Generic Drugs, A Need to the Public: USA and India- Government Plans to Reduce the Price of ANDA and List of Generic Drugs Approved in Year 2018

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Abstract
Health is the prime component for every person and in the world, there are different traditions have their own approaches to treat and cure illness. The dosage form of the drug may appear different but medically, however a generic medicament has the same mechanism in the body as that of the costlier brand-name drugs. They acquire the equal active ingredient and must pass the same satisfactory standards with respect to manufacturing and packaging of medicaments. The Generic medicinal drug beneath the regulation of U.S. Food and Drug Administration must have the equal quality and performance as that of the brand-name drugs. The FDA states: “Generics have the identical quality as brand identity drugs. When a generic drug product is approved, it has met rigorous standards established via the FDA with respect to identity, strength, quality, purity, and potency. India started Jan Aushadhi scheme to make quality medicines handy to the shoppers at affordable prices. Given the socio-economic conditions and the level of ignorance and illiteracy with vast disparities of income in the country, the advantage of the scheme can be taken by the consumers or should reach the consumers particularly the poor and the needy, only when a proper multimedia publicity programmed is mounted to educate the consumers of all strata of society. India is still a developing country where quality and inexpensive remedy are still major issues.

Keywords: Generic drugs; Approval system; USA; India; Obamacare act; Jan aushadi scheme; Drugs approved

Introduction
All Cultures have extraordinary systems of health beliefs, that give an explanation for the cause of illness, how it can be cured or treated, and who should be involved in the process. The extent to which patients are aware the patient education having a cultural significance for them that can have a deep impact on their reception to information provided and their willingness to use it [1]. Western industrialized societies such as the United States, which sees disease as an end result of natural scientific phenomena, promotes medical remedies that battle microorganisms or use sophisticated technology to diagnose and treat disease [1]. Other societies believe that illness is the result of supernatural phenomena and promote prayer or different non secular interventions that counter the assumed disfavor of powerful forces. Cultural issues play a primary role in affected person compliance. Access to medications is part of the wider issue of the right to health, which in turn is part of the international debate on fairness and human rights [1,2]. Approaching the issue from an moral standpoint is greater complex than from a legal viewpoint considering the fact that it means going beyond individual comfort to assume a commitment to the community, the nation, and humankind. According to the ethical concept of consequentialism, an action is ethical or not relying on its consequences. Our analysis then focus on the consequences of the behavior of present day world systems of research, manufacturing, distribution and use of medications; and on what we can do to alter these consequences to gain higher population health and equity [2,3]. Generic medicine are the look alike product of branded drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as that of the original drug. In other words, their pharmacological effects are exactly same as those of their brand-name counterparts. These drugs come into the market, when the patent of innovator drug expires [3,4]. Although they may not be associated with a specific company, generic drugs are concern to the guidelines of the governments of countries where they are dispensed. Generic drugs are labelled with the name of the manufacturer and the adopted title (non-proprietary name) of the drug. A generic drug needs to contain the same active ingredients as the original formulation. In addition, a generic drug have to be bioequivalent to the brand drug, that is there should be no significant difference between the generic and brand product in the rate or the extent to which the active ingredient is delivered to the patient [5,6]. According to the USA, a generic drug is the equal as that of the branded drug with recognize to the circumstance of use, active ingredients, and route of administration, dosage form, strength, quality, safety, performance characteristics, and labelling. Moreover, the generic drug has to be bioequivalent to branded drug. It must have the identical intended use as that of the innovator [7,8]. In most cases, generic products are available once the patent protections afforded to the origin product have expired. When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms. Generic drugs are usually sold for significantly lower prices than their branded equivalents. Generic drugs do not require the submission of clinical data regarding safety and efficacy since this information was already provided for the pioneer product. Since the original active ingredient was already proven safe and effective, the manufacturer must now prove bioequivalence for the pharmaceutically equivalent generic drug product [9-11].

Governing Bodies and Regulatory Bodies of USA
The U.S. Food and Drug Administration (FDA) regulate the drug intended for use in the cure, diagnosis, mitigation, treatment, or prevention of disorder and to affect the shape or any function of the body of human beings or animals. Registrar Corp provides Registration, U.S. agent and Compliance Assistance for U.S. and Non-U.S. Companies in the Drug Industry. In the United States, 9 out of 10 companies have to comply with these requirements. The FDA is responsible for the regulation of all pharmaceuticals, including generic drugs. The FDA ensures that generic drugs are safe and effective, and meet the same quality standards as the brand-name drug. The FDA also ensures that generic drugs are bioequivalent to the brand-name drug, meaning that they have the same amount of active ingredient and produce the same effects.

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10 prescriptions filled are for generic drugs. Increasing the availability of generic pills helps to create opposition in the marketplace, which then helps to make treatment more inexpensive and increases access to fitness care for more patients [12,13].

**Organization Chart of Generic Drug Industry in USA**

The Office of Generic Drugs (OGD ensures, through a scientific and regulatory process, that Americans obtain safe, effective, and splendid generic drugs) (Figure 1). FDA-approved generic pills account for greater than 88% of prescriptions filled in the United States. All authorised generic drugs have the same excessive quality, strength, purity and stability as brand-name drugs [14]. The generic manufacturing, packaging, and testing sites have to pass the same quality requirements as these of brand-name drugs. OGD is comprised of an immediate office and four subordinate offices, totaling about 450 employees [1]. The FDA’s Office of Generic Drugs (OGD) within the Centre for Drug Evaluation in Research ensures that humans have access to safe, low cost generic drugs by following a rigorous assessment method that includes:

- Managing the regulatory manner to facilitate drug approvals
- Establishing science initiatives to research generic drugs
- Publishing facts and reports on generic drug improvement and review
- Offering educational materials and information

**Registration and Approval Process**

**Hatch- waxman rule**

- Provide a period of patent and marketing exclusivity to manufacturer (innovator) drug producers to allow them to earn investment in drug development and discovery.
- It gives the purchaser with a gain of speedy availability of lower-priced generic variations of innovator drugs.
- The Hatch Waxman Act keeps a balance between the pursuits of the brand drug industry, generic producer and the consumer (Table 1) [15,16].

**Approval Procedure of Generic Drugs in USA**

FDA requires drug companies to display that the generic medicinal drug can be effectively substituted and grant the identical scientific benefit as the brand-name medication that it copies [1]. The abbreviated New Drug Application (ANDA) submitted by drug organizations ought to exhibit the generic medication is the identical as the brand-name model in the following ways:

- The active ingredient in the generic medication is the identical as in the brand-name drug/innovator drug.
- The generic medication has the equal strength, use indications, shape (such as a pill or an injectable), and route of administration (such as oral or topical).
- The inactive ingredients of the generic medication are acceptable.
- The generic medicine is manufactured beneath the identical strict requirements as the brand-name medicine.
- The container in which the remedy will be shipped and bought is appropriate, and the label is the identical as the brand-name medicines label [17-19].

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>For the products for which no patent information is reachable in the orange book.</td>
</tr>
<tr>
<td>II</td>
<td>Used for the products for which all the applicable patents are expired.</td>
</tr>
<tr>
<td>III</td>
<td>Used for the products for which some or all the applicable patents are legitimate and the applicant confirms that the product will not be placed in the market until such patents are expired.</td>
</tr>
<tr>
<td>IV</td>
<td>Used for the products for which some or all the applicable patents are valid and applicant attempt to file the product, which does no longer infringe those patents or applicant, invalidates the granted patents. On a profitable outcome, the generic applicant enjoys the six-month exclusivity in the market.</td>
</tr>
</tbody>
</table>

**Table 1: Regulatory Requirement of Generic Drug.**

- Generic drugs must meet high standards to receive FDA approval.

**The CTD is comprised of following modules**

- Module 1: Administrative Information
- Module 2: CTD Summaries
- Module 3: Quality
- Module 4: Nonclinical study reports
- Module 5: Clinical study reports

The generic drug development can be produced in USA after the patent of the innovator drug gets expired. The timeline approval of generic drug is 18 months. The document is submitted in an ectd format. With only one copy submitted at the time of approval (Figures 2 and 3) [20-22].
The Patient Protection & Affordable Care Act

The Patient Protection and Affordable Care Act were once signed into law via President Obama in March 2010. Its principal provisions go into effect on Jan 1, 2014, though massive changes went into effect before that date and will proceed in years to come [1]. This Obama Care act is in a written document, which is composed of over 1000 pages and in general consists of the reforms of insurance plan and healthcare industries. It is structured in a way, such that the most important reforms are placed in the first one hundred forty pages. It aims to furnish Americans with low-cost and first-rate health care [23,24].

► Impose an Individual Mandate: Most humans are now not covered through Medicare or Medicaid. They will be required to have fitness insurance or pay a penalty ("play or pay"). In addition, insurance organizations will no longer be in a position to deny coverage for pre-existing conditions, rescind present fitness insurance plan insurance when a person gets ailing or impose annual or lifetime limits on benefits [22,25].

► Strive to Provide Affordable Coverage: Lower-income individuals and families, collectively with some middle-income individuals and families, will acquire financial assistance to assist pay for fitness insurance. In addition, insurance corporations will have to yearly record the share of top rate dollars spent on true medical care and furnish the customer rebates for plans that spend a lower percentage of premium dollars on medical offerings than that required by using the ACA [26,27].

► Require an Employee Mandate: With the exception of small businesses, employers that do no longer supply qualifying fitness insurance plan coverage will be difficult to an extra tax. Small employers will be influenced to supply fitness care coverage through a new tax credit [28,29].

► Cover Preventive Health Services: New group health insurance plan plans, as well as person fitness insurance plan policies, will have to grant “first dollar” insurance for certain preventive offerings and immunizations.

► Transform the Health Care Delivery System: Provide funding for research and demonstration initiatives to check payment and provider transport models designed to limit health care charges and enhance the quality of care provided [30].

Implementation of obama care act

The authorities are planning to put into effect the Obama care act in quite a few phases. Some of the phases include the growth of Medicaid, enforcing marketplaces and enhancement of Medicare by 2014. Also, the regulation requires all Americans to have insurance plan cover by 2014. Those who will fail will have to pay an extra tax of 1% of the total income and through 2016 they will be paying 2.5% tax on their complete income [31]. It is meant to take care of all the people in different training of life and organizational size. For example, there is a fee assistance coverage that assists the families and men and women that are terrible and also the small businesses. There are also future plans which are meant to be put in place beginning from 2016 where companies will be paying an insurance rate for their employees [32].

Pros and cons of affordable care act

The affordable act introduced to furnish Americans with low-cost and first-rate health care but it has some advantages and disadvantages related to many issues. Enlists various pros and cons related to affordable care act (Table 2) [33,34].

The uncertain future of ACA

The US healthcare enterprise has been on a rollercoaster trip for the last seven years. The future of the healthcare reform regulation is still unsure in the arms of the new Republican administration and Congress, led with the aid of President Donald Trump. Individual consumers, businesses, and insurers are caught in the center of two opposing aspects- one side pushing for the repeal of the healthcare regulation and the other battle to maintain it in place. Healthcare industry corporations have proven concern regarding the GOP’s decision to retract the ACA barring any clear and stable plans to address the viable consequences [35,36]. Whether lawmakers choose to repeal-and-delay, repeal-and-replace or just amend the present ACA provisions, any of these choices will nevertheless translate to changes in policies, regulations, and approaches across more than one sectors. These adjustments will have an effect on not only the millions of humans covered by means of ACA-based health plans, but additionally the insurance companies, hospitals and even small corporations that all count on the provisions and rules set by way of the Affordable Care
Act [37,38]. To avoid confusion, stress, and mistakes during these instances of uncertain procedure and coverage changes, turning to a dependable healthcare outsourcing agency is one of the quality ways to make certain that your organization is absolutely organized for any feasible modifications in the healthcare landscape. Always up to date with the modern-day statistics and technologies, the professionals and professionals are geared up to deal with issues and troubles about healthcare finance and insurance plan services so you can spend more time focusing on your organization’s core things to do and less time worrying [39]. The list of medicines sold under affordable care act is given in Table 3 and the list of generic drug approved in USA 2018 is given in Table 4 [40,41].

### Indian Drug Regulatory System

**Governing bodies and regulatory bodies**

The Indian drug regulatory system was originated in the year 1940. The Drugs & Cosmetics Act was passed to address the sudden and fast expansion of pharmaceutical merchandise in the country. The Drugs Rules had been framed in 1945 to give impact to the provisions of the Act. Both the Act and Rules have been consequently amended many times and number legislative texts had been passed to alter the import, manufacture, distribution, and sale of drugs [42].

**Central drug standard control organization**

In India, the Central Drugs Standard Control Organization (CDSCO) is the foremost regulatory body presently regulating import, sale and manufacture of medical devices. The CDSCO regulates the standards of drugs, cosmetics, diagnostics and units and issues licenses to drug producers and importers. It additionally lays down regulatory measures, amendments to Acts and Rules and regulates market authorization of new drugs, medical research in India and standards of imported pills etc. Headquartered in New Delhi, the CDSCO is India’s predominant regulatory body for prescribed drugs and scientific devices and Within the CDSCO, the Drug Controller General of India (DCGI) is responsible for the rules of prescription drugs and medical devices. The Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC) advise the DCGI. The Central Licensing Approval Authority (CLAA) handles Licensing and classification of medical devices. The CLAA is also responsible for placing and implementing security standards, appointing notified our bodies to oversee conformity assessment, conducting post-market surveillance and issuing warnings and remembers for unfavorable events. The CDSCO establishes safety, efficacy, and quality standards for prescription drugs and medical gadgets The CDSCO is additionally divided into a number of zonal offices, which do pre-licensing, and post-licensing inspections, post-market surveillance, and recalls when necessary [43,44].

### Chart of Organization Structure

The CTD is only a format for submission of information to CDSCO. Although applicants can modify the format at some of the

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsidies make health insurance more cost-effective for those who qualify. By applying the 80/20 rule, 80% of your premiums are spent on fitness care alternatively than administrative resources. The price has now not diminished for everyone.</td>
<td>Many non-public plans have been cancelled due to the fact they did not comply with Obama care.</td>
</tr>
<tr>
<td>Free Preventive Care All certified health insurance plan plans must provide 10 imperative health benefits, including free preventive and wellbeing visits. No copay. No deductible. No coinsurance.</td>
<td>Loss of company-sponsored health plans</td>
</tr>
<tr>
<td>No surprise cancellations or pre-existing denials Insurance groups can’t cancel your policy because of a mistake on an application. Tax penalties</td>
<td></td>
</tr>
<tr>
<td>Dependent stay under parents’ sketch longer You can proceed to have your children insured under your health plan till they are 26</td>
<td></td>
</tr>
<tr>
<td>No more unreasonable limits Limits on lifetime benefits have been definitely banned and annual limits phased out. (This does now not consist of grandfathereed plans.) Shopping for insurance can be complicated</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2:** Pros & Cons of Affordable Care Act.

<table>
<thead>
<tr>
<th>Drug or Drug Category</th>
<th>Criteria for Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin for Cardiovascular Disease – Generic OTC® 81 mg and 325 mg</td>
<td><strong>Men</strong></td>
</tr>
<tr>
<td>Aspirin for Preeclampsia – Generic OTC 81 mg</td>
<td><strong>Ages 45 to 79 years and women ages 55 to 79 year</strong></td>
</tr>
<tr>
<td>Fluoride – Generic OTC and Rx** products</td>
<td>Women through 55 years of age</td>
</tr>
<tr>
<td>Folic Acid – Generic OTC and Rx products (0.4 – 0.8 mg)</td>
<td>Children 6 months through 5 years old</td>
</tr>
<tr>
<td>Iron Supplements – Generic OTC and Rx products</td>
<td>Women through age 50</td>
</tr>
<tr>
<td>Vitamin D and some Vitamin D combinations</td>
<td>Children 6 months to 12 months</td>
</tr>
<tr>
<td>Contraceptives – Generic OTC and Rx, and some brand Rx Hormonal contraception: Oral, Transdermal, Intravaginal, Injectable Contraceptives - Barrier, Cervical Caps Implantable Contraceptives – Intrauterine Contraceptives Emergency Contraceptives OTC Contraceptives (except male condoms)</td>
<td>Patients 65 years and older</td>
</tr>
<tr>
<td>Bowel preparation for colonoscopy screening – Generic OTC and Rx</td>
<td>Women through age 50</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Women and men, age 50 through 75 years Limited to 2 prescriptions in 365 days</td>
</tr>
</tbody>
</table>

**Table 3:** List of medicine sold under Affordable Care Act.
subsection levels, if needed to provide the best possible presentation of the information, in order to facilitate the understanding and evaluation (Figures 4-6) [45]. The generic drug development can be produced in India after the patent of the innovator drugs expired. The timeline of ANDA and List of Generic Drugs Approved in Year 2018.

**Table 4:** List of Generic Drug Approved in USA 2018.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Generic Name</th>
<th>ANDA Applicant</th>
<th>Brand Name</th>
<th>ANDA Approval Date</th>
<th>ANDA Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Buprenorphine and Naloxone Sublingual Film, 4 mg/1 mg and 12 mg/3 mg</td>
<td>Dr. Reddy’s Laboratories SA</td>
<td>Suboxone</td>
<td>6/14/2018</td>
<td>For the treatment of opioid dependence.</td>
</tr>
<tr>
<td>5.</td>
<td>Tadalafl Tablets USP</td>
<td>Teva Pharmaceutical USA, Inc.</td>
<td>Cialis Tablets, 2.5 mg</td>
<td>5/22/2018</td>
<td>For the treatment of erectile dysfunction (ED)</td>
</tr>
<tr>
<td>7.</td>
<td>Colesevelam Hydrochloride Tablets, 3.0 mg</td>
<td>Impax Laboratories, Inc.</td>
<td>Welchol</td>
<td>4/27/2018</td>
<td>• Reduce LDL-C levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy</td>
</tr>
<tr>
<td>9.</td>
<td>Succinylcholine Chloride Injection USP</td>
<td>Zydus Pharmaceuticals (USA), Inc</td>
<td>Quelicin</td>
<td>5/4/2018</td>
<td>Indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation</td>
</tr>
<tr>
<td>10.</td>
<td>Phenylephrine Hydrochloride Injection USP</td>
<td>Cipla Limited</td>
<td>Phenylephrine Hydrochloride</td>
<td>4/27/2018</td>
<td>Indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anaphylaxis</td>
</tr>
<tr>
<td>11.</td>
<td>Hydromorphone Hydrochloride Injection USP</td>
<td>Eurohealth International Sarl</td>
<td>Dilaudid (Hydromorphone Hydrochloride)</td>
<td>4/27/2018</td>
<td>For management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate</td>
</tr>
<tr>
<td>12.</td>
<td>Miglustat Capsules, 100 mg</td>
<td>Amerigen Pharmaceuticals Limited</td>
<td>Zavesca (Miglustat) Capsules, 100 mg</td>
<td>4/17/2018</td>
<td>A glucosylceramide synthase inhibitor indicated as monotherapy for treatment of adult patients with mild/moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option</td>
</tr>
<tr>
<td>13.</td>
<td>Loratadine Chewable Tablets USP</td>
<td>Sun Pharma Global FZE</td>
<td>Children’s Claritin (Loratadine) Chewable Tablets</td>
<td>4/16/2018</td>
<td>For seasonal allergic rhinitis and idiopathic urticarial</td>
</tr>
<tr>
<td>14.</td>
<td>Everolimus Tablets, 0.25 mg, 0.5 mg, and 0.75 mg</td>
<td>West-Ward Pharmaceuticals International Limited</td>
<td>Zortress (Everolimus) Tablets, 0.25 mg, 0.5 mg, and 0.75 mg</td>
<td>4/12/2018</td>
<td>For organ rejection prophylaxis in renal transplant patients with low-moderate immunologic risk, in combination with basiliximab induction and reduced doses of cyclosporine and corticosteroids</td>
</tr>
<tr>
<td>15.</td>
<td>Clozapine Orally Disintegrating Tablets, 50 mg</td>
<td>Barr Laboratories Inc.</td>
<td>Fazaco (Clozapine) Orally Disintegrating Tablets, 50 mg</td>
<td>4/9/2018</td>
<td>For use as an anti-psychotic</td>
</tr>
</tbody>
</table>

**Jan Aushadhi Scheme in India**

In India, the Central Government, as well as numerous state governments, took several steps in merchandising a generic medicinal drug via rules and schemes. Within this, in 2008, Jan Aushadhi scheme was launched by the Department of Pharmaceuticals in affiliation with Central Pharma Public Sector Undertakings, to supply quality drugs at less expensive prices to the common people’s [1]. The shops of Jan Aushadhi Kendra have been proposed to be set up all over the country (at least one per district) to supply generic drugs, which would be available at lesser expenses however are equal in fine and efficacy to branded drugs. In November 2008 first generic drug shop was opened at the public sector civil health center in Amritsar, Punjab state, and the second store in February 2009 at Shastri Bhawan, New Delhi. Eighteen
Role of bureau of Pharma public sector undertaking of India (BPPI)

- It is the implementation organization of PMBJK
- The agency was hooked up in December 2008 under the (Department of Pharmaceuticals, Government of India).
- The medicines, which are below regulation, at a low-priced price and different permission to run a drug store, need to make sure the ample place of storage for medication marketed under the PMBJAK.
- Procurement of medicine from central pharm PSU and private sectors.
- Monitoring the acceptable running of Pradhanmantri Bharatiya Jan Aushadhi Kendra (PMBJAK) [49].

Table 6 enlists the list of medicine sold under Pradhan Mantri Jan Aushadhi Kendra [50] and (Table 7) enlist the list of Generic Medicine Approved by FDA in India [51] and (Table 8) Comparative Study of ANDA Filling Checklist between USA & India.

Recommendation

It is very necessary to clear the myths about generic medicine; this can be accomplished with the aid of doctors, pharmacist, nurses and any other healthcare profession via promotion the benefits of preferring generic medicine. In the USA, eCTD is Compulsory with the paper CTD. India needs to put up its application through paper CTD (Table 9). Some amendments are warranted in Hatch-Waxman Act 1984 for growing a generic drug in a higher way. The ACA act should be an amendment to all the Americans. This have to grant higher services and scheme via bringing generic medicinal drug in a way by making insurance plans according to the specifically designed want of individuals. People who are living in the rural areas, private doctors greater such shops have been opened as of September 2009 in the states of Punjab, Haryana, and Rajasthan [47]. The numbers of shops have opened however until now, 87 are nowadays useful as provided by using a legit website of Jan Aushadhi. The government has proposed that each of the 660 districts in India will have at least one Jan Aushadhi store. In spite of the fact that these stores are being mounted through the authorities of India in the large public interest, however the reports from few of these stores advise that sales are minimal [47,48]. The limited grant of the ordinary drug in the JAS causes the major drawback of its recognition amongst the common people. A study observed that only 33% of the drug treatments had been available. This constrained portfolio of drug treatments coupled with chronic stock-outs has significantly eroded the credibility of these shops as customers want a one-stop shop for all prescribed drugs (Table 5) [48].

<table>
<thead>
<tr>
<th>Module</th>
<th>Non-CL (Non-Med)</th>
<th>CL (CL)</th>
<th>Overall Summary</th>
<th>Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-4</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-5</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-6</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-7</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Module-8</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>The CTD</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Figure 5: Indian Common Technical Document.

Figure 6: Approval Procedure of Generic Drug in India.

Table 5: Documents Required for Jan Aushadhi Store.

<table>
<thead>
<tr>
<th>For Individual</th>
<th>Institutions/NGO/Charitable Institute/Hospital</th>
<th>Government/ Govt Nominated Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Adhaar card</td>
<td>1. Aadhaar card</td>
<td>1. Details of department who has allocated the space, along with supporting documents/ sanction order</td>
</tr>
<tr>
<td>2) Pan card</td>
<td>2. Pan card</td>
<td>2. Pan card</td>
</tr>
<tr>
<td></td>
<td>3. Certificate for incorporation</td>
<td>3. Adhaar card</td>
</tr>
<tr>
<td></td>
<td>4. Registration certificate</td>
<td></td>
</tr>
</tbody>
</table>
### Table 6: List of Medicine sold under Pradhan Mantri Jan Aushadhi Kendra.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Generic Name</th>
<th>Therapeutic Uses</th>
<th>Date of Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tenofovir Alafenamide Hemi</td>
<td>In combination with other antiretroviral agents for treatment of Human Immunodeficiency Virus type-1 (HIV-1) infection in adults and adolescents with aged 12 years and older</td>
<td>10.01.2018</td>
</tr>
<tr>
<td>2.</td>
<td>Clofarabine Bulk &amp; Injection</td>
<td>For the treatment of patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukaemia after at least two prior regimens. This indication is based upon response rate</td>
<td>16.01.2018</td>
</tr>
<tr>
<td>3.</td>
<td>Denaverine Hydrochloride</td>
<td>Cattle: Facilitation of parturition in heifers; activation of interrupted parturitions; insufficient opening of the soft birth canal; narrowing of the cervix of first and second degree after correction of uterine torsions; improvement of the conditions for foetotomy; regulation of labour contractions of the uterus Dogs: Activation of Interrupted parturition</td>
<td>16.01.2018</td>
</tr>
<tr>
<td>4.</td>
<td>Netupitant 300 mg + Palonosetron</td>
<td>For the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. For the prevention of acute and delayed nausea and vomiting associated with moderate emetogenic cancer chemotherapy in adult</td>
<td>20.02.2018</td>
</tr>
</tbody>
</table>
5. Fipronil 6.1 % m/v + Permethrin
   In dogs, to be used against infestations with fleas and/or ticks when repellent (anti feeding) activity is necessary against sand-flies and/or mosquitoes
   20.02.2018

6. Praziquantel 0.0065 g + Abamectin 0.00025 g tablets for cat
   In infestation of cats with endoparasites tapeworms (teniae), flukes, roundworms (nematodes); with ectoparasitises lice, fleas, parasite licks, notedic mange (feline scabies), "walking" dandruff (cheyletieliosis) and other mange, and particularly in cases of complex endo and ectoparasitic invasion
   20.02.2018

7. Cadexomer Iodine Bulk & Powder 100 % w/w
   For the treatment of chronic excuding wounds such as leg ulcers, pressure ulcers and diabetes ulcers infected traumatic and surgical wounds
   05.03.2018

8. Dalfampridine Bulk & Film coated extended release tablet
   For treatment to improve walking in patients with multiple Sclerosis (MS)
   12.03.2018

9. Ulipristal Acetate 5 mg tablets
   For the pro-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
   14.03.2018

10. Ulipristal Acetate bulk & 5 mg tablets
   For the pro-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
   02.04.2018

11. Riociguat bulk & 0.5 mg/1.0 mg/1.5 mg/2.0 mg/2.5 mg tablet
   For the treatment of persistent/ recurrent chronic Thromboembolic pulmonary Hypertension (CTEPH) WHO Group 4) After surgical treatment or imoperable CTEPH to improve exercise capacity and WHO function
   16.04.2018

12. Baricitinib 2 mg/4 mg film coated tablets
   For the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modification anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate
   07.05.2018

13. Vortioxetine Hydrochloride 5mg/10mg/15mg/20mg film coated tablets
   For the treatment of major depressive disorder in adult
   14.05.2018

14. Vardenafil Hydrochloride Trihydrate(BULK) & Vardenafil 2.5mg/5mg/10mg/20mg Tablets
   Treatment of erectile dysfunction in adult men.
   11.06.2018

15. Trientine Hydrochloride bulk & 250mg caspule
   For the treatment of Wilson’s disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life endangering side effect
   11.06.2018

Table 7: List of Generic Medicine Approved by FDA in India.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Requirements</th>
<th>US- Food And Drug Administration</th>
<th>India-Central Drug Standard Control Organization (CDSCO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Application</td>
<td>ANDA</td>
<td>MAA</td>
</tr>
<tr>
<td>2.</td>
<td>Departments Certification</td>
<td>Required</td>
<td>Not Required</td>
</tr>
<tr>
<td>3.</td>
<td>No. of Copies</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Approval timeline</td>
<td>18 months</td>
<td>12 months</td>
</tr>
<tr>
<td>5.</td>
<td>Fees</td>
<td>No Fees</td>
<td>50,000</td>
</tr>
<tr>
<td>6.</td>
<td>Presentation</td>
<td>eCTD</td>
<td>CTD</td>
</tr>
</tbody>
</table>

Finished products Control

7. Justification | ICHQ6A | ICHQ6A
8. Assay         | 90-100% | 90-110%
9. Disintegration | Not Required | Required
10. Colour Identification | Not required | required
11. Water content | Required | Required

Manufacturing and Control

12. No. of batches | 01 | 1
13. Packaging     | A min of 1,00,000 units | Not required
14. Process validation | Not required at the time of submission | required

Stability

15. No. of batches | 03 | 02
16. Day and Time submission Long Term | 3 Month Accelerate & 3 Month Long term | 6 Month Accelerate & 6 Month & 6 Month accelerated & 3 Month Long term
17. Container Orientation | Do not address | Inverted and upright

Bioequivalence

18. CRO | Audited by CRO | Audited by CDSCO

Table 8: Comparative Study of ANDA Filling Checklist between USA & India.

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>MODULE 1.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US</td>
<td>India</td>
</tr>
<tr>
<td>1.</td>
<td>General information Covering letter, Table of Components (Module 1 to Module 5)</td>
<td>Required</td>
</tr>
<tr>
<td>2.</td>
<td>Administrative Information</td>
<td>A. Forms</td>
</tr>
<tr>
<td></td>
<td>Form 356 h Annexure IX) (Application to market a New or Abbreviated New Drug or Biological for Human Use) Form 3794 (GDUFA Generic drug user fee cover sheet) Fee- $58,530</td>
<td>Form 44 Annexure V) (Application for grant of permission to import or manufacture a new drug or to undertake clinical trials) Along with treasury challan of requisite amount Fee- Rs.15,000</td>
</tr>
</tbody>
</table>
respectively, whereas in EU, there are three regulatory agencies, they may be initiated at global level. The regulatory agency developed for Japan, European Union, and United States. Hence, the Common Technical Document (CTD) guidance has been increased demand for generics.

Thus, the proper validated regulation is required for manufacturing US is very bright as Indian government extending health care insurance whereas re-election of Barack Obama in US provides positive increase generic drugs in India and US which requires proper symbiotic need to be involved in these sectors and helps in promotion the use of generic at a low-priced price. The initiation started out via Government of India is to uplift the availability of generic medication at a cost effective rate by opening the Pradhan Mantri Bharatiya Jan Aushadhi Kendra (PMBJAK). Till now 660 shops have opened and nevertheless the wide variety counts for the good. In situations where demand for medicines exceeds supply, and cost effective drug in demand with minimum expenditure, generic drug are best choice fulfilling this demand. The current and future prospective of generics in India and US is very bright as Indian government looking towards generic drugs for providing better health care to public. Indian pharmaceutical industries grow rapidly all over the world and one of largest generic exporter in world whereas, US being the major destination for export. Thus, the proper validated regulation is required for manufacturing generic drugs in India and US which requires proper symbiotic relation between India and US. Some amendments are warranted in Hatch Waxman Act 1984 for developing generic drug in better way whereas re-election of Barack Obama in US provides positive increase in generic market as his government extending health care insurance for additional 30 million Americans in the health care ambit, creating increased demand for generics.

The International Conference on Harmonization (ICH) process, the Common Technical Document (CTD) guidance has been developed for Japan, European Union, and United States. Hence, India also follows the same. This step will ultimately reduce the need to duplicate work carried out during the research and development of new drugs. Therefore, harmonization of drug approval processes either by ICH or WHO may be initiated at global level. The regulatory agency for INDIA and US is a single agency i.e. CDSCO [7,10] and USFDA respectively, whereas in EU, there are three regulatory agencies, they are EMEA, CHMP and NATIONAL HEALTH AGENCY. Europe also has multiple regulatory procedures when compared to US and INDIA. The approval time in all the countries is almost the same i.e., 12 to 18 months. The fee for the new drug approval in US is very high when compared to EUROPE [12] and INDIA.

### Conclusion

The Drug approvals in the India, Europe & US are the most thought due in the world. The primary purpose of the rules governing medicinal products in India, Europe & US is to safeguard public health. It is the role of public regulatory authorities to ensure that pharmaceutical companies comply with regulations. There are legislations that require drugs to be developed, tested, trailed, and manufactured in accordance to the guidelines so that they are safe and patient’s well-being is protected.

### References


40. http://www.odasco.nic.in/forms/list.aspx?id=2121&i=0


