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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Important Questions
Chapter 14 : New Drug Development

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Chapter 14
New Drug Development
IMPORTANT Questions

Q1. Describe note on Basic Concepts of Clinical trials.

Ans.

Basic Concepts of clinical trials

- → Clinical trials are research and studies performed with volunteer people,
- → Clinical trial is done to test safety and efficacy of new drugs or new surgery procedure.

Types of clinical trial

- **Treatment trial :** This is performed for experimental treatments , test of new combination of drugs, or for new surgery procedure.
- **Preventions trial :** This is performed test a drugs foe prevention of disease , like vaccines , vitamins etc.
- **Screening trails (early detections) :** This trail is performed for detection of certain disease or health condition.
- **Diagonstic trail :** This is performed for diagnosing a particular disease or condition, of people have sign and symptoms.
- **Quality of life trail :** This performed to explore the ways which can improve comfort and quality of life in chronic illness.

Phases of Clinical Trials

1) Phase I trials test the safety and tolerability of a new intervention in a small group of healthy volunteers.
2) Phase II trials test the effectiveness and safety of the intervention in a larger group of patients.
3) Phase III trials test the effectiveness and safety of the intervention in an even larger group of patients, and compare the intervention to standard treatment or placebo.

Phase IV trials are conducted after the intervention has been approved for use, and evaluate its long-term safety and effectiveness

Q2. Write a note on Abbreviated New Drug Application (ANDA). New Drug Application.

Ans.

Abbreviated New Drug Application (ANDA)

- ANDA is an application submitted to FDA for the review and approval of a generic drug for production , this application contains necessary data of related drugs.
- Once FDA approved the application , the applicant can manufacture and market that generic drug, to offer a safe , effective and lower cost alternative drug to the brand name drug.
- Generic drug application are not required to provide pre clinical(on animal) and clinical (on human) data to prove safety and effectiveness of drugs , that is why they are called ”abbreviated applications ".

Q3. Write the difference between Generic drugs vs Brand Name Drugs

Ans.

Features	Generic Drugs	Brand Name Drugs
Definition	A generic drug is an off-patent pharmaceutical product that is manufactured by a pharmaceutical company in the same strength, dosage form, route of administration, safety, quality, performance characteristics, and intended use after expiring the patent of the relevant brand name drug (Innovator drug).	A Brand name drug is a pharmaceutical product that is developed and marketed under a patent or registered trademark by a pharmaceutical company. But it is approved after establishing the drug's safety and effectiveness through animal and clinical (human) studies. Also, brand name drugs known as innovator drugs.
Patents	Off patent.	Patent protected.
Trade Name	Marketed under the Generic name of the drug.	Marketed under a unique proprietary name given by the company.
Application	ANDA required for USFDA approval.	NDA required for USFDA approval.
Manufactured by	Manufactured by several pharmaceutical companies after patents expiration of the relevant brand name drug.	Developed and manufactured by an innovator company.
Animal & Clinical study	Not required to perform.	Essential to perform.
Price	Cheaper.	Costly than generic drugs.
Appearance (Color, Shape, Size)	Look different from relevant brand name drug.	Unique look as design during product development.
Name variation	Same Generic drug name in any country.	Same or different brand names in different countries.
Excipients	May contain the same or altered but acceptable excipients from relevant brand name drug.	Uses acceptable excipients by the innovator company during development.
Availability	After expiration of patents and exclusivities	From product launch after proving the safety and effectiveness.
Examples	Paracetamol tablet	Tylenol, Para, NAPA, Mapap, Nortemp,

Q4. Write a note on Emergency use Authorisation (EUA).

Ans.

Emergency use authorisation (EUA)

→ Emergency use authorisation is an authorisation(Permission) issued for use of unregistered drugs and vaccines in a public health emergency by FDA even in the lake of complete information about the safety and efficacy of the product The FDA determine that , it is appropriate to give permission for use of a drug or vaccine in a declared emergency

Conditions for issuing EUA

➢ FDA may determine (confirm) before issuing emergency use authorisation the

- The agent mentioned in the emergency condition may be serious life threatening illness or not ?
- The available scientific evidence indicates that the product may be useful in diagnosing , treating or preventing a serious life threatening illness
- The known and potential (which may be occur) benefits must be more than the known and potential risk of the product . (Risk reward ratio)

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