



European Union Meeting Performance Goals for New Drug Review, But Lags Behind U.S. in New Drug Availability

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BOSTON – Jan. 16, 2007 – Review times for new drugs in the European Union have met mandated performance goals, but many medicines are available in the United States prior to the EU, according to a study recently completed by the Tufts Center for the Study of Drug Development.

The study found that mean approval times for new products approved in both the EU and the U.S. during 2000-05 were nearly identical: 15.8 months for products approved by the European Medicines Agency (EMA) and 15.7 months for those approved by the Food and Drug Administration (FDA).

Recently enacted EMA regulations enabled the agency to meet, or come close to meeting, its performance timeline goals for all product categories for each approval stage, the study found.

"While similar development times for new medicines on both continents is good news for patients, it's especially important for drug developers, because it enables them to pursue a coordinated global development program and marketing strategy," said Tufts CSDD Director Kenneth I. Kaitin.

He added, "Looking ahead, we expect that greater collaboration between the EMA and FDA will further enhance product development in both regions. It will also help avoid duplicative testing and provide another way to hold down development costs."

The study, reported in the January/February *Tufts CSDD Impact Report*, released today, also found that:

- * For 71 products receiving both FDA and EMA approval, the FDA acted faster than the EMA in 47 of the cases.
- * While the FDA approved a greater number of products faster than the EMA during 2000-05, there was greater variability in FDA approval review times.
- * Regulatory designation does not appear to have as much impact in the EMA as in the U.S., as exceptional circumstance approvals are, on average, only 1.5 months faster than non-exceptional approvals.
- * Approval times for orphan products in the EU and the U.S. were nearly identical to those for non-orphan products in the same region.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu/>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums on related topics, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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