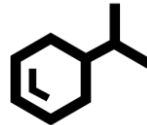


Approval in PMDA 2013

PMDA HAD A TOTAL OF 28 NASs APPROVED IN 2013, WITH A MEDIAN APPROVAL TIME OF 342 DAYS



5 BIOLOGIC NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 332 DAYS



23 CHEMICAL NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 345 DAYS

7 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 270 DAYS



21 NASs IN OTHER THERAPY AREAS APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 360 DAYS



Type of Medicine

Designation and Review Type



11 EXPEDITED NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 237 DAYS, THIS IS A MEDIAN 123 DAYS FASTER THAN THE 17 STANDARD NAS APPROVALS IN 2013

8 ORPHAN NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 252 DAYS, THIS IS A MEDIAN 108 DAYS FASTER THAN THE 20 NON-ORPHAN NAS APPROVALS IN 2013



Availability in PMDA



36% OF THE NASs APPROVED IN 2013 BY PMDA WERE APPROVED IN PMDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA



64% OF THE NASs APPROVED IN 2013 BY PMDA WERE APPROVED AT EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN PMDA

THE MEDIAN SUBMISSION GAP TO PMDA FOR THESE NASs WAS 1057 DAYS

