



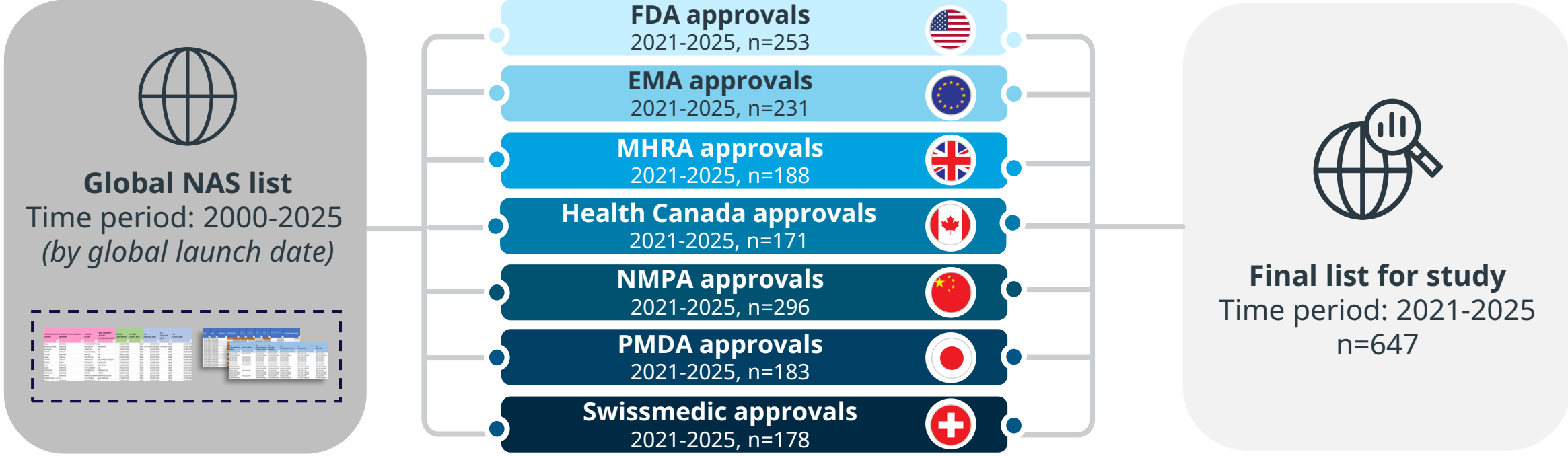
Regulatory approval assessments in the EU and comparator countries

Annual analysis

Published May 2026

Regulatory approvals were measured on the basis of all novel active substances approved in at least one of 7 countries

Product scoping and methodology



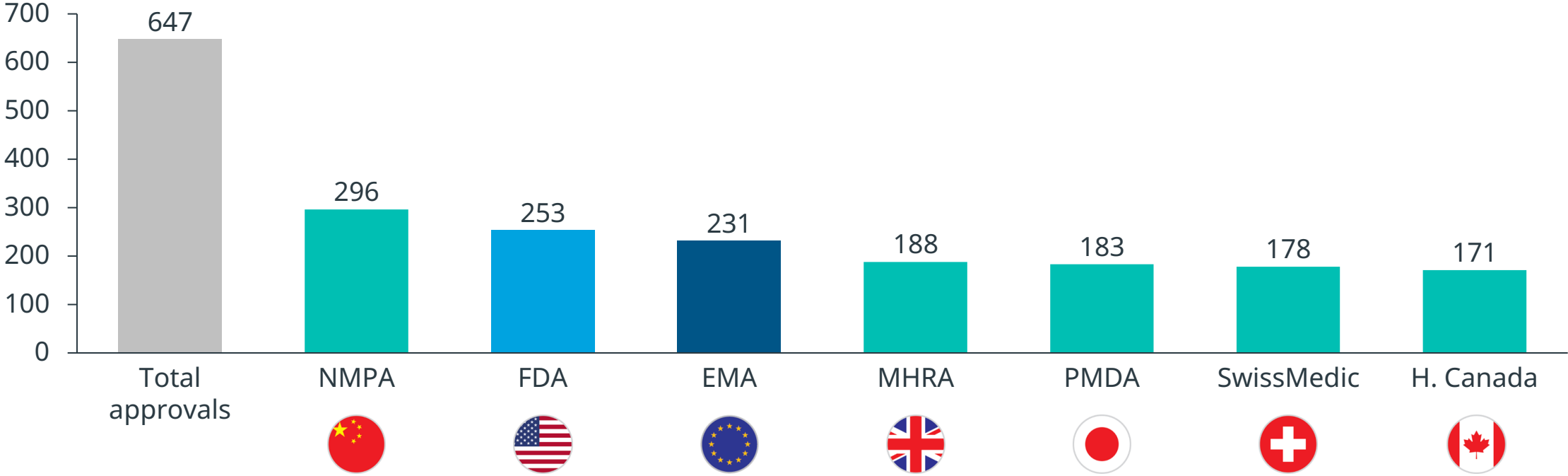
Methodology notes / caveats:

- Novel active substances (NASs) that were approved in the U.S., EU, UK, China, Japan, Canada and Switzerland from 2021-2025 were selected separately and then combined for the total product list of 649 NASs. Medicines are considered a NAS if at least one active ingredient has not been previously marketed globally (therefore, products that have been included in the EFPIA WAIT indicator that are not NASs, e.g. orphan medicines that are not NAS, are not in this scope).
- Medicines approved in at least one of the seven countries were included within the scope of the analysis. For instance, FDA approvals includes NAS that have not been approved by the EMA, Health Canada, PMDA, NMPA, MHRA, or Swissmedic.
- Marketing authorisation withdrawals are excluded (removed) from the analysis where known and visible in published data.
- Data accurate as of April 2026.

Total number of regulatory approvals by region (2021-2025)

The **total number of regulatory approvals by region** is the number of innovative medicines approved between 1st January 2021 and 31st December 2025, split by the regulatory agency granting marketing authorisation in Europe, the US and a group of comparator countries.

All products

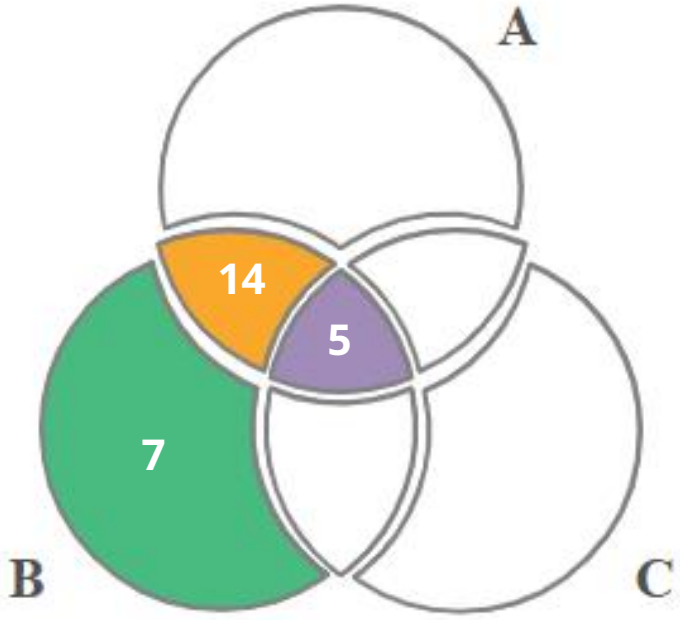


Note: This analysis measures the number of NAS approvals by each regulatory within the time period January 1st 2021 to December 31st 2025, and therefore provides a snapshot of the number of regulatory approvals during a specific time period.
 Source: IQVIA Institute, NAS dashboard (2021-2025). NAS defined as products where at least one active ingredient was novel at the time of first global launch. Only the first product introducing a new mechanism or vaccine type for a given disease is counted as a NAS. Vitamins, cosmetic products and reformulations without a novel active ingredient are excluded. Analysis also excludes COVID-19 products and NAS belonging to the following ATC classes: ATC K, ATC T and V. Vaccines were assessed at the disease level; only the first authorised vaccine per disease was classified as a NAS. H. Canada= Health Canada.

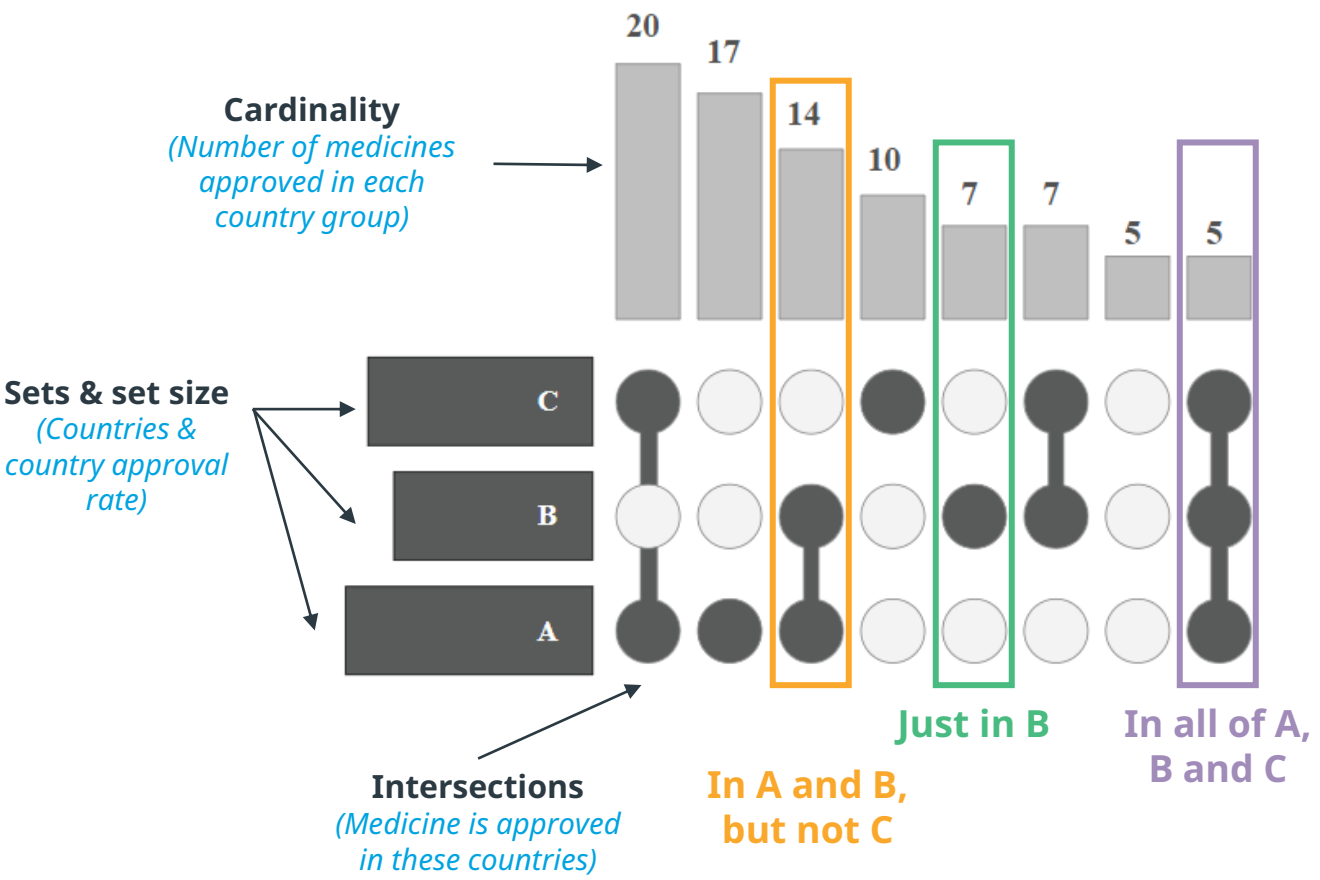
An 'UpSet plot' is an alternative to a Venn diagram for visualising intersecting sets, especially for data with >3 sets

How to read an 'UpSet' plot

Venn diagram



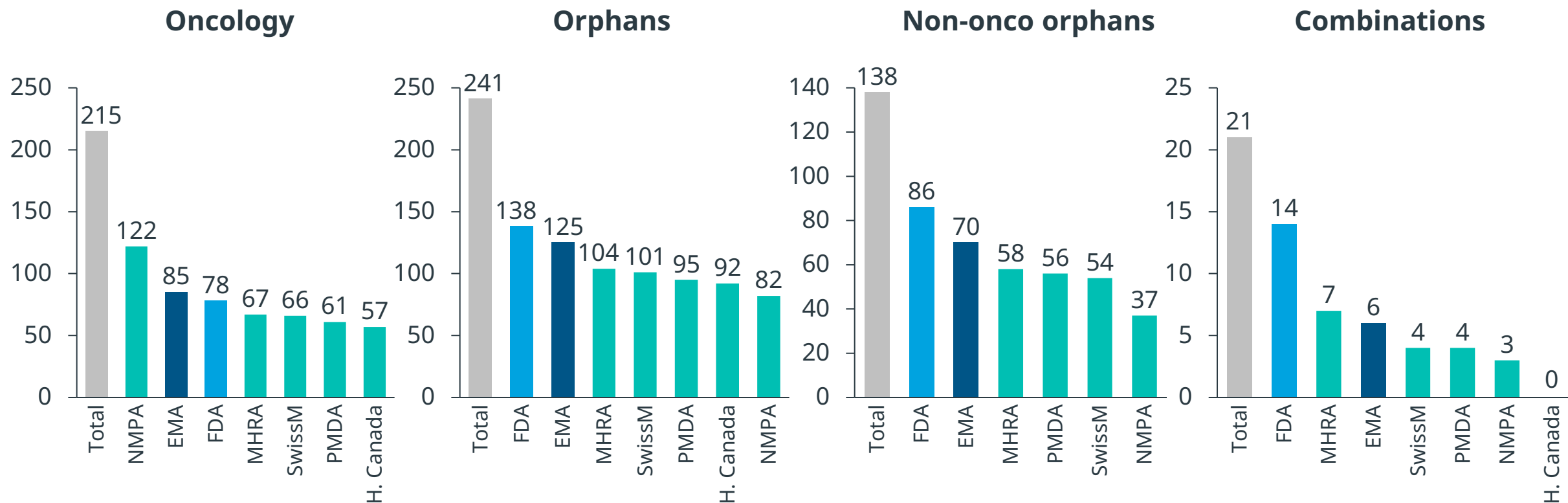
'UpSet' plot



Alexander Lex, Nils Gehlenborg, Hendrik Strobel, Romain Vuillemot, Hanspeter Pfister. UpSet: Visualization of Intersecting Sets IEEE Transactions on Visualization and Computer Graphics (InfoVis), 20(12): 1983--1992, doi:10.1109/TVCG.2014.2346248, 2014.

Total number of regulatory approvals by region (2021-2025) (by cohort)

The **total number of regulatory approvals by region** is the number of innovative medicines approved between 1st January 2021 and 31st December 2025, split by the regulatory agency granting marketing authorisation in Europe, the US and a group of comparator countries.

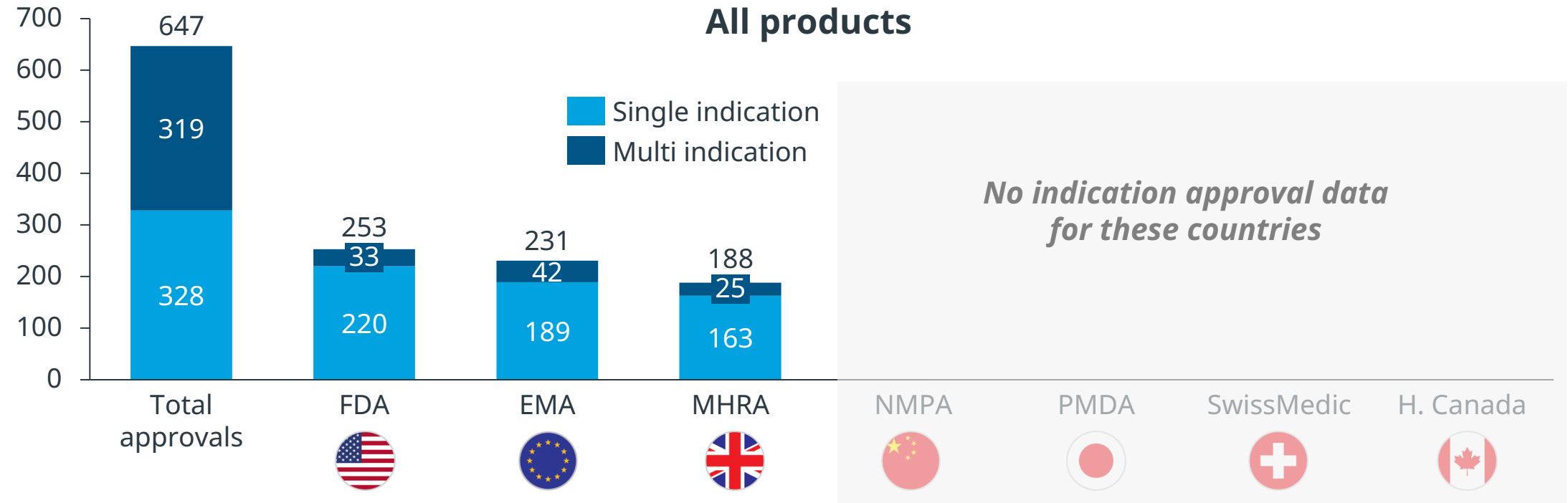


Note: This analysis measures the number of NAS approvals by each regulatory within the time period January 1st 2021 to December 31st 2025, and therefore provides a snapshot of the number of regulatory approvals during a specific time period.

Source: IQVIA Institute, NAS dashboard (2021-2025). NAS defined as products where at least one active ingredient was novel at the time of first global launch. Only the first product introducing a new mechanism or vaccine type for a given disease is counted as a NAS. Vitamins, cosmetic products and reformulations without a novel active ingredient are excluded. Analysis also excludes COVID-19 products and NAS belonging to the following ATC classes: ATC K, ATC T and V. Vaccines were assessed at the disease level; only the first authorised vaccine per disease was classified as a NAS. H. Canada= Health Canada.

Total number of single vs multi-indication approvals by region (2021-2025)

The **total number of single- and multi-indication approvals** is the number of innovative medicines approved between 1st January 2021 and 31st December 2025 for one indication only (single-indication) or more indications over time (multi-indication), split by the regulatory agency granting marketing authorisation in Europe, the US and a group of comparator countries.

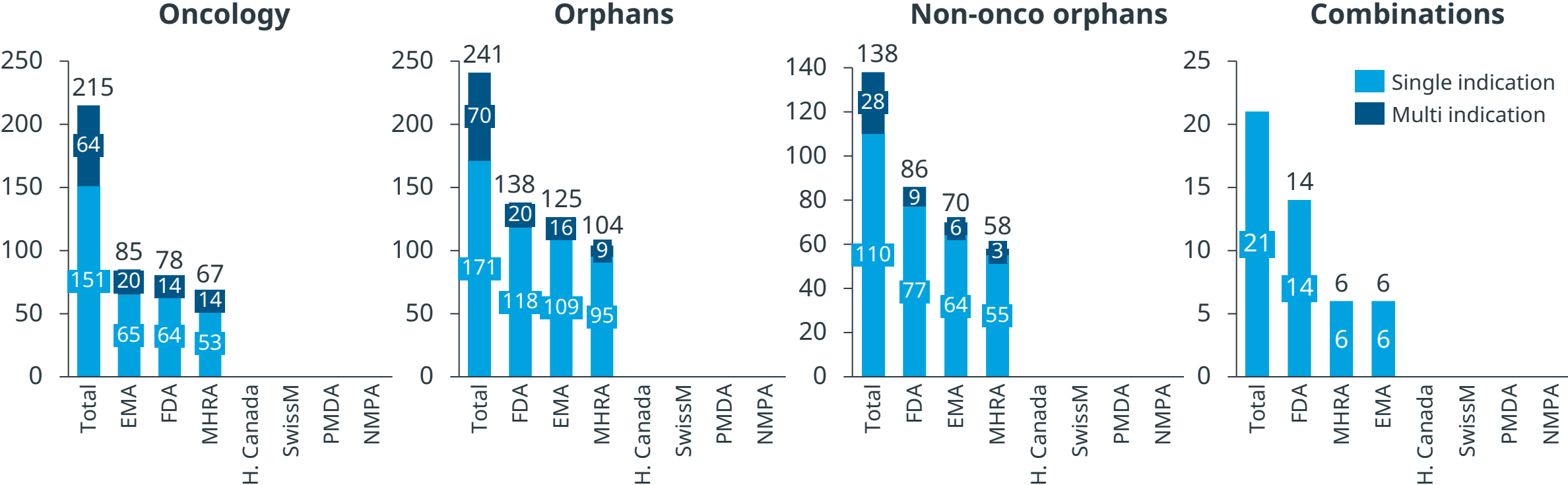


Note: This analysis measures the number of NAS approvals by each regulatory within the time period January 1st 2021 to December 31st 2025, and therefore provides a snapshot of the number of regulatory approvals during a specific time period.

Source: IQVIA Institute, NAS dashboard (2021-2025). NAS defined as products where at least one active ingredient was novel at the time of first global launch. Only the first product introducing a new mechanism or vaccine type for a given disease is counted as a NAS. Vitamins, cosmetic products and reformulations without a novel active ingredient are excluded. Analysis also excludes COVID-19 products and NAS belonging to the following ATC classes: ATC K, ATC T and V. Vaccines were assessed at the disease level; only the first authorised vaccine per disease was classified as a NAS. Single-indication= product approved for 1 authorised therapeutic indication only. Multi-indication products are defined as medicines that received at least 1 additional indication following the initial marketing authorisation during the period.

Total number single vs multi-indication approvals by region (2021-2025) *(by cohort)*

The **total number of single- and multi-indication approvals** is the number of innovative medicines approved between 1st January 2021 and 31st December 2025 that have received one or more post-approval extensions of indication, split by the regulatory agency granting marketing authorisation in Europe, the US and a group of comparator countries.



Note: This analysis measures the number of NAS approvals by each regulatory within the time period January 1st 2021 to December 31st 2025, and therefore provides a snapshot of the number of regulatory approvals during a specific time period.

Source: IQVIA Institute, NAS dashboard (2021-2025). NAS defined as products where at least one active ingredient was novel at the time of first global launch. Only the first product introducing a new mechanism or vaccine type for a given disease is counted as a NAS. Vitamins, cosmetic products and reformulations without a novel active ingredient are excluded. Analysis also excludes COVID-19 products and NAS belonging to the following ATC classes: ATC K, ATC T and V. Vaccines were assessed at the disease level; only the first authorised vaccine per disease was classified as a NAS. Single-indication= product approved for 1 authorised therapeutic indication only. Multi-indication products are defined as medicines that received at least 1 additional indication following the initial marketing authorisation during the period.



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