

Approval at Health Canada 2015

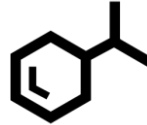
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HEALTH CANADA APPROVED A TOTAL OF 36 NASs IN 2015 WITH A MEDIAN APPROVAL TIME OF 355 DAYS



14 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 366 DAYS



22 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 354 DAYS

13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 353 DAYS

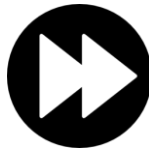


23 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 356 DAYS



Type of Medicine

Designation and Review Type



5 EXPEDITED* NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 277 DAYS, THIS IS A MEDIAN 102 DAYS FASTER THAN THE 31 STANDARD NAS APPROVALS IN 2015

HEALTH CANADA DOES NOT HAVE AN ORPHAN POLICY; HOWEVER, 15 NASs THAT WERE CLASSIFIED AS ORPHAN BY EITHER FDA, EMA OR TGA WERE APPROVED BY HC IN 2015 WITH A MEDIAN APPROVAL TIME OF 350 DAYS



Availability in Health Canada



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



89% OF THE NASs APPROVED IN 2015 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 198 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.