Follow-on Drugs Are Key to World Health Organization, According to the Tufts Center for the Study of Drug Development

BOSTON – July 10, 2007 – Follow-on drugs play a central role in World Health Organization (WHO) drug policy, suggesting that initiatives which impede follow-on drug research and development would likely have a detrimental impact on public health, according to a study by the Tufts Center for the Study of Drug Development.

Since 1987, the share of follow-on drugs on WHO’s essential drug list (EDL) surged by 14 percentage points, the study found, and today 60% of medicines on the EDL are follow-on drugs.

“Growing reliance on follow-on drugs by the World Health Organization reflects the role of incremental improvement on first-in-class drugs as a critical mechanism of pharmaceutical innovation,” said Tufts CSDD Research Fellow Joshua Cohen, who conducted the analysis.

He added, “Follow-on drugs provide back-up if the first-in-class drug is withdrawn, and also enhance choice for patients who may not respond well to other similar medicines. If development of follow-on drugs were curtailed, many people, especially in poorer regions of the world, would likely suffer.”

Drugs on the EDL are selected on the basis of public health impact, evidence of safety and effectiveness, and cost. Follow-on drugs are new medicines in a therapeutic class defined by another drug that first received regulatory approval for marketing.

Cohen also noted that more than 90% of EDL drugs are medications whose patents have expired, which lowers their cost and increases their affordability in developing countries.

Study results, reported in the July/August Tufts CSDD Impact Report, released today, also found that:

* While follow-on drugs as a share of drugs on the EDL increased from 47% to 63% since 1977, the share of follow-on indications fell from 19% to 15%.
* The number of follow-on drugs in each WHO-defined category appears to be a function of the category’s age: the older the category, the more follow-on drugs it includes.
* The U.S. Food and Drug Administration assigned a priority rating to 49% of post-1962 approved follow-on drugs on the EDL, further highlighting the therapeutic value accorded these medicines.

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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