

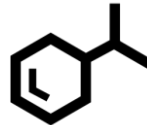
Approval at PMDA 2017

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PMDA APPROVED A TOTAL OF 22 NASs IN 2017, WITH A MEDIAN APPROVAL TIME OF 333 DAYS



7 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 331 DAYS



15 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 343 DAYS

11 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 304 DAYS

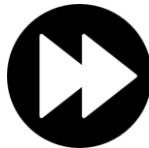


11 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 359 DAYS



Type of Medicine

Designation and Review Type



8 EXPEDITED NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF 275 DAYS; THIS IS A MEDIAN 82 DAYS FASTER THAN THE 14 STANDARD NAS APPROVALS IN 2017

7 ORPHAN NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF 281 DAYS; THIS IS A MEDIAN 74 DAYS FASTER THAN THE 15 NON-ORPHAN NAS APPROVALS IN 2017



Availability in PMDA



18% OF THE NASs APPROVED IN 2017 BY PMDA WERE APPROVED IN PMDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA



82% OF THE NASs APPROVED IN 2017 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 524 DAYS



'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.