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Pharmacovigilance: Supportive System in Pharma Field

Gaware Prashant[1*], Gaurav Jagtap[2], Hrushikesh Gadhave[2], Sonawane Mahadev[2], Keshe Sudarshan[2], Hrushikesh Dhumal[2], Rongte Ramchandra[2]
[1,2] *Sanjivani college of pharmaceutical education and research, kopargaon , Ahmednager ,India*
Corresponding Author: Gaware prashant[1]*

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ABSTRACT
Pharmacovigilance (PV) are the soul of pharmacy. As we know that PV play very vital role in management of adverse drug reaction (ADR) . Due to the PV patients are more assure about safely used of drug , hence PV act as a lock & key for pharmacy sectors. The main importance of PV in pharmacy sectors are maintaining benefit risk ratio by eliminating ADR by using computerised generated software programmed with in short period of time. In this review article we looking brief view of pharmacovigilance in pharmacy compnay & how they become effective for maintain current competition with other pharmacy companies.

Keywords : ADR , Pharmacovigilance , Clinical trials , Thalidomide disaster , Jobs etc.

I. INTRODUCTION

Pharmacovigilance is the ratio of benefit risk management. It is necessary for drug evaluation drug safety profile. It also have a record keeping function of ADR & also testing or monitoring of the drug which are controlled by Uppsala Monitoring Centre under FDA & European medicine agency (EMA)[1,3]. The role of this agency is to controlled patient safety. 'The term pharmacovigilance come from Greek words pharmakon means drug & vigil are means keep to watch'[4]. "according to WHO PV is defined as the branch of the science which deals with studies of activity relating to the detection , assessment , understanding & prevention of adverse drug reaction and other drug related problem".[1,4] The important purpose of PV programme are focused on patient care , benefit risk , improve public health service. It is specific tool for predicting ADR those are not identified by highly skilled & train person by its own knowledge , such type of ADR are identified by Pharmacovigilance programme & do the role as successful launch a new drug in market. For
this unique feature of this programme , Pharmacovigilance programme established in everywhere in pharmaceutical industries. Now the focus of PV is to detect ADR in preclinical trials , it means that before drug in post clinical trials ADR totally clearout from drug.

II. HISTORY

The history of Pharmacovigilance are originated before 18th century given in the table as follow [2-6,13].

Tab 1 history of Pharmacovigilance

YEARS	HISTORY OF PHARMACOVIGILANCE
1747	Effectiveness of lemon juice in preventing scurvy for time reported by James lined in clinical trials.
1848	Young girl H. greener after taking chloroform anesthesia lead cardiac arrhythmia.
1937	Sulfonamide disaster , sulphanilamide elixir with diethylene glycol harmful solvent ,107 children death.
1950	ADR of Chloramphenicol , gray baby syndrome, plastic anemia reported.
1955	Sir Alexander , reaction include drug therapy prove acetylsalicylic acid (ASA) caused GI toxicity.
1961	Thalidomide disaster ,lead Phocomeliea in fetus.

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1965	Issue EC directive to European unions
1968	Pilot project starts by WHO to collect ADR from different nations.
1970	Practolo disaster lead multisystem disorder/ocular Mucocitaneous syndrome.
1980	Prescription event monitoring , result Benoxaprofen (NSAID) photosensitive, hepatic , renal damage, death finally withdrawn from the market .
1992	European society of PV(ESOP) change to international society of PV (ISOP)
1993	Revised UK guidelines , safety assessment of market ,medicines (SAMMA), Blue print for EU level guidance
1995	Set of European medicine agency (EMA)
1996	India starts clinical trials of global standard.
1997	India join ADR monitoring programmed.
1998	PV in India.
1999	Draft Med , revised Med watch.
2001	Eudravigilance was founded, managing , analyzing European database on suspected ADR.
2002	National Pharmacovigilance centre no. 67 was established in India .
2004	National Pharmacovigilance programmed launch in India .
2005	To give final risk management guidelines , also organized clinical trials in India .
2009	PVPI started.
2010	European PV legislation passed.
2012	New European PV legislation.
2017	New Edravigilance formulate

Basic term used in Pharmacovigilance :-

Pharmacovigilance :- The science and activity relating to the detection, assessment ,understanding and prevention of ADR or any other drugs related problems called as Pharmacovigilance [1,4,6,15].

Adverse drug reactions :- Any response to a drug which is noxious and unintended and which occur at a dose normally using man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function[6,15].

Benefit risk analysis :- Examination of the favourable beneficial and unfavourable result undertaking up speak course of action ratio of risk of action to the potential of benefit[15].

CIOMS :- Council For International Organisation Of Medical Science .CIOMS organised under WHO and UNESCO[13,15].

Harm :- Harmful effect of the drug. E.g. Chloramphenicol caused gray baby syndrome[14,15].

MedDRA :-MedDRA or medical dictionary for regulatory authorities use by regulatory authorities and also regulate biopharmaceutical industry. It contain regulatory process from pre marketing to post marketing surveillance and for data entry up to evolution and presentation of the drug[13].

Eudravigilance :- It contain European data processing network and support to system for reporting system for reporting and evolution of the suspected adverse drug reaction which observe in clinical trials and which is authorise in European medicinal agency[13,15].

Absolute risk :- Absolute risk affecting member of particular population (example 1 in1000) absolute reached can measure incidence or prevalence[13,15].

Benefit :- An estimated response gain for an individual.

Pharmacoepemiology :- Study of effect and use of drug in large population[6,13].

Prescription event monitoring:- (PEM)System for monitors ADR in population[6,13].

Prescription only medicine :- (POM) Drug available to public only on prescription[15].

Safety single :- Safety single referred to concern about or excess of adverse event compared to what would be accepted to be associated with product use . which can arise from post marketing data and other source such as pre clinical data and event associate with other product in the same pharmacological class[6,15].

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Post marketing surveillance :- Post marketing surveillance is the practice of monitoring the safety of pharmaceutical drug after it has been released in the market[6,15].

Adverse event :- An adverse event is define as any untoward medical occurrence that may present during treatment with a drug but which does not necessarily have a relationship with its use[6,15].

Clinical trial:- Clinical trial are set of test in medical research and drug development that generate safety and efficacy data or more specifically information about adverse drug reaction and adverse effect of other treatment for health intervention[6,13,15].

Safety:- Safety may be define at relative absence of harm[15].

Adverse drug reactions (ADR) :-

Definition :-Any unintended or noxious effect of medicine occurred when drug is given normal range of dose for prophylaxis, diagnosis, treatment, and prevention of abnormal physiology[4].

Side effects :- The side effects is unintended effect of drug . Example – Beta blocker caused hypertension[14].

As per 1970 traditional of Adverse drug reactions are given in below.

1. **Type A**
2. **Type B**
3. **Type C**
4. **Type D**
5. **Type E**
6. **Type F**
7. **Type G**
8. **Type H**
9. **Type U**

Type-A :- (Augmented ,dose related Reaction ,Normal dose Reaction)[4,13,14] .

This type of ADR results from exaggeration of drug normal dose . It depends on dose ,and can be minimised by reducing in dose. This type of ADR are preventable and reversible eg. Nitrates cause headache ,Beta blockers cause Bradycardia , Anticoagulant cause bleeding , Sulphone urea cause hypoglycaemia ,Tricyclics antidepressant caused serotonin syndrome and Anticholinergic effect .

Type B :- (Bizarre response , non dose related Reaction , unpredictable reaction[4,13,14] .This type of ADR occurred From the know pharmacology effect .it is less common ,not depend on dose and it is irreversible .e.g. penicillin cause anaphylaxis , antibiotic cause skin rashes , anticonvulsant cause hypersensitivity reaction , hepatitis cause by halothane , Granulises caused by Clozapine.

Type C :- (Chronic , chemical reaction , dose and time depend).

This type of adverse drug reaction obtained from chemical structure of the drug which is dose and time dependent..e.g. Paracetamol lead liver toxicity, Osteonecrosis of jaw by Bisphosphonate , adrenal suppression by corticosteroid[4,13,14] .

Type D :- (Delayed ,time related).

This type of ADR due to prolong used of drug. Occurs after long period of time ,in year due to accumulation .e.g. antipsychotic – Tardive Dyskinesia , analgesic – Nephropathy, Phenytoin – Teratogenic , chemotherapy – Secondary tumours[4,13,14] .

Type E (exit /end of treatment , withdrawal reaction) .Occurs when withdrawal of drug. E.g. Phenytoin withdrawal – seizure , steroids withdrawal – Adrenocortical insufficiency[4,13,14.]

Type F :- (Familial , unexpected failure of therapy)

E.g. decrease clearance of drug by dialysis, decrease effect of Antibiotics due to resistance[4,13,14]**.**

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Type G :- (Geno toxicity, irreversible genetic damage) e.g. Teratogenic Thalidomide genetic damage to foetus [13,14]

Type H :- (Hypersensitivity) Also called drug allergies [4,13,14] .

Type U (Unclassified) :- occurs due to unclear mechanism of action of drug e.g. Simvastatin – taste disturbance[4,13,14] .

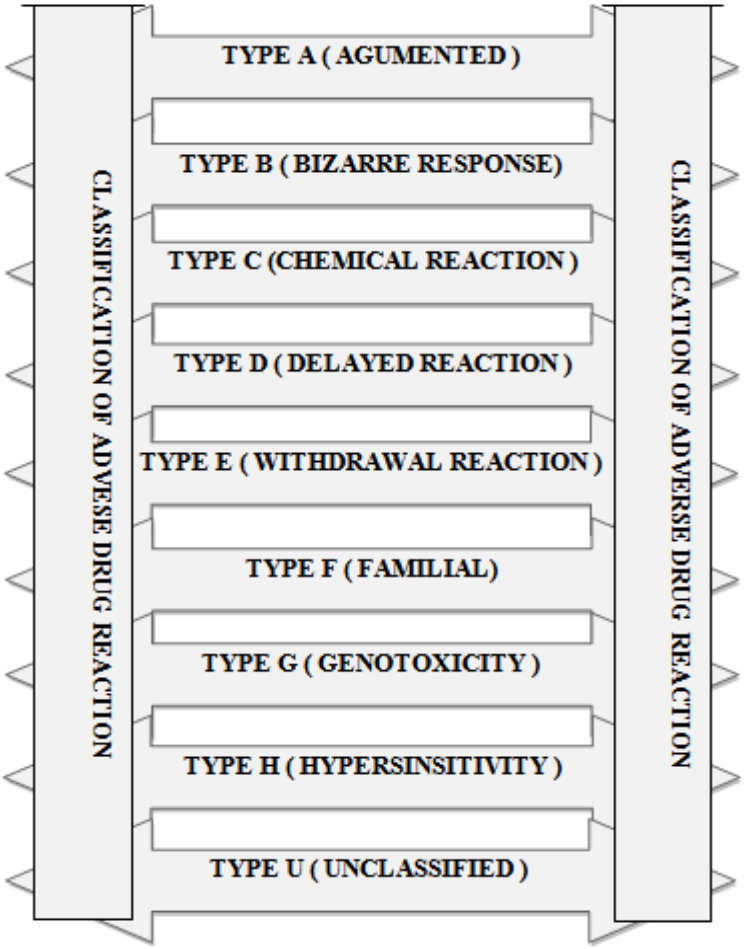

Fig.1 Classification of ADR

Tab 2 DRUG BANNED BY CSDCO ACCORDING TO D & C ACT 1940 IN SOME CASES [6,10]

DRUDS	REASON FOR DRUG BANNED
Practolol	Multisystem disorder, ocular Mucocitaneous syndrome
Sulphonamide Elixir	Due to harmful solvent Diethylene glycol
Thalidomide	Phocomelia , organ damage of fetus
Analgin , Oxyphenbutazone	Bone marrow depression
Chloral hydrate	Genotoxic and carcinogenic
Furazolidone ,	Cancer

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Nitrofurazone	
Quinlodochlor	Damage to sight
Nimesulide	Liver damage below 12year age
Tegaserod	Heart attack
Sibutramine	Risk of heart problems
Adderall	Addiction
Piprazine	Nerve damage
Dextropropoxyphene	Cardiac toxicity
Gatifloxacine	Hyperglycemia
Cisapride , Droperidol	Irregular heart attack
Valdecoxib	Stroke and heart attack
Rofecoxib	Myocardial infraction
Phenformin	Lactic acidiosis , heart and kidney damaged
Cerivastatin	Rhabdomyolysis in renal function
Alpidem Film coated tablet	Hepatic toxicity
Pergolide	Cardiac valvular damage

Tab 3 Drug & side effect [4,6,10]

Sulphonamide	Crystalurea ,Stevens Johnson syndrome
Penicillin	Jarish herxheimer reaction
Chloramphenicol	Gray baby syndrome
Aminoglycoside	Ototoxicity , Nephrotoxicity
Vancomycin	Red men syndrome
Dapsone	Sulfone syndrome
Rifampin	Orange red color urine
Pyrazinamide	Hyperuricemia
Ethambutol	Color urine
Chloroquine	Loss of vision, hearing ,graying of hair
Quinine	Cinchonism
Cisplatin	Emesis
Pyrimidine antagonist	Hand foot syndrome
Anticancer antibiotic	Red color urine
Tretinoin	Retinoic acid syndrome
Thalidomide	Phocomelia , internal organ damage

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Androgens	Limbs defects
Warfarin	Eye, hand defect , growth retardation
Phenobarbital	Malformations
Alcohol	Foetal alcohol syndrome, low IQ baby
Insulin	Severe hypoglycemia

CLINICAL SURVEILLANCE [4,11.13,14] :- the drug safety is evaluated by different phase (Phase 0 to phase 4) i.e. Micro dosing Studying to Post marketing surveillance , from this sequence drug should be approved by FDA (food and drug administration) before post marketing surveillance . In these point we discussed about drug evaluation from preclinical studies to phase 4 up to the drug in market. Any uncontrolled response to drug in clinical trials should be happened suddenly drug should be rejected and finally omitted from clinical trials .and further process of drug evaluation should be stop. Drug should be withdrawn before approval in marketing. So uncontrollable adverse effects of drugs should be find out in early development of the drug , so that drug should be effective or harmful decided in clinical trials .this study are categorised in different phase . Drug should be approved than drug should be passed successful to this phase. This phase given in Fig.2. Different types of clinical trials phase are as follows [4,14] .

Phase 0 :- (Micro dosing studies) this is new phase added to clinical trials for reduction in time period and coast of drug micro dosing study should be done before phase -1 clinical trials ,called as phase -0 phase of clinical trials . Drug should be successful passed phase-0 clinical studies than drug enter into phase -1 . If drug should be unfilled the phase -0 condition than drug also enter into next phase . because phase – 0 are not necessarily and not mandatory [4,14] .

Phase 1 :- (Human pharmacology & safety) In this phase Drug should be administered to human body in small population of about 20-80healthy volunteers and patients .under a train person and skills , experience physician to monitoring safety of drug and also pharmacokinetic & Dynamics. In these phase of clinical trials drug should be administered as small as small dose range in specific period of time , to find out effective dose of drug . by subsequently increase in dose of drug and to find out toxic level of drug. From this phase Drug should be approved for testing in humans [4,14].

Phase -2 (Therapeutic efficacy & dose ranging) In this phase of clinical trials determination of therapeutic efficacy of the drug and also determine dose range from effective action of drugs to toxic level of drugs. All entered process done on 100-500 healthy volunteers or patients, from drug compiled to these phase they should be approved for phase -3 and moving towards approve of drugs. All entered process done on 100-500 healthy volunteers or patients .from drug compiled to these phase they should be approved for phase -3 and moving towards approve of drugs [4,14].

Phase 3 (Therapeutic confirmation / comparison) These studies done in multiple centre study on large number of patients (500 – 3000) .the main aim of this phase is to determine the long term effectiveness of drugs. And also compared drug to other medicines [4,14] .

FDA APPROVAL OF DRUGS :- the FDA approved drug by review all submitted data with proper formatting and all other applications done with all phase reports documents the time required for FDA approved for drug is 1week-8 week. Drugs full fill all conditions than drug should be approved by FDA. After approval of drug should be entered into post marketing surveillance [4,14],

Phase – 4 (Post marketing surveillance / data gathering studies) . Drug safety surveillance in real life of patients. This is continuous phase for testing of safety and effectiveness. The study is done on large number of people. This is drug study in market surveillance to survey of Adverse drug report. It involves security police work [4,14].

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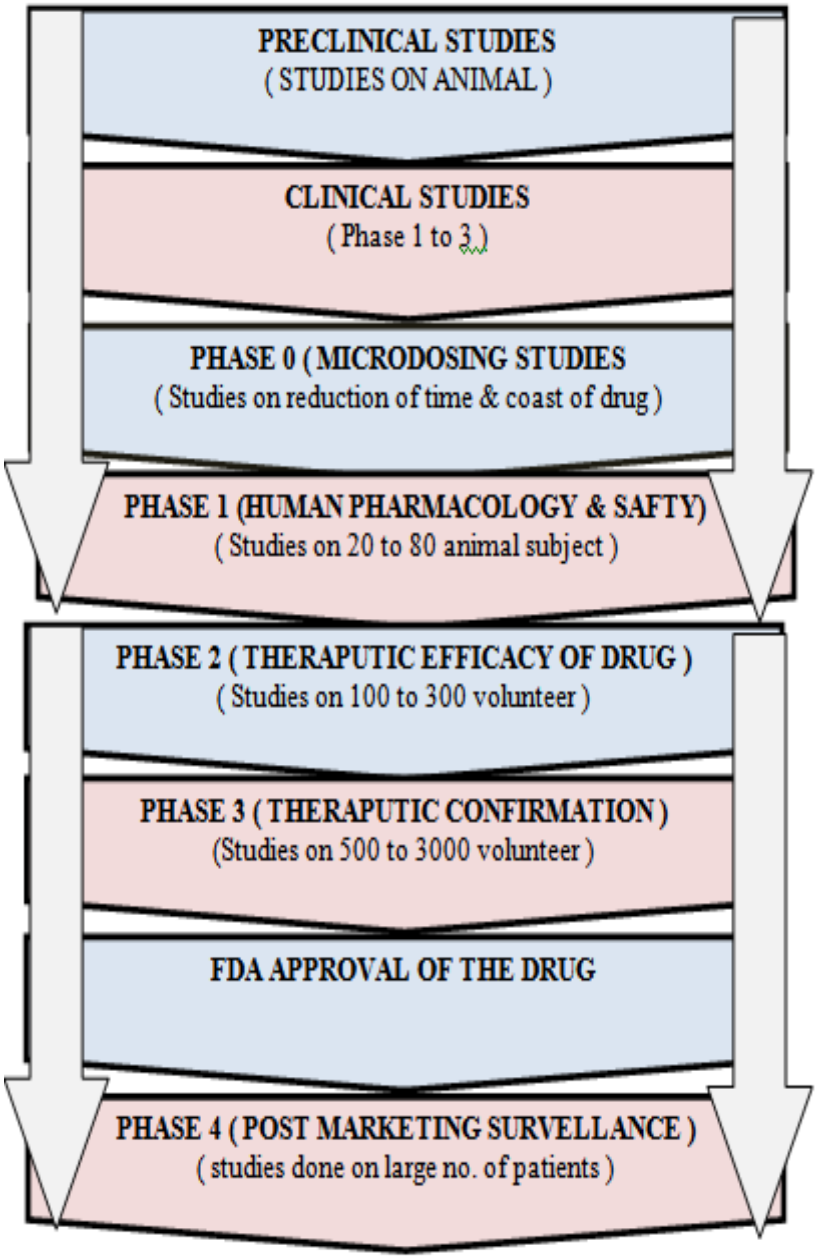

Fig.2 Phase of clinical trials

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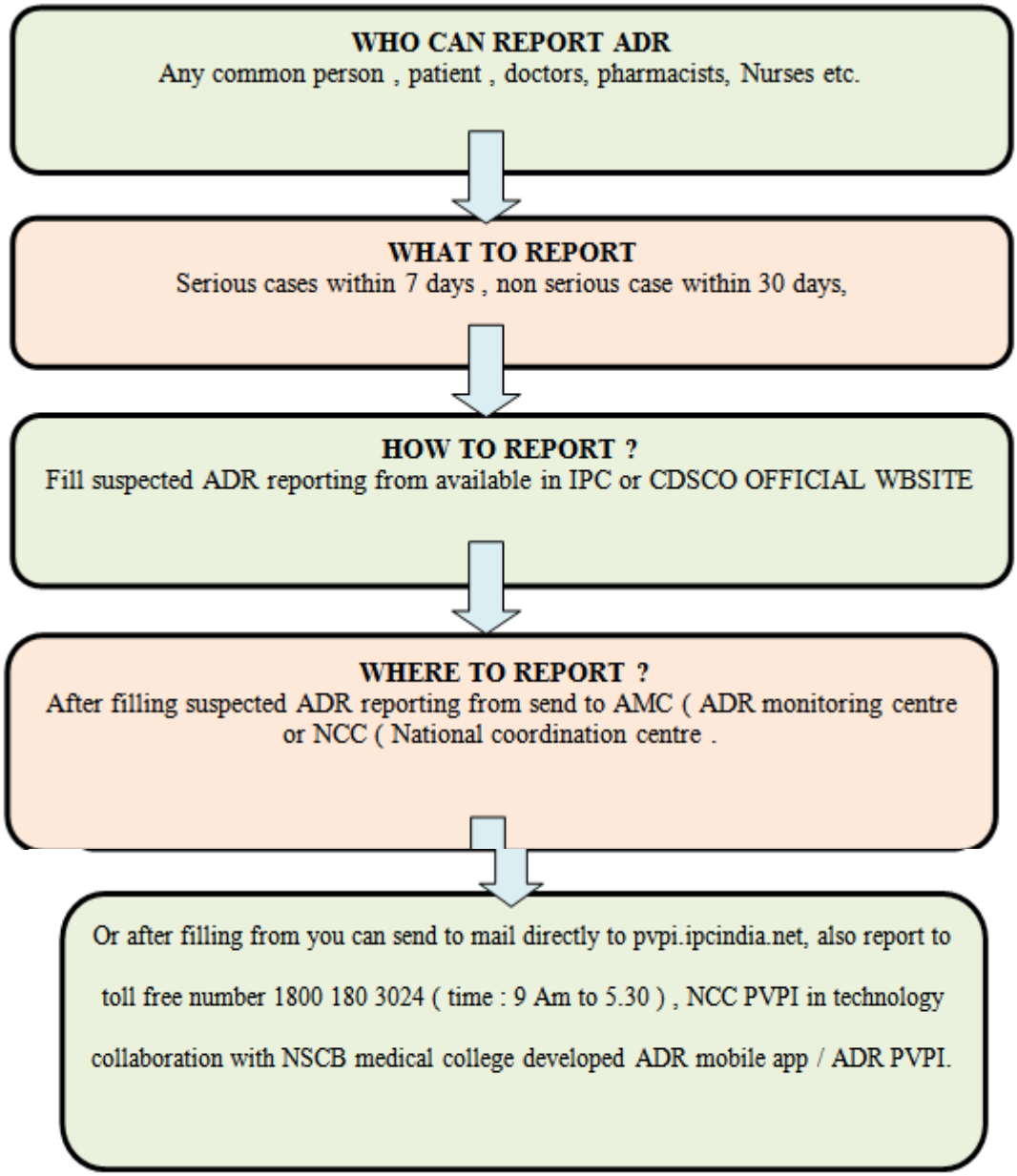

Fig.3 Reporting of ADR to AMC / NCC.

Pharmacovigilance drug information :- drug information are collected from different sources they are as followed : Primary sources , Secondary sources ,Tertiary sources.

Primary sources : The primary sources comes from different journal's , clinical trials Report ,case reports , already published articles , different scientific data from different sources ,main source from manufacturers & Research information

Secondary sources:- Information comes from abstract , primary literature , article (telegraphic abstract, indicative abstract, informative abstract) bibliographic database.

Tertiary sources :-Drug information come from the reference book , drug compendia , essential drugs list ,drug formularies ,drug bulletins pharmacopoeia ,handbook .

Other sources :-Drug information centre (DICs) Physicians, pharmacist , patients , general public , Library , Research association, Government bodies , analyst labs. And poison centre.

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Anatomical Therapeutic Chemical Classification (ATC) : In drug dictionary we give information about used of medical dictionary in the different sectors in pharmacy and also in drug safety surveillance . Medical dictionary are reference book give information about special area of pharmacy filed. Drug should be code in drug dictionary should be done on the basis of Anatomical-Therapeutic Chemical Classification (ATC) in Tab 4. According to these Classification of ATC ,they give information about the arrangement of classes ,their sub classes as per their therapeutic and site of action. as per Classification of ATC we discussed three example of coding , in which way drug or medicine should be coded in the medical dictionary[13].

In first example Main class for code A , code A for alimentary tract and metabolism containing drugs . Under the code A there is sub class A01 for Stomatological preparation. Under sub class A01 there is another sub class is A01A for mouth and teeth preparation. And finally A01AA for caries prophylactic agents. After A01 next class is A02 for drug for acid related disorders , A03 for drug for functional GI disorders, A04 for antiemetic and Antinauseants ,A05 for bile and liver function , and different classes are A06,A07,A08,A09,A10,A11,A12,A13,A14,A15.

Each class should be categorised into there different subclass Upto the individual drugs , given in table no.5.In second example of drug coding mainly for the cardiovascular systemic drug. In that theses drug should be coded in two main code I.e. code C01 for cardiac therapy or C02 for antihypertensive drugs. Under the code C01 there is another sub code C01A,C01B,C01C and under C02 sub code is C02A,C02B,C02C for antihypertensive drugs. Shown in table no. In third example of

coding , code R for Respiratory systemic Drugs. In that R01for Nasal preparation. R02 for throat preparation. R03, R05, R06 , R07 for other Respiratory drugs shown in tab. Above three example should be show about drugs coding according to their Class ,subclasses therapeutic action , and used of different drug. Anatomical Therapeutic. Classification of drug coding[13].

Tab. 4 ATC Classification of drug.

CODE	CLASS OF DRUG AS PER ATC SYSTEM
A	Alimentary tract and metabolism
B	Blood and blood forming agent
C	Cardiovascular system
D	Dermatological agents
G	Genitourinary system and sex Hormone
H	Systemic hormonal preparation except sex hormone
J	General anti-infective for systemic used
L	Antineoplastic and Immunomodulatory agent
M	Musculoskeletal system
N	Nervous system
P	Antiparasite products , insecticide , and repellent.
R	Respiratory system
S	Sensory organs
V	Other agents

Tab 5 Example of ATC class A , C , R.

A01	Stomatological preparation	
	A01A	Mouth and teeth preparation
	A01A A	Caries prophylactic

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		agents
	A01A B	Antinfective & antiseptic for local oral treatment
	A01A C	Corticosteroid for local oral treatment
	A01A D	Other agents for local oral treatment
A02	A02A	Drug for acid related disorders
A03	A03	Drugs for functional GI disorders
	A03 A	Drug for constipation
	A03 B	Belladonna and derivatives, plain
	A03 C	Antispasmodic in combination with psycholeptics.
	A03 D	Antispasmodic in combination with analgesic
	A03 E	Combination ofantispasmodic , Ach Antiemetic and Antinauseants
A05	A05 A	Bile and liver therapy
A06	A06 A	Drug for constipations
A07	A07 A	Antidiarrhoeal , intestinal anti-inflammatory drugs
A08	A08 A	Antiobesity preparation
A09	A09 A	Digestive , including Enzymes
A10	A10 A	Drug used in diabetics
A11	A11 A	Vitamins
A12	A12 A	Mineral supplements
A13	A13 A	Tonics
A14	A14 A	Anabolic agents for systemic used
A15	A15 A	Appetite stimulants

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A16	A16 A	Other alimentary tract metabolism products .

C01	Cardiac therapy	
C01A	C01A	Cardiac glycosides
	C01A A	Digitalis glycosides
	C01A B	Scilla glycosides
	C01A C	Strophantus glycosides
	C01A X	Other glycosides
C01B	C01B	Antiarrhythmics , Class I ,III
	C01B B	Antiarrhythmics , class IB
	C01B C	Antiarrhythmics , Class IC
	C01B D	Antiarrhythmics , class III
	C01B G	Other class I Antiarrhythmics
C01C	C01C	Cardiac stimulants
	C01C A	Adrenergic & dopaminergic Drug
	C01C E	Phosphodiesterase inhibitors
	C01C X	Other cardiac stimulants
C02	C02	Antihypertensive drugs
C02A	C02A	Antiadrenergic agents centrally acting
	C02A A	Rauwolfia alkaloids
	C02A B	Methyldopa
	C02A C	Imidazoline receptor agonists
C02B	C02B	Antiadrenergic agents , ganglion blocking agents
	C02B A	Sulfonium derivatives
	C02B B	Secondary ,tertiary amines
	C02B C	Bisquaternary ammonia compound

R	Respiratory systemic drugs	
R01	R01A	Nasal preparation
R02	R02A	Throat preparation
R03	R03	Antiarrhythmics drugs
	R03B	Other antiasthmatics , inhalants
	R03C	Adrenergic for systemic used
	R03D	Other antiasthmatics for systemic used
R05	R05A	Cough & cold preparation
R06	R06A	Antihistamines for systemic used
R07	R07A	Other Respiratory drugs

Fig. 4 Jobs & level of pharmacovigilance .

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JOBS	LEVEL OF JOBS
Drug safety Associate junior , senior	TRAINEE ⇩ SENIOR DRUG PV ASSOCITE
Safety surveillance associate	
Pharmacovigilance associate	⇩ ASSISTANT MANAGER
Drug Safety office / Manager	⇩ MANAGER
Drug Safety Project Manager	⇩ SENIOR MANAGER
Quality Associate Drug Safety	⇩ ASSOCIATE DIRECTOR
Drug safety Regulatory Compliance Manager	⇩ DIRECTOR
Subject Matter Expert Medical Reviewer	⇩ VICE PRESIDENTS
Pharmacovigilance officers	⇩ PRESIDENTIAL
Drug Safety and Medical Affairs Executive	
Drug Safety Analyst	
Drug say Scientist	
Medical Writer	
Drug safety Reviewer	

METHODS USED IN PHARMACOVIGILANCE

Based on hypothesis, pharmacovigilance method are categories in two categories [6,11,13]

- ❖ **hypothesis generating methods:**
  - ✓ spontaneous ADR reporting
  - ✓ prescription event monitoring
- ❖ **hypothesis testing methods :**
  - ✓ case controlled study
  - ✓ cohort studies
  - ✓ randomized controlled trials
- ❖ **Other methods of pharmacovigilance**[2,4,6,9] :
  - ✓ Digamous French methods
  - ✓ Kramer et al methods
  - ✓ Naranjo et al methodology
  - ✓ Australian method
  - ✓ Loupi et al method

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- ✓ Roussel Uclaf causality assessment methods
- ✓ Ciba Geigy method
- ✓ Balanced assessment methods

Companies offers Pharmacovigilance job:

- ✓ Cognizant Technology Solution India Pvt Ltd.
- ✓ Canila pharmaceuticals limited.
- ✓ Harish corporate services Pvt Ltd.
- ✓ Accenture
- ✓ Tata consulting services (TCS)
- ✓ Abbott Healthcare
- ✓ Bcforward India technologies Pvt Ltd.
- ✓ Bluefish pharmaceuticals
- ✓ Africure pharmaceutical Mumbai

NEED OF PHARMACOVIGILANCE IN COVID 19 DISEASE

At the time of covid 19 the lots of peoples gets affected due to corona virus at that time to stop the spreading infection of covid 19 virus we need a proper medicine. but at virus spared there infection within a small period of time. And another side is to develop proper medicine against Coved 19 virus they required more numbers of day. the scientist developed drug without any side effect , without any harm & safe drug they required more day. At this time most medicine tested for short term efficacy & safety. Now the Pharmacovigilance help to detection ADR or introduced certain measure to minimising the risk of drug. The evaluation of covid 19 vaccines are more difficult due to current restriction of physical contact , freely movement , travel , isolation , quarantine etc. but at that time Pharmacovogilance play vital role.

III. CONCLUSION :-

In new Era of pharmacy , Pharmacovigilance must be mandatory to in each and every pharma drug manufacturing company . Safe ensuring of drug is done by established Pharmacovigilance programmes in India and also other countries . Health care group , different hospital , groups of consumer and other different bodies take part in collecting and analysing Adverse drug reaction . In this review we discussed about risks benefits ratio by ensuring drug safety , efficacy , source and others drug related parameters. When any condition arise relating to ADR than we can Report to CDSCO and IPC by filling Suspected ADR reporting form and maintain drug safety. From 2022 each and every manufacturing company have there own Pharmacovigilance department for efficient running of drug development without any ADR related problems. After reading of this article readers should perfectly know about history of PV , Aim of PV , different basic term , ADR and its type , side effects of drugs, drug banned by CDSCO , Drug evaluation , clinical surveillance , how to Report ADR? , drug coding and other PV related data.

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