The EMEA and the FDA: a Comparison

Although the Food and Drug Administration and the European Medicines Agency have similar evaluative processes, the final outcome of the benefit-risk assessment is not necessarily the same in all cases.

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The European Medicines Agency (EMEA) and the FDA share similar objectives, including "promoting and protecting public health, evaluating the safety and efficacy of therapeutic products, working collaboratively with outside experts, reducing the regulatory burden through international harmonization, providing regulatory and health information, and enhancing product development."[1] However, these agencies differ in structure and benefit-risk assessment.

REGULATORY VERSUS REVIEWING

The FDA is a centralized agency that oversees the drug development process in a single country, whereas the EMEA is a reviewing body that manages the process in many European nations. In the FDA, drug evaluation applications and the drug development process are monitored by the FDA's own staff. In the EMEA, the assessment is conducted by the national agencies of the member states.[1,2] According to the EMEA's Web site, the agency brings together the scientific resources of more than 40 national competent authorities in 30 European Union (EU) and European Economic Area-European Free Trade Association countries in a network of more than 4,500 European experts.[3] Once the EMEA renders an opinion, approval is granted or denied by the European Commission.

PHASE 1 THROUGH 3 AND FINAL APPROVAL

Under both the EMEA and the FDA, the drug development process includes preclinical testing; clinical trials with phase 1, 2, and 3 testing; and a final approval procedure. In the United States, an investigational new drug application is filed with the FDA for drugs that appear safe in the preclinical phase. In the EU, an application for a marketing authorization license is filed with the EMEA, which is valid in all EU member states, plus the European Economic Area-European Free Trade Association countries of Iceland, Liechtenstein, and Norway. This centralized authorization procedure is mandatory "for all medicinal products developed by biotechnologic process; for

REGULATORY OVERSIGHT

United States	European Union
FDA	**National Authorities.** Each country is responsible for monitoring the safety profile of the product in its territory and and taking action when needed
	European Commission. This body is responsible for the legal framework and authorization.
	European Medicines Agency. This agency evaluates and supervises medicinal products and provides advice on measures to ensure safety and efficacy.
	Committee for Medicinal Products for Human Use. This committee prepares opnions for the European Medicines Agency and makes recommendations for human use.

new active substances indicated for the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder, or diabetes; and also for designated orphan medicinal products."[1]

For drugs that do not fall under these categories, companies may apply for a centralized marketing authorization if the drug constitutes a significant therapeutic, scientific, or technical innovation. Other authorization procedures—the national procedure, decentralized procedure, and mutual-recognition procedure—exist for drugs that do not fall within the scope of the centralized procedure.

DRUG VERSUS PLACEBO OR DRUG VERSUS EXISTING DRUGS

Although the FDA and the EMEA have similar evaluative processes, the final outcome of the benefit-risk assessment is not necessarily the same in all cases. Clinical investigations of new drugs in the United States compare the drug with a placebo. In the EU, the benefit-risk assessment has become increasingly based on comparisons between the new and existing drugs. This is not always the preferred method of benefit-risk assessment, however. For example, a three-armed study using placebo and an active treatment as controls is preferable in the EU, when possible.[1]

Despite the differences between these bodies, the FDA and EMEA recently standardized the orphan medicines designation process. In an effort to simplify part of the orphan medicines designation process, in November 2007, the EMEA and the FDA adopted a common application form for drugs for rare diseases in both jurisdictions. According to the EMEA and FDA, rare diseases are defined as those affecting fewer than five in 10,000 people in the EU and fewer than 200,000 people in the United States. This common application format allows sponsors to apply to both jurisdictions at the same time with one application. ■

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1. San Miguel MT, Vargas E. Drug evaluation and approval process in the European Union. *Arthritis Rheum.* 2006;55(1):12-14.
2. Lipsky MS, Sharp LK. From idea to market: the drug approval process. *J Am Board Fam Pract.* 2001;14:362-367.
3. European Medicines Agency. Overview. Available at: http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm. Accessed April 28, 2009.