Medicines from R&D to Access

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WE WILL NOT REST IN PEACE ACT UP
FIGHT AIDS
RESEARCH ALTERNATIVE TREATMENTS NOW!
FIGHT AIDS
WE WILL NOT REST IN PEACE ACT UP
ACT UP FOR A CURE

What are medicines

A medicine/drug is a chemical substance, typically of known structure, which, when administered to a living organism, produces a biological effect.A pharmaceutical drug, also called a medication or medicine, is a chemical substance used to treat, cure, prevent, or diagnose a disease or to promote well-being.

Consumption of drugs can be via inhalation, injection, smoking, ingestion, absorption via a patch on the skin, or dissolution under the tongue.

What is Research

In 1928, at St. Mary's Hospital, London, Alexander Fleming **discovered penicillin**. This **discovery** led to the introduction of antibiotics that greatly reduced the number of deaths from infection.

Fleming was a famously poor communicator and orator, which meant his findings were not initially given much attention.He was unable to convince a chemist to help him extract and stabilize the antibacterial compound found in the broth filtrate.

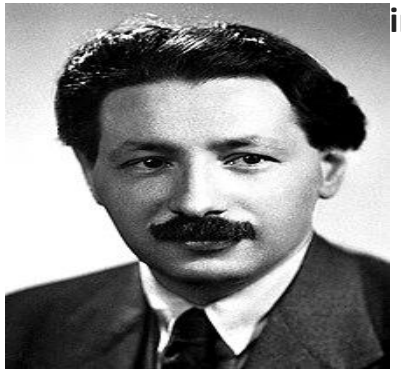
Where does Research and Development happen?

- **Globally, it is estimated that the public pays for two-thirds of all upfront drug R&D costs, with around a third of new medicines originating in public research institutions. On top of this, many medicines developed by pharmaceutical companies are often built upon a large body of scientific work undertaken and paid for by the tax payer.**
  Pills and Profits by Global Justice Now

- **A study of the Public Sector Research Institutes in USA points out that , 46% of the drugs developed in public sector offered a substantial improvement over existing treatments, compared with 20% of the drugs from the private sector.**

What is development

In 1939, Ernst Chain joined Howard Florey to investigate natural antibacterial agents produced by microorganisms. This led him and Florey to revisit the work of Alexander Fleming, who had described penicillin nine years earlier.It was Florey and Chain who actually made a useful and effective drug out of penicillin, after the task had been abandoned as too difficult. Chain and Florey discovered how to isolate and concentrate the germ-killing agent in penicillin and conducted the clinical trials.



Clinical trial

A research study in which candidate therapies are tested on human subjects to identify their clinical, pharmacological or other effects, adverse reactions and absorption, distribution, metabolism and excretion in the human body in order to ascertain their safety and efficacy. There are four phases of clinical trials

- **Preclinical- Testing of drug in non-human subjects, to gather efficacy, toxicity and pharmacokinetic info**
- **Phase 0- Pharmacokinetics; particularly, oral bioavailability and half-life of the drug**
- **Phase I (a candidate therapy is given to a small group of people for the first time);**
- **Phase II (the candidate therapy is given to a larger group of people to further evaluate its safety and efficacy);**
- **Phase III (the candidate therapy is given to larger groups of people to confirm its efficacy, monitor side effects, compare it to commonly used treatments and collect safety information); and**
- **Phase IV (post-marketing studies gather information on the health technology's efficacy in various populations and a side-effect associated with long-term use).**

Industrial production

In 1941, they treated a policeman, Albert Alexander, with a severe face infection; his condition improved, but then supplies of penicillin ran out and he died.

The challenge of mass-producing this drug was daunting. On March 14, 1942, the first patient was treated for streptococcal sepsis with US-made penicillin produced by Merck & Co.[] Half of the total supply produced at the time was used on that one patient, Anne Miller. By June 1942, just enough US penicillin was available to treat ten patients. In July 1943, the War Production Board drew up a plan for the mass distribution of penicillin stocks to Allied troops fighting in Europe.

Methods for mass production of penicillin were patented by Andrew Jackson Moyer in 1945. Florey had not patented penicillin, having been advised by Sir Henry Dale that doing so would be unethical.

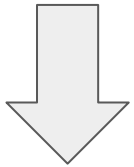
Patent- Patent-Patent-Patent

Patent: A statutory, time-limited exclusive right granted by a national authority to prevent others from legally making, using, offering for sale or selling a qualifying invention.

- Product Patent
- Process Patent

What are the phases/levels of manufacture

API or Bulk Drug



Formulation

API or Bulk Drug

API (Active Pharmaceutical Ingredient) means the active ingredient which is contained in medicine. API and raw material are often confused due to the similar usage of the two terms. However, raw material refers to chemical compounds that are used as a base to make an API.

API manufacturer make a chemical compound which becomes an API in the laboratory. Also taken into consideration are the degree of concentration and which temperature allows a high quality of API to be manufactured efficiently. In order to find answers to these questions, development department set about conducting a series of experiments. Once decided production department manufacture a high quantity of APIs using the large reactors.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What is a formulation.

- In pharmacy, a **formulation** is a mixture or a structure such as a capsule, tablet, or an emulsion, prepared according to a specific procedure (called a “formula”). Formulations are a very important aspect of creating medicines, since they are essential to ensuring that the active part of the drug is delivered to the correct part of the body, in the right concentration, and at the right rate (not too fast and not too slowly).

- The medicines also need to have an acceptable taste (in the case of pills, tablets or syrups), last long enough in storage still to be safe and effective when used, and be sufficiently stable both physically and chemically to be transported from where they are manufactured to the eventual consumer.

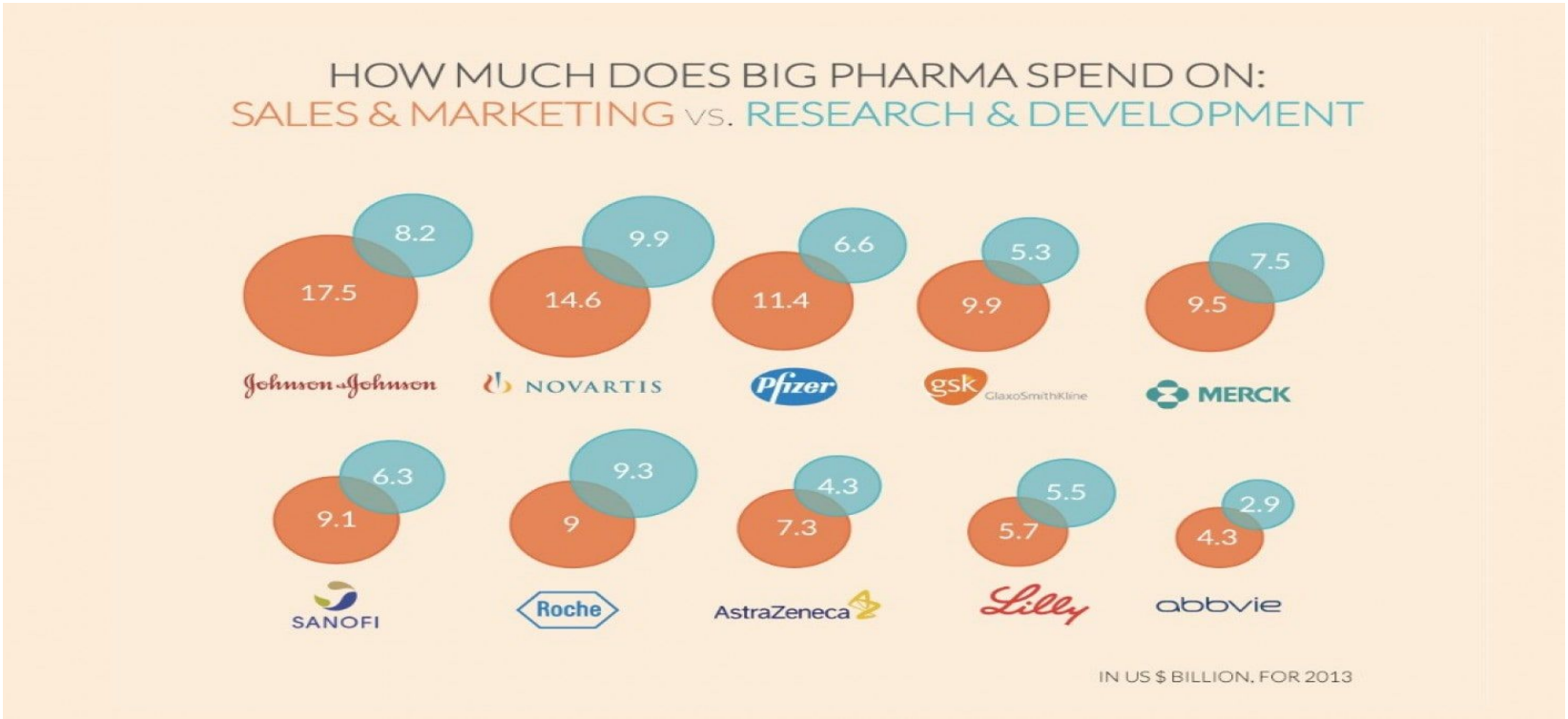
Video

https://www.youtube.com/watch?v=tHL8j0wCcH0

The following are the main components in the price of a drug :

R&D and Manufacturing i. Research and Development ii. Raw material iii. Manufacturing cost iv. Quality control v. Yield/loss:	Post manufacturing expenses a. Transportation costs b. Trade margins- given to agents/distributors/retailers c. Promotion costs marketing/hiring/incentives	Profit margin – to the manufacturer included as post manufacturing expense	Taxes a. Goods and Services Tax (GST) b. Customs tax

R&D costs – a wide range of estimates


HOW MUCH DOES BIG PHARMA SPEND ON:
SALES & MARKETING VS. RESEARCH & DEVELOPMENT
8.2
17.5
Johnson & Johnson
9.9
14.6
NOVARTIS
6.6
11.4
Pfizer
5.3
9.9
gsk GlaxoSmithKline
7.5
9.5
MERCK
6.3
9.1
SANOFI
9.3
9
Roche
4.3
7.3
AstraZeneca
5.5
5.7
Lilly
2.9
4.3
abbvie
IN US $ BILLION, FOR 2013

But are people able to access medicines ?

A study in India by Selvaraj et al looking at data from 1993 to 2014 says that around 3.09% of the population has moved into poverty due to costs of medicines. While that for Health was 4.48 %

Only 36% of Cancer patients are able to buy medicines in India

A third (33%) of the total OOP expenditure was spend on medicine, meaning patients spend around R9 billion rand out of their pockets on medicine alone.

Three types of diseases distinguished by the Commission on Macroeconomics and Health (WHO, 2001a)

- **Type I diseases are found in both rich and poor countries, and affect large numbers of vulnerable populations in both. Examples of communicable diseases include measles, hepatitis B, and Haemophilus influenzae type b. Examples of non-communicable diseases include diabetes, cardiovascular diseases and tobacco-related illnesses.**

- **Type II diseases are incident in both rich and poor countries, but with a substantial proportion of cases in poor countries. Examples of such diseases include HIV/AIDS and TB. While both diseases are present in rich and poor countries, more than 90 per cent of cases occur in poor countries.**

- **Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. Examples of such diseases include African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis).**

Thank You

Essential Movie list- How to Survive a Plague