DRUG DEVELOPMENT STEPS FOR THE U.S.

The development of patented prescription drugs in the United States, whether discovered in-house or licensed from other companies, can take as long as 12-15 years on average from discovery to marketing. As in the development process in other parts of the world, several factors are taken into consideration when companies decide to pursue research in certain therapeutic areas, including the degree of information currently available regarding the mechanism(s) of a particular condition and the current status of research conducted to date in the scientific community on that condition and on products intended to treat it. Given the often rapid diffusion of scientific findings among research scientists, a number of firms might start discovery efforts in the same therapeutic area(s) at the same time. The first product to reach the market, whether or not a "blockbuster" product, usually earns a significant degree of market recognition. Although subsequent products intended for similar use then need to differentiate themselves to gain market share, industry sources state that many of these latter products are generally more successful in the market because they are based on more recent scientific discoveries.[1]

The drug development process has several distinct phases, each of which takes several years to complete. Following completion of the initial research phase and preclinical testing (on average about 6.5 years), an investigational new drug application (INDA) is filed. Three phases of clinical testing then follow, with the patient population increasing substantially in each phase (total time is, on average, about 7 years). The final phase in the development process is the filing of the new drug application (NDA) with the U.S. Food and Drug Administration (FDA).[2]

According to information provided by FDA, the annual median approval time for all NDAs is approximately 12 months.

The steps & approval process required to comply with FDA regulations:

- Must conduct required preclinical laboratory evaluations of the product's chemistry, formulation and stability, and animal studies to access the efficacy and safety of the product
- Submit the findings to of the results to the FDA, along with manufacturing information and analysis information, in an Investigational New Drug Application, or IND
- Make the IND effective after the review and revisions of any safety or regulatory issues of the FDA
- Obtain approval of Institutional Review Boards, or IRBs, to introduce the drug into human clinical trial stages
- Conduct controlled clinical trials that prove the efficacy and safety of the drug or drug candidate for the intended use, typically in Phase I/II stage then Phase III stage as follows:

Phase I. The drug or biologic is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion.

Phase II. The drug or biologic is studied in patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal dosage, and to collect initial efficacy data.

[1] USITC, Global Competitiveness, publication 2437, pp. 4-17 to 4-18.
[2] New Drug Approvals p. 18.