

Drug Chemistry and Technology Basics,
Cleaner Production and Mega-Trends in Pharmaceutical Industry

Terminology of drugs

Dr. As. Prof. Anastasya Sladkova
Dr. Sci. Prof. Natalya Loginova

A decorative graphic in the top left corner showing a molecular structure with blue and white spheres connected by lines, set against a light blue background.

Questions

1. Why nature of pharmaceutical sciences is multidisciplinary? Give examples of such disciplines
2. Describe the global pharmaceutical market
3. What classifications of drugs do you know?
4. What is International Nonproprietary Name?
5. What sources for drugs do you know?



LECTURES

- 1. Introduction**
- 2. ➡ Terminology of Drugs**
- 3. Drug Design and Quality standards**
- 4. Falsification of Medicines**
- 5. Quality Assurance in Medicines**
- 6. Control by Pharmacopeias**
- 7. Trends in Pharmaceutical Industry**

What is Drug

Drug (WHO) – Any substance or product that is used or intended to be used to modify or explore the physiological system or pathological state for the benefit of the recipient



*The Apothecary or
The Chemist by
Gabriël Metsu (c. 1651–67)*

The main terms



Pharmacy – (*from Greek: φάρμακον*) the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs

Pharmaceutics – the discipline of pharmacy that deals with the process of turning a **new chemical entity (NCE)** or old drugs into a medication to be used safely and effectively by patients

(includes pharmaceutical formulation, pharmaceutical manufacturing, dispensing pharmacy, pharmaceutical technology, physical pharmacy, pharmaceutical jurisprudence)

Pharmacology – the branch of medicine and biology concerned with the study of drug action, where a drug can be broadly defined as any man-made, natural, or endogenous (from within body) molecule which exerts a biochemical and/or physiological effect on the cell, tissue, organ, or organism

The main terms

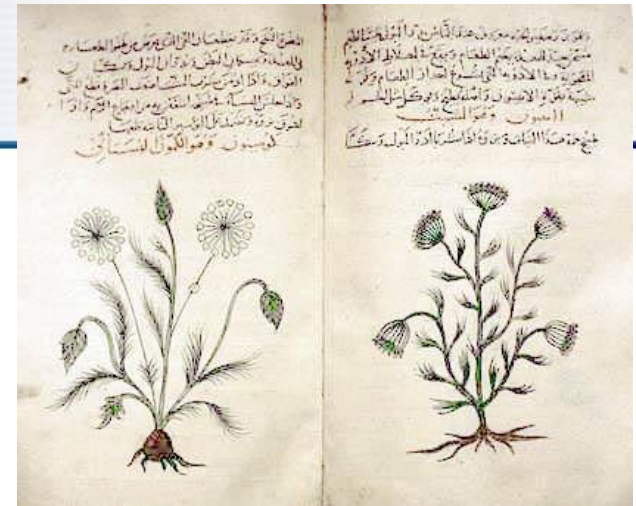
Pharmacognosy – the study of medicinal drugs derived from plants or other natural sources

Pharmaceutical Chemistry – the study of drug design to optimize **pharmacokinetics** and **pharmacodynamics**, and synthesis of new drug molecules

Pharmacodynamics – quantitative study of drug action

Pharmacokinetics – quantitative study of how drugs are taken up, biologically transformed, distributed, metabolized, and eliminated from the body

Pharmacogenomics – the study of the role of genetics in drug response (more general)

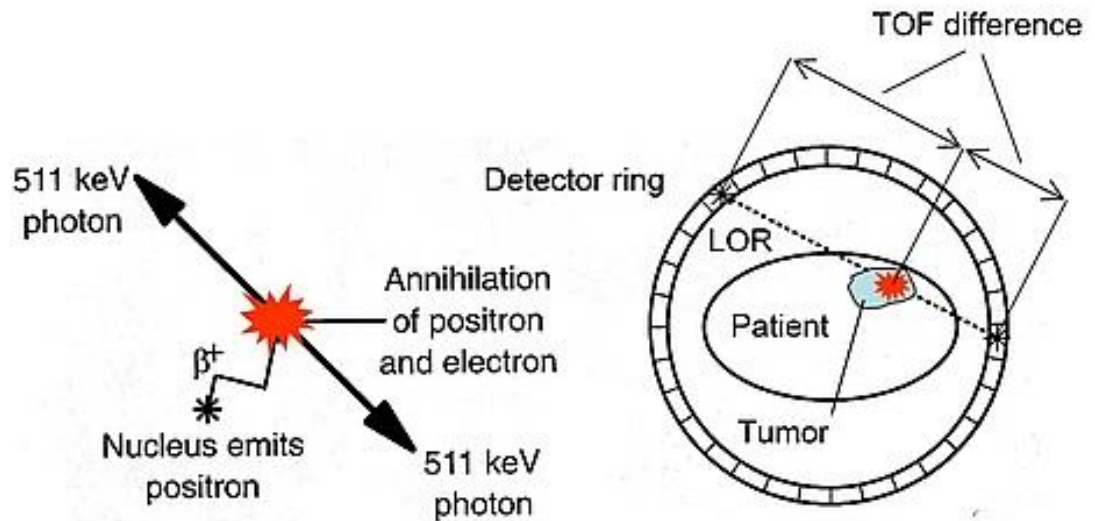


The main terms

Pharmacogenetics – the study of inherited genetic differences in drug metabolic pathways which can affect individual responses to drugs, both in terms of therapeutic effect as well as adverse effects

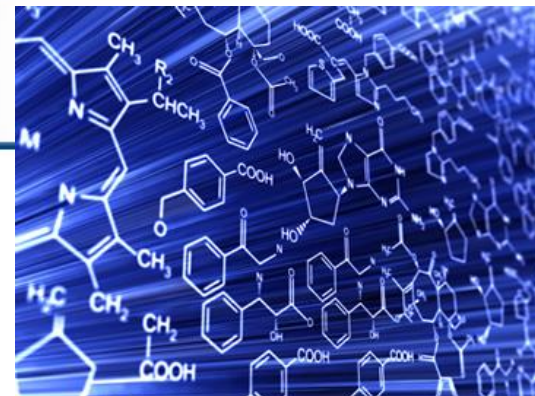
Nuclear Pharmacy

– the safe and effective use of radioactive drugs for not only diagnosis but also therapy



*Positron emission technology
(PET)*

The main terms



Drug Design – the inventive process of finding new medications based on the knowledge of a biological target

Medicinal Chemistry – the discipline at the intersection of chemistry, especially synthetic organic chemistry, and pharmacology and various other biological specialties, where they are involved with design, chemical synthesis and development for market of pharmaceutical agents, or bio-active molecules (drugs)

Drug Development – the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery



The main terms

Pharmacy Practice – the discipline of pharmacy which involves developing the professional roles of pharmacists

Pharmaceutical Industry develops, produces, and markets drugs or pharmaceuticals for use as medications

Regulatory Agency – agency that regulates manufacturing of medicines, enforces good manufacturing practice (GMP), and approves importation, promotion, marketing and labeling of medicines

Pharmacopeia – book containing directions for the identification of compound medicines, and published by the authority of a government or a medical or pharmaceutical society

Terminology of Drugs

Pharmaceutical drug (also **medication** or **medicine**) – chemical substance used to treat, cure, prevent, or diagnose a disease or to promote well-being

So, medicines are substances or combinations thereof coming in contact with the human or animal body, penetrating into the organs and tissues of the human or animal body, used for prophylaxis, diagnostics treatment of disease, rehabilitation, as well as for maintenance, prevention or interruption of pregnancy, as may be derived from blood, blood plasma, human or animal organs and tissues, plants and minerals by synthesis methods or using biological technologies

Terminology of Drugs

API (active pharmaceutical ingredient) – the chemical molecule in a pharmaceutical product (medicines we buy from the chemist) that lends the product the claimed therapeutic effect

Bulk drug – API in bulk (unpacked)

Excipient – non-active pharmaceutical ingredient

Medicine = API + Excipients

Terminology of Drugs

It should be emphasized that drugs are only **products authorized in the prescribed manner for medical use**

Pharmacological activity – ability of a substance or a combination of several substances to change the state and functions of a living organism

Placebo – a substance having no pharmacological effect but administered as a control in testing experimentally or clinically the efficacy of a biologically active preparation



Terminology of Drugs

Herbal medicinal raw material – fresh or dried plants or parts thereof used for manufacturing of medicines by institutions producing medicines, or for compounding of medicinal products by pharmacy institutions, veterinary pharmacy institutions and individual entrepreneurs holding pharmaceutical licenses

Pharmaceutical – synthetic chemical used as drug (cf.)

Biopharmaceutical (biologic) – biotechnology-based drug

Terminology of Drugs

OTC – over the counter (OTC drugs can be bought without prescription as they have proven long term safety)

POM – prescription-only medicine (these medicines cannot be purchased without a doctor's prescription)

Blockbuster drug – a drug that has made more than US\$1 billion/year

Terminology of Drugs



Dosage form – the physical form of a drug

It is a medicinal product form that conditions its state, with a view to the method of administration for achievement of the optimal efficiency of the medicinal product

Formulated drug (medicine) – dosage form of drugs made from APIs mixed with excipients

Dosage forms of drugs

Classification by...

Route of administration

Oral (tablet, capsule, pill)

Topical (gel, plaster)

Rectal (suppository)

Parenteral (intravenous injection)

Vaginal (vaginal ring)

Inhaled (nebulizer)

Ophthalmic (eye drops)

Otic, Nasal, Transbuccal

Physical form

Solid (tablet, capsule)

Semisolid (plaster)

Liquid (oral solution, syrup)

Gaseous (nebulizer)



How The Medicines Work In Our Body



Terminology of Drugs

Pharmaceutical substance – any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials (this includes active pharmaceutical ingredients and pharmaceutical excipients)

Finished pharmaceutical product – finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling

Shelf life – the period of time during which a pharmaceutical product, if stored as indicated on the label, is expected to comply with the specification as determined by stability studies on a number of batches of the product

The shelf life is used to establish the **expiry date** of each batch

Medicine should be

Medicine

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graph TD; A[Medicine] --> B[safety]; A --> C[efficiency]; A --> D[availability];
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safety

a positive medicinal product characteristic which is based on comparative analysis of its efficiency and assessment of the risk of causing harm to human life and health

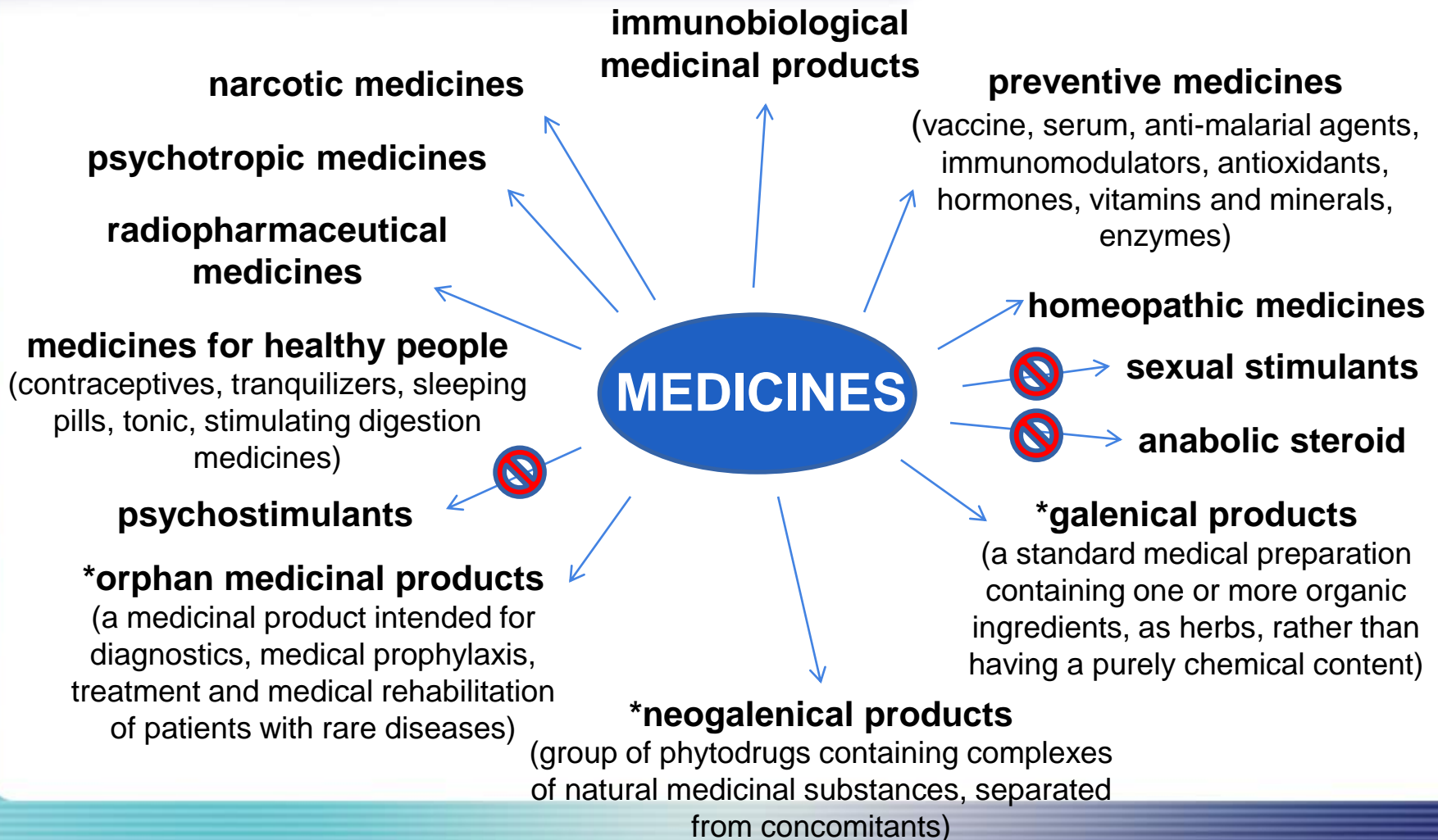
efficiency

characteristic of the degree of positive impact exerted by the medicinal product on prevention, course or duration of the disease or condition, prevention of pregnancy, recovery of normal vital activity of a human organism and compensation of its functions impaired as a result of disease

availability

providing the population with timely medical care: the saturation of the domestic market with safe, effective and good quality medicines

Is it medicine or no?



Parapharmaceuticals (not drugs)

- ✓ biologically active food additives (dietary supplements)
Supplements as generally understood include **vitamins, minerals, fiber, fatty acids, or amino acids**, among other substances
- ✓ food colorants and additives
- ✓ medical cosmetics
- ✓ synthetic and natural polymers for medical purposes
- ✓ wound dressings and sutures
- ✓ etc.

Generics



Generic Drug

WHO : “A pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights”

Original (Brand Name) Drugs and Generics

In **Lipitor** (reduces levels of "bad" cholesterol), for example, the **API** is **atorvastatin**

It's the API that will allow us to generalize data and studies with the drug, linking the original bench science and preclinical research, to the tablet dispensed by the pharmacy – it's the same chemical

The fact that drugs have an **API** allows generic drugs to be marketed, because when we compare generics, **the API is the same**

Original (Brand Name) Drugs and Generics

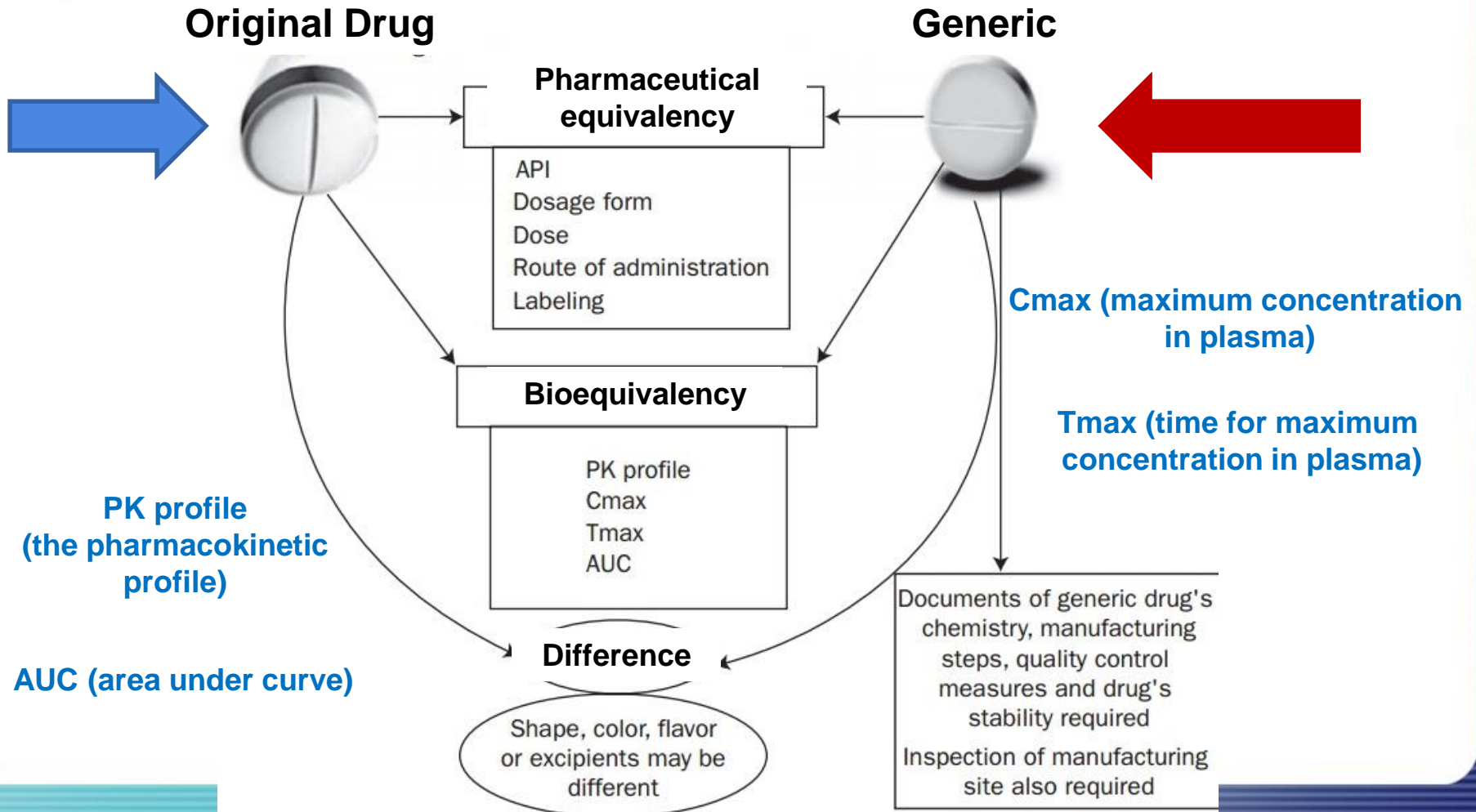
Pharmaceutical equivalency – equivalency between brand name and generic name drugs on APIs, dosage forms, dose, and route of administration

*While **patent protection** usually secures a monopolistic market power for a limited time, the threat of generics is immense*

Sales of branded products that have been established over years will erode within weeks

Most pharmaceutical companies still don't know how to handle this competitive threat

Equivalence Relationships

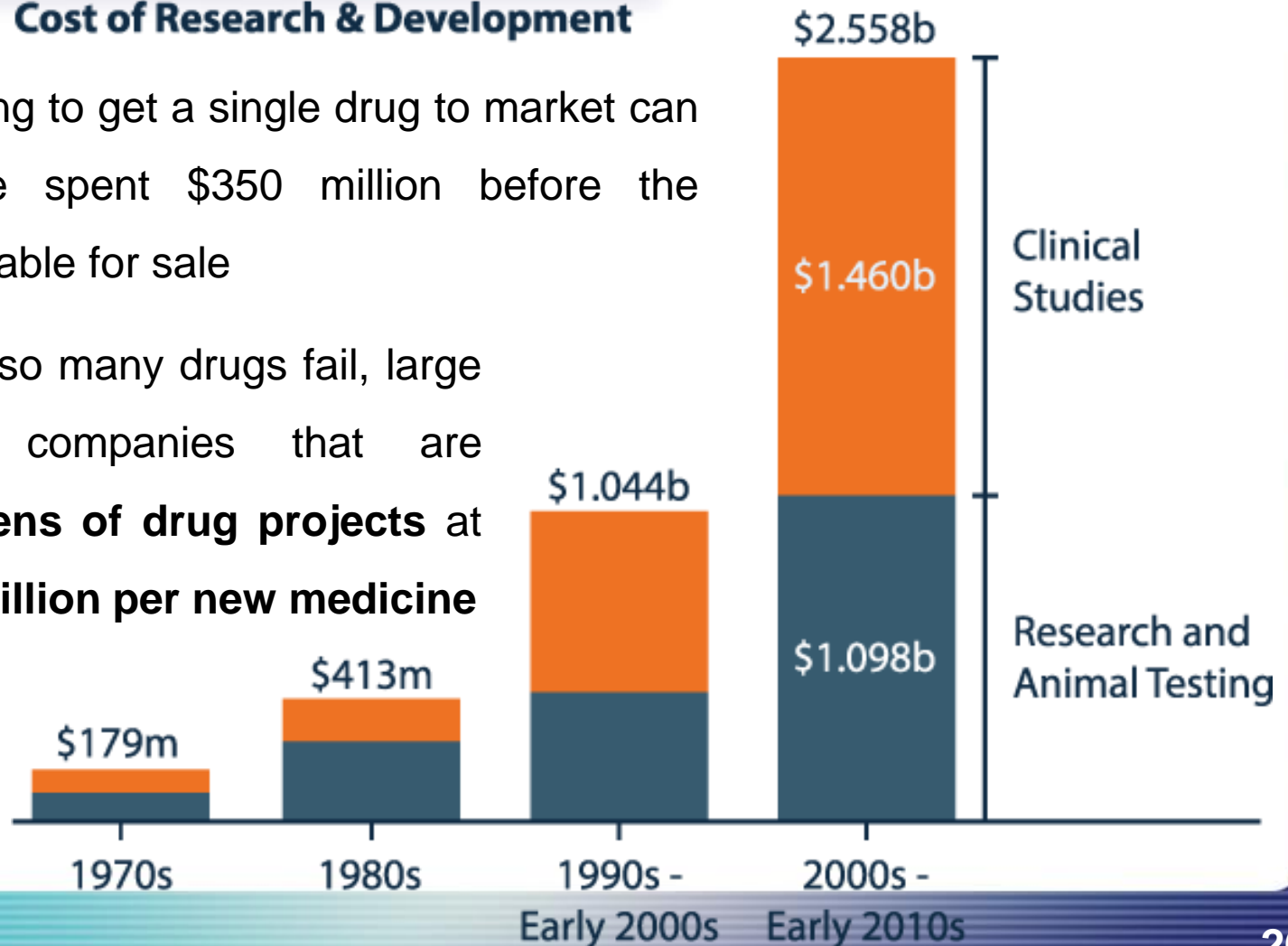


Why Generics?

Cost of Research & Development

A company hoping to get a single drug to market can expect to have spent \$350 million before the medicine is available for sale

In part because so many drugs fail, large pharmaceutical companies that are working on **dozens of drug projects** at once spend **\$5 billion per new medicine**



Why Generics?



High Risks in Drug Development (R&D)

Drug development success rates

Disease Group	Rate
Central nervous system	14.5%
Cardio vascular	17.5%
Immunology	15.4%
Infections	28.1%
Oncology	15.8%

Reasons of abandonment

Reason	Rate
Efficacy	37.6%
Economics	33.8%
Safety	19.6%
Other	9.0%

Source: Bogdan, B and Villiger, R. Valuation in Life Sciences, 2007, Springer



Questions

1. What dosage forms of drugs do you know?
2. What is difference between original drugs and generics?
3. Why does a 500 mg paracetamol tablet weigh more than 500 mg?
4. What is the classification of dosage forms?
5. What do “pharmaceutical equivalency” and “bioequivalency” mean? Are there any differences between bioavailability and bioequivalency?



Thank You !

sladkova-an@yandex.ru