NINTH ISSUE
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PHARMACOALERT
NEWSLETTER

Drug Safety Alert, New Drug Marketed, Drug Interactions And Banned Drugs

Contents

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From the Desk of Editorial Team

The department of Pharmacology, Dr. RMLIMS, Lucknow, is pleased to present the January 2021 issue of our newsletter 'PHARMACOALERT'.

Today all of us are anxiously waiting for arrival of COVISHIELD & COVAXIN in India. Considering this we have presented an article on updates on various types of vaccines, their safety profile & other parameters in which all of us will be interested.

Also, we have come up with the drug information of Fostemsavir, an antiretroviral drug newly approved for HIV infection in patients who are failing the conventional antiretroviral regimen due to intolerance or other reasons. Another article on Schedule Y, hopefully will be useful in regard to guidelines for conduct of clinical research. The next article in relation to Pharmacovigilance is about 'Causality Assessment' and its usefulness to find out how much chances are there for the suspected drug to be actually related with the adverse drug reaction.

Apart from these articles, in this issue we have new drug approvals and drug safety alert as our regular feature. Lastly, but most important as per today's scenario, we have summarised the upcoming vaccines for COVID 19.

Currently, new COVID-19 cases are showing a downward trend and if this trend continues with vaccination, probably by June /July 2021 we may expect to control this pandemic and only sporadic cases will remain.

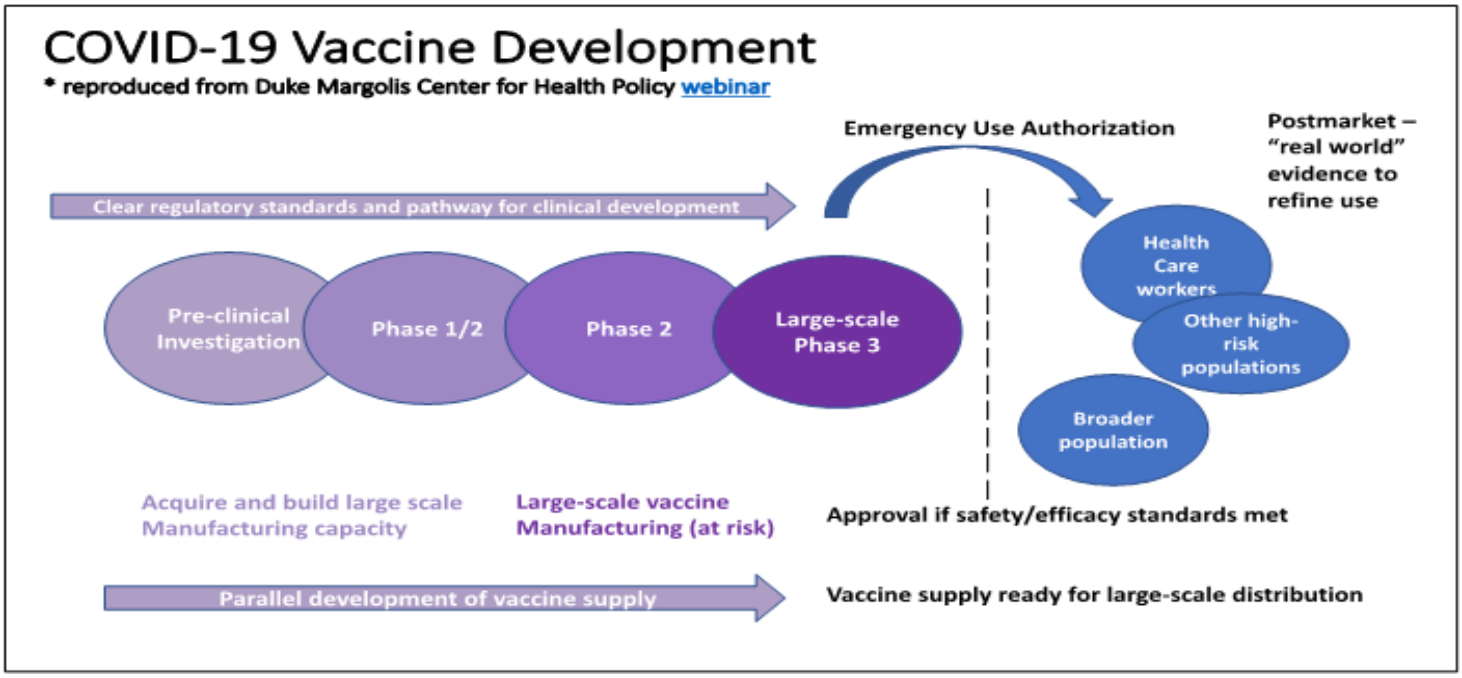
With this hope to soon tide over this pandemic we wish all our readers a very Happy New Year 2021‼

Keep reading and Stay Safe

THE WORLD ON PAUSE : URGENT NEED OF VACCINE

COVID-19 caused by SARS-CoV-2 has emerged as a public health emergency in 21st century. The pandemic has caused immense mortality and morbidity worldwide. Till date there is no specific drug which proved to have definite role in the permanent cure of the disease and can bring lifeto normalcy. This leaves us with only one choice that is…..VACCINE.An effective and safe vaccine has the power to generate herd immunity in the communities, which will not only reduce the incidence of disease, block transmission, but also reduce the social and economic burden resulted from this crisis.

Very high immunization coverage can effectively fight the pandemic, prevent secondary waves of infection, and control the seasonal endemic infection outbursts. Several potential COVID 19 vaccines have made through the trials giving us the hope of eradication of this catastrophic pandemic.



Comparative Analysis of Different COVID-19 Vaccines

S. N	Covid 19 Vaccine Developer /Company	Vaccine platform	No., Timing & Route of Administration of doses	Efficacy & Safety Profile
1	BioNTech/FosunPharma /Pfizer	3 LNP-mRNAs	2 doses 0, 28 days IM	Efficacy -90% Suspected ADRs • Severe allergic reactions to vaccines - rare but can occur • Four cases of Bell's palsy have been reported
2	Gamaleya Sputnik V	Non-Replicating Viral Vector Gam-COVID-Vac Adeno based	2 doses 0,21 days IM	Efficacy -92% Suspected ADRs • Pain at the injection site • Flu-like symptoms including fever, weakness, fatigue, and headache
3	Moderna/NIA I2	LNP-encapsulated mRNA	2 doses 0, 28 days IM	Efficacy - 95% Suspected ADRs • Injection site pain, fatigue, headache, muscle & joint pain, chills
4	University of Oxford/Astra Zeneca	Non-Replicating Viral Vector (ChAdOx1-S)	2 doses 0,28 days IM	Efficacy – 60- 90% (70%) Suspected ADRs • Transverse myelitis, neurological disorder have been reported
5	Bharat Biotech	Whole-Virion Inactivated	2 doses 0, 14 days IM	Efficacy - 70% Suspected ADRs • Pain at the injection site, fever, headache

DO YOU KNOW ????

- Covishield is co-developed by University of Oxford, Astra Zeneca in collaboration with Serum Institute of India
- After Serum's Covishield, governments expert panel recommends restricted emergency approval for Bharat Biotech's Covaxin
- Anyone receiving Covid vaccine should AVOID drinking alcohol because it can reduce the body's immune response
- A second coronavirus vaccine developed in India by Zydus Candila is set to enter phase III clinical trial soon

Comparative Sheet of COVISHIELD & COVAXIN

INDICATOR	COVISHIELD	COVAXIN
Type of Vaccine	Recombinant COVID 19 vaccine based on viral vector technology	Whole virion inactivated corona virus vaccine
No. of doses in each vial	10	20
Shelf life	6 months	6 months
Expiry date available on vial	Yes	Yes
Vaccine vial monitor	Not Available	Not Available
Route	Intramuscular (IM) Injectable	Intramuscular (IM)Injectable
Physical appearance of vaccine	Clear to slightly opaque, colourless to slightly brown	Whitish Translucent
Dose	0.5 ml each dose	0.5 ml each dose
Course	2 doses	2 doses
Schedule	4 week apart	4 week apart
Vaccination during Pregnancy	Not Recommended	Not Recommended
Vaccination ‹ 18 years of age	Not Recommended	Not Recommended
Vaccination to lactating mother	Not Recommended	Not Recommended
Storage and Transportation	2-8^{o} C at all levels	2-8^{o} C at all levels
Cold chain storage space in secondary packaging	2.109 cm^3	1.7187 cm^3
Shake test	Not Applicable	Not Applicable
Open vial policy	Not Applicable	Not Applicable

Comparative Sheet of COVISHIELD & COVAXIN

INDICATOR	COVISHIELD	COVAXIN
Freeze sensitive	Yes	Yes
Discard the vaccine vial if found	Frozen or frozen and thawed	Frozen or frozen and thawed
Discard the vial if	Solution is discoloured or visible particles are observed	Presence of particulate matter or other colouration
AEFI	Some mild AEFI may occur like injection site tenderness &pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia &nausea	Some mild AEFI may occur like injection site pain& swelling, headache, fatigue, fever, bodyache, abdominal pain, nausea& vomiting, dizziness, giddiness, tremors, sweating, cold, cough
AEFI Other	Paracetamol may be used to provide symptomatic relief from post-vaccination adverse reactions Very rare events of de-mylenating disorders have been reported following vaccination with this vaccine without the causal relationship establishment As with other IM injections, COVISHIELD should be given with caution to individuals with thrombocytopenia	
Any other information		Shake well, before use Use of chloroquine and corticosteroids may impair antibody response

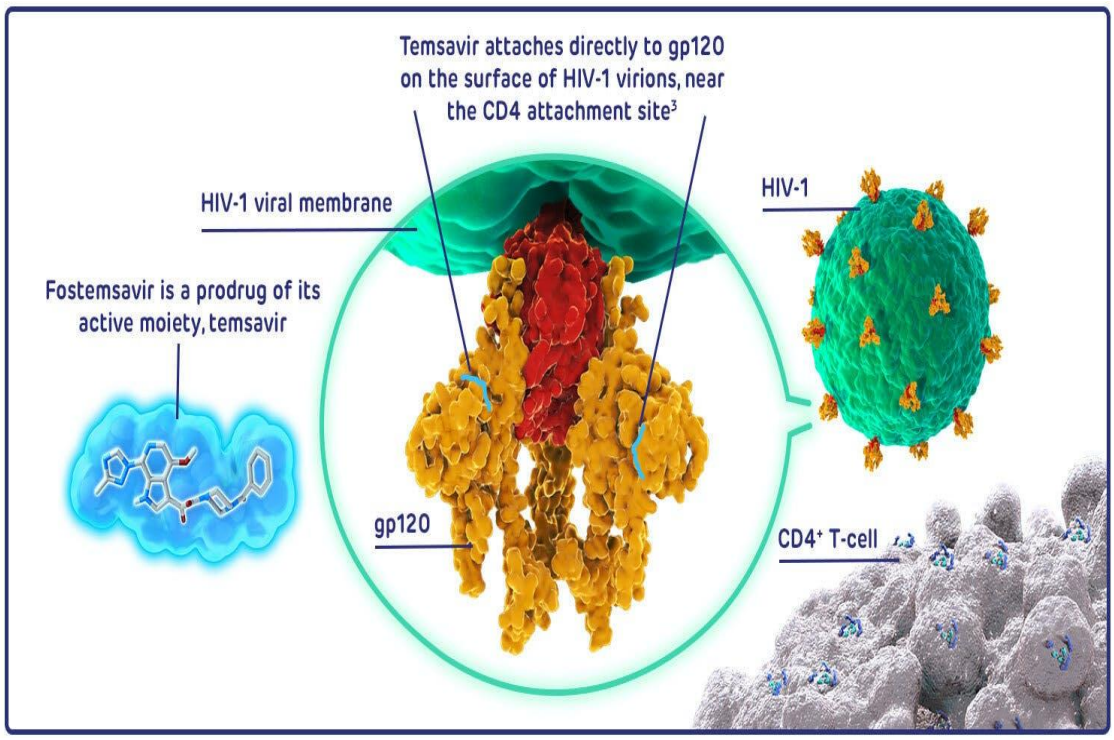
*Adopted from Comparative Factsheet by Govt. of India, MOHFW DO No. T-22020/14/2020-Imm dated 14th January 2021

NOVEL DRUG FOSTEMSAVIR

Fostemsavir is an antiretroviral drug, development by ViiV healthcare, for use in the treatment of HIV-1 infection in adult patient. It is intended to be taken as an adjuvant antiretroviral drug for the treatment of multi drug resistant HIV patients, who are failing the current antiretroviral regimen due to factors such as intolerance or other safety concerns. The FDA approved the drug in July 2020.

➢ **MECHANISM OF ACTION:**

- Fostemsavir is a prodrug, hydrolyzed to the active moiety, Temsavir (HIV-1 attachment inhibitor).
- Temsavir binds directly to the gp120 subunit within the HIV-1 envelope glycoprotein gp160 and selectively inhibits the interaction between the virus and cellular CD4 receptors, thereby preventing attachment.



1. **DOSAGE AND ADMINISTRATION:**

- Recommended dosage of Fostemsavir is one 600 mg tablet to be taken orally twice daily with or without food.
- Tablets are to be swallowed as whole and the tablet cannot be split.

2. **CONTRAINDICATIONS:**

- Hypersensitivity to Fostemsavir or any of the components of formulation

- Co administration with cytochrome P450 CYP3A inducers, as they significantly decrease the Temsavir plasma concentrationsoccurs which may result in loss of virologic response.

3. **WARNINGS AND PRECAUTIONS:**

- Immune Reconstitution Syndrome has been reported in patients treated with combination of antiretroviral therapies.

- QTc Prolongation: Use of Fostemsavir with caution in patient with a history of QTc prolongation or with pre-existing cardiac disease.

- Elevations in Hepatic transaminases in Patients with Hepatitis B or C Virus Co-infection

4. **ADVERSE REACTIONS:** The most common adverse reactions (all grades) observed in >5% of randomized and non-randomized participants were :

- Nausea
- Fatigue
- Diarrhoea.

5. **DRUG INTERACTIONS**

- Temsavir may increase plasma concentrations of grazoprevir and voxilaprevir. Use an alternative hepatitis C virus regimen if possible.

- Use the lowest possible starting dose for statins and monitor for statin-associated adverse events.

- Patients receiving Fostemsavir should not take doses of Estrogen-based therapies, including oral contraceptives, that contain more than 30 mcg/day of Ethinylestradiol. Caution is advised particularly in patients with additional risk factors for thromboembolic events

6. **USE IN SPECIFIC POPULATIONS**

- **Pregnancy:** Insufficient human data on the use of Fostemsavir during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage.

- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance, and adverse reactions in a breastfed infants

Schedule- Y

HISTORY

India was largely dependent on import of modern medicines after first world war. It was only in August 1930, the government of India appointed a Drug Enquiry Committee under the chairmanship of R.N. Chopra, to go in to the question of adulterated & substandard drugs sold in country & to regulate the import of drugs into British India. Later, the Drug Import Bill was passed & received assent of Governor General in Council & became **DRUG AND COSMETIC ACT** in **1940.** The **DRUGS & COSMETICS RULES** was laid down under this act in **1945,**which contains provision for classification of drugs under given schedules (Schedule A to Y) and guidelines for storage, sale, display and prescription of drugs under each schedule.

Hence, for the demonstration of safety and efficacy of the drug product for use in humans, it is essential the drug product should be approved for import or manufacturing and marketing in the country before its use. The Rules 122A, 122B and 122D, 122DA, 122DAA, 122E of Drugs and Cosmetics Rules and Appendix I, IA and VI of Schedule Y, describe the information/data required for approval of clinical trial and/or to import or manufacture of new drug for marketing in the country.

DEFINITION

- Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials.

SCHEDULE Y FOR INDIA IS A LAW AND NOT A MERE GUIDELINE

PURPOSE OF SCHEDULE Y

- To frame guidelines for conduct of clinical research
- Control and regulation for manufacturing and import of new drugs

CDSCO (Central Drugs Standard Control Organisation) and DTAB formulated GCP (Good Clinical Practice) under schedule Yin 2005 for better guidance principles for research and new drug development

MAJOR CONTENTS OF SCHEDULE Y

1. APPLICATION FOR PERMISSION

It shall made in **FORM 44**accompanied with following data in accordance with appendices, namely

- Chemical and pharmaceutical Information
- Animal pharmacology data
- Animal toxicology data
- Human clinical pharmacology data
- Regulatory status in other countries
- Prescribing Information

2. CLINICAL TRIAL

A) Approval for clinical trial

- Clinical trial on a new drug shall be initiated only after the permission has been granted by the licensing authority under rule 21 (b), and the approval obtained from the respective ethics committee (s).
- All trial Investigator(s) should possess appropriate qualifications, training and experience and should have access to such investigational and treatment facilities as are relevant to the proposed trial protocol.
- Protocol amendments if become necessary before initiation or during the course of a clinical trial, all suchamendments should be notified to the Licensing Authority in writing along with the approval by the ethics committee.

B) Responsibilities of sponsor

- Sponsor is responsible for implementing and maintaining quality assurance systems.
- Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity
- Any report of the serious adverse event, after due analysis shall be forwarded by the sponsor to the Licensing Authority.
- The sponsor (whether a pharmaceutical company or an Institution) or his representative shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority

C) Responsibilities of the Investigator

- The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance.
- Standard operating procedures are required to be documented by the investigators for the tasks performed by them.
- The investigator should ensure that adequate medical care is provided to the participant for any adverse events.
- Investigator(s) shall report all serious and unexpected adverse events.
- He shall also inform/guide the subject for the purpose of making claims in the case of trial related injury or death

D) Informed consent

- In all trials, a freely given, informed, written consent is required to be obtained from each study subject.
- The Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject.
- The subject's consent must be obtained in writing using an 'Informed Consent Form'.
- Patient information sheet as well as the Informed Consent Form should be approved by the ethics committee and furnished to the Licensing Authority

E) Responsibilities of the Ethics Committee

- To review and accord its approval to a trial protocol so as to safeguard the rights, safety and wellbeing of alltrial subjects.
- Ethics Committee(s) should make, at appropriate intervals, an ongoing review of the trials for which they review the protocol.

- In case an ethics committee revokes its approval accorded to a trial protocol, it must record the reasons for doing so
- In case of serious adverse event occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion on the financial compensation

F) Human Pharmacology (Phase I)

- The objective of studies in this Phase is the estimation of safety and tolerability with the initial administration of an investigational new drug into human(s)
- Studies in this phase of development usually have non- therapeutic objectives and may be conducted in healthy volunteers subjects or certain types of patients. Drugs with significant potential toxicity e.g. cytotoxic drugs are usually studied in patients.
- Phase I trials should preferably be carried out by Investigators trained in clinical pharmacology

G) Therapeutic exploratory trials (Phase II)

- To evaluate the effectiveness of a drug for a particular indication or indications in patients under study
- To determine the common short-term side-effects and risks associated with the drug.
- Studies should be conducted in a group of patients who are selected by relatively narrow criteria leading to a relatively homogeneous population.
- An important goal is to determine the dose(s) and regimen for Phase III trials.

H) Post Marketing Trial Phase (IV)

- Post Marketing trials are studies (other than routine surveillance) performed after drug approval and related to the approved indication(s)
- These trials go beyond the prior demonstration of the drug's safety, efficacy and dose definition
- These trials may not be considered necessary at the time of new drug approval but may be required by the Licensing Authority for optimizing the drug's use. Phase IV trials include additional drug-drug interaction(s), dose-response or safety studies and trials designed to support use under the approved indication(s),e.g. mortality/morbidity studies, epidemiological studies etc.

3. STUDIES IN SPECIAL POPULATIONS

A. Geriatrics
B. Paediatrics
C. Pregnant or nursing women
D. Post marketing surveillance
E. Special studies: Bioavailability / Bioequivalence Studies

A. Geriatrics

Geriatric patients should be included in Phase III clinical trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers, if:

a) The disease intended to be treated is characteristically a disease of aging; or
b) The population to be treated is known to include substantial numbers of geriatric patients; or
c) When there is specific reason to expect that conditions common in the elderly are likely to be encountered; or
d) When the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient

B. Paediatrics

- The timing of paediatric studies in the new drug development program will depend on the medicinal product, the type of disease being treated, safety considerations, and the efficacy and safety of available treatments.
- For a drug expected to be used in children, evaluations should be made in the appropriate age group.
- It is usually appropriate to begin with older children before extending the trial to younger children and then infants.
- If the new drug has a potential for use in paediatric patients – Paediatric studies should be conducted.

C. Pregnant or nursing women

- Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant/nursing women or foetus/nursing infants and where the data generated from women who are not pregnant or nursing, is not suitable. For new drugs intended for use during pregnancy, follow-up data (pertaining to a period appropriate for that drug) on the pregnancy, foetus and child will be required.
- Where applicable, excretion of the drug or its metabolites into human milk should be examined and the infant should be monitored for predicted pharmacological effects of the drug

D. Post Marketing Surveillance

- The applicant shall have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant in the country.

(a) The system shall be managed by qualified and trained personnel and the officer in-charge for collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

(b) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.

E. Special studies: Bioavailability / Bioequivalence Studies

- It is conducted according to the guideline for BA and BE studies.

SCOPE

- Schedule Y plays an important role by providing statutory support to Indian GCP guidelines
- In spite of the appreciable steps taken so far, our law framers further need to put efforts to raise the standard for a more rigid and stricter vigilance mechanism on the Pharmaceutical Companies
- This guideline does not apply to biologicals and vaccines.

REFERENCES

1. https://rgcb.res.in/documents/Schedule-Y
2. *https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/*

CAUSALITY ASSESSMENT IN PHARMACOVIGILANCE

An inherent challenge in Pharmacovigilance is evaluating Adverse Drug Reactions (ADRs) to determine the causal relationship between the drug and undesirable clinical events. **CausalityAssessment** is defined as the evaluation of the likelihood that a medicine was the causative agent of an observed adverse event.

Confirming the timeliness between reaction onset and drug use, compatibility between the nature of the event and drug pharmacology (including knowledge of the nature and frequency of ADR), medical or pharmacological plausibility (signs and symptoms, laboratory tests and mechanism of action) are key points for a causality assessment. It is also important to verify the possibility or exclusion of other causes for the observed event. The causality assessment consists of the assessment of the likelihood that an adverse event is a consequence of the use of the drug when it refers to an individual case.

The suspected adverse drug reactions are rarely specific for the drug, diagnostic tests are usually absent and a rechallenge is rarely ethically justified. In practice few adverse reactions are 'certain' or 'unlikely'; most are somewhere in between these extremes, i.e. 'possible' or 'probable'. In an attempt to solve this problem many systems have been developed for a structured and harmonized assessment of causality. None of these systems, however, have been shown to produce a precise and reliable quantitative estimation of relationship likelihood. Nevertheless, causality assessment has become a common routine procedure in pharmacovigilance.

Table 1. Advances and limitations of standardised case causality assessment

What causality assessment can do	What causality assessment cannot do
Decrease disagreement between assessors	Give accurate quantitative measurement of relationship likelihood
Classify relationship likelihood	Distinguish valid from invalid cases
Mark individual case reports	Prove the connection between drug and event
Improvement of scientific evaluation; educational	Quantify the contribution of a drug to the development of an adverse event
	Change uncertainty into certainty

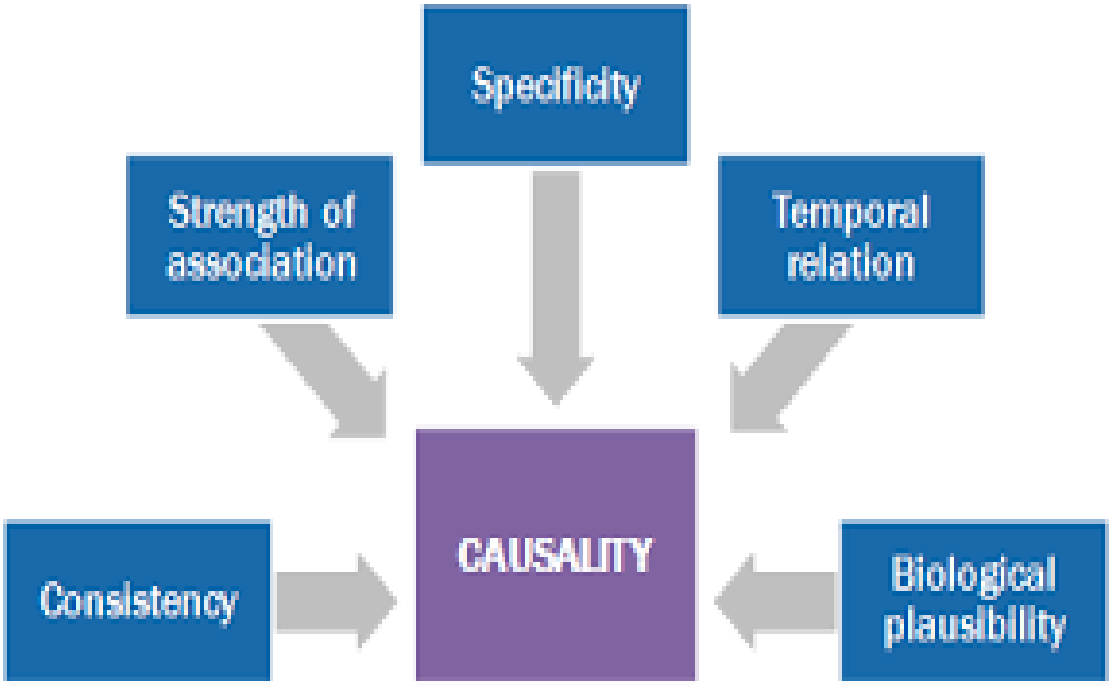
The PvPI follows **WHO-UMC causality assessment** scale for establishing the relation between the suspected drug and suspected adverse drug event. The WHO -UMC causality assessment system has been developed in consultation with the National Centers participating in the Programme for International Drug Monitoring and is meant as a practical tool for the assessment of case reports. It is basically a combined assessment taking into account the clinical-pharmacological aspects of the case history and the quality of the documentation of the observation.

Table 2. WHO-UMC Causality Categories

Causality term	*Assessment criteria**
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

* All points should be reasonably complied with

This causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Center (WHO-UMC) is the generally accepted and one of the most widely used method for causality assessment in clinical practice as it offers a simple methodology. Still more developed high-quality assessment tools which can meticulously establish suitable diagnostic criteria for ADRs with universal acceptance to improvise the fundamental aspect of drug safety can be applied.



Positive impact on quality of healthcare services can be significantly observed by reduction of ADRs in patients and one of the most important key factors in reducing the incidence of ADRs is undoubtedly its precise diagnosis for which causality assessment is important. Thus, causality is crucial for risk benefit assessment, particularly when it involves post marketing safety signals.

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DO YOU KNOW ?

CDC had reported that SEVERE ANAPHYLACTIC REACTION can occur with COVID 19 Vaccine developed by Pfizer BioNTech

CDC advises people to abstain from getting vaccination who ever had a severe allergic reaction to any ingredient in COVID19 vaccine

DRUG SAFETY ALERT

➢ Systemic and inhaled fluoroquinolones : small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk

Advice for healthcare professionals:

- Fluoroquinolones are authorised for use in serious, life-threatening bacterial infections
- Systemic (by mouth or injection) and inhaled fluoroquinolones have been associated with a small increased risk of heart valve regurgitation, with one retrospective case-control study suggesting a 2-fold increased relative risk with current oral fluroquinolone use compared with the risk with use of amoxicillin or azithromycin
- Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of othertherapeutic options in the following patients at risk:

1. Patients with congenital heart valve disease or pre-existing heart valve disease
2. Patients diagnosed with connective tissue disorders (for example, Marfan syndrome or Ehlers-Danlos syndrome)
3. Patients with other risk factors or conditions predisposing for heart valve regurgitation (for example, hypertension, Turner's syndrome, Behçet's disease, rheumatoid arthritis, and infective endocarditis)

➢ FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid

- FDA warned that the use of Non Steroidal Anti-Inflammatory Drugs (NSAIDs) around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby and possible complications.
- After around 20 weeks of pregnancy, the unborn babies' kidneys produce most of the amniotic fluid, so kidney problems can lead to low levels of this fluid. Amniotic fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop.
- At around 30 weeks, NSAIDs can cause a problem that may result in heart issues in the unborn baby.
- Use of NSAIDs if deemed necessary, between 20 and 30 weeks of pregnancy should be limited to the lowest effective dose for the shortest duration.

➢ FDA adds Boxed Warning for increased risk of cardiovascular related mortality with gout medicine Uloric (febuxostat)

- FDA concluded there is an increased risk of heart-related death with Uloric (active ingredient febuxostat) compared to another gout medicine, allopurinol
- This conclusion is based on our in-depth review of results from a safety clinical trial that found an increased risk of heart-related death
- Uloric prescribing information to require a Boxed Warning (most prominent warning) and a new patient Medication Guide.
- FDA limits the approved use of Uloric to certain patients who are not treated effectively or experience severe side effects with allopurinol.

NEW DRUG APPROVAL

SL No	Drug	Mechanism of Action	Indication	Date of Approval
1	Gallium 68 PSMA-11	Ga 68 PSMA-11 binds to cells that express PSMA, including malignant prostate cancer cells, which usually overexpress PSMA	For detection and localization of prostate cancer	12/1/2020
2	Naxitamab-gqgk	Humanized anti-GD2 3F8 monoclonal antibody; stimulates antibody-dependent cell-mediated cytotoxicity against GD2-expressing tumor cells	To treat high-risk refractory or relapsed neuroblastoma	11/25/2020
3	Setmelanotide	Melanocortin-4 receptor (MC4R) agonist designed to restore impaired MC4R pathway function caused by genetic variants that occur upstream of the receptor	To treat obesity and the control of hunger associated with pro-opiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age	11/25/2020
4	Lumasiran	Lumasiran, a HAO1-directed double-stranded small interfering ribonucleic acid, reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 mRNA in hepatocytes through RNA interference	To treat hyperoxaluria type 1	23/11/2020
6	Lonafarnib	Oral farnesyltransferase inhibitor (FTI); farnesyltransferase is an enzyme involved in modification of proteins through a process called prenylation	To treat rare conditions related to premature aging	11/20/2020
7	Remdesivir	Remdesivir is a monophosphoramidate nucleosideprodrug that undergoes intracellular metabolic conversion to its active metabolite nucleoside triphosphate (NTP).	To treat COVID-19	10/22/2020
8	Atoltivimab, Maftivimab, and Odesivimab-ebgn	Combination of 3 monoclonal recombinant human IgG1-kappa monoclonal antibodies that simultaneously bind to the glycoprotein on the Ebola virus surface and block attachment and entry of the virus on the host cell membrane	To treat Ebola virus	10/14/2020