Marketing

Approval of Authorities

 Drug is approved for marketing by the Authorities.

**Food and Drug Administration (FDA)**

The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

**European Medicines Agency (EMA) in Europe**

 The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products. From 1995 to 2004, the European Medicines Agency was known as European Agency for the Evaluation of Medicinal Products.

 Roughly parallel to the U.S. Food and Drug Administration (FDA), but without FDA-style centralization, the European Medicines Agency was set up in 1995 with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from member states, in an attempt to harmonise (but not replace) the work of existing national medicine regulatory bodies. The EU is currently the source of about one-third of the new drugs brought onto the world market each year.

**Institutional Review Board (IRB)**

Institutions that perform clinical trials are required to establish a committee to review the ethics, scope, and merits of any clinical trial conducted within their institution. The committee is composed of physicians not involved in the trial under review, medical ethicists, and lay people. It is their charge to review all the documentation supporting the trial, especially the patient consent form and the medical and scientific rationale for the study. They take a keen interest in trial procedures that can cause distress to trial participants and make a medical and ethical assessment of the risks and benefits of the trial. Once they approve the trial and budgets are agreed upon between the institution and the sponsor, the trial can commence and recruitment of patients begins. The IRB will continue to monitor the trial for any issues affecting patient welfare.

Market the Drug

 Drug is placed on the market and patients are monitored for side effects.

*Phase IV*studies

 Phase IV is any organized collection of data from patients who are taking a drug that has already received approval from the FDA. In Phase IV studies, patients may check boxes on a list (as in phase III studies) or they may just report other symptoms. Phase IV studies are commonly called "post-marketing studies."

 Investigate specific questions within the frame of the approved indication:

* Expanded benefit-risk-profile
* Combination with other drugs
* Optimization (e.g. dosage, application)

E.g.The worldwide use of the approved drug might lead to the occurrence of very rare side effects*.*