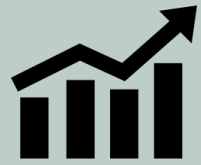


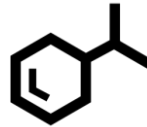
Approval in TGA 2013



TGA HAD A TOTAL OF 25 NASs APPROVED IN 2013, WITH A MEDIAN APPROVAL TIME OF 391 DAYS



3 BIOLOGIC NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 363 DAYS



22 CHEMICAL NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 401 DAYS

9 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 391 DAYS

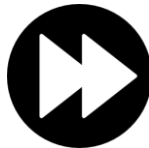


16 NASs IN OTHER THERAPY AREAS APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 406 DAYS



Type of Medicine

Designation and Review Type



0 EXPEDITED NASs APPROVALS IN 2013 TGA DOES NOT CURRENTLY HAVE AN EXPEDITED EVALUATION PROGRAMME

7 ORPHAN NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 362 DAYS, THIS IS A MEDIAN 44 DAYS FASTER THAN THE 18 NON-ORPHAN NAS APPROVALS IN 2013



Availability in TGA



4% OF THE NASs APPROVED IN 2013 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 2013 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 559 DAYS

