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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 of brand-name drugs. The FDA states: "Generics have the identical quality as brand identify 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 is 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 of larger scope: with 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 original developer 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

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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].

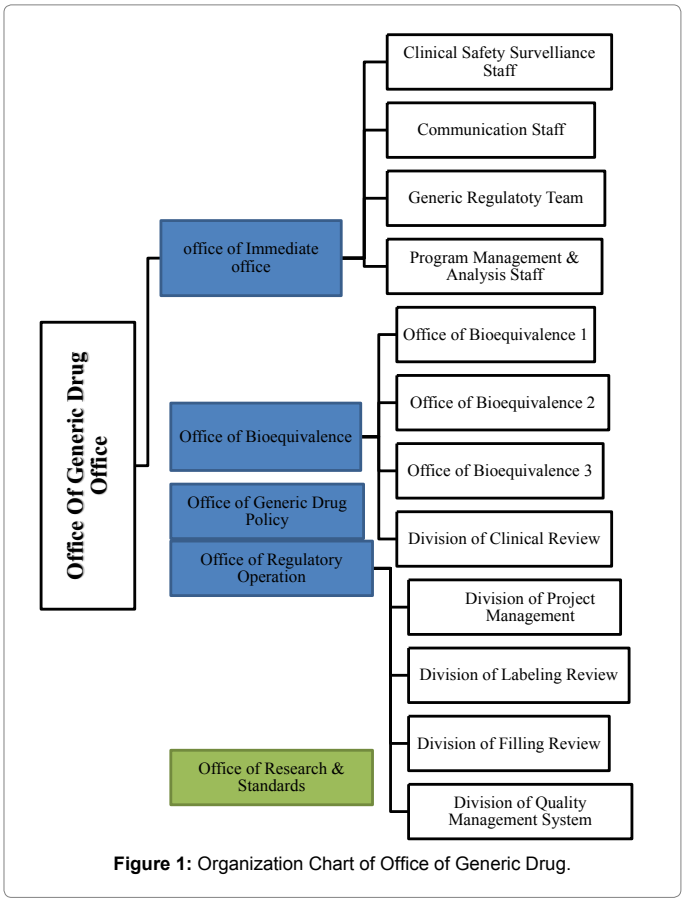

Figure 1: Organization Chart of Office of Generic Drug.

Paragraph I	For the products for which no patent information is reachable in the orange book
Paragraph II	Used for the products for which all the applicable patents are expired.
Paragraph III	Used for the products for which the 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.
Paragraph IV	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

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].

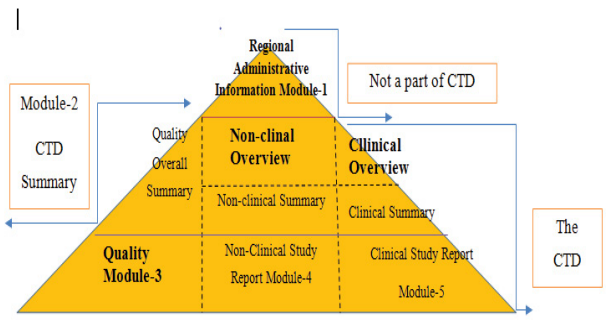

Figure 2: Common Technical Document of USA.

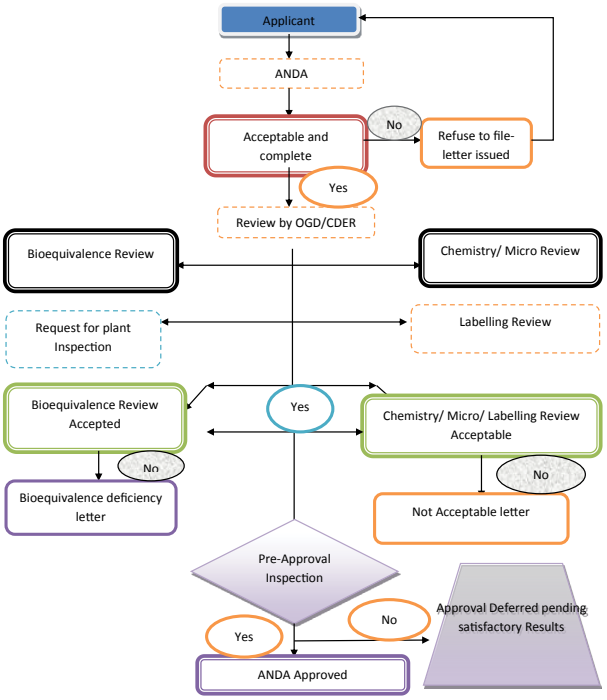

Figure 3: Flow process of ANDA Filing in USA.

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

Pros	Cons
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	Many non-public plans have been cancelled due to the fact they did not comply with Obama care.
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.	**Loss of company-sponsored health plans** Some businesses may also find it greater least expensive to pay the penalty and let their employees buy their very own insurance plan on the exchanges alternatively than furnish employer-sponsored coverage
No surprise cancellations or pre-existing denials Insurance groups can't cancel your policy because of a mistake on an application. Tax penalties	**Tax Penalties** If you are uninsured, you may additionally face large tax penalties. You will see the amount when you file your each year taxes.
Dependents stay under parents' sketch longer You can proceed to have your children insured under your health plan till they are 26	**Shrinking networks** Many insurance organizations made their issuer networks smaller in an effort to reduce expenses while implementing ACA requirements.
No more unreasonable limits. Limits on lifetime benefits have been definitely banned and annual limits phased out. (This does now not consist of grandfathered plans).Shopping for insurance can be complicated	**Shopping for Coverage can be Complicated** With the confusion surrounding the rollout of the ACA and the marketplace, constrained enrollment periods, difficulties with the web sites and extra options to pick from, purchasing for insurance can be more complicated.

Table 2: Pros & Cons of Affordable Care Act.

Drug or Drug Category	Criteria for Medication
Aspirin for Cardiovascular Disease – Generic OTC* 81 mg and 325 mg	• Men • Ages 45 to 79 years and women ages 55 to 79 year
Aspirin for Preeclampsia – Generic OTC 81 mg	Women through 55 years of age
Fluoride – Generic OTC and Rx** products	Children 6 months through 5 years old
Folic Acid – Generic OTC and Rx products (0.4 – 0.8 mg)	Women through age 50 years
Iron Supplements – Generic OTC and Rx products	Children 6 months to 12 months
Vitamin D and some Vitamin D combinations	Patients 65 years and older
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)	Women through age 50
Bowel preparation for colonoscopy screening – Generic OTC and Rx	Women and men, age 50 through 75 years Limited to 2 prescriptions in 365 days
Vaccines	Various childhood and adult vaccines are covered under the plan, in accordance with age restrictions based on vaccine

Table 3: List of medicine sold under Affordable Care Act.

S.No	Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indicator
1.	Buprenorphine and Naloxone Sublingual Film	Mylan Technologies Inc.	Suboxone	6/14/2018	For the treatment of opioid dependence.
2.	Buprenorphine and Naloxone Sublingual Film, 4 mg/1 mg and 12 mg/3 mg	Dr. Reddy's Laboratories SA	Suboxone	6/14/2018	For the treatment of opioid dependence.
3.	Buprenorphine and Naloxone Sublingual Film	Dr. Reddy's Laboratories SA	Suboxone	6/14/2018	For the treatment of opioid dependence.
4.	Oxybutynin Chloride Gel,	Par Pharmaceutical, Inc.	Gelnique	5/31/2018	A muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
5.	Tadalafil Tablets USP	Teva Pharmaceutical USA, Inc.	Cialis Tablets,	5/22/2018	Indicated for the treatment of: Erectile dysfunction (ED) • The signs and symptoms of benign prostatic hyperplasia (BPH) • Ed and the signs and symptoms of BPH (ED/BPH)
5.	Methylphenidate Hydrochloride for Extended-Release Oral Suspension	Actavis Laboratories FL, Inc.	Quillivantxr	5/17/2018	A central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)
6.	Colesevelam Hydrochloride Tablets,	Impax Laboratories, Inc.	Welchol	4/27/2018	• 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
7.	Phytonadione Tablets	Amneal Pharmaceuticals Company GmbH	Mephyton	5/11/2018	1. Anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives. 2. Hypoprothrombinemia secondary to antibacterial therapy. 3. Hypoprothrombinemia secondary to administration of salicylates. 4. Hypoprothrombinemia secondary to obstructive jaundice or biliary fistulas but only if bile salts are administered concurrently, since otherwise the oral vitamin K will not be absorbed
8.	Succinylcholine Chloride Injection USP	Zydus Pharmaceuticals (USA), Inc	Quelicin	5/4/2018	Indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation
9.	Phenylephrine Hydrochloride Injection USP,	Cipla Limited	Phenylephrine Hydrochloride	4/27/2018	Indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anesthesia
10.	Hydromorphone Hydrochloride Injection USP,	Eurohealth International Sarl	Dilaudid (Hydromorphone Hydrochloride) Injection	4/27/2018	For management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate
11.	Miglustat Capsules, 100 mg	Amerigen Pharmaceuticals Limited	Zavesca (Miglustat) Capsules, 100 mg	4/17/2018	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
12.	Loratadine Chewable Tablets USP	Sun Pharma Global FZE	Children's Claritin (Loratadine) Chewable Tablets	4/16/2018	For seasonal allergic rhinitis and idiopathic urticarial
13.	Ertapenem for Injection. 1 gram (base)/ Single-dose vial	ACS DOBFAR SPA	Invanz (Ertapenem) for Injection, 1 gram (base)/ Single-dose vial	4/16/2018	A penem antibacterial indicated in adult patients and pediatric patients (3 months of age and older) for the treatment of the following moderate to severe infections caused by susceptible bacteria: • Complicated intra-abdominal infections.
14.	Everolimus Tablets, 0.25 mg, 0.5 mg, and 0.75 mg	West-Ward Pharmaceuticals International Limited	Zortress (Everolimus) Tablets, 0.25 mg, 0.5 mg, and 0.75 m	4/12/2018	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
15.	Clozapine Orally Disintegrating Tablets,	Barr Laboratories Inc.	Fazaclo (Clozapine) Orally Disintegrating Tablets,	4/9/2018	For use as an anti-psychotic

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

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 approval of generic drug is 12-18 months. The document is submitted in actd paper. With only one copy submitted at the time of approval [46].

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

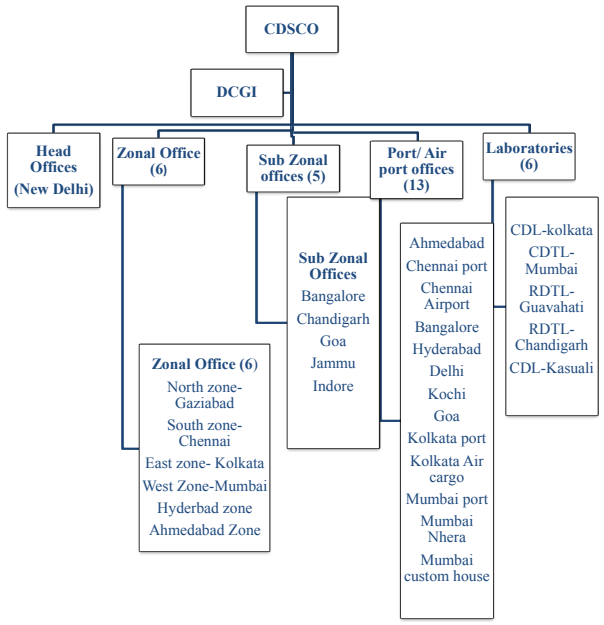

Figure 4: Chart of Organization Structure.

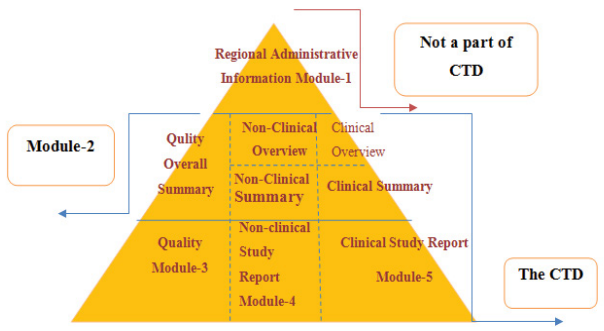

Figure 5: Indian Common Technical Document.

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].

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

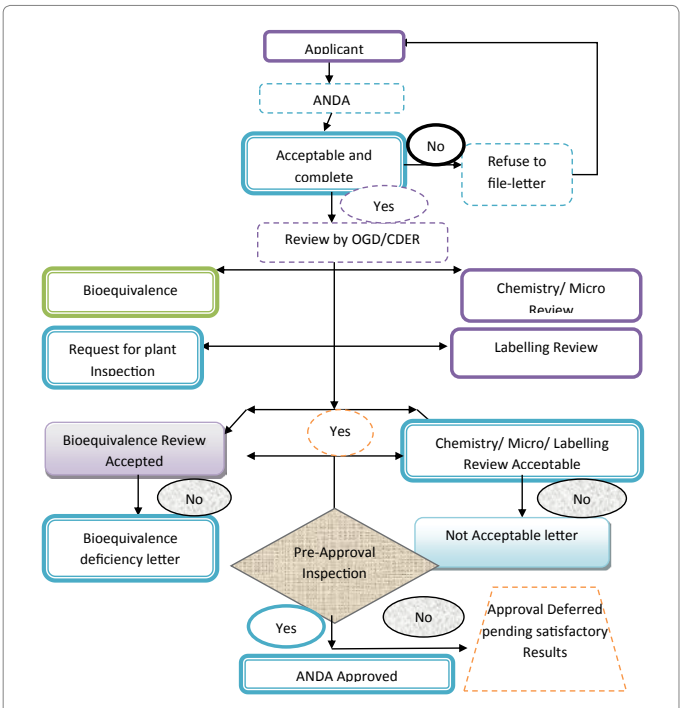

Figure 6: Approval Procedure of Generic Drug in India.

For Individual	Institutions/NGO/ Charitable Institute/Hospital	Government/ Govt Nominated Agency
1) Adhaar card 2) Pan card	1. Aadhaar card 2. Pan card 3. Certificate for incorporation 4. Registration certificate	1. Details of department who has allocated the space, along with supporting documents/ sanction order 2. Pan card 3. Aadhaar card

Table 5: Documents Required for Jan Aushadhi Store.

S. No	Generic Name	Strengh	Type	Jan Price (in Rs)	Brand Name	Manufacture	MRP (in Rs)
A. Analgesic Anti-Inflammatory							
1.	Diclofenac Sodium	50 mg	tablets	2.10	Diclomax	Torrent	7.65
					Vovoren	Novartis	12.60
2.	Ibuprofen	200 mg	tablets	2.66	Ibugesic	Cipla	3.63
					Sugafen	Nicholas Piramal	3.69
3.	Paracetamol	500 mg	tablets	2.45	Crocin	Glaxo-smithkline	11.00
					Calpol	Glaxo-smithkline	10.70
4.	Nimesulide	100 mg	tablets	2.70	Novogesic	Glenmark	17.90
					Nise	Dr. Reddy's lab	32.00
5.	Aceclofenac	100 mg	tablets	8.00	Hifenac	Intas	19.50
					Zerodol	Ipca	22.00
B. Anti-Bacterial							
1.	Amikacin	100 mg / 2 ml	Vials/ Ampoules	6.25	Amexel	Nicholas Piramal	15.10
					Aminat	Natco	14.97
2.	Amoxycillin	125mg	Tablet	9.95	Moxibact	Sun	20.10
					Dynamox	Micro Lab	16.00
3.	Ampicillin	500mg	Capsule	21.85	Zycilin	ZydusCadila	58.00
					Roscillin	Ranbaxy	62.50
4.	Azithromycin	250 mg	Tablets	41.80	Azee	Cipla	107.83
					Zathrin	FDC	89.00
5.	Cefadroxil	250 mg	Tablets	14.55	Cimdrox	D C M Lab	21.50
					Cedril	Stallion Lab	37.45
C. Anti-Infective							
1.	Povidine Iodine	7.5%w/v	lotion	106.70	Alphadine	Nicholas	155.0
					Betadine	Win-medicare	308.00
2.	Benzyl benzoate	25%w/v	lotion	14.00	Benzyl benzoate application	Agarwal	29
					Dermin Lotion	Bal. Pharma	24
3.	Silver sulphadiazine	1%w/v	Ointment	9.00	Silvindon	Zy.Indon	11.53
D.Gastro-Intestinal tract							
1.	Pantaperazole	20 mg	Tablets	7.80	Aciban	Cadila	18.55
					Pan-20	Alkem	31.00
2.	Ondanstron	4 mg	Tablets	8.00	Anset	Bennet Pharma	39.00
					Emeset	Cipla	98.44
3.	Rabeprazole	20 mg	Tablets	13.70	Rab	Khandelwal	49.00
					Rabium	Intas	17.70
4.	Ranitidine	300 mg	Tablets	7.50	Acibloc	Marc Labs	12.75
					Histac	Ranbaxy	8.74
E. **Respiratory Tract**							
1.	Cetrizine Hydrochloride	10 mg	Tablets	2.75	Cetpine	Petrosolv	12.00
					Cetiriz	Alkem	29.95
2.	Cetrizine Syrup	5 mg per 5 ml	Oral Liquid	9.60	Zyncet	Unichem	26.00
					Taurcet	Taurus Lab	24.90
3.	Levocetrzine	5 mg	Tablets	5.80	L-cetrizet	Sun	29.70
					Ly- Zyncet	Unichem	33.15
4.	Doxofylline	400 mg	Tablets	14.67	Asmadox	Alchemist	59.00
					Doxobid	Dr. Reddy's lab	78.30

Table 6: List of Medicine sold under Pradhan Mantri Jan Aushadhi Kendra.

S.No	Generic Name	Therapeutic Uses	Date of Issue
1.	Tenofovir Alafenamide Hemi fumarate. Bulk & Emtricitabine 200 mg/200 mg + Tenofovir Alafenamide	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	10.01.2018
2.	Clofarabine Bulk & Injection	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	16.01.2018
3.	Denaverine Hydrochloride	cattle : Facilitation of parturition in heifers; activation of cattle : Facilitation of parturition in heifers; activation of interrupted parturitions; insufficient opening of the soft birth canal; narrowness 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	16.01.2018
4.	Netupitant 300 mg + Palonosetron	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	20.02.2018

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-files 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 ectoparasites- lice, fleas, pasture ticks, notedric mange (feline scabies), "walking" dandruff (cheyletiellosis) 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 exuding 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 Thromoembolic 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/10 mg/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.

S.No	Requirements	US- Food And Drug Administration	India-Central Drug Standard Control Organization (CDSCO)
1.	Application	ANDA	MAA
2.	Debartments Certification	Required	Not Required
3.	No. of Copies	3	1
4.	Approval timeline	18 months	12 months
5.	Fees	No Fees	50,000
6.	Presentation	eCTD	CTD
	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 Month6 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.

S. No	MODULE 1.		
	Parameters	**US**	**India**
1.	**General information Covering letter, Table of Components (Module 1 to Module 5) Required**	Required	Required
2.	**Administrative Information**		
	A. Forms	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	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

	B. Agent Authorization	Required	Not required
	C. General information of drug product	Required	Required
	D. Data/market exclusivity	Patent certification	Not required
B.	**Module-2**		
1.	**Quality based review**	Required	Not required
C.	**Module-3**		
1.	**(3.2.S.1.1) Specified numbers**	Central File Number (CFN), Data Universal Numbering System (DUNS), Facility Establishment Identifier (FEI	Chemistry Abstract number
2.	**(3.2.S.4.6) Justification of Specification**	required	Not required
3.	**(3.2.R) Regional Information**	i) Executed batch record and blank master batch record for manufacturing and packaging are provided ii) According to USP declaration is impurities given for the residual solvents limits or present indrug substance and excipient iii) Information on components including and not limited to applicant and suppliers COA for drug substance lots, package material etc. are provided) Comparability protocol are provided iv) Comparability protocol are provided v) Methods validation packages are provided vi) Certificate of suitability are not provided vii) BSE and TSE certificate are to be attached	Not applicable
D.	**Module-5**		
1.	**Study design**	Randomized, Crossover, Non replicated	Two separate (one in fasted state and other in the fed state), Two way cross over design, Parallel design
2.	**Fasting/Fed state studies**	Fasting and feed	Fasting and feed
3.	**Number of subjects**	Sufficient to achieve adequate power	Minimum number of subjects not less than 16
4.	**Sampling points**	3 samples during absorption phase, 3-4 at Tmax, 4 points during elimination phase	12-18 samples to be collected, to be continued upto 3 or more half-lives, atleast 3-4 samples should be collected at Tmax
5.	**Analytical method validation parameters**	Stability of the drug, Specificity/Selectivity, Sensitivity, Precision, Accuracy, Recovery, Range and Linearity	Accuracy, Precision, Sensitivity, Selectivity, Reproducibility, and Calibration curve, LOQ and Stability.

Table 9: Comparative Study of CTD Requirement for Filing of Generic Drug.

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 Bharitiya 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.

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