Postmarketing studies are becoming the norm in U.S., Europe, and Japan

Over 75% of new drug approvals in the U.S. & EU, and over half of those in Japan, had postmarketing study commitments

- The average number of postmarketing studies per new drug, of those requiring studies, ranges from 10.8 in Europe to 8.9 in the U.S. to 1.7 in Japan.
- The number of postmarketing commitments also 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.
- The timing of agreements regarding postmarketing commitments between sponsors and the regulatory agency is more consistent in Japan than in the EU and U.S.

In the three major global pharmaceutical markets—the United States, EU, and Japan—postmarketing commitments (PMCs), in which drug sponsors are required by the respective regulatory agency to study a new drug after it enters the market, have become an increasingly common condition of approval. Today, more than three-fourths of new pharmaceutical and biological products approvals in the U.S. and EU, and half of those in Japan, come with PMCs attached to them.

To more fully understand the degree to which PMCs have become integral to the drug approval process, Tufts CSDD assessed new drug approvals between 1998 and 2008 in the three major global markets, the first analysis of its kind. In addition to requirements for pharmacovigilance and risk management, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMEA), and Japanese Ministry of Health, Labour and Welfare (MHLW) have steadily increased their demands that drug developers conduct post-approval research. While PMCs increase the cost of marketing new medicines—adding to growing pressures on developers to improve R&D productivity and reduce development costs—postmarketing studies may offer a silver lining: the earlier that potential safety issues are identified and the more known about the drug’s safety and efficacy, the better drug sponsors can serve patient populations.