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Postmarketing Studies Are Becoming the Norm in the U.S., Europe, and Japan, According to Tufts Center for the Study of Drug Development

BOSTON – July 10, 2008 – Post-approval study commitments, in which drug developers, as a condition of regulatory approval, agree to conduct research on newly marketed prescription drugs, are becoming routine in the United States, Europe, and Japan, according to a recently completed analysis conducted by the Tufts Center for the Study of Drug Development.

Seventy-five percent of new drugs approved in the U.S. and the EU between 1998 and 2008, and 50 percent of those approved in Japan during the same time, had postmarketing study commitments attached to them, Tufts CSDD found.

“What used to be the exception is increasingly becoming the rule for new drug approvals,” said Christopher-Paul Milne, associate director at Tufts CSDD and the study’s author.

“While post-approval studies increase the cost of marketing new medicines, they may offer a silver lining in that potential safety issues are identified earlier and the increased knowledge of a drug’s safety and efficacy allows drug sponsors to serve patient populations better.”

Postmarketing commitments, referred to as post-approval commitments in the EU and as postmarketing surveys in Japan, aim to generate information on, for example, a product’s safety and efficacy, its prescribing or use, and its consistency of manufacturing.

The Tufts CSDD analysis, reported in the July/August *Tufts CSDD Impact Report*, released today, also found that:

- * The average number of postmarketing studies per new drug, of those requiring studies, ranges from 10.8 in the EU to 8.9 in the U.S. to 1.7 in Japan, and varies by therapeutic area.
- * When required, postmarketing commitments in the EU and Japan are more likely than in the U.S. to relate to safety concerns.
- * Half of the products approved with postmarketing commitments in the U.S. and EU had pediatric study requirements, compared to only 6% in Japan.

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, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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