Approval at EMA 2017

EMA **APPROVED A TOTAL OF 30 NASs IN 2017 ,**WITH A MEDIAN APPROVAL TIME OF **419 DAYS**

Type of Medicine

13 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **397 DAYS**

17 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **423 DAYS**

14 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **416 DAYS**

16 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **421 DAYS**

Designation and Review Type

5 EXPEDITED NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF **235 DAYS;** THIS IS A MEDIAN **206 DAYS FASTER** THAN THE **25 STANDARD NAS APPROVALS IN 2017**

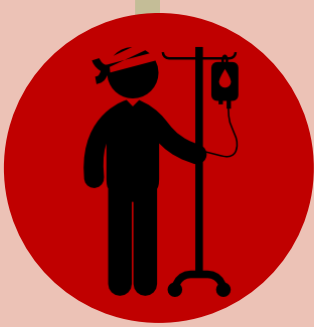
10 ORPHAN NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF **416 DAYS;** THIS IS A MEDIAN **5 DAYS FASTER** THAN THE **20 NON-ORPHAN NAS APPROVALS IN 2017**

Availability in EMA

33% OF THE NASs APPROVED IN 2017 BY EMA WERE APPROVED BY EMA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, PMDA, HEALTH CANADA , SWISSMEDIC OR TGA**

67% OF THE NASs APPROVED IN 2017 BY EMA WERE APPROVED AT FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN EMA**

THE MEDIAN **SUBMISSION GAP** TO EMA FOR THESE NASs WAS **91 DAYS**



EMA approval time includes the EU Commission time.
'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.