

Approval at TGA 2016

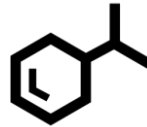
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TGA APPROVED A TOTAL OF 32 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 372 DAYS



10 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 383 DAYS



22 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 351 DAYS

13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 352 DAYS

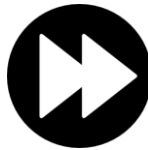


19 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 377 DAYS



Type of Medicine

Designation and Review Type



0 EXPEDITED NAS APPROVALS IN 2016; TGA DID NOT APPROVE ANY NASs IN 2016 UNDER ITS RECENTLY INTRODUCED PRIORITY PROGRAMME

8 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 376 DAYS; THIS IS A MEDIAN 4 DAYS SLOWER THAN THE 24 NON-ORPHAN NAS APPROVALS IN 2016



Availability in TGA



0% OF THE NASs APPROVED IN 2016 BY TGA WERE APPROVED BY TGA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC



100% OF THE NASs APPROVED IN 2016 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 223 DAYS



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