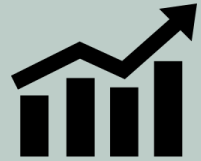


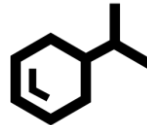
Approval at PMDA 2016

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PMDA APPROVED A TOTAL OF 48 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 311 DAYS



13 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 311 DAYS



35 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 312 DAYS

15 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 312 DAYS

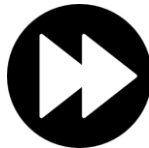


33 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 308 DAYS



Type of Medicine

Designation and Review Type



22 EXPEDITED\* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 279 DAYS; THIS IS A MEDIAN 56 DAYS FASTER THAN THE 26 STANDARD NAS APPROVALS IN 2016

18 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 280 DAYS; THIS IS A MEDIAN 43 DAYS FASTER THAN THE 30 NON-ORPHAN NAS APPROVALS IN 2016



Availability in PMDA



12.5% OF THE NASs APPROVED IN 2016 BY PMDA WERE APPROVED IN PMDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA



87.5% OF THE NASs APPROVED IN 2016 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 1333 DAYS



\*'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'.

\*\*Date of submission at the first regulatory agency to the date of regulatory submission to the target agency.