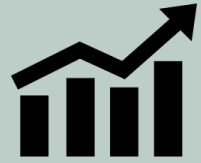


Approval at TGA 2017
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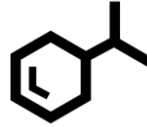
TGA APPROVED A TOTAL OF 24 NASs IN 2017, WITH A MEDIAN APPROVAL TIME OF 364 DAYS



10 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 352 DAYS



14 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 383 DAYS



8 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 357 DAYS



16 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 383 DAYS



Type of Medicine

Designation and Review Type



0 EXPEDITED NAS APPROVALS IN 2017; TGA DID NOT APPROVE ANY NASs IN 2017 UNDER ITS RECENTLY INTRODUCED PRIORITY REVIEW PROGRAMME

7 ORPHAN NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF 351 DAYS; THIS IS A MEDIAN 17 DAYS FASTER THAN THE 17 NON-ORPHAN NAS APPROVALS IN 2017



Availability in TGA



8% OF THE NASs APPROVED IN 2017 BY TGA WERE APPROVED BY TGA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC



92% OF THE NASs APPROVED IN 2017 BY TGA WERE APPROVED BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY TGA

THE MEDIAN **SUBMISSION GAP** TO TGA FOR THESE NASs WAS **532 DAYS**



Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.