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Pharmaceuticals from Production to Sale

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Drugs are substances used to correct or examine physiological systems or pathological conditions for the benefit of the user. Medicines are used to fight against infection (antibiotics), to protect from disease or infection (vaccines), to provide elements missing in the organism (vitamins, minerals), to temporarily block normal functions (anesthetics) [1,2].

Efforts to treat people's illnesses in various forms are as old as human history. In the early days, there were remedies with plants for diseases. The development of medicines and medicines in today's sense has come about in the 19th century when science has made a leap. In the 19th century, innovations in mathematics, physics and astronomy have led to significant developments in chemistry, anatomy and physiology. The 20th century is the modern period in which drug design emerges.

The fact that more than 20,000 products are on the market when there are more than five drug active ingredients is due to the fact that the same drug substance is applied to the market as different pharmaceutical products in different dosage forms (such as atorvastatin active ingredient in the market in the name of various pharmaceutical products such as Lipitor ®, kolestor ®, torvaxal®...). Active ingredient combinations also increase the number of medications (eg, the use of ergotamine-caffeine in the treatment of migraine) [1-4].

The objective of developing new drug molecules is to develop beneficial therapeutic compounds that are stronger, less toxic and have the least side effects. Drug investigations are still ongoing as these features are difficult to provide precisely.

With the development of better compounds (low toxicity, better pharmacodynamics) many medicines that are widely used for many years are getting out of use and new therapies are on the agenda. Obviously, when there are many developments and many diseases are found, more permanent solutions for these diseases can be calculated [2].

What stages do the drugs take to become pharmacological products? With many screening methods in the first stages, the active substances are destroyed without medication. About 4,000 to 10,000 molecules, which may be drugs, are synthesized in laboratories. After a number of pharmacological screening tests, advanced pharmacological activity and toxicity tests are performed (see whether the desired effect is present and whether there are side effects). After these studies the number of molecules can be reduced to 9-10 [1-6].

Causes of elimination at these stages;

- not have any expected effect
- low impact potency
- effective enough but at the same time have serious side effects
- not stable
- difficult and expensive to obtain
- difficult to be medicine

A single molecule is then achieved by phase I/II/III/IV tests. And these processes take about 20 years on average.

Before coming to the pharmacy sale, the synthesis of the active ingredients of the medicines and the preparation of these active ingredients in the form of tablets, syrups, ampoules together with auxiliary substances (dissolving, reaching the effect area, helping to improve the taste) are the last steps.

Phase studies consist of preclinical and clinical stages. Clinical stages have four phase steps.

Preclinical animal studies

In these studies, priority is to select the animal (rat, mouse, rabbit) which is most suitable for human body structure for the disease to be investigated. Experiments can be done in various forms. In this preliminary study on test animals, the aim is to identify the possible scars of treatment and the molecules that must be removed from the process from the beginning due to side effects. Only a very few of these studies pass to clinical phases.

Phase 1 studies: Usually 20-80 healthy volunteers. In this phase, the aim is to detect that the drug is reliable. The dose range is calculated, tolerance and pharmacokinetics (processes of drug dissolution, attainment of efficacy, breakdown processes).

Phase 2 studies: It is performed in 100-300 volunteer patients with target disease. The effectiveness and safety of the medicine is checked. Side effects, dose response relationships are examined.

Phase 3 studies: are performed in a wider patient population. It is multi-centered, multi-national, randomized. Proof of your effectiveness and side effects are the monitoring phase. However, after sufficient data have been obtained with phase 3 trials, they must be approved for use as medicines.

Phase 4 studies: Clinical trials conducted after the product has been used as a drug. Long-term reliability determination is performed. Side effects that have not been found in clinical trials are observed and examined from the economic point of view and the impact on quality of life [7-9].

Because these processes are both long-lasting and costly, the production of new drugs is gradually declining. For this purpose, microdose studies (phase 0) are on the project. In these microdose studies, 6 healthy volunteers are working on doses below 1/100th of human dose. Although this dose seems to be less, the changes in the

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target can be examined with advanced imaging techniques. More informed models can be created in phase studies with the information obtained in these studies [10-11].

From all these, we can say that we have been studying for many years from medicinal production to sale.

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