3) Abbreviated Review: 180 days

B. FOR NON NCE :

(1) Non-NCE/NAS new drug: 200days
(2) Domestic innovative Product: 100 Days

C. FOR UNMET MEDICAL NEED:

(1) Priority Review: 240days

(2) Priority review + Abbreviated review : Total Review Period is 150 days.

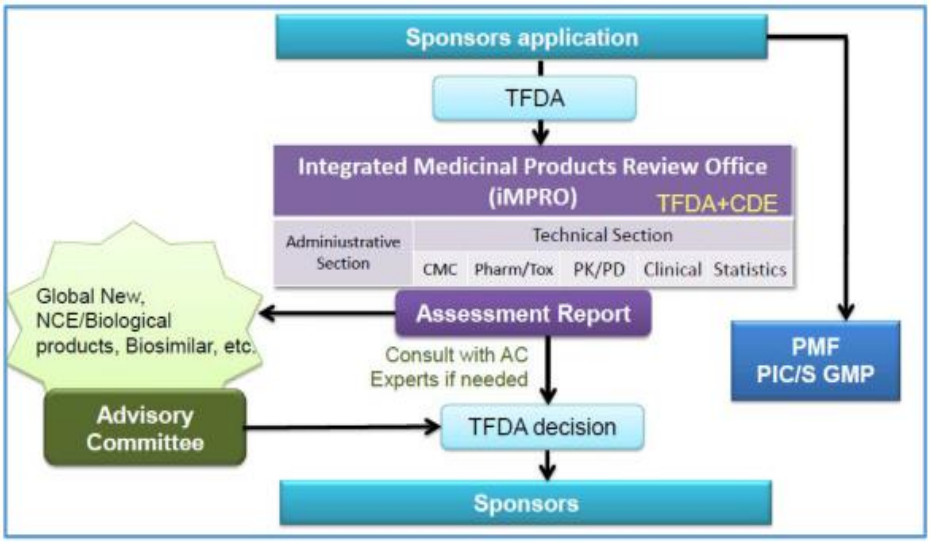

Figure 12. Registration of New Drug Approval

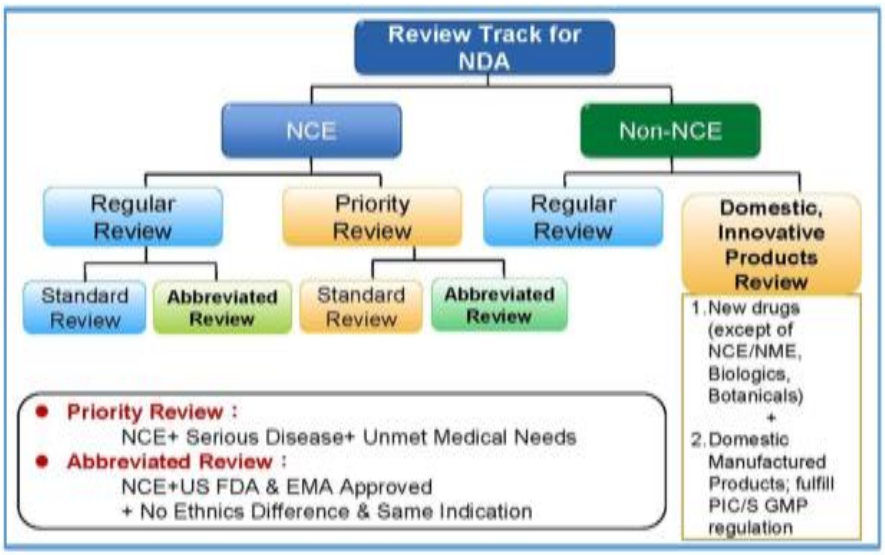

Figure 13. The review period of NDA applications

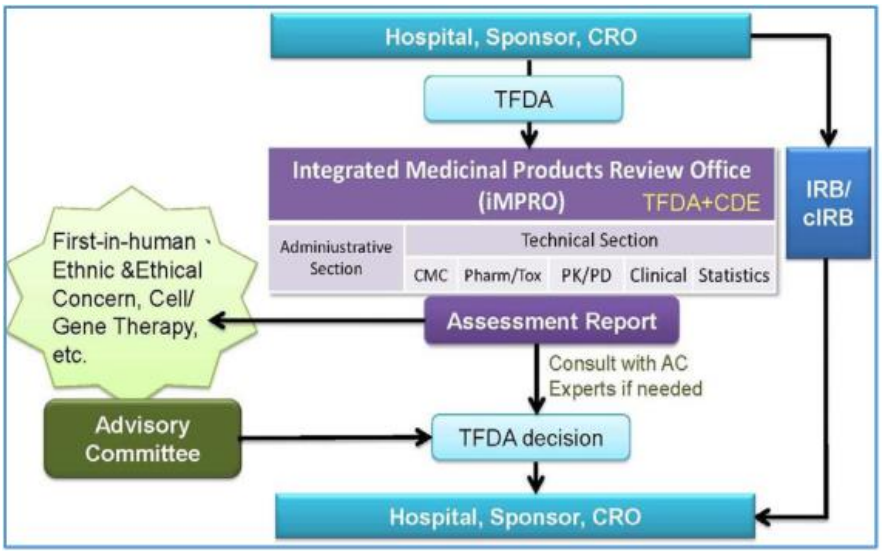

Figure 14. The review period of IND applications

Table 3. Required documents for dossier submission in Hong Kong, South Korea & Taiwan

DOCUMENTS ATTACHED AS DOSSIER	HONG KONG	SOUTH KOREA	TAIWAN
Application Form	✓	✓	✓ original copy and duplicate copy
Applicant Details(Name & Address)	X	✓	✓
Letter of Authorization (LOA) from Product Owner to the applicant or manufacturer	✓	X	✓
Copy of business registration certificate of applicant	✓	X	X
Cover Letter from Applicant	✓	X	X
Certified True copy of Licence of Manufacturer	✓	X	✓
GMP certification	✓	✓	✓
CoPP or original True copy of free sale certificate	✓	✓	✓
Certificate of analysis	✓	✓	✓
Product details , Product formula & master formula(details of both active & inactive ingredients)	✓	✓	✓
Manufacturing and Control Standards or batch records of the tentative production batch	X	X	✓
Particulars of packing	✓	X	X
Outer carton Labelling	✓	✓	X
Details of the Drug listed in specified pharmacopeia	✓	X	X
Method of Analysis of Finished Product	✓	✓	✓
Stability testing data (months Real time stability at 25-30°C Accelerated data at 40°C	✓	✓ Real time stability at 25°C	✓ Real time stability at 30°C
New drug approval evidence in 2 or more specified countries	✓	X	✓
Expert evaluation of safety & efficacy data	✓	✓	✓
Risk assessment Report of elemental impurities as pe ICH Q3D	✓	X	
Clinical & scientific documents & reports	✓	✓	✓
Package insert in form of PIL/See package insert	✓	✓	✓
BA/BE STUDY Report For Generic	✓	X	X
Certificate of manufacturing issued by govt or public agencies stating drug is manufactured in their economy	X	✓	X
Certificate of marketing(granting of approval of new drug for sale)	X	✓	✓
DMF APPLICATION & data	X	✓	✓
Name & Address of API manufacturer	X	✓	X
Name & Address of contract manufacturer & manufacturing site (if applicable)	X	✓	✓
Patent Certificate & supporting data (if applicable)	X	✓	X
Form for licence	X	X	✓
Form for sticking label and package insert (two copies)	X	X	✓

Table 4. Comparative fees structure for approval of drug in Hong Kong, South Korea & Taiwan

FEES STRUCTURE	HONG KONG	SOUTH KOREA	TAIWAN
NEW DRUG	HK$1100	KRW 6,177,850	1. For new api : NT $ 600,000 2. For new route :NT$50,000
GENERIC DRUG	HK$1100	KRW 2,007,350	NT $ 35,000
RENEWAL CERTIFICATE	HK$575	-	-
ORPHAN DRUG	HK$1100	KRW 3,398,150	-

Table 5. Approval time and validity of Applications in Hong Kong, South Korea & Taiwan

PARAMETERS	HONG KONG	SOUTH KOREA	TAIWAN
Total Registration Fees	Rs 10955/- As per INR(New drug)	Rs 3,97,101/- As per INR(New Drug)	Rs -15,34,263/- As per INR (New drug API)
Approval Time	After or within 5 Months of application	Verification-NIFDS 90 days (Review)	Verification – CDE 360 days(Review)
Validity	5 yr	5 yr	5 yr
No. Of Documents Required for Registration	24	35	33
Total Export of Pharmaceutical product	In 2017, Hong Kong's pharmaceutical market is worth $1.8 billion , 2019 it was grown to over US$2 billion .	South Korea market approximately 23.1 trillion in 2018.Increase upto 17.2 trillion in a decade	Taiwan stood at approximately NT$110 billion (US$ 3.19 billion) in 2002. Taiwan's pharmaceutical market is currently worth $5.6 billion, and is projected to grow at 4% in 2017. & Reach $5.5 Billion by 2018
INDIA 's Total Pharma product Export	From India the export of many finished products, excipients & products the Indian pharma market share (export) was 4.5% of total export share in 2018	From India the export of many finished products, raw materials & herbal formulation still stands the market size of export of $177. 8 billion in 2017 And share of pharma product to india's total export was about 6.36%	From India the export of many finished products medication & drugs have been exported whose data shows increase in Taiwan pharmaceutical market size of export is 9.0800 USD mn in 2018 which has almost increase on an average 4.645 USD mn in between 1997-2018.

- **Application for Registration of Generic Drug Approval:**
  - Basically same the process of new drug.

  In REVIEW Period & Process:

  - The applicant has to send NOTICE of SUBMISSION to TFDA before filing of ANDA for generic drug approval.
  - The Standard Review Time & Period are same for ANDA & NDA filing.

Review Process:

- The review period is same as that of standard review for NDA filing .Notice Before Submission of ANDA:

a) Applicants may submit requests for pre-ANDA meetings for the discussion of the format and content of the submitted document.

b) For further details, please refer to the web page of Chinese version or contact the subsidiary of the company, the local agent or the Contract Research Organization (CRO).

4.6. Application for Registration of Orphan Drug

Orphan drugs are reviewed by the Committee for the Review and Examination of Rare Diseases and Orphan Drugs (hereafter referred to as the Committee), established by the central competent authority in Chinese Taipei.

Review period: With applied for priority process, review period is 240 days or 150 days (for abridged dossier)

5. Conclusion

From the above summarized table, it provide a basic conclusion that for North East Asian market is a leading growing Pharmaceutical market And it would be more beneficial & easy for India to trade with the growing large export With growing markets of North East Asia having strong and well developed regulations providing easy access & less time consuming pathway for marketing of Indian product with North East Asian countries like Hong Kong , South Korea & Taiwan leading to growth of Both North East Asia & India Market at global level.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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