A Review on the Drugs Approved By US-FDA and DCGI

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Introduction

Drugs : Drug is the chemical substance may be synthesized or derived naturally and is use for its therapeutic effect It plays a vital role in life it is meant to diagnose, mitigate, cure, prevent, or treat or modify the physiological condition. Drug is meant for the safeguard of public health.

Importance of the medicines: medicines are considered to be one of the vital need of the human being. One has to rely upon this once or oftenly in their life time in order to maintain their physical and mental health. In ancient times the illness was considered to be gods wish but after certain period the revolution came and now that is era and till date continuous introduction of drugs to the patient need is available. After continuous Discovery and introduction of the drug the public health is being improved. And the mortality rate compare to ancient time has been reduced.

But there are lot more risks are also associated with a drug along its benefits if not taken cautiously some of major among them are:

1. ADR(adverse drug reaction)
2 drug addiction
3. SAE(serious adverse event)

1 ADR(ADVERSE DRUG REACTION): it is some untoward reaction of a drug other than its therapeutic effects.

2. Drug addiction: these are those drugs also known as opioids drugs some times greatly required. But these drugs as the name suggested are habit forming.

3 SAE:this is known as serious adverse event may be associated with that particular medicine or may be by any other medicines but this event can lead to permanent disfuction of body or may even death of patient.

FDA and its role in drug approval

The food and drug administration in usa is the organization which responsible for approving and non. approving of the drug. the main aim of FDA is to keep uneffective and unsafe drugs off the market to ensure, protect and increase the good public health. just to ensure that the public good think that if the drug is approved it means it met all the standard for its safety and efficacy when a research molecule is researched then the pharmaceutical company file for IND(investigational new drug)to FDA. The IND filed by company contains whole data of preclinical study i.e trials performed on animals. The number of sheet would be around of 100000 pages in which the whole information about the new drug is written after reviewing the data if the criteria meets the standard then FDA gives approval for clinical trails for that particular drug. Each year FDA approve wide range of new drugs and biological products some of the products are new one or may be already in market but are seeking approval of FDA either for its other therapeutic effect or may be in combination to increase the efficacy.

In order to review the drug in proper way by the FDA the drugs are classified and the new innovative drug is considered to be as NEW MOLECULE ENTITY.

Following are the stages which a drug undergo with to come in market and at every and new stage the company has to file to FDA-:

1. Preclinical trials: inventing product are testing on animals
2. clinical trials-:
Phase 1:perform on healthy volunteers to check the safety of product
Phase 2: Perform on patients to check the safety and efficacy of product

Phase 3 :perform on larger population of patient to make sure the safety and efficacy in larger population.

Phase-4: It is also known as post marketing of product done after launching of the product to market on periodic basis.

There are enormous numbers of the drugs which have been researched and many of these are in pipeline to come in market. it take a lot of time around 10-12 yrs it take to come a researched drug from lab to market. only 5 in 5000 drugs are approved for trials on human body after preclinical trial by FDA.

Reasons of not approving much drugs in recent time and then sudden increase in approvals

The industry and FDA both plays very important role in approval of a drug. There were a sudden decline in the approval of the drugs in past years because of the reason that the pharmaceutical company's r&d process that is they are not meeting the criteria for safety and efficacy and many other parameters which result into long term decline in pharmaceutical R&D productivity which ultimately led to decrease in probability of success and increased cost for discovery and development of drug. In order to avoid it the biopharmaceutical company taken the initiative to improve their r&d status and reducing their fixed costs by outsourcing it to CROS.

The average number of approval rate over time

From 2004-2012 CDER has 26 NME average approval per anum but in 2012 CDER had approved 39 NME and in 2013 it was 27. The number of approval of the drug remains steady and the maximum number of approval were in 2014 that is total 41 approval of novel drugs in past decades.

1. The reason for sudden increase in approving of new drugs is emergence of drug for life threating dieases through accelerated approval of drug from FDA.
2. the time reduce by FDA in reviewing data process for NME.
3. the inclination of pharmaceutical companies toward r&d requirement to meet the standard

The innovative therapies approved in past few years given major advances in the field of oncology, cardiovascular disease, type 2 diabetes, hepatitis C and in HIV.

The novel drug of 2014-:

Following are the drugs approved by us-fda in 2014

LIST OF THE NOVEL DRUGS OF 2014

Drug name	Active ingredients	Approval date	What it is used for
Opdivo	Nivolumab	12/22/2014	To treat patient with unressectable or metastatics melanoma who no longer respond to other drugs
Rapivab	Peramivir	12/19/2014	To treat influenza in adult patient
Zerbaxa	Cetolazane/tazobactum	12/19/2014	To treat patient with intra abdominal infection
Viekira pak	Ombitasvir, paritaprevir, ritonair Tablets	12/19/2014	To treat patient with chronic hepatisis c with genotype 1 infection and complicated urine infection
Lynnparza	Olaparib	12/19/2014	To treat advance ovarian cancer
Xtoro	Finafloxacin otic susp	12/17/2014	To treat acute otititis eternal
Blincyto	Blinatumomab	12/3/2014	To treat patient with philodelphia chromosome-

			negative precursor
Esbriet	Pirfenidone	10/15/2014	For treat patient with idiopathic pulmonary fibrosis
Ofev	Nintedanib	10/15/2014	For treat patient with idiopathic pulmonary fibrosis
Lumason	Sulfur hexafluoride lipid Microsphere	10/10/2014	For patient whose ultrasound images is hard to see with ultrasound wave
Akynzeo	Netupitant and palonosetron	10/10/2014	To treat patient with nose and vomiting for chemotherapy patient
Harvoni	Ledipasvir/sofosbuvir	10/10/2014	To treat patient with chronic hepatitis c with genotype 1
Trulicity	Dulaglutide	9/18/2014	To treat adult with type 2 diabeties
Movantik	Naloxegol	9/16/2014	To treat opioid induced constipation
Keytruda	Pembrolizumab	9/4/2014	To treat patient with advance unresctable melanoma where other treatments fails to work
Cerdelga	Eliglustat	8/19/2014	For the log term treatment in adult patient with type 1 goucher disease
Plegridy	Peginterferon	8/15/2014	To treat patient with relapsing form of multiple scelerosis
Belsomra	Suvorexant	8/13/2014	To treat patient for inducing sleep
Orbactiv	Oritavancin	8/6/2014	To treat patient with adult infection
Jardiance	Empagliflozin	8/1/2014	To improve glycemic control in adult with type 2 diabeties
Striverdi respimat	Olodaterol	7/31/2014	To treat patient with chronic pulmonary diseases
Zydelig	Odelalisib	7/23/2014	To treat patient with three type of blood cancer
Kerydin	Tavaborole	7/7/2014	For the treatment of onychomycosis of toenails
Beleodaq	Belinostat	7/3/2014	To treat patient with peripheral t-cell lymphoma
Sivextro	Tedizolid phosphate	6/20/2014	To treat adult with skin infection
Jubila	Efinaconazole	6/4/2014	To treat mil to moderate fungal infection
Dalvance	Dalbavancin	5/23/2014	To treat skin infection

The 41 drugs approved by FDA in 2014 contributes a major role in public health and these 41 drugs are placed and divided according to their categories. Few are discussed below:

1. first in class drugs
2. accelerated drug

1. first in class drug: these are those new drugs which are using for new and unique mechanism to treat the medical condition following are the first in class medicines approved by FDA in 2014:

1. belsomera 2. blincyto 3. esbriet 4. harvoni 5. impavido 6. kerydin 7. keytruda 8. lynparza 9. Myalopt 10. northera 11. ofev 12. otezia 13. sylvant 14. viekira pak 15. vimizim 16. zontivity 17. zydelig

s.no.	Drugs	Treatment
1	Harvoni	To treat patient with chromic hepatisis C
2	Keytruda	To treat patient with unresectable or metastaticmelanoma
3	zontivity	To reduce risk of thromobotic cardiovascular events

ACCELERARED APPROVAL: These drugs are those drugs which gets early approval because of their urgent demand in public health for a serious or life threatening illness for better treatment over the used drugs. After approval of these drugs, the drug must undergo additional testing to confirm the benefits.

Following are the drugs approved as accelerated drugs by FDA in 2014:

1. beleodaq 2. keytruda 3. Northera 4. zydelig 5. blincyto 6. lynparza 7. opdivo 8. Zykadia

s.no	Drug	Treatment
1	Beleodaq	To treat patients wth peripheral T-call lymphoma
2	Keytruda	To treat patients with melanoma
3	Northera	To treat patient neurogenic orthostatic hypotension
4	Zydelig	To treat patient patient with 3 types of cancer
5	Blincyto	To treat patient with Philadelphia chromosome-negative
6	lymparza	To treat patient with ovarian cancer
7	Opdivo	It is human programmed death receptor-1 blocking
8	zykadia	To treat metastatics non-small cell lung cancer

DCGI and its role in approving drugs

The drug controller general of india was established in 1998 the govt added schedule 'Y' to DRUG AND COSMETIC ACT-1940 scheduleY has detailed information for clinical trial and pre-clinical trials. However the pre-clinical trial is not approved in india. Though for the approval for the new drug to become approve and come in the market the same procedure like in us has to follow in india also. For the approval of the drug it is very necessary that the drug should meet all the criteria or guidelines provided in schedule Y. Then the application should be submitted to ethical committee. A clinical trial can only be performed after approval from DCGI for every next phase of the trial for the particular drug the application should be submitted to ethics committee and DCGI. DCGI is having the power to terminate the clinical trial in mid if the result or the data produce is not up to mark. In 2012 the pharmaceutical company were told to submit the safety report for the new drug in six months.

Drugs approved by DCGI in india 2014

The drugs approved by DCGI are mainly the drug which are already in market or approved already. They come in approval either in combination or with other therapeutic effect unlike previous or for further safety and efficacy purpose. Following are the drugs which were approved by dcgi in 2014-:

Drug	Approval date	Therapeutic use
Tolreridone tartrate extended release tables 2/4mg	31/01/2014	For the treatment of overactive bladder
Botezomib for injection 3.5mg	28/01/2014	For the treatment of overactive bladder
Paclitaxel inj. Concentrated for nano dispersion 100 nd 300 mg	22/02/14	For the treatment of breast cancer after failure of combination therapy
Heparin sodium topical solution	16/1/2014	For thetreatment of fluctuence of post infusion superficial thrombophlebitis

Eltrombopag olamine tab 25/50mg	7/4/2014	To treat patient with hepatitis c
Decitabine lyophilized powder for injection	9/4/2014	For elderly patient to treat secondary acute myeloid leukemia
Glycopyrronium inhalation powder	1/4/2014	To treat chronic obstructive pulmonary disease
Micafungin sodium for inj	2/5/2014	To treat fungal infection
Apixaban tab 2.5mg	16/5/2014	Prevention of stroke and systemic embolism in sdult patient with non-valvular
Mometasone furoate nasal spray 50 mcg	21/5/2014	To treat perennial allergic rhinitis
Tadalafil 10mg,20mg	30/7/2014	For erectile dysfuction
Hydroxychloroquine sulphate	28/7/2014	To treat patient with type 2diabetes
Nevirapine extender release tab 400mg	1/7/2014	To treat patient with HIV-1
Cerebrolysin inj	25/7/2014	To treat amelioration of cranial injury
Artesunate powder	2/7/2014	To treat patient with severe falciparum malaria
Lactobacillus brevis CD logenges 100mg	9/8/2014	Prevention of radiotherapy and chemotherapy induced oral mucositis in cancer patients
Rivaroxaban tab15/20mg	2/9/2014	To treat patient with deep vein thrombosis and to prevent DVT and pulmonary embolism
Hydroxychloroquine tab 300mg	9/8/2014	To treat patient rheumatoid arthritis with lower body patient
Ginko biloba extract	9/12/2014	To treat patient dementia, vertigo and tinnitus
Bendamustine hydrochloride inj 25mg	19/9/2014	To treat patient with chronic lymphocytic leukemia
Metformin ER750mg	25/9/2014	To improve glycemic control in type2 diabetis
Sorafenib tsylate tab 200mg	25/9/2014	To treat patient with thyroid carcinoma refractory
Deferasirox dt 100/400mg	26/9/2014	Treatment of chronic iron overload in patient with non-transfusion dependent thalassemia
Imatinib mesilate 100/400 cap	9/9/2014	To treat paediatrics patient with newly diagnosed Philadelphia
Olanzepine pamoate powder	14/10/14	To treat patient with schizophrenia
Rivastigmine trandermal patch	28/10/2014	To treat patient with severe dementia of the alzheimers disease

Dabigatran etexilate mesilsate cap 75/110/150mg	17/11/2014	Treatment of acute deep vein thrombosis
Pegasperagase 3750 iu/5ml	7/3/2014	Indicated as a component of multi agent chemotherapeutic regimen for the treatment of patient with acute lymphoblastic leukemia
Tulobuterol transdermal patch 0.5mg/1.0mg/2.0mg	24/4/2014	To treat patient with asthma and COPD
Azacitidine100mginj	29/4/2014	TO treat adult patient wth myelodysplastic syndrome
Azacitidine	23/7/2014	Same as above
Regorafenib 40mg tab	1/7/2014	To treat patient with mtastatic colorectal cancer
Roflumilast 500m	17/7/2014	For the treatment of severe COPD
Dimethyl fumarate 120/240mg tab	27/8/2014	Relapsing remitting

Conclusion

The revolution in drug discovery and its approval is proved as boon for public health. It results in improved health both mentally and physically in human race. The pace of drug approval is quite high in present time as compare to past few years. The high rate of approval of drug is good initiative by the government authorities to maintain and sustain good public health. Specially in case of life threatening illness like cancer, HIV, cardiovascular and many more. By approving these drugs on fast basis and keeping all quality and standard of these drugs in mind many lives can be saved in time. This is good move for both india and usa. Population. Specially in india as india is developing country and illness rate and variety of illness is more here than in any other country and due to lack of heigene and lack of awareness the chances are more to spread of dieases in contagious way specially in rural area. So it is very necessary demand for approval of these drugs so that preventive action can be taken against illness in time.

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