Pace of CNS drug development and FDA approvals lags other drug classes

Clinical-plus-approval time for CNS drugs 35% longer vs. non-CNS drugs

- The clinical approval success rate for central nervous system (CNS) drugs from 1993 to 2004 was about one in 10, compared to one in six for all self-originated drugs.
- The Phase III-to-regulatory-submission transition rate for self-originated CNS drugs was 50% for drugs with clinical testing initiated during 2002-07.
- Clinical approval success rates for self-originated CNS drugs declined since the early 2000s.
- Since the mid-1990s, CNS drugs had relatively few priority approvals (18% vs. 46% for other drugs).
- During 1996-10, mean clinical phase time for CNS drugs, compared to non-CNS drugs, was 40% longer, while mean approval phase time was 13% longer.

Developers of CNS drugs face the same stumbling blocks common across the R&D-based drug industry: long development and regulatory review times and a decline in annual approvals while patents continue to expire on top-selling products. Compounding the issue for CNS drugs: development takes longer and costs more, and development failures occur more often than for products in other therapeutic areas. However, the CNS new product pipeline is among the richest, having experienced 6% annual growth during the past decade, currently accounting for about 11% of all drug development projects worldwide.

To better understand how CNS drugs fare through development, Tufts CSDD assessed clinical approval success rates and the pace of regulatory approvals in the U.S., results of which are summarized in this report. Mean clinical-plus-approval time for CNS drugs lengthened from 1996 through 2010 and was substantially longer compared to non-CNS drugs. Longer and more complex clinical trials for CNS drugs reflect the complexity of disorders that these drugs seek to treat. These findings underscore the need for CNS product developers to embrace new and more efficient approaches to R&D, with the goal of boosting productivity and increasing the number of CNS drugs reaching patients.