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Review Article

Understanding Regulatory Affairs In The Pharmaceutical Industry: Roles, Importance, And Global Perspectives

Sanskruti Wagh*[1], Waghmare S. U.[2], Priyanka Narode[3], Prasad Shelke[4], Vaishnavi Borhade[5], Rohini Kawar[6]

[1,3,4,5,6]UG Scholar, Rashtriya College of Pharmacy, Hatnoor, Kannad, Chh. Sambhajinagar, Maharashtra, India
[2]Assistant Professor, Rashtriya College of Pharmacy, Hatnoor, Kannad, Chh. Sambhajinagar, Maharashtra, India

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ABSTRACT

Regulatory affairs (RA) professionals play critical roles in the pharmaceutical industry because they are concerned about the healthcare product lifecycle Direction and support for working within rules to speed up the development and delivery of safe and effective healthcare goods to people worldwide, including strategic, tactical, and operational guidance. In pharmaceutical companies, regulatory affairs is a respected, intellectually stimulating, and challenging career.

INTRODUCTION

Regulatory Affairs, also known as government Affairs, is a profession in regulated industries, including pharmaceuticals, clinical gadgets and so on. The Regulatory Affairs profession at its heart is all about gathering, studying and speaking about the danger & amp; advantages of healthcare products to regulatory organizations and the public all globally. Drug Regulatory Affairs is a brand new carrier that has been initiated by governments to defend public health with the say of controlling the production efficacy of products in the area together with prescribed drugs, veterinary drugs treatment, medical devices, insecticides, agrochemicals, cosmetics & amp; complementary medicines. success of regulatory strategies is less dependent on the regulations than on how they are interpreted, applied and communicated within companies and outside constituent. (1)

Importance of Regulatory Affairs

The first point of contact between the corporation and the government agency is the regulatory affairs division. Aids in coordinating research efforts with regulatory requirements. Maximize

***Corresponding Author:** Sanskruti Wagh
Address: *UG Scholar, Rashtriya College of Pharmacy, Hatnoor, Kannad, Chh. Sambhajinagar, Maharashtra, India.*
Email : waghsankruti@gmail.com

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resource efficiency for the business. Inform the company of the perspective of the government. Impact their companies, strategic decisions. Assist in getting the medication onto the market on time, as even a small delay could negatively impact the company's financial standing. Notify higher authorities with the specific marketing information. .(2)

Need of Regulatory Affairs

Ensuring that their companies namely with all of the system policies and laws pertaining to their business. collaborating with national, state, and local regulatory organizations, including the Food and Drug Administration or the European Medicines Agency. advising their businesses on the regulatory landscapes and issues that could impact suggested initiatives like the support of prescription medication .(3)

Drug regulatory Affair professional

The duty of the Regulatory Affairs expert is to keep up with the continuously changing rules in all of the countries where The business wants to to sell its products. Experts in regulatory affairs are in charge of submitting registration documents to regulatory bodies and conducting all required negotiations to maintain the products' availability on the market. They provide technological and strategic support at the highest levels of their businesses from the outset of a product's development, making a significant financial and clinical contribution to the development effort's advancement and the company's overall success.

The Regulatory Affairs Department's duties are listed below:

- Stay up to date on international regulations, rules, and consumer behavior.
- Keep abreast of a company's product offerings.
- Verify if a company's products comply with current laws.
- The Regulatory Affairs professional's role is to stay on top of the constantly evolving regulations in all of the countries where the organization wants to sell its goods. They will acquire, compile, and evaluate the scientific data produced by their colleagues in research and development, in addition to offering legal and technical advice.
- Create a regulatory plan and include all required submissions for contract, international, and domestic projects. Coordination, planning, and review of all pertinent paperwork, including dossiers, should be done in conjunction with the agency. All paperwork should be sent to regulatory authorities on time. Create and research SOPs pertaining to RA Records linked to BMR, MFR, shift control, and other topics are examined.
- Monitor the status of each and every registration. Observe approved applications and registration costs paid for DMFs and other documentation. Give R&D, the Pilot Plant, ADL, and RA training. members of the team regarding current legal obligations.. (4).

COMMON TECHNICAL DOCUMENT (CTD):

A standardized set of standards for the application dossier used to register medicines is known as the Common Technical Document (CTD).It is intended for use in the United States, Europe, and Japan. For the goal of getting ready to submit new medication applications to regional authorities in these countries, the CD format is widely recognized. The Food and Drug Administration (FDA) in the US, the Ministry of Health, Labor, and Welfare in Japan, and the European Medicines Agency (EMA) in Europe worked together to generate this paper. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is in charge of maintaining the CTD. (5)

Objectives of CTD

- The main objective is to reduce the time required and resources utilized to assemble apps.
- It will facilitate the process of getting ready to submit electronically.
- To facilitate simultaneous submission in three regions.
- It will facilitate the sharing of regulatory data, ensuring quicker availability of new medicine.(6)

Regulatory Bodies Around Worldwide:

Region	Country name	Regulatory agencies/ body	Reference
Australia / New Zealand	Australia	Therapeutic goods Administration (TGA)	https://www.tga.gov.au/
	New Zealand	MEDSAFE	https://www.medsafe.govt.nz/
North America	Canada	Health Canada	https://www.canada.ca/en/health-canada.html
	USA	Food and Drug Administration (FDA)	https://www.fda.gov/
Europe	America	Scientific Centre for Drug and Medicinal Technology Expertise	https://www.pharm.am/index.php/en/contacts
	Austria	Agency for Health and Food Safety (AGES).	https://www.ages.at/en/
	Bulgaria	Bulgarian Drug Agency.	https://bda.bg/en/
	Belgium	Federal Agency for Medicines and Health Products	https://www.famhp.be/en
	Cyprus	Ministry of Health	https://www.moh.gov.cy/moh/moh.nsf/index_gr/index_gr?OpenDocument
	Croatia	Agency for Medical Products and Medical Devices of Croatia	https://www.halmed.hr/en/
	Czech Republic	State Institute for Drug Control	https://www.sukl.eu/
	Denmark	Danish Medicines Agency.	https://laegemiddelstyrelsen.dk/en
	Estonia	State agency of Medicines	https://www.ravimiamet.ee/en
	Finland	Finish Medicines Agency	https://fimea.fi/web/en
	Germany	Federal Institute for Drugs and Medical Devices	https://www.bfarm.de/EN/Home/_node.html
	Georgia	Regulation agency for Medical and Pharmaceutical Activities	https://matsne.gov.ge/en/document/view/29836?publication=30
	Greece	National Organization for Medicines	https://www.eof.gr/web/guest;jsessionid=3a269778c27ce43bdd7b334a0b69
	Hungary	National institute of pharmacy.	https://egeszsegvonal.gov.hu/en/health-care-system/national-institute-of-pharmacy-and-nutrition-ogyei.html
	Ireland	Irish Medicines Board.	https://www.hpra.ie/
	Iceland	Icelandic Medicines Agency	https://www.ima.is/
	Italy	National institute of Health	https://www.iss.it/web/iss-en
	Lithuania	State Medicines Control Agency	https://globaledge.msu.edu/global-resources/resource/10379
	Luxembourg	Ministry of health	https://m3s.gouvernement.lu/en.html

	Malta	Maltese Medicines Authority. And Moldova Medicines Agency	https://medicinesauthority.gov.mt/
	Netherlands	Medicines evaluation Board.	https://english.cbg-meb.nl/
	Norway	Norwegian Medicines Agency	https://www.dmp.no/en
	Portugal	National Authority of Medicines and Health Products	https://www.infarmed.pt/web/infarmed-en/human-medicines
	Romania	National Medicines Agency	https://www.anm.ro/en/
	Poland	The Office for Registration of Medicinal Products, Medical Devices and Biocidal product	https://www.infarmed.pt/web/infarmed-en/human-medicines
	Russia	Ministry of Health of the Russian federation.	https://minzdrav.gov.ru/en
	Serbia	Medicines and Medical Devices Agency of Serbia	https://www.alims.gov.rs/english/
	Slovakia	State Institute for drug Control	https://www.sukl.sk/hlavna-stranka/english-version?page_id=256
	Slovenia	Ministry of Health.	https://www.gov.si/en/state-authorities/ministries/ministry-of-health/
	Spain	Spanish Medicines Agency.	https://www.aemps.gob.es/?lang=en
	Sweden	Medical Products Agency	https://www.lakemedelsverket.se/en
	Switzerland	Swiss Agency for Therapeutic Products.	https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products.html
	Ukraine	Ministry of Health.	
	United Kingdom	Medicines and Healthcare regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency?ref=vzk.ru
Middle East	Egypt	Ministry of Health	
	Iran	Ministry of Health	https://irangov.ir/ministry-of-health-and-medical-education
	Israel	Ministry of Health	https://www.gov.il/en/departments/ministry_of_health/govil-landing-page
	Jordan	Jordan Food and Drug Administration	https://portal.jordan.gov.jo/wps/portal/Home/GovernmentEntities/Ministries/Ministry/Ministry%20of%20Health/Jordan%20Food%20and%20Drug%20Administration/!ut/p/z1/hdDJCsIwEAbgV4kPIBNjKvQYutlNsArWXCTQLaBJiXXp21tqr9a5DXzD_DPAIQeuxFPWopNaievQn_nmwqh3tHDAwj3JKGbJzvGCJIv2GYHTCPCPYhj4_PyhVBD9Q0MKYlInrYG3omuWUlUa8lQqee9Mj3SFtqW4dg3kkTaFUMjXukBCFcg1jxqx4v

			al41VDZD67kJJ5wFabCVi2GwZOjFPsE2sAdmzH1FpjTCcw85f2lr_6tx3KkC0-kS9Oiw!!/
	Saudi Arabia	Saudi Food and Drug authority.	https://www.sfda.gov.sa/en
Central /South America	Argentina	ANMAT	https://www.argentina.gob.ar/anmat
	Brazil	Agencia Nacional de Vigilancia Sanitaria	https://www.gov.br/anvisa/pt-br/english
	Columbia	Instituto Nacional de VigilanciaMedicamentos y Alimentos. (INVIMA)	https://www.invima.gov.co/
	Jamaica	Ministry of Health	https://www.moh.gov.jm/
Asia- Pacific	India	Central drug Standards Control Organization (CDSCO).	https://cdsco.gov.in/opencms/opencms/en/Home
	Bangladesh	Bangladesh Indonesia – POM (pengawasObat Dan Makanan)	https://en.wikipedia.org/wiki/Indonesian_Food_and_Drug_Authority
	Japan	Ministry of Health, Labor and Welfare. (MHLW)	https://www.mhlw.go.jp/english/
	South Korea	Korean Food and Drug Administration. (KFDA).	https://www.mfds.go.kr/eng/index.do
	Laos	Food and drug Department	
	Malaysia	Ministry of Health. (MOH)	https://www.moh.gov.my/
	Nepal	Department of Health Administration.	https://mohp.gov.np/en/
	Philippines	Department of Health. (DOH).	https://doh.gov.ph/
	Singapore	Health Sciences Authority (HAS).	https://www.hsa.gov.sg/
	Sri-Lanka	Ministry of Health	https://www.health.gov.lk/
	Taiwan (Republic of china)	Taiwan food and Drug Administration	https://www.fda.gov.tw/ENG/index.aspx
	Thailand	Food and Drug Administration of Thailand	https://en.fda.moph.go.th/
	Vietnam	Drug Administration of Vietnam	https://dav.gov.vn/en
Africa	Algeria	Ministry of Health and Population	https://ghdx.healthdata.org/organizations/ministry-health-population-and-hospital-reform-algeria
	Botswana	Ministry of Health	https://www.moh.gov.bw/
	Ghana	Food and Drug Authority.	https://www.fdaghana.gov.gh/
	Kenya	Pharmacy and Poison Board.	https://web.pharmacyboardkenya.org/
	Morocco	Ministry of Health	https://www.sante.gov.ma/Pages/Accueil.aspx
	Rwanda	Ministry of Health	https://www.moh.gov.rw/
	South Africa	Medicines Control Council. (MCC).	https://www.mccza.com/main/
	Swaziland	Ministry of Health	https://www.gov.sz/index.php/ministries-departments/ministry-of-health

	Uganda	National Drug Authority	https://www.health.go.ug/cause/annual-pharmacovigilance-report-national-drug-authority/

Table No.: 1 Regulatory Bodies Around Worldwide

Modules of CTD

Goals of CTD:

- The principal aim is to minimize the amount of time and resources needed for application compilation.
- It will aid in the preparation of electronic application submissions.
- To enable concurrent submission in three areas.
- It will facilitate the exchanging regulatory data, resulting in expedited access to novel medications. (7)

It can be organized into 5 Modules:

- Module 1: administrative and prescribing information
- Module 2: common technical documents CTD summaries
- Module 3: Quality data
- Module 4: Nonclinical study reports
- Module 5: Clinical study reports

Significance

- It offers data in an appropriate manner that is simple to comprehend and aids in data evaluation.
- CTD is is relevant to every all kinds of goods. This additional format makes the reviewer's job easier as well.
- In addition, CTD facilitates the exchange of regulatory data and the simultaneous filing of archives for approval in three locations. Additionally, it facilitates electronic submissions and expedites the provision of novel pharmaceutical treatments to patient cohorts. (8)

Benefits of CTD

1.Establishing a standard submission format is primarily intended to streamline the application review process and prevent the omission of important information or analysis. If these particulars are omitted, approvals may be unduly delayed.

2. the amount of effort and materials required to to put together applications in order to register human medicines will be significantly reduced by the adoption of a standard layout for technical material. It will also make the process of preparing electronic submissions easier.

3. The utilization of a standardized document containing recurring components will enhance regulatory examinations as well as facilitate communication between the regulatory authorities and the applicant.

4. It is projected that the industry will save a great deal of time and money by using the Common Technical Document (CTD) instead of assembling applications for worldwide registration.

5. Furthermore to raising the bar for Indian norms, the CTD gives the application process broad a methodical framework. The CTD's adoption will also facilitate the ability of regulatory bodies to to communicate information about regulations with one another. (9)

eCTD: Electronic Common Technical Document

The electronic Common Technical Document (eCTD) is used by the pharmaceutical industry to send regulatory data to regulatory agencies. It is based on the Multidisciplinary Group 2 Expert Working Group of the International Conference on Harmonization (ICH) (ICH M2 EWG), which created the Common Technical Document (CTD) format. The eCTD's transport format, which is designed to be easily transferred into the review setting of an agency, environment, makes electronic submissions viable. It facilitates the agency's receipt of regulatory data from the industry and eases the creation, evaluation, life-

cycle management, and archiving of electronic submissions. The requirements for guaranteeing the technical correctness of electronic submissions are outlined in the eCTD specifications. This progress in information submission is very helpful to the new drug approval procedure. With a single keystroke in the future, businesses might even be able to submit their applications to several regulatory bodies at once (10)

1. The benefits of eCTD Better storing and handling of submissions advantages of computerized prescription medication
2. Improved data arrangement
3. Support for life cycle management
4. Quick access to up-to-date and thorough information
5. Reviewers' improved tracking abilities and search tools
6. A more efficient evaluation procedure and enhanced process transparency
7. Minimal effort and information use for assessment reports
8. Managed communication with other experts
9. Optimal utilization of accessible resources
10. Better communication with the industry.
11. Optimized business processes. (11)

Requirements to submission of eCTD Documents:

❖ **Transmitting A Submission:**

There are two ways For Electronically submission to CDER:

- ESG, or Electronic Submissions Gateway, is the recommended approach. Physical media, which could be a DVD/CD-ROM or USB drive
- The FDA Electronic Submissions Gateway is the mandatory mode of transmission for eCTD 10GB or less and is an agency-wide system for receiving electronic regulatory submissions. (12)

❖ **Clinical Study Report:**

The overview, report body, and individual appendices are its constituent sections. A top-level folder hierarchy is necessary. A "backbone" file in Extensible Markup Language (XML) that gives the receiving system lifecycle instructions and metadata about content files.(13)

❖ **Hyperlink, Bookmark, Numbering :**

Hypertext links and bookmarks are techniques used to improve navigation through PDF files. Hypertext links can be identified by blue text or by rectangles with thin lines around them.. The bookmark hierarchy must match the contents table exactly, with no further bookmark levels added on top of what is already there. It is advised to employ no more than four tiers in the hierarchy. When When establishing bookmarks and hyperlinks, make sure to use the Inherit Zoom magnification setting, which will ensure that the destination page appears at the same magnification level as the rest of the content. (14)

❖ **File Naming:**

File names, including the extension, must not exceed 64 characters. Also, folder names must not exceed 64 characters and the total file folder path length must not exceed 180 characters.

❖ **PDF Size:**

FDA page size for US Letters

All four sides of pages should have a one-inch margin, plus extra space for the binding edge (to prevent problems if documents need to be printed). Either Times New Roman or Ariel fonts must be used for the content, with body text set at 12 points and tables no less than 10 points.

❖ **Version:**

Agencies should be capable of use Acrobat Reader version 4.0 or higher to read all PDF files. It should not be required for agencies to use any extra software to be able to view and navigate PDF files.

❖ **Harmonize documents, data and submission Standard:**

Reusing transferring content from one area to another is made possible by harmonizing standards and all content related to submissions in one location.This is among the greatest ways to accomplish this. This would expedite the submission process by drastically lowering the quantity of repetitive work needed to submit an applicationmany nations or regions. (15)

- **Quality Control reviewing at the right point:**

The publishing workflow shouldn't begin until all source documents have undergone quality control checks.

It is recommended to review all published PDF files on a screen.

Verify the links and bookmarks in published PDF files.

eCTD submissions should always be validated and conformity-checked before being submitted

- **Submitting of eCTD Sample :**

To submit a sample eCTD, you must first obtain an application number from the Electronic Submissions Team at esub-testing@fda.hhs.gov; this number should only be used for the sample and not for the real eCTD submission. Following submission of our request and contact information, a member of the Electronic Submissions Capability Team will be in contact. and include a Sample Application Number along with additional instructions..

- **Requesting** an application number that was pre-assigned:**:**

We must obtain a priori issued application number submitting an application in in eCTD configuration to CDER. Pre-assigned application numbers are distinct six-digit numbers, such as 012345, that are given to sponsors so they may be identified

usage. It is required by the FDA to use this number.

whenever you submit an application for eCTD

Advantage of eCTD :

1) advantage over paper submissions is that it is more efficient.

2] Increased Procedure Visibility.

3] Shorter Lead Time and Speedier Approvals.

4] A uniform submission procedure and format.

5] Growth within the marketplace and Revenue.

6] Enhanced Capability to Track.

Publishers may try to prevent validation problems if the annual report is written as a single document by organizing it into a single node that corresponds to one of the annual report sections (e.g., Summary for Nonclinical Studies). This strategy, nevertheless, runs the possibility of creating confusion throughout the review process because the content will not match the node description exactly(16)

NDA APPLICATION

An NDA application must be submitted to the FDA prior to a novel medicine being put on the market. In order to receive this approval, the sponsor provides the NDA A clinical and preclinical examination findings for the analysis of drug information along with a description of the production methods. After the agency receives the NDA, it goes through a technical screening and evaluation process. The evaluation and its supporting documentation ensure that sufficient information and data have been supplied in each area to back up the FDA's official review.

The sponsor may be advised of three possible courses of action once the FDA evaluates an NDA:

Not Approvable: This letter lists the shortcomings and provides an explanation of the decision.

2. Approvable: Thus, it follows that while the drug might be approved, there might be a few minor problems that must be resolved, like labeling changes or a possible need for a commitment to conduct post-approval study.

3. Approval: This signifies that the drug has been given the go-ahead.

Clinical studies are conducted in many phases:

Pre-clinical research: In this study, mice, rats, rabbits, and monkeys are used to evaluate the medication.

- Phase I: It's a human pharmacology trial that focuses on estimating the safety and tolerability of the drug.
- Phase II: This one's an exploratory trial designed to evaluate the drug's short-term side effects and effectiveness.
- Phase III - Confirmatory trials: These studies are carried out to verify the therapeutic advantages of a certain intervention

Phase IV - post-marketing trial: These studies were carried out after a medication's approval to gather further details.

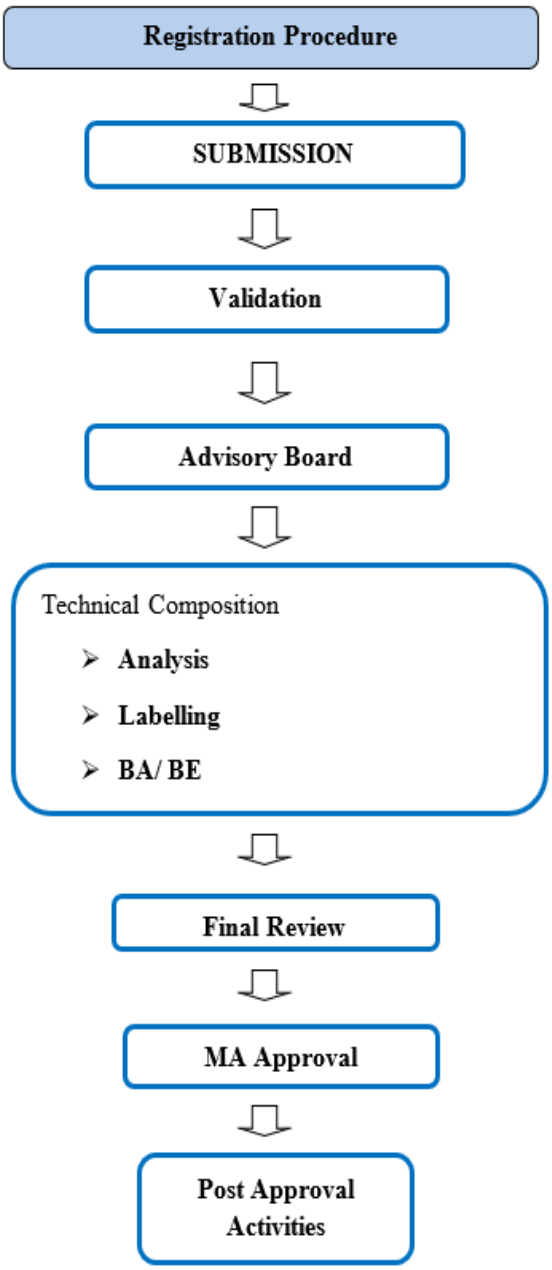

Fig. 1: NDA Approval Procedure

List of New Medicines Authorized for the Year 2023

1)	Name of Drugs	Indication	Date of issue
	Fesoteroterodine Fumarate Extended ReleaseTablets 4mg and 8mg and Fesoteroterodine Fumarate Bulk	In large recommended for the management of overactive bladder symptoms, including urgency, frequency, and urge urine incontinence	06-01-2023
2)	Trifarotene 50 microgram/g (0.005% w/w) Cream	Indicated for the cutaneous treatment of Acne Vulgaris of the face and /or trunk inpatients12 years of age and older.	13-01-2023
3)	Crisaborole Ointment 2%	Indicated for topical treatment of mild to moderate a topic dermatitis in adult and paediatric patients 2 years of age and older	20-01-2023
4)	Prussian Blue Insoluble 340 mg and Magnesium Hydroxide500 mg Capsule	In order to improve the rates of removal, this decorporation agent is recommended for patients who have internal contamination with radioactive cesium and/or radioactive or non-radioactive thallium, whether it is known or suspected..	20-01-2023
5)	Bulk Drug Prussian Blue Insolube and Prussian Blue Insolube 340 mg Capsule	As decorporation agent recommended to boost the rates of removal in individuals with known or suspected internal contamination with radioactive cesium and/or radioactive or non-radioactive thallium.	27-01-2023
6)	Imeglimin Hydrochloride Tablet 500mg/1000mg	Type2diabetesMellitus	06-01-2023
7)	Crisaborole Bulk Drug	Suitable for mild to moderate topical treatment a topic dermatitis in adult and pediatric patients 2 years of age and older	10-02-2023
8)	1 mg and 2 mg of remifentanil hydrochloride for injection	As an analgesic during the onset and maintenance of general anesthesia, for both inpatient and outpatient treatments. For continued use as an analgesic in adult patients in a postoperative anesthetic care unit or critical care facility during the immediate postoperative period, under the close supervision of an anesthesiologist.	15-02-2023
9)	Cannabidiol Bulk Drug, Cannabidiol Oral Solution100mg/ml	praised for treating children with seizures related to Lennox-V-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex who were one year of age or older.	06-04-2023
10)	Ibuprofen Sodium Dihydrate Bulk Drug, Ibuprofen Sodium Dihydrate 256/512mg Tablet	For the symptomatic treatment of mild to moderate pain, including fever, sore throat, rheumatic and muscle pain, headache, backache, menstrual pain, tooth pain, neuralgia, and migrane symptoms.	26.04.2023
11)	Niraparib Tablet 100 mg	Adult patients with advanced epithelial (FIGO stage III and IV) high-grade ovarian, fallopian tube, or primary peritoneal cancer who show partial or full response to first-line platinum-	01.05.2023

		based chemotherapy can benefit from niraparib as a monotherapy for maintenance. As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partia) to platinum-based chemotherapy	
12)	Polmacoxib Bulk Drug, Polmacoxib Capsule2mg	Indicatged for treatment of Idiopathic (primary) osteoarthritis of Hip / Knec	01.05.2023
13)	Dalbavancin Hydrochloride Bulk Drug, Dalbavancin Injection 500mg	Acute bacterial skin and skin structure infections (ABSSSI) are caused by susceptible isolates of the following Gram-positive microorganisms: streptococcus pyogenes, streptococcus agalactiae, streptococcus dysgalactiae, and staphylococcus aureus (including methicillin-resistant and methicillin-susceptible strains), streptococcus agalactiae, streptococcus dysgalactiae, streptococcus anginosus group (including S.anginosus, S.intermedius,S.constellatus) and Enterococcus faecalis (vancomycin susceptible strains).	23.05.2023
14)	LobeglitazoneSulfate 0.5mg + Glimepiride 1mg Tablets	Indicated an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a thiazolidinedione and sulphoryl urea or who have inadequate glycemic control on a thiazolidinedione alone or a sulphonyl urea alone.	23.05.2023
15)	Sovateltide Bulk Drug &Sovateltide Injection 30µg	Cerebral ischemic Stroke.	31.05.2023
16)	Lifitegrast Bulk drug &Lifitegrast Ophthalmic Solution 5 %w/v	recommended for the management of dry eye disease (DED) symptoms and indicators.	05.06.2023
17)	Plecanatide Bulk Drug &Plecanatide Tablets 3 mg	1.) Chronic idiopathic constipation (CIC)2.) Irritable bowel syndrome with constipation (IBS-C)	08.06.2023
18)	Treprostinil Bulk Drug and Treprostinil Solution for infusion 1mg/ml & 10mg/ml	For the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of disease in patients classifiedas New York Heart Association (NYHA) functional class III	27-07-2023
19)	Icaridin API and Icaridin 20% w/v Spray	Indicated for mosquito and insect repellent	19-09-2023
20)	Inclisiran solution for injection in prefilled syringe 284 mg/1.5 ml	Inclisiran is is recommended as a dietary supplement for persons with mixed dyslipidemia or primary hypercholesterolemia (both heterozygous familial and non-familial): - - when combined with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goal with the maximum tolerated dose of a statin, or - alone or in combination with other lipid	22-09-2023

		lowering therapies in patients who are statin in tolerant, or for whom a statin is contraindicated	
21)	Relugolix Bulk Drug and Relugolix Tablet 120 mg	For the treatment of adult patients with advance prostate cancer	16-10-2023
22)	Asciminib film – coated 20 mg and 40 mg tablets	Asciminib is indicated for therapy for adult individuals with -Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronicphase (CP), previously treated with two or more tyrosinekinase inhibitors (TKIs) -Ph+CML in CP with the T315I mutation	20.10.2023
23)	Lasmiditan Hemi succinate Bulk Drug &Lasmiditan Tablet 50 mg/100 mg	Indicated for the acute treatment of migraine with or without aura in adult	29.11.2023
24)	Abrocitinib Tablets 50mg,100mg &200 mg	Indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other with other systemic drug products, including biologics, or when use of those therapies is inadvisable	29.11.2023

Table No. 2 : List of New Drugs approved in the year 2023

List of New Drugs approved in the year 2024 till date

Sr.no.	Name of drug	Indication	Date of issue
1)	Tirzepatide 2.5mg /0.5ml, 5mg/0.5ml,7.5mg/0.5 ml,10mg/0.5 ml,12.5mg/0.5ml,15mg/0.5 ml solution for injection in aprefilledpen	recommended as a supplement to diet and exercise in persons with diabetes to enhance glycemic control	19-01-2024
2)	Plazomicin injection 500mg /10ml (50mg/ml)	Indicated in individuals who are to treat complex UTIs (complex urinary tract infections), which include pyelonephritis brought on by the following susceptibility microorganism(s) • Escherichiacoli, • Klebsiellapneumoniae, • Proteusmirabilis,and Enterobactercloacae	02-02-2024

Table No. 3 : List of New Drugs approved in the year 2024

List Of Pharmaceuticals Prohibited By The Ministry Of Health And Family Welfare From Being Made Or Sold Through Gazettle Notifications Under Section 26a Of The Drugs & Cosmetics Act 1940

Sr. No.	Drugs Name	Notification No. & Date
1)	Amidopyrine.	GSR NO. 578(E)Dated23.07.1983
2)	Combinations of vitamins at fixed dosages with tranquilizers and anti-inflammatory drugs	GSR NO.578(E) Dated23.07.1983
3)	Atropine fixed dose combinations for antipyretics and analgesics	GSR NO. 578(E)Dated23.07.1983
4)	Strychnine and caffeine at fixed dose combinations in tonics.	GSR NO.578(E)

		Dated23.07.1983
5)	Fixed dosage combos of vitamins, testosterone, and strychnine with yohimbine	GSR NO.578(E) Dated23.07.1983
6)	Fixed dosage combos of iron, arsenic, and strychnine and Yohim.	GSR NO.578(E) Dated23.07.1983
7)	Phenacetin.	GSR NO.578(E) Dated23.07.1983
8)	Combinations of antihistaminic and anti-diarrheal medications at fixed dosages	GSR NO.578(E) Dated23.07.1983
9)	Combinations of Penicillin with Sulphonamides at fixed doses..	GSR NO. 578(E)Dated23.07.1983
10)	Any other tetracycline at fixed dose combinations with vitamin C	GSR NO. 578(E)Dated23.07.1983
11)	Hydroxyquinoline group of medications at fixed dose combinations with any other drug, with the exception of preparations intended forexternaluse.	SubstitutedvideGSRNO.793(E) Dated13.12.1995
12)	Fixed dosage mixes of corticosteroids and other medications intended for internal consumption, with the exception of mixtures intended for use in dry powder inhalers and meter dose inhalers.	SubstitutedvideGSRNO.738(E) Dated 09.10.2009
13)	Fixed dosage combinations of crude ergot preparations, except those intended for the treatment of conditions involving caffeine, ergotamine, analgesics, and antihistamines of migraine,headaches	SubstitutedvideGSRNO.304(E) Dated07.06.1991
14)	Penicillin skin /eye Ointment.	GSR NO. 578(E)Dated23.07.1983
15)	Nialamide.	GSR NO. 578(E)Dated23.07.1983
16)	Practolol.	GSR NO. 578(E)Dated23.07.1983
17)	Methapyrilene,itssalts.	GSR NO. 578(E)Dated23.07.1983
18)	Methaqualone.	GSR NO. 578(E)Dated23.07.1983
19)	Oxytetracycline Liquid Oral preparations.	GSR NO. 322(E)Dated03.05.1984
20)	Demeclocycline Liquid Oral preparations.	GSR NO. 322(E)Dated03.05.1984
21)	Phenypropanolamineand its formulations for human use.*	GSR NO. 82(E)Dated10.02.2011
22)	With the exception of its preparations for human use, human placental extract 1. applied topically to promote wound healing, 2. injection to treat inflammation in the pelvis	Substitutedvide GSRNO.418(E) Dated30.05.2011
23)	Dextropropoxyphene and preparations for human use that contain it human use**	G.S.R.332(E)dated23.5.2013
24)	Fixed dose combination of Flupenthixol + Melitracen for human use	G.S.R.377 (E)dated18.6.2013and 498 (E) dated11.07.2014
25)	Aceclofenac+Paracetamol+Rabeprazole***	S.O.705(E)Dated10.03.2016
26)	Nimesulide +Diclofenac	S.O.706(E)Dated 10.03.2016

27)	Nimesulide +Cetirizine +Caffeine	S.O.707(E)Dated 10.03.2016
28)	Nimesulide+Tizanidine	S.O.708 (E) Dated10.03.2016
29)	Paracetamol+cetrizine+caffeine	S.O.709(E)Dated 10.03.2016
30)	Amoxicillin+Cefixime+Potassium Clavulanic Acid	S.O.757 (E) Dated10.03.2016
31)	Combikit of Azithromycin dihydrate, secnidazole andfluconazole	S.O.760(E)Dated 10.03.2016
32)	Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets	S.O.769(E)Dated 10.03.2016
33)	Atorvastatin +vitaminD3+folicacid+vitaminB12+pyridoxine	S.O.784 (E) Dated10.03.2016
34)	Imipramine +Diazepam	S.O.795(E)Dated 10.03.2016
35)	Metformin 1000/1000/500/500mg +Pioglitazone7.5/7.5/7.5/7.5mg+Glimepiride1/2/1/2 mg	S.O.802 (E) Dated10.03.2016
36)	Metformin Hydrochlopride +Gliclazide + Piogllitazone + Chromium Polynicotinate	S.O.820 (E) Dated10.03.2016
37)	Clotrimazole +Beclomethasone +Lignocaine +Ofloxacin+ Acetic Acid + Sodium Methyl Paraben+ Propyl Paraben***	S.O.1048(E)Dated10.03.2016
38)	Fixed Dose Combinations Of Etodolac + Paracetamol	S.O.1853(E) DATED08.06.2017
39)	Fixed Dose Combinations Of Glucosamine + Ibuprofen	S.O.1854 (E)DATED 08.06.2017
40)	Fixed Dose Combinations Of Gemifloxacin + Ambroxol	S.O.1855(E)DATED 08.06.2017
41)	AmmoniumCitrate+VitaminB12+FolicAcid+ZincSulphate	S.O.1042(E)Dated 10.03.2016
42)	Telmisartan + Metformin	S.O.1041(E)Dated10.03.2016
43)	Bromhexine +Phenylephrine + Chlorpheniramine + Paracetamol	S.O.1039(E) Dated10.03.2016
44)	Neomycin +Doxycycline	S.O.1008(E)Dated 10.03.2016
45)	Clobetasole + Gentamicin + Miconazole + Zinc Sulphate	S.O.1004(E) Dated10.03.2016
46)	Ambroxol + Salbutamol +Theophylline	S.O.942(E)Dated 10.03.2016
47)	Ketotifen + Theophylline	S.O.941(E)Dated 10.03.2016
48)	Terbutaline +Bromhexine +Etofylline	S.O.940(E)Dated 10.03.2016
49)	Levocetirizine + Dextromethorphan + Zinc	S.O.931(E)Dated 10.03.2016
50)	Dextromethorphan +Phenylephrine +Cetirizine + Paracetamol + Caffeine	S.O.929(E)Dated 10.03.2016

Table No. 4: List of banned Drugs 1940 by the ministry of health and family welfare

*Presently stayed by the Hon'ble High Court of Madras.

**Prohibition was revoked with following conditions vide.

G.S.R.No.367(E)dated13.04.2017:

a) The manufacturer shall indicate in a conspicuous manner on the package-inserts and promotion a lliterature of the dextropropoxyphene and its formulations:
   - "Use of drug for cancer pain only" ,and
   - "Daily administered dose shall not exceed 300mg. Per day".

b) The following terms must be written on the medicine's container that contains dextropropoxyphene:
   - medication only used to treat cancer pain
   - "Daily administered dose shall not exceed 300mg. per day"

c) The manufacturer shall advise the registered medical practitioners to administer or prescribe the said medication and its formulations for use in individuals suffering from cancer pain only.

***The Notification from S.O.Nos 705 (E) to 1048 (E) dated 10.03.2016 were quashed by Hon'ble Delhi High Court vide its order dated 01.12.2016Through the SLP, the Union of India had appealed the Delhi High Court's ruling to the Supreme Court.

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