

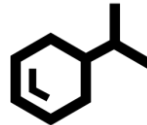
Approval at EMA 2016

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EMA APPROVED A TOTAL OF 28 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 422 DAYS\*



10 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 380 DAYS



18 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 447 DAYS

12 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 390 DAYS



16 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 433 DAYS



Type of Medicine

Designation and Review Type



5 EXPEDITED\*\* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 254 DAYS; THIS IS A MEDIAN 182 DAYS FASTER THAN THE 23 STANDARD NAS APPROVALS IN 2016

11 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 391 DAYS; THIS IS A MEDIAN 32 DAYS FASTER THAN THE 17 NON-ORPHAN NAS APPROVALS IN 2016



Availability in EMA



36% OF THE NASs APPROVED IN 2016 BY EMA WERE APPROVED BY EMA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA



64% OF THE NASs APPROVED IN 2016 BY EMA WERE APPROVED AT FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN EMA

THE MEDIAN SUBMISSION GAP\*\*\* TO EMA FOR THESE NASs WAS 34 DAYS



\*EMA expedited review includes 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.