

Approval at Swissmedic 2017

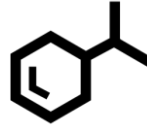
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SWISSMEDIC APPROVED A TOTAL OF 29 NASs IN 2017, WITH A MEDIAN APPROVAL TIME OF 470 DAYS



10 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 419 DAYS



19 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 483 DAYS

14 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 433 DAYS

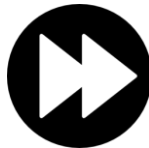


15 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 507 DAYS



Type of Medicine

Designation and Review Type



7 EXPEDITED NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF 274 DAYS; THIS IS A MEDIAN 213 DAYS FASTER THAN THE 22 STANDARD NAS APPROVALS IN 2017

10 ORPHAN NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF 442 DAYS; THIS IS A MEDIAN 40 DAYS FASTER THAN THE 19 NON-ORPHAN NAS APPROVALS IN 2017



Availability in Swissmedic



10% OF THE NASs APPROVED IN 2017 BY SWISSMEDIC WERE APPROVED BY SWISSMEDIC FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, EMA, PMDA, HEALTH CANADA OR TGA



90% OF THE NASs APPROVED IN 2017 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 272 DAYS



'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.