

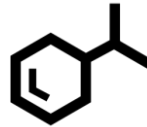
Approval at Health Canada 2016

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HEALTH CANADA APPROVED A TOTAL OF 33 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 351 DAYS



9 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 355 DAYS



24 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 347 DAYS

11 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 289 DAYS



22 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 358 DAYS



Type of Medicine

Designation and Review Type



13 EXPEDITED\* NAS APPROVALS IN 2016 WITH A MEDIAN APPROVAL TIME OF 279 DAYS; THIS IS A MEDIAN 90 DAYS FASTER THAN THE 20 STANDARD NAS APPROVALS IN 2016

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 HEALTH CANADA IN 2016, WITH A MEDIAN APPROVAL TIME OF 322 DAYS



Availability in Health Canada



15% OF THE NASs APPROVED IN 2016 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 2016 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 187 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.