

Approval at Swissmedic 2016

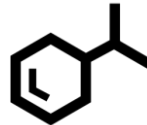
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SWISSMEDIC APPROVED A TOTAL OF 40 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 481 DAYS



19 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 460 DAYS



21 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 521 DAYS

8 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 438 DAYS

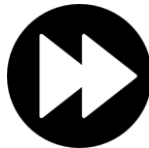


32 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 506 DAYS



Type of Medicine

Designation and Review Type



7 EXPEDITED* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 272 DAYS; THIS IS A MEDIAN 241 DAYS FASTER THAN THE 33 STANDARD NAS APPROVALS IN 2016

16 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 441 DAYS; THIS IS A MEDIAN 74 DAYS FASTER THAN THE 24 NON-ORPHAN NAS APPROVALS IN 2016



Availability in Swissmedic



5% OF THE NASs APPROVED IN 2016 BY SWISSMEDIC WERE APPROVED BY SWISSMEDIC FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, EMA, PMDA, HEALTH CANADA OR TGA



95% OF THE NASs APPROVED IN 2016 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 274 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.