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1	Certificate of Head of Institution
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1.	D.SAMYUKTA 261821507513	DR.N.SENTHILKUMAR	II	REGULATORY CHALLENGES AND OVERSIGHT IN THE WORLDWODE MARKET OF BRANDED AND GENERIC PHARMACEUTICAL	-	-
2.	R.LANCY JENIFER 261821507508	DR.N.SENTHILKUMAR	II	REGULATORY REQUIREMENTS FOR GRUD,DEVICE AND BIOLOGICALS OF COMBINATION PRODUCTS AS PER USFDA GUIDELINES	-	-
3.	K.RANJITH KUMAR 261821507511	DR.B.SENTHILKUMAR	II	REGISTRATION OF INSTITUTIONAL ETHICS COMMITTEE IN CENTRAL DRUG STANDARD ONTROL ORGANIZATION	-	-
4.	S.PRAKASH 261821507510	DR.N.SENTHILKUMAR	II	COMPARISION OF FIXED DOSE COMBINATION REGULATION OF JAPAN,EUROPE,USA WITH INDIA	-	-
5.	VIDHYA.P. 261821507514	MR.R.NEELAMEGARAJAN	II	TO STUDY THE VACCINE APPROVAL PROCESS IN EUROPEAN MEDICINE EVALUATION AGENCY(EMEA)OF EUROPEAN UNION	-	-
6.	ROSELIEN.B. 261821507512	MR.A.SHEIK ALISHA	II	FDA'S PROCEDURE FOR GRANTING AND REVOKING EMERGINCY USE AUTHORIZATION (EUA)	-	-

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7.	NASEELA.V.V. 261821507509	MR.A.SHEIK ALISHA	II	A COMPARATIVE OVERVIEW OF GENERIC DRUG REGULATIOIN IN USA,UK AND INDIA	-	-
8.	AJMALKHAN.M. 261821507501	DR.K.JAGANATHAN	II	ESTABLISHING A CORE DOSSIER FOR REGULATORY FILLING IN EU AND USA	-	-
9.	HEMALATHA.A. 261821507504	R.NEELAMEGARAJAN	II	COMPARSON OF DRUGS AND COSMETICS ACT 1940 AND WITH DRAFT OF NEW DRUGS,MEDICAL DEVICES AND COSMETIC BILL-2022	-	-
10.	R.KABILAN 261821507506	DR.B.SENTHILKUMAR	II	COMPARATIVE ANALYSIS OF DRUG REGISTRATION PROCESS IN JAPAN AND SOUTH KOREA:UNDERSTANDING REGULATROY FRAMWORK ANDPROCEDURES	-	-
11.	B.DINESHKUMAR 261821507502	DR.J.JAGANATHAN	II	STREAMLINING REGULATROY APPROVAL PROCESSES IN ASEAN COUNTRIES:A COMPREHENSIVE ANALYSIS OF MEDICATION REGISTRATION REQUIREMENTS AND PREPARATION OF THE COMMON TECHNICAL DOCUMENT		
12.	P.JAIKUMAR 261821507505	DR.K.JAGANATHAN	II	COMPARISON OF ADMINISTRATIVE INFORMATION(MODULE 1)IN EAST AFRICAN COUNTRIES	-	-
13.	S.KARTHIK KUMAR 261821507507	DR.B.SENTHILKUMAR	II	STRATEGIC APPROACH TO DEVELOPING A COMPREHENSIVE CORE DOSSIER FOR REGULATORY SUBMISSION: INSIGHTS FROM THE AUSTRALIAN MEDICATION REGISTRATION AND APPROVAL PROCESSES	-	-

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Dissertation submitted to

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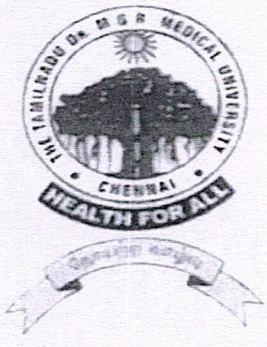

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RESULT AND DISCUSSION

The main thing to bring the draft bill is to ensure the second schedule of the pre-colonial era Drug and Cosmetic act recognizes only legally binding standards for drugs, so there are no standards for medical devices and no way to prosecute a manufacturer who manufactures medical devices. The new draft regulation aims to come up with a certain provision that aims in regulating medical devices, cosmetic, clinical trials etc.

- The Bill has introduced a new definition of medical devices and the setting up of a regulatory body.
- It has specifically broadened the regulations on the import of medical devices.
- Another important aspect this Bill has inculcated is the regulation of AYUSH drugs.
- The Bill also introduces provisions for clinical trials for drug testing.
- A highlight of this Bill is the regulation of online pharmacies since there are currently no specific and explicit rules relating to the sale for pharmaceutical products online.
- The penalties for certain offences have also been maximised to create a deterrent effect.

Currently the comparison of this study is to know about the clinical trial which may include in the new draft bill. The draft bill includes all the related guidelines that will be known for the new draft bill. Drugs and Clinical Trial Rules, 2019 are the only regulation in this regard. Here a separate Chapter has been included in the draft Bill for clinical trials and clinical trial investigation. The draft Bill prohibits all the clinical trials or clinical investigations of drugs and medical devices without permission from the central licensing authority.

A COMPARATIVE OVERVIEW OF GENERIC DRUG REGULATION IN USA, UK AND INDIA

Dissertation submitted to

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6. RESULTS AND DISCUSSION

The Food and Drug Administration (FDA) in the United States, the European Medicine Agency (EU) in Europe, the Central Drug Standard Control Organization (CDSO) in India, and the Ministry of Health Labor in India are all examples of internationally recognized institutions. Within the pharmaceutical industry, the procedures and rules that regulate the filling of pharmaceutical items vary from country to country across the globe. This is as a result of the fact that numerous countries own their own distinctive producing methods. As part of their duties, these regulatory agencies are accountable for ensuring that all pharmaceuticals in their respective countries are not only safe but also effective and of the greatest possible quality. One of the industries that is subject to the most stringent regulations is the pharmaceutical industry. The government has established a great number of laws and guidelines in order to safeguard the health of the general people. It is the responsibility of the national government to establish stringent laws concerning quality assurance and medicine regulation, as well as to establish robust regulatory frameworks in the various areas. One of the primary objectives of the pharmaceutical industry is to recognize and develop a generic medical product. For the purpose of developing a generic pharmaceutical product, a formulator needs to have a comprehensive awareness of the specific regulatory requirements and filling technique of each nation that is relevant to the process. It is necessary to use a different approach and strategy while developing generic drugs in comparison to the procedures and methods that are utilized in the production of revolutionary drug goods. Generic drug manufacturers are required to develop a pharmaceutical product that is equal to the brand-named medication in terms of its therapeutic, safety, and performance characteristics. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, the Therapeutic Good Administration (TGA) in Australia, and the Health Product and Food Branch (HPFB) in Canada are some examples of regulatory bodies that are utilized. Welfare (MHLW) is another example.

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ESTABLISHING A CORE DOSSIER FOR REGULATORY FILLING IN EU AND USA

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8. CONCLUSION

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) regulates generic drugs by harmonizing technical requirements across regions like the EU and USA. The ICH has developed over 60 guidelines covering drug development, safety, efficacy, and quality. Generic drugs must demonstrate bioequivalence to the reference product, meet quality standards, and undergo clinical trials and efficacy. Manufacturers submit ANDAs or DMFs, and post-approval monitoring ensures ongoing safety. ICH's harmonization efforts facilitate efficient development, approval, and access to high-quality generic drugs worldwide.

The generic drug filings in the USA & EU are the most demanding and most stringent in the world with high registration costs and lengthy schedules. The primary purpose of the rules governing medicinal products in US & Europe is to safeguard public health and patient well-being. The European Union (EU) and the United States (US) have distinct drug registration and approval procedures for generic drugs. The EU uses a centralized procedure, obtaining marketing authorization for medicines across the EU. The US uses an Electronic Common Technical Document (eCTD) for electronic submission of regulatory information to the FDA. The US also requires ANDAs, and Drug Master Files (DMFs) for confidential information about manufacturing facilities. Understanding these procedures ensures efficient drug approvals and patient access to safe, effective generic medicines.

The Common Technical Document (CTD) for generic drugs is a standardized format for submitting information to regulatory agencies. It consists of five modules, including administrative and prescribing information, quality and pharmaceutical equivalence, bioequivalence studies, quality documentation, clinical data, and regulatory submissions. Generic drugs must demonstrate pharmaceutical equivalence to the reference product, undergo bioequivalence studies, and provide detailed information on the drug's chemical and pharmaceutical data, stability studies, manufacturing process, and control of raw materials and finished products. CTD provides a globally harmonized format that is accepted in many regions, avoiding the need to compile different registration dossiers for different regulatory authorities.

REGULATORY REQUIREMENTS FOR DRUG, DEVICE AND BIOLOGICALS OFCOMBINATION PRODUCTS AS PER USFDA GUIDELINES

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CHAPTER- 7

CONCLUSION

The main drawback of the regulatory authority in drug-device, biologic-device of the combination products are not given the proper regulatory requirements in FDA, Its major problems related to the development and distribution of combination products and making the regulatory documents it is complicated to make the submission of combination products. The possible complications can be exacerbated due to the highly dynamic design of these products. we need individual regulatory requirements of the drug-device, device-biological, in each category of the combination products documents. for the regulatory writer, it is difficult to write the documents, and there are a lot of the guidelines is listed on the FDA site. we need an individual guideline of the drug-device, biological - device of the requirement in combination products.

The development of innovative biomaterials and technologies has led to the research and development of combination products, which are defined and designated by regulatory authorities. The goal is to ensure safety and efficacy through a systematic approach focusing on design rationale, preclinical evaluation, and clinical evaluation. However, challenges arise due to controversial MOAs and different definitions in different countries. Advanced regulatory evaluation systems and post-market surveillance systems are needed for these complex products.

Combination products are rapidly growing due to drug and biologic therapies innovations and delivery system design. This market category has led to increased adoption of medical devices, increased complexity, and increased product experience and risk awareness.

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COMPARISON OF ADMINISTRATIVE INFORMATION (MODULE 1) IN EAST AFRICAN COUNTRIES

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7. CONCLUSION

- Since there are different drug approval processes around the world, it is crucial, especially for generic manufacturers, to carefully assess the market need, development costs, target regions, and regulatory requirements prior to the development of drugs. Therefore, it is essential to plan and coordinate all of the activities for a timely and successful product launch. East African countries are a significant market for pharmaceutical firms because of the region's huge population, rapid economic development, and high prevalence of diseases.
- From the comparative analysis of administrative information in East African countries that the administrative information systems within the area exhibit substantial differences. Some nations have advanced significantly, but others are languishing behind. By comparing the **administrative information (Module 1)**, we can better understand the differences between Module 1 in East African countries like Eritrea, Ethiopia, Uganda, Tanzania & Kenya. The major contents like manufacturing and marketing authorization & Registration status exhibit the majority of differences in comparison with the listed East African countries.
- To conclude, the comparative analysis in East African countries like Eritrea, Ethiopia, are the region's has absences of (Table of contents for Module 1, Quality Information Summary, Mock-ups & specimens, Information about experts, Good Clinical Practice (GCP) or Good Laboratory Practice (GLP), Paediatric Development Program, vidence of API and/or FPP prequalified by WHO, Requirement for submission of Risk Mitigation Plan and Submission for Risk Mitigation Plan). The registration procedure for pharmaceutical businesses operating in the area has been made easier because of the East African community's efforts to harmonize regulatory criteria for pharmaceutical goods across member nations. As such, registering a dossier in these nations may be a crucial part of a company's strategy for accessing the African market.

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CONCLUSION

This thesis works covers the regulatory requirements of medical products for the issuance of an Emergency Use Authorization (EUA), revocation of an EUA and also reporting EUA's adverse event by FDA. EUA is a vital new technique for clinical and public health professionals. The EUA enables the FDA to respond quickly to emerginginfections such as ebola, Zika virus, and now COVID-19. EUA approves medical equipment, medicinal products, diagnostic equipment, and others in a quick and efficient manner. When the appropriate product has not yet been licenced or authorizedfor this intended use by the FDA, it meets the requirement for rapid and effective medical treatment. EUA will be issued by using the supporting data relevant to the disease when there are no alternatives available. After issuing, FDA will continuouslycollect the data and evaluation the conditions and the suitability of an EUA, in additionthe revocation of the EUA also which warrants. FDA will either revise or revoke an EUA if the justification given by the sponsor no longer exist, and the standards for which the issuance has been given are no longer met, or other environmental issues tosafe the public health the revocation or revision should be made. EUAs may easily become normal procedure, particularly if epidemics become more widespread or dangerous in the future, given the surge of EUAs during the present COVID-19 outbreak. When the present crisis COVID-19 is over, it's worth thinking about how toeffectively govern these channels.

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COMPARISION OF FIXED DOSE COMBINATION REGULATION OF JAPAN , EUROPE , USA WITH INDIA

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CONCLUSION

The development of fixed dose combination is becoming increasingly important from a publichealth prespective. In recent years for easy usage and higher efficacy fixed dose combination drugs are mostly used but because of lack of coordination between State & Central Regualtory bodies, all these issues were developed it should be rectified and transparency should be maintained in all aspects of regulatory process. Fixed Dose Combinations (FDCs) offer several potential benefits, including improved convenience, enhanced efficacy through synergistic effects, and better patient compliance. However, the regulation of FDCs varies across different jurisdictions, including Europe, Japan, the United States, and India.In Europe, Japan, and the United States, regulatory agencies such as the EMA, PMDA, and FDA oversee the approval and regulation of FDCs through rigorous scientific assessment processes. These jurisdictions emphasize safety, efficacy, and quality, and their regulatory frameworks are generally considered robust. However, the regulatory processes can be complex and time-consuming.In India, while efforts have been made to strengthen the regulation of FDCs in recent years, challenges remain, including concerns about the proliferation of irrational and unsafe combinations. The Central Drugs Standard Control Organization (CDSCO) oversees the approval and regulation of FDCs in India, but there have been criticisms of the regulatory framework and enforcement mechanisms.Overall, the effectiveness of regulatory oversight of FDCs depends on factors such as the robustness of the regulatory framework, the transparency of the regulatory process, the enforcement of regulations, and the ability to adapt to emerging challenges. It's essential for regulatory authorities to prioritize patient safety while facilitating access to innovative and effective treatments through FDCs. Additionally, collaboration and harmonization efforts among regulatory agencies globally can help ensure consistency and quality in the regulation of FDCs across different jurisdictions.

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STRATEGIC APPROACH TO DEVELOPING A COMPREHENSIVE CORE DOSSIER FOR REGULATORY SUBMISSION : INSIGHTS FROM THE AUSTRALIAN MEDICATION REGISTRATION AND APPROVAL PROCESSES

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6. CONCLUSION

If a new drug is registered for marketing in Australia, prescribers can be assured that its safety and efficacy have been evaluated by the TGA with advice from the ADEC. The price of a drug does not influence the decision to allow the drug to be registered. By 1997, half the costs of the TGA will be met by the pharmaceutical industry. This requires the TGA to be accountable for its performance, with an increased emphasis on the timely availability of new drugs. Unregistered drugs may be available through clinical trials or the Special Access Scheme which are also part of the TGA's function.

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CHAPTER – 6

CONCLUSION

In European Union, vaccine preparation and monitoring are governed by a set of rules. The initial stages are meant to be exploratory. The amount of regulation and supervision increasesas the vaccine progresses through the process. Vaccines in the European Union (EU) are basedon a thorough regulatory approval procedures to ensure their safety, efficacy, and accuracy. Depending on the product, this process can take months or years. Centralised, decentralised, and mutual recognition are the three different approaches to get a pharmaceutical product licenced in the EU.

The European Medicines Agency receives a single Marketing Authorization Application (MAA) from companies (EMA) for approval of the vaccines. Common Technical Document is a standardised electronic framework for new products. Europe was the first to implement injection, and it has been at the forefront of the global injection industry ever since, playing a critical role in vaccine research and development. After a vaccine is agreed for use, the European Medicines Agency (EMA) and national authorities in the EU/EEA monitor side effects in publics who take conventional the vaccine. Individual European countries determineif vaccines should be included in their national vaccine programmes and paid by their health- care systems.Most national vaccination programmes in the EU/EEA provide vaccines for up to twenty diseases to people of various ages. The European Medicines Agency (EMA) develops, scientifically evaluates, approves, and monitors COVID-19 inoculations in the European Union(EU). COVID-19 vaccines are being mass-produced, evaluated, and approved in accordance with current regulatory and legal requirements.

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STREAMLINING REGULATORY APPROVAL PROCESSES IN ASEAN COUNTRIES: A COMPREHENSIVE ANALYSIS OF MEDICATION REGISTRATION REQUIREMENTS AND PREPARATION OF THE COMMON TECHNICAL DOCUMENT

Dissertation submitted to

THE TAMILNADU Dr.M.G.R MEDICAL UNIVERSITY,

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In partial fulfillment of the requirements

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IN

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7. SUMMARY AND CONCLUSION

ASEAN is an example of a regional integration movement that is evolving and developing. Amidst heightened international competition and economic upheavals, this regional association of developing nations has emerged as a highly effective catalyst for promoting trade and collaboration. ASEAN, which has undergone substantial change since its inception four decades ago, is presently situated at a juncture in its evolution from a regional organization to a prosperous, interdependent economic community. The territories comprising the Gulf Cooperation Council (GCC) and the Association of Southeast Asian Nations (ASEAN) are classified as "Emerging markets" in the context of pharmaceutical export. The Gulf and ASEAN nations encourage the importation of premium generic medications from other countries through their drug product regulations. ASEAN member states utilized the ACTD standard format for pharma product submissions with the intention of registering the product in the reference country. In both locations, the climatic zone stability parameters are 30°C and 2°C, and the relative humidity is 65% and 5%, respectively.

ASEAN's pharmaceutical regulatory agencies and industry have collaborated extensively on the development of standardized documents, both domestically and, to a greater extent, with international organizations. The ASEAN Common Technical Dossier and ASEAN Common Technical Requirements are continuously evolving documents. Since the mutual recognition of pharmaceutical registrations and the establishment of a standardized placement system have been substantially accomplished, the subsequent course of action will be to focus on these matters. In the realm of implementation, a substantial amount of labor remains. An illustrative instance of an effective pharmaceutical harmonization policy can be found in ASEAN. The pharmaceutical sector is witnessing an expansion of ASEAN's importance. In several countries, including Malaysia, Thailand, and Indonesia, the evaluation of approved generic products is a critical process. In order to ascertain the safety of generic medications for consumer consumption, this assessment examines both their effectiveness and safety. Malaysia, Thailand, and Indonesia, the evaluation of approved generic products is a critical process. In order to ascertain the safety of generic medications for consumer consumption, this assessment examines both their effectiveness and safety. The purpose of this essay is to discuss the findings of a

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6. SUMMARY AND CONCLUSION

When compared to other nations, Japan's market is distinct and heavily regulated because to the PMDA's strict CMC data requirements. When compared to other nations, Japan has a far more complex regulatory framework. The Japanese regulatory body occasionally requires even more accuracy and information than the US FDA or any other regulatory body. Nevertheless, due to regional requirements, not just for Module 1, it is not always possible to synchronize the entire dossier. Since Module 2 in Japan contains more information than the EU and US Module 2 documents, it is advised to update the entire Module 2 section with the appropriate data. International biopharmaceutical businesses often finish developing for the US and EU markets before thinking about Japan.

It is obvious that this is a crucial step in the drug development process, and Japan must be taken into account concurrently with efforts aimed at other significant regulatory bodies (the US and EU). To successfully obtain clearance of new biologic drug products in Japan, a clear and thorough country-specific regulatory application is required. Understanding Japanese culture is crucial since it differs greatly from Western society, in addition to PMDA demands and regulations unique to Japan. Incorporating Japan-specific specifications throughout the first phases of development might also aid producers in resolving issues with data requirements for Japan submission. There are variations in the ICH guidelines followed by the US, EU, and Japan. Out of the three, Japanese contributions are the most elaborate and detailed. In order to smooth your entry into the Japanese market, it is crucial to have a regulatory plan in place before you actually start executing your regulatory procedures because challenges still exist in this dynamic environment where regulations are continuously changing.

For the purposes of disease diagnosis, treatment, and prevention, pharmaceutical products are absolutely necessary. The development of these products has also improved the quality of life of individuals, assisted them in maintaining their health, and brought significant benefits to the economy of the nation as well as to individual inhabitants. In spite of this, pharmaceutical products are required to fulfill the two most important standards, which are safety and efficacy, because they have the potential to induce unpleasant reactions. As a consequence of this, the government

REGISTRATION OF INSTITUTIONAL ETHICS COMMITTEE IN CENTRAL DRUG STANDARD CONTROL ORGANIZATION

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CONCLUSION:

Current criteria require ethics committee clearance before starting a biomedical research study. To issue approval letters for clinical trials, investigators must ensure their ethics committee is registered with the Central Drugs Standard Control Organization (CDSCO). Otherwise, the committee may not have the authority to do so. To approve biomedical research other than clinical trials, the committee must register with the Department of Health Research. This article focuses on the registration process for ethics committees in DHR and CDSCO. Institutional Ethics Committees (IECs) protect the rights, safety, and welfare of research participants. The IEC also considers the interests of the investigators. The committee examines research ideas from the institute and is impartial, with members from both the medical and non-medical sector. Even these panels require monitoring, accountability, and transparency in their composition and operations.

- This thesis works covers the regulatory requirements for the registration of New Institutional Ethics Committee with CDSCO on online SUGAM Portal. The real time evidence of registering a new educational institution ethics committee with the CDSCO. The final registration copy of the Ethics Committee and the Form CT-02 has obtained.

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REGULATORY CHALLENGES AND OVERSIGHT IN THE WORLDWIDE MARKET OF BRANDED AND GENERIC PHARMACEUTICAL

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8.CONCLUSIONS AND RECOMMENDATIONS

Generic medicines are cheaper alternative to the costly branded medicines, which provide the same medical benefits to the suffering mankind as these are certified to be perfect substitute for the innovator branded product. A generic medicine is identical in dose, strength, route of administration, safety, efficacy, and intended use. It must contain the same active ingredients as the original formulation. These are produced after patent expiry or when a patent has never existed. They are cheaper than the equivalent brand name drug because of much lower marketing and development costs. Further, generic companies do not incur the cost of drug discovery, burden of proving safety and efficacy through clinical trials. Competition subsequent to patent expiry also leads to reduction in the prices of generics. Thus, generic versions help the suffering mankind by providing the drug available at affordable prices while retaining the quality.

High costs of medicines have always been a matter of great concern to the health authorities in providing healthcare to the mankind. Efforts are made globally to provide quality medicines at affordable prices to the public at large. The States are switching to the generic medicines at a very fast pace to achieve the goal of affordability of medicines in view of their advantage of being cost effective over innovator drug product. Since, generics are alternative products with same contents and therapeutic action, their comparatively low cost provides additional benefits to the healthcare providers.

Generics are considered better substitute to their innovator counterpart throughout the world. The States are promoting their utilization to contain the escalating healthcare expenditure by adopting various generic promotion schemes like generic prescribing, generic substitution, reference pricing, INN labeling, generic friendly approval process etc. The generic medicine market is undergoing significant change throughout the world in view of the large-scale expiry of the patents in years to come. Majority of the overseas countries are going for amendments or revision in their medicine policies to promote generics.

However, several outstanding issues and concerns continue to undermine the patient