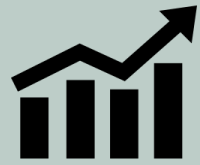


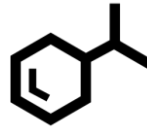
Approval at TGA 2015
© CIRS, R&D Briefing 59



TGA APPROVED A TOTAL OF 27 NASs IN 2015 WITH A MEDIAN APPROVAL TIME OF 373 DAYS



7 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 309 DAYS



20 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 383 DAYS

14 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 365 DAYS



13 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 382 DAYS



Type of Medicine



Designation and Review Type

0 EXPEDITED NAS APPROVALS IN 2015 TGA DOES NOT CURRENTLY HAVE AN EXPEDITED EVALUATION PROGRAMME

6 ORPHAN NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 369 DAYS, THIS IS A MEDIAN 4 DAYS FASTER THAN THE 21 NON-ORPHAN NAS APPROVALS IN 2015



Availability in TGA



4% OF THE NASs APPROVED IN 2015 BY TGA WERE APPROVED BY TGA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC



96% OF THE NASs APPROVED IN 2015 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 194 DAYS



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