

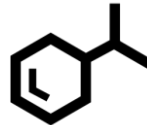
Approval at PMDA 2015

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PMDA APPROVED A TOTAL OF 32 NASs IN 2015 WITH A MEDIAN APPROVAL TIME OF 284 DAYS



7 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 287 DAYS



25 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 282 DAYS

9 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 273 DAYS



23 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 311 DAYS



Type of Medicine

Designation and Review Type



15 EXPEDITED* NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 269 DAYS, THIS IS A MEDIAN 68 DAYS FASTER THAN THE 17 STANDARD NAS APPROVALS IN 2015

11 ORPHAN NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 269 DAYS, THIS IS A MEDIAN 44 DAYS FASTER THAN THE 21 NON-ORPHAN NAS APPROVALS IN 2015



Availability in PMDA



34% OF THE NASs APPROVED IN 2015 BY PMDA WERE APPROVED IN PMDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA



66% OF THE NASs APPROVED IN 2015 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 836 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.