

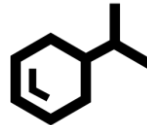
Approval in EMA 2013



EMA HAD A TOTAL OF 30 NASs APPROVED IN 2013 , WITH A MEDIAN APPROVAL TIME OF 478 DAYS



8 BIOLOGIC NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 471 DAYS



22 CHEMICAL NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 478 DAYS

13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 442 DAYS



17 NASs IN OTHER THERAPY AREAS APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 483 DAYS



Type of Medicine



Designation and Review Type

3 EXPEDITED NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 336 DAYS, THIS IS A MEDIAN 145 DAYS FASTER THAN THE 27 STANDARD NAS APPROVALS IN 2013

4 ORPHAN NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 427 DAYS, THIS IS A MEDIAN 54 DAYS FASTER THAN THE 26 NON-ORPHAN NAS APPROVALS IN 2013



Availability in EMA



17% OF THE NASs APPROVED IN 2013 BY EMA WERE APPROVED IN EMA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, PMDA, HEALTH CANADA , SWISSMEDIC OR TGA



83% OF THE NASs APPROVED IN 2013 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 6 DAYS

