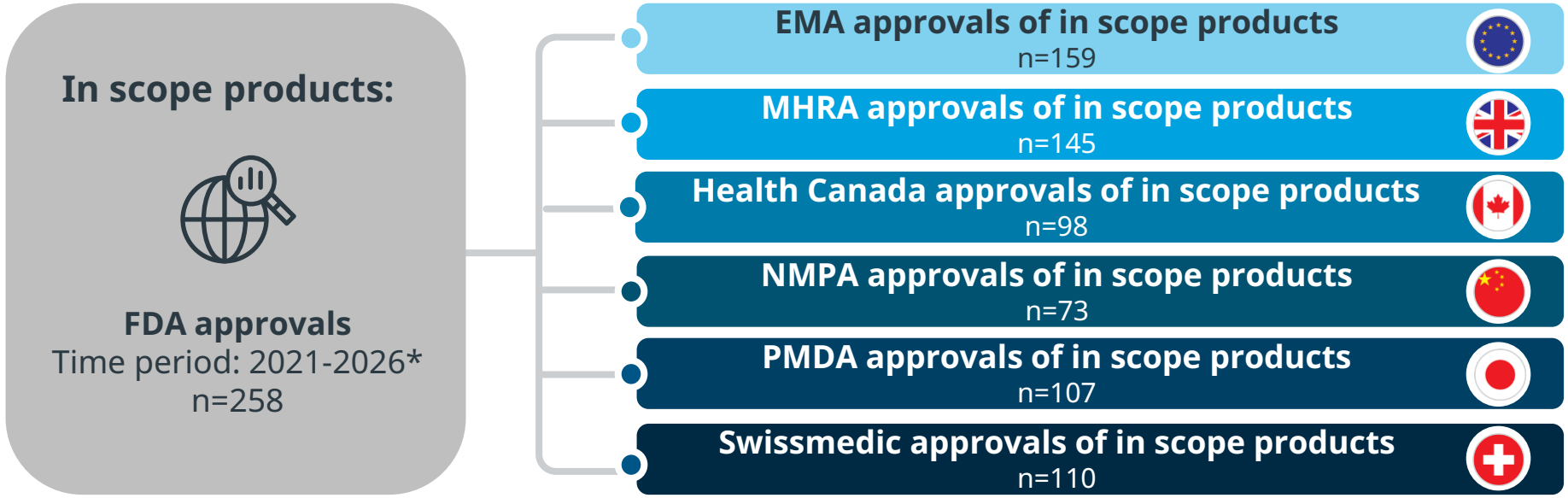
Regulatory approval assessments in the EU and comparator countries

Quarterly analysis

Published May 2026

The quarterly regulatory approval tracker measures local approvals relative to total FDA approvals (2021-2026*)

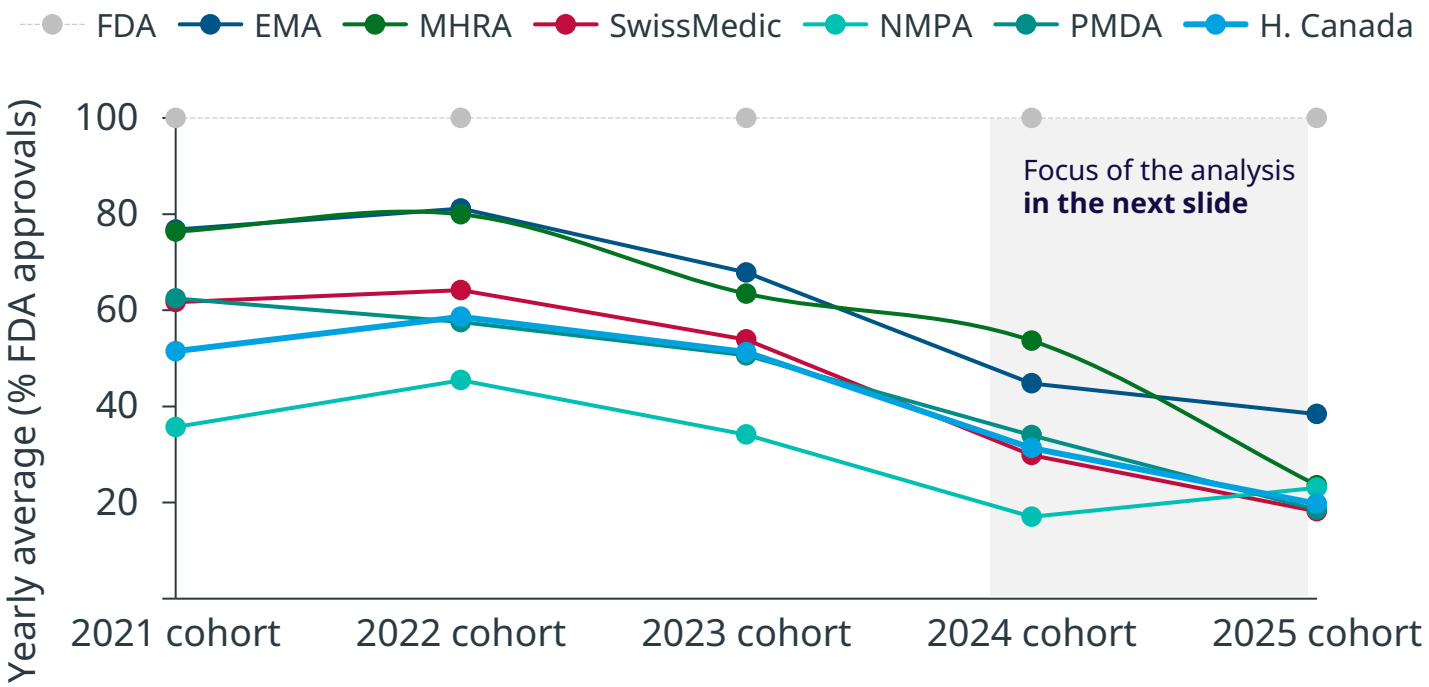
Product scoping and methodology



otes / caveats:

- Novel active substances (NASs) that were approved in the U.S. from 2021-2026* resulting in a total product list of 258 NASs. The approvals of these in scope products were tracked across the six comparator countries (timeframe of local regulatory approvals was not limited to 2021-2026*).
- 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 NASs, are not in this scope).
- *2026 approvals include NASs approved by the FDA between Jan 1st and 28th Feb 2026.
- Marketing authorisation withdrawals are excluded (removed) from the analysis where known and visible in published data.
- Data accurate as of April 2026.

Between 2021 and 2025, Europe's share of yearly FDA approvals has fallen from 77% to 38%



Approval year	Total FDA approvals	Orphans	Oncology
2021	50	29 (58%)	16 (32%)
2022	35	21 (60%)	13 (37%)
2023	63	35 (55%)	18 (29%)
2024	55	33 (60%)	17 (31%)
2025	50	20 (40%)	14 (28%)

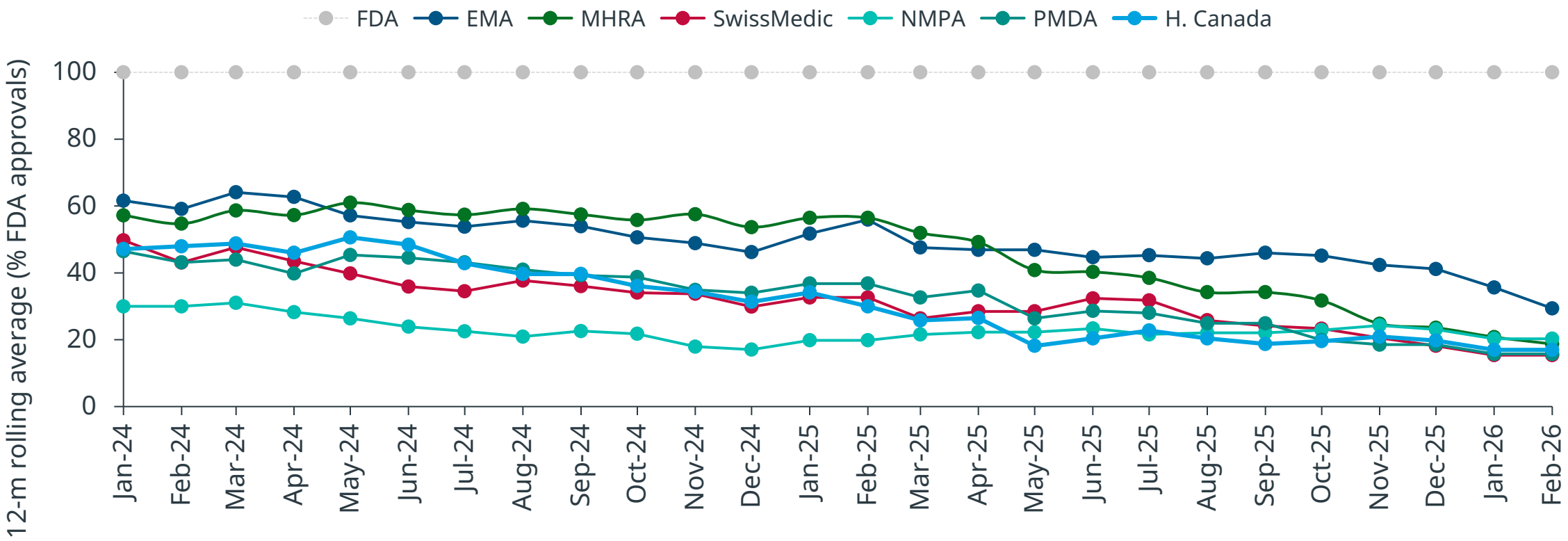
Note: The analysis tracks whether NAS approved by the FDA in any given year subsequently receive approval in other countries. Thus, earlier cohorts are likely to show higher percentages as they will have been on the market for longer.

Interpretation

- Lower percentage of FDA approvals in some countries can sometimes reflect a **higher share orphan or oncology products approvals** by the FDA
- **Higher % indicate greater alignment with the FDA**, meaning a larger % of medicines approved by the FDA are also approved in other countries
- Year on year changes are impacted by **regulatory timing differences**: approvals may lag in some countries due to delays in approval procedures

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. 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. Products are matched based on approval status, regardless of differences in approved indications. H. Canada= Health Canada.

Measuring monthly data on a 12-month rolling basis shows that Europe's decline in approvals accelerates in H2 2025



Interpretation

- A declining trend over time indicates that the country is **falling further behind FDA approvals**, while an increasing trend shows greater convergence
- Higher values indicate **greater alignment with FDA approvals**, meaning more FDA-approved medicines are available in the comparator countries
- Lower values suggest a **larger approval gap**, meaning a greater share of FDA-approved medicines are not yet authorized

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. 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. Products are matched based on approval status, regardless of differences in approved indications. H. Canada= Health Canada.

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Appendix

FDA approved New Actives Substances (NASs) in 2024 (1 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
berdazimer	5/01/2024						
lifileucel	16/02/2024						1/08/2025
cefepime, enmetazobactam	22/02/2024	21/03/2024	4/04/2024				
tislelizumab	13/03/2024	15/09/2023	13/12/2023	27/12/2019	27/03/2025	11/04/2024	1/12/2025
resmetirom	14/03/2024	18/08/2025					
atidarsagene autotemcel	18/03/2024	17/12/2020	17/12/2020			7/12/2023	
aprocitentan	19/03/2024	27/06/2024	8/01/2025			18/09/2025	1/12/2025
givinostat	21/03/2024	6/06/2025	20/12/2024				
sotatercept	26/03/2024	22/08/2024	27/12/2024		24/06/2025	16/10/2024	1/08/2024
vadadustat	27/03/2024	24/04/2023	19/05/2023		29/06/2020	19/06/2023	
danicopan	29/03/2024	19/04/2024	2/08/2024		18/01/2024	30/04/2024	1/07/2024
ceftobiprole medocaril	3/04/2024		20/11/2013	6/11/2020			
pegulicianine	17/04/2024						
nogapendekin alfa inbakicept	22/04/2024	16/02/2026	04/07/2025				
tovorafenib	23/04/2024						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2024 (2 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
fidanacogene elaparvovec	26/04/2024	24/07/2024					1/12/2023
mavorixafor	26/04/2024						
tarlatamab	16/05/2024		31/12/2024		27/12/2024		1/09/2024
imetelstat	6/06/2024	7/03/2025					
elafibranor	10/06/2024	19/09/2024	4/10/2024				1/04/2025
sofpironium	18/06/2024				25/09/2020		
crovalimab	20/06/2024	22/08/2024	7/08/2024	7/02/2024	26/03/2024	13/02/2025	1/06/2025
ensifentrine	26/06/2024						
donanemab	2/07/2024	24/09/2025	23/10/2024	17/12/2024	24/09/2024	22/01/2026	
deuruxolitinib	25/07/2024						
afamitresgene autoleucel	2/08/2024						
vorasidenib	6/08/2024	17/09/2025	16/09/2025		19/09/2025	15/11/2024	
palopegteriparatide	9/08/2024	17/11/2023	23/04/2024		25/08/2025	9/12/2025	1/01/2026
nemolizumab	12/08/2024	12/02/2025	17/02/2025		28/03/2022	17/02/2025	1/12/2025
axatilimab	14/08/2024						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2024 (3 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
seladelpar	14/08/2024	20/02/2025	16/01/2025			9/12/2025	
lazertinib	19/08/2024	20/01/2025	6/03/2025	29/07/2025	27/03/2025	7/02/2025	
lebrikizumab	13/09/2024	16/11/2023	19/12/2023		18/01/2024	30/08/2024	1/06/2024
arimoclomol	20/09/2024						
levacetylleucine	24/09/2024	19/01/2026					
xanomeline and trospium chloride	26/09/2024			23/12/2025			
flurpiridaz f 18	27/09/2024						
inavolisib	10/10/2024	18/07/2025	26/11/2025	11/03/2025		31/01/2025	1/02/2025
marstacimab	11/10/2024	18/11/2024	17/04/2025		27/12/2024	23/12/2024	
foscarbidopa and foslevodopa	16/10/2024		23/11/2022		23/12/2022		
zolbetuximab	18/10/2024	19/09/2024	14/08/2024	25/12/2024	26/03/2024	19/02/2025	1/12/2024
sulopenem etzadroxil, probenecid	25/10/2024						
obecabtagene autoleucel	8/11/2024	17/07/2025	25/04/2025				
eladocagene exuparvovec	13/11/2024	18/07/2022	17/11/2022				
revumenib	15/11/2024						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2024 (4 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
zanidatamab	20/11/2024	27/06/2025	19/02/2026	27/05/2025			01/01/2026
landiolol	22/11/2024		14/06/2022			19/10/2022	
acoramidis	22/11/2024	10/02/2025	24/04/2025		27/03/2025	18/12/2025	
zenocutuzumab	4/12/2024						
crinecerfont	13/12/2024						
cosibelimab	13/12/2024						
ensartinib	18/12/2024			20/11/2020			
olezarsen	19/12/2024	17/09/2025					
concizumab	20/12/2024	13/12/2024	6/10/2025		25/09/2023	22/08/2023	01/07/2023
vanzacaftor, tezacaftor, deutivacaftor	20/12/2024	30/06/2025	7/03/2025			15/10/2025	

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2025 (1 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
datopotamab deruxtecan	17/01/2025	4/04/2025		22/08/2025	27/12/2024	28/05/2025	
treosulfan	21/01/2025	20/06/2019	20/06/2019				1/06/2021
suzetrigine	30/01/2025						
mirdametinib	11/02/2025	17/07/2025	11/12/2025				
Vvmseltinib	14/02/2025	17/09/2025					
revakinagene taroretcel	5/03/2025						
gepotidacin	25/03/2025		27/08/2025				
fitusiran	28/03/2025			11/12/2025			
atrasentan	2/04/2025						
penpulimab	23/04/2025			3/08/2021			
prademagene zamikeracel	29/04/2025						
nipocalimab	29/04/2025	28/11/2025			19/09/2025	18/12/2025	1/12/2025
avutometinib and defactinib	8/05/2025						
telisotuzumab vedotin	14/05/2025						
acoltremon	28/05/2025						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2025 (2 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
clesrovimab	9/06/2025					22/01/2026	1/01/2026
taletrectinib	11/06/2025			20/12/2024	19/09/2025		
garadacimab	16/06/2025	10/02/2025	24/01/2025		20/02/2025	24/02/2025	1/08/2025
linvoseltamab	2/07/2025	23/04/2025					
sunvozertinib	2/07/2025			22/08/2023			
sebetralstat	3/07/2025	17/09/2025	15/07/2025		22/12/2025	17/09/2025	
zopapogene imadenovec	15/07/2025			28/03/2025			
delgocitinib	23/07/2025	19/09/2024	29/11/2024		23/01/2020	13/11/2024	1/08/2025
sepiapterin	28/07/2025	19/06/2025			22/12/2025	5/08/2025	1/10/2025
aceclidine	31/07/2025						
dordaviprone	6/08/2025						
zongertinib	8/08/2025			8/08/2025	19/09/2025		
brensocatib	12/08/2025	18/11/2025	20/02/2026				
donidalorsen	21/08/2025	19/01/2026					
rilzabrutinib	29/08/2025	22/12/2025					

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2025 (3 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
pembrolizumab and berahyaluronidase alfa	19/09/2025						
elamipretide	19/09/2025						
imlunestrant	25/09/2025	9/01/2026	24/02/2026		22/12/2025		
paltusotine	25/09/2025						
remibrutinib	30/09/2025			25/11/2025			
nerandomilast	7/10/2025			22/10/2025			
elinzanetant	24/10/2025	17/11/2025	8/07/2025			5/08/2025	1/07/2025
doxecitine and doxribtimine	3/11/2025						
ziftomenib	13/11/2025						
plozasiran	18/11/2025			16/01/2026			1/01/2026
aficamten	18/11/2025	12/02/2026		16/01/2026			
sevabertinib	19/11/2025						1/01/2026
sibeprenlimab	25/11/2025						
etuvetidigene autotemcel	9/12/2025	9/01/2026					
lerodalcibep	12/12/2025						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2025 (4 of 4)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
zoliflodacin	12/12/2025						
etripamil	12/12/2025						
depemokimab	16/12/2025	17/02/2026	15/12/2025		22/12/2025		
narsoplimab	23/12/2025						
tradipitant	30/12/2025						

Source: IQVIA Institute NAS list; FDA approvals

FDA approved New Actives Substances (NASs) in 2026 (1 of 1)

Approval dates across all regions

New active substance	FDA approval date	EMA approval date	MHRA approval date	NMPA approval date	JPMA approval date	SwissMedic approval date	H. Canada approval date
copper histidinate	12/01/2026						
difamilast	12/02/2026						
milsaperidone	20/02/2026						
pegzilarginase-nbln	23/02/2026	15/12/2023	20/12/2023				
navepegritide	27/02/2026						

Source: IQVIA Institute NAS list; FDA approvals