CNS drugs take 20% longer to develop and to approve vs. non-CNS drugs

CNS share of all U.S. approvals has remained steady at 10%-12% since the 1980s

Due to the complex nature of the conditions they are developed to treat, central nervous system—or CNS—drugs face greater development challenges compared to non-CNS drugs, due in large part to our poor understanding of the underlying pathophysiology of many of the disorders, as well as difficulty identifying and measuring appropriate clinical endpoints. As a result, CNS drugs typically spend more time in clinical development and regulatory review, and they experience lower approval rates, compared to non-CNS drugs. Despite these challenges, CNS drug approvals by the FDA as a share of all drug approvals not only has remained relatively steady over nearly four decades, but has increased slightly over that time.

The opportunity and challenge for drug developers is clear. Opportunity arises from the estimate that CNS disorders will constitute nearly 15% of the global disease burden by 2020. The challenges are to decrease development time and increase success rates without sacrificing safety, while simultaneously reigning in overall development costs. This report summarizes a recent Tufts CSDD analysis of 509 drugs and biologics that received FDA approval from 2000 to 2017.

- Mean clinical development time was 36% longer for CNS compared to non-CNS approvals in 2000-05, 41% longer for 2006-11, but 6% shorter for 2012-17.
- During 2000-17, mean approval phase time for CNS drugs was 38% longer than for non-CNS drugs.
- Mean total phase time (sum of clinical and approval phase lengths) for CNS drugs ranged from 8.2 years for anti-psychotics to 12.6 years for multiple sclerosis treatments.
- The most prevalent disease areas among the 57 CNS drug approvals during 2000-17 were epilepsy and psychosis, each with 10 new drug approvals.
- During 2000-17, 28.1% of CNS drugs, vs. 51.4% of non-CNS drugs, received a priority rating from the U.S. Food and Drug Administration (FDA) and 22.8%, vs. 33.1% of non-CNS drugs, obtained an orphan drug designation.