

Approval at Health Canada 2017

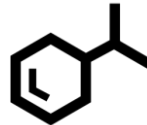
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HEALTH CANADA APPROVED A TOTAL OF 33 NASs IN 2017, WITH A MEDIAN APPROVAL TIME OF 350 DAYS



13 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 332 DAYS



20 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 359 DAYS

9 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 270 DAYS



24 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF 354 DAYS



Type of Medicine

Designation and Review Type



6 EXPEDITED NAS APPROVALS IN 2017 WITH A MEDIAN APPROVAL TIME OF 209 DAYS; THIS IS A MEDIAN 141 DAYS FASTER THAN THE 27 STANDARD NAS APPROVALS IN 2017

HEALTH CANADA DOES NOT HAVE AN ORPHAN POLICY; HOWEVER, 12 NASs THAT WERE CLASSIFIED AS ORPHAN BY EITHER FDA, EMA OR TGA WERE APPROVED BY HEALTH CANADA IN 2017, WITH A MEDIAN APPROVAL TIME OF 265 DAYS



Availability in Health Canada



15% OF THE NASs APPROVED IN 2017 BY HEALTH CANADA WERE APPROVED BY HEALTH CANADA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, FDA, PMDA, SWISSMEDIC OR TGA



85% OF THE NASs APPROVED IN 2017 BY HEALTH CANADA WERE APPROVED AT EMA, FDA, PMDA, SWISSMEDIC OR TGA FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN HEALTH CANADA

THE MEDIAN SUBMISSION GAP TO HEALTH CANADA FOR THESE NASs WAS 491 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.