

Approval at Swissmedic 2015

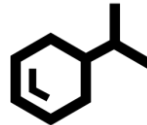
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SWISSMEDIC APPROVED A TOTAL OF 27 NASs IN 2015 WITH A MEDIAN APPROVAL TIME OF 464 DAYS



7 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 464 DAYS



20 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 454 DAYS

16 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 413 DAYS

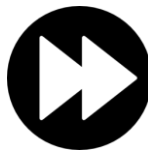


11 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 553 DAYS



Type of Medicine

Designation and Review Type



9 EXPEDITED* NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 230 DAYS, THIS IS A MEDIAN 309 DAYS FASTER THAN THE 18 STANDARD NAS APPROVALS IN 2015

6 ORPHAN NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 364 DAYS, THIS IS A MEDIAN 126 DAYS FASTER THAN THE 21 NON-ORPHAN NAS APPROVALS IN 2015



Availability in Swissmedic



11% OF THE NASs APPROVED IN 2015 BY SWISSMEDIC WERE APPROVED BY SWISSMEDIC FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, EMA, PMDA, HEALTH CANADA OR TGA



89% OF THE NASs APPROVED IN 2015 BY SWISSMEDIC WERE APPROVED AT FDA, EMA, PMDA, HEALTH CANADA OR TGA FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN SWISSMEDIC

THE MEDIAN SUBMISSION GAP** TO SWISSMEDIC FOR THESE NASs WAS 231 DAYS



*'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'.

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