

23 October 2026  
EMA/245297/2013 Rev. 148  
Human Medicines Division

## List of medicinal products under additional monitoring

**Related Information:**

**Additional monitoring explained:**

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring>

**Good Pharmacovigilance Practice Module on additional monitoring:**

[https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-x-additional-monitoring\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-x-additional-monitoring_en.pdf)

*For the UK, as from 1st January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI*

**To note: All products added to the list in October 2026 are shown in red font. All products removed from the list are shown with a strikethrough for the period of one month after which they are excluded. For products newly added to the list, EMA will update the 'Product details' section of the medicine page on EMA's corporate website when it publishes the revised summary of product characteristics.**

| Product name | Active substance (s)                                        | Reason (s) on list                                                               | Marketing authorisation holder (s)          | Link to product information                                                                                                                                                                                                 | Date of inclusion |
|--------------|-------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Abecma       | idecabtagene vicleucel                                      | New biological, new active substance, PASS <sup>1</sup>                          | Bristol-Myers Squibb Pharma EEIG            | <a href="https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/abecma-epar-product-information_en.pdf</a>           | September 2021    |
| Abrysvo      | Respiratory syncytial virus vaccine (bivalent, recombinant) | New active substance and new biological                                          | Pfizer Europe MA EEIG                       | <a href="https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf</a>         | September 2023    |
| Acvybra      | denosumab                                                   | New biological                                                                   | Reddy Holding GmbH                          | <a href="https://www.ema.europa.eu/en/documents/product-information/acvybra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/acvybra-epar-product-information_en.pdf</a>         | November 2025     |
| ADSTILADRIN  | nadofaragene firadenovec                                    | New biological, new active substance and Conditional marketing authorisation     | Ferring Pharmaceuticals A/S                 | <a href="https://www.ema.europa.eu/en/documents/product-information/adstiladrin-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/adstiladrin-epar-product-information_en.pdf</a> | June 2026         |
| Adynovi      | Rurioctocog alfa pegol                                      | PASS <sup>1</sup>                                                                | Baxalta Innovations GmbH                    | <a href="https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/adynovi-epar-product-information_en.pdf</a>         | January 2018      |
| ADZYNMA      | rADAMTS13                                                   | New biological, new active substance, authorized under exceptional circumstances | Takeda Manufacturing Austria AG             | <a href="https://www.ema.europa.eu/en/documents/product-information/adzynma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/adzynma-epar-product-information_en.pdf</a>         | September 2024    |
| Afiveg       | aflibercept                                                 | New biological                                                                   | STADA Arzneimittel AG                       | <a href="https://www.ema.europa.eu/en/documents/product-information/afiveg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/afiveg-epar-product-information_en.pdf</a>           | September 2025    |
| Afqlir       | aflibercept                                                 | New biological                                                                   | Sandoz GmbH                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/afqlir-epar-product-information_en.pdf</a>           | November 2024     |
| AGAMREE      | vamorolone                                                  | New active substance                                                             | Santhera Pharmaceuticals (Deutschland) GmbH | <a href="https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/agamree-epar-product-information_en.pdf</a>         | January 2024      |

| Product name                       | Active substance (s)                                                          | Reason (s) on list                                                                           | Marketing authorisation holder (s)       | Link to product information                                                                                                                                                                                                                           | Date of inclusion |
|------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Ahzantive                          | aflibercept                                                                   | New biological                                                                               | Formycon AG                              | <a href="https://www.ema.europa.eu/en/documents/product-information/ahzantive-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ahzantive-epar-product-information_en.pdf</a>                               | January 2025      |
| Alhemo                             | concizumab                                                                    | New active substance, new biological                                                         | Novo Nordisk A/S                         | <a href="https://www.ema.europa.eu/en/documents/product-information/alhemo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/alhemo-epar-product-information_en.pdf</a>                                     | January 2025      |
| Alternaria alternata Prick Test RX | allergen extract from spores of Alternaria alternata                          | New biological                                                                               | Roxall Medizin GmbH                      | <a href="https://www.ema.europa.eu/en/documents/product-information/altuvoc-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/altuvoc-epar-product-information_en.pdf</a>                                   | June 2026         |
| ALTUVOCT                           | efanesoctocog alfa                                                            | New active substance and new biological                                                      | Swedish Orphan Biovitrum AB (publ)       | <a href="https://www.ema.europa.eu/en/documents/product-information/alyftrek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/alyftrek-epar-product-information_en.pdf</a>                                 | June 2024         |
| Alyftrek                           | deutivacaftor/tezacaftor/vazacaftor                                           | New active substance                                                                         | Vertex Pharmaceuticals (Ireland) Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/amvuttra-epar-product-information_en.pdf</a>                                 | July 2025         |
| Amvuttra                           | vutrisiran                                                                    | New active substance                                                                         | Alnylam Netherlands B.V.                 | <a href="https://www.ema.europa.eu/en/documents/product-information/andembry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/andembry-epar-product-information_en.pdf</a>                                 | September 2022    |
| ANDEMBRY                           | garadacimab                                                                   | New active substance and new biological                                                      | CSL Behring GmbH                         | <a href="https://www.ema.europa.eu/en/documents/product-information/anktiva-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/anktiva-epar-product-information_en.pdf</a>                                   | February 2025     |
| ANKTIVA                            | nogapendekin alfa inbakicept                                                  | New active substance, new biological and Conditional Marketing Authorisation                 | ImmunityBio Ireland Limited              | <a href="https://www.ema.europa.eu/en/documents/product-information/anzupgo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/anzupgo-epar-product-information_en.pdf</a>                                   | March 2026        |
| Anzupgo                            | delgocitinib pneumococcal polysaccharide conjugate vaccine (20-valent,        | New active substance                                                                         | LEO Pharma A/S                           | <a href="https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/apexxnar-epar-product-information_en.pdf</a>                                 | October 2024      |
| Apexxnar                           | vaccine (20-valent,                                                           | New biological                                                                               | Pfizer Europe MA EEIG                    | <a href="https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/apretude-epar-product-information_en.pdf</a>                                 | March 2022        |
| Apretude                           | cabotegravir                                                                  | New active substance                                                                         | ViiV Healthcare BV                       | <a href="https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aquipta-epar-product-information_en.pdf</a>                                   | September 2023    |
| AQUIPTA                            | atogepant Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted) | New active substance                                                                         | AbbVie Deutschland GmbH & Co. KG         | <a href="https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/arexvy-epar-product-information_en.pdf</a>                                     | September 2023    |
| Arexvy                             |                                                                               | New active substance and new biological                                                      | GlaxoSmithKline Biologicals S.A.         | <a href="https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/artesunate-amivas-epar-product-information_en.pdf</a>               | June 2023         |
| Artesunate Amivas                  | artesunate                                                                    | New active substance                                                                         | Amivas Ireland Ltd                       | <a href="https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;gripsQuery=STATUS%3DCURRENT+AND">https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;gripsQuery=STATUS%3DCURRENT+AND</a> | December 2021     |
| Atgam                              | anti-human T-lymphocyte immunoglobulin                                        | New biological                                                                               | Pfizer Pharma GmbH                       | <a href="https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf</a>                                 | March 2022        |
| Atriance                           | Nelarabine                                                                    | Authorised under exceptional circumstances                                                   | Sandoz Pharmaceuticals d.d.              | <a href="https://www.ema.europa.eu/en/documents/product-information/aucatzyl-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aucatzyl-epar-product-information_en.pdf</a>                                 | April 2013        |
| Aucatzyl                           | obecabtagene autoleucel                                                       | New active substance, new biological, conditional marketing authorisation, PASS <sup>1</sup> | Autolus GmbH                             | <a href="https://www.ema.europa.eu/en/documents/product-information/augtyro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/augtyro-epar-product-information_en.pdf</a>                                   | July 2025         |
| AUGTYRO                            | repotrectinib influenza vaccine (surface antigen, inactivated, adjuvanted,    | New active substance, conditional marketing authorisation                                    | Bristol Myers Squibb Pharma EEIG         | <a href="https://www.ema.europa.eu/en/documents/product-information/aujemflu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/aujemflu-epar-product-information_en.pdf</a>                                 | January 2025      |
| Aujemflu                           |                                                                               | New active substance and new biological                                                      | Seqirus Netherlands B.V.                 | <a href="https://www.ema.europa.eu/en/documents/product-information/awigli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/awigli-epar-product-information_en.pdf</a>                                     | September 2026    |
| Awigli                             | insulin icodec                                                                | New active substance, new biological                                                         | Novo Nordisk A/S                         |                                                                                                                                                                                                                                                       | May 2024          |

| Product name             | Active substance (s)                       | Reason (s) on list                                            | Marketing authorisation holder (s)       | Link to product information                                                                                                                                                                                                                           | Date of inclusion |
|--------------------------|--------------------------------------------|---------------------------------------------------------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| AYVAKYT                  | avapritinib                                | Conditional marketing authorisation                           | Blueprint Medicines (Netherlands) B.V.   | <a href="https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf</a>                                   | September 2020    |
| Avtozma                  | tocilizumab                                | New biological                                                | Celltrion Healthcare Hungary Kft.        | <a href="https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf</a>                                   | March 2025        |
| Avzivi                   | Bevacizumab                                | New biological                                                | FGK Representative Service GmbH          | <a href="https://www.ema.europa.eu/en/documents/product-information/avzivi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/avzivi-epar-product-information_en.pdf</a>                                     | Sepetmber 2024    |
| Baiama                   | aflibercept                                | New biological                                                | Formycon AG                              | <a href="https://www.ema.europa.eu/en/documents/product-information/baiama-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/baiama-epar-product-information_en.pdf</a>                                     | January 2025      |
| Balversa                 | erdafitinib                                | New active substance                                          | Janssen-Cilag International NV           | <a href="https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf</a>                                 | September 2024    |
| BEKEMV                   | eculizumab                                 | New biological                                                | Amgen Technology (Ireland) UC            | <a href="https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bekemv-epar-product-information_en.pdf</a>                                     | April 2023        |
| Beyfortus                | nirsevimab                                 | New active substance and <i>new biological</i>                | Sanofi Winthrop Industrie                | <a href="https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf</a>                               | November 2022     |
| BEYONTTRA                | acoramidis                                 | New active substance                                          | Bayer AG                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/beyonttra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/beyonttra-epar-product-information_en.pdf</a>                               | February 2025     |
| Bildyos                  | denosumab                                  | New biological                                                | SciencePharma Sp. z o.o.                 | <a href="https://www.ema.europa.eu/en/documents/product-information/bildyos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bildyos-epar-product-information_en.pdf</a>                                   | September 2025    |
| Bilprevda                | denosumab                                  | New biological                                                | SciencePharma Sp. z o.o.                 | <a href="https://www.ema.europa.eu/en/documents/product-information/bilprevda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bilprevda-epar-product-information_en.pdf</a>                               | September 2025    |
| BIMERVAX                 | COVID-19 Vaccine (recombinant, adjuvanted) | New active substance and new biological                       | Hipra Human Health, S.L.U.               | <a href="https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bimervax-epar-product-information_en.pdf</a>                                 | April 2023        |
| BLENREP                  | belantamab mafodotin                       | New biological                                                | GlaxoSmithKline Trading Services Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/blenrep-epar-product-information_en.pdf</a>                                   | July 2025         |
| Blinicyto                | Blinatumomab                               | PASS <sup>1</sup>                                             | Amgen Europe B.V.                        | <a href="https://www.ema.europa.eu/en/documents/product-information/blincyto-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/blincyto-epar-product-information_en.pdf</a>                                 | December 2015     |
| Boey                     | trenibotulinumtoxinE (EB-001)              | New active substance and new biological                       | AbbVie Limited                           | <u>Not available</u>                                                                                                                                                                                                                                  | July 2026         |
| Bomynta                  | denosumab                                  | New biological                                                | Fresenius Kabi Deutschland GmbH          | <a href="https://www.ema.europa.eu/en/documents/product-information/bomynta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bomynta-epar-product-information_en.pdf</a>                                   | July 2025         |
| Brennessel Prick Test RX | allergen extract from nettle pollen        | New biological                                                | Roxall Medizin GmbH                      | <a href="https://www.ema.europa.eu/en/documents/product-information/brennessel-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/brennessel-prick-test-rx-epar-product-information_en.pdf</a> | June 2026         |
| Breyanzi                 | lisocabtagene maraleucel                   | New biological, new active substance, PASS <sup>1</sup>       | Bristol Myers Squibb Pharma EEIG         | <a href="https://www.ema.europa.eu/en/documents/product-information/breyanzi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/breyanzi-epar-product-information_en.pdf</a>                                 | April 2022        |
| Brineura                 | Cerliponase alfa                           | authorised under exceptional circumstances, PASS <sup>1</sup> | BioMarin International Limited           | <a href="https://www.ema.europa.eu/en/documents/product-information/brineura-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/brineura-epar-product-information_en.pdf</a>                                 | June 2017         |
| Brinsupri                | brensocatib                                | New active substance and PASS <sup>1</sup>                    | Insmed Netherlands B.V.                  | <a href="https://www.ema.europa.eu/en/documents/product-information/brinsupri-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/brinsupri-epar-product-information_en.pdf</a>                               | November 2025     |
| Briumvi                  | ublituximab                                | New active substance and new biological                       | Neuraxpharm Pharmaceuticals, S.L.        | <a href="https://www.ema.europa.eu/en/documents/product-information/briumvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/briumvi-epar-product-information_en.pdf</a>                                   | June 2023         |

| Product name                                                                | Active substance (s)                                                         | Reason (s) on list                                                                              | Marketing authorisation holder (s)                                                                | Link to product information                                                                                                                                                                                                                                       | Date of inclusion                             |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Bylvay                                                                      | Odevixibat                                                                   | Authorised under exceptional circumstances                                                      | Ipsen Pharma                                                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/bylvay-epar-product-information_en.pdf</a>                                                 | July 2021                                     |
| Byooviz                                                                     | ranibizumab                                                                  | New biological                                                                                  | Samsung Bioepis NL B.V.                                                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/byooviz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/byooviz-epar-product-information_en.pdf</a>                                               | April 2024                                    |
| Bysumlog                                                                    | Insulin lispro                                                               | New biological                                                                                  | <del>Gan &amp; Lee Pharmaceuticals Europe GmbH</del> <span style="color: red;">Sandoz GmbH</span> | Not available                                                                                                                                                                                                                                                     | June 2026                                     |
| CAMZYOS                                                                     | mavacamten                                                                   | New active substance                                                                            | Bristol Myers Squibb Pharma EEIG                                                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/camzyos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/camzyos-epar-product-information_en.pdf</a>                                               | July 2023                                     |
| CAPVAXIVE                                                                   | Pneumococcal polysaccharide conjugate vaccine (21-valent)                    | New biological and New active substance                                                         | Merck Sharp & Dohme B.V.                                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/capvaxive-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/capvaxive-epar-product-information_en.pdf</a>                                           | April 2025                                    |
| CARVYKTI                                                                    | ciltacabtagene autoleucel                                                    | New active substance, new biological                                                            | Janssen-Cilag International NV                                                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/carvykti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/carvykti-epar-product-information_en.pdf</a>                                             | June 2022                                     |
| Casgevvy                                                                    | exagamglogene autotemcel                                                     | New active substance, new biological and conditional marketing authorisation, PASS <sup>1</sup> | Vertex Pharmaceuticals (Ireland) Limited                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/casgevvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/casgevvy-epar-product-information_en.pdf</a>                                             | February 2024                                 |
| <span style="color: red;">Cavoley</span>                                    | <span style="color: red;">Pegfilgrastim</span>                               | <span style="color: red;">New biological</span>                                                 | <span style="color: red;">CuraTeQ Biologics s.r.o</span>                                          | Not available                                                                                                                                                                                                                                                     | <span style="color: red;">October 2026</span> |
| Cejemly                                                                     | sugemalimab                                                                  | New active substance and new biological                                                         | CStone Pharmaceuticals Ireland Limited                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/cejemly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/cejemly-epar-product-information_en.pdf</a>                                               | July 2024                                     |
| Celldemic                                                                   | Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, | New biological                                                                                  | Seqirus Netherlands B.V.                                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/celldemic-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/celldemic-epar-product-information_en.pdf</a>                                           | May 2024                                      |
| Cenrifki                                                                    | tolebrutinib                                                                 | New active substance                                                                            | Sanofi Winthrop Industrie                                                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/cenrifki-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/cenrifki-epar-product-information_en.pdf</a>                                             | July 2026                                     |
| Ceplene                                                                     | Histamine dihydrochloride                                                    | Authorised under exceptional circumstances                                                      | Laboratoires Delbert                                                                              | <a href="https://www.ema.europa.eu/en/documents/product-information/ceplene-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ceplene-epar-product-information_en.pdf</a>                                               | April 2013                                    |
| Cevenfacta                                                                  | eptacog beta (activated)                                                     | New active substance and new biological                                                         | Laboratoire français du Fractionnement et des Biotechnologies                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/cevenfacta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/cevenfacta-epar-product-information_en.pdf</a>                                         | September 2022                                |
| Chenodeoxycholic acid Leadiant (previously Chenodeoxycholic acid sigma-tau) | Chenodeoxycholic acid                                                        | Authorised under exceptional circumstances                                                      | Leadiant GmbH                                                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/chenodeoxycholic-acid-leadiant-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/chenodeoxycholic-acid-leadiant-epar-product-information_en.pdf</a> | April 2017                                    |
| Choriongonadotrophin Genevri                                                | chorionic gonadotropin                                                       | New biological                                                                                  | Laboratoires Genévrier                                                                            | N/A                                                                                                                                                                                                                                                               | January 2022                                  |
| Cidofovir 75 mg/ml Concentrate for Solution for Infusion                    | Cidofovir                                                                    | PASS <sup>1</sup>                                                                               | Emcure Pharma UK Limited                                                                          | <a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1466141046287.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1466141046287.pdf</a>                                                                                     | May 2016                                      |
| Colevance                                                                   | enoxaparin sodium                                                            | New biological                                                                                  | Venipharm                                                                                         | N/A                                                                                                                                                                                                                                                               | January 2022                                  |
| Columvi                                                                     | glofitamab                                                                   | New active substance, new biological                                                            | Roche Registration GmbH                                                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/columvi-epar-product-information_en.pdf</a>                                               | July 2023                                     |
| Comirnaty                                                                   | COVID-19 mRNA Vaccine (nucleoside modified)                                  | New active substance and new biological                                                         | BioNTech Manufacturing GmbH                                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf</a>                                           | January 2021                                  |
| Conexxence                                                                  | denosumab                                                                    | New biological                                                                                  | Fresenius Kabi Deutschland GmbH                                                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/conexxence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/conexxence-epar-product-information_en.pdf</a>                                         | July 2025                                     |

| Product name                         | Active substance (s)        | Reason (s) on list                                                                  | Marketing authorisation holder (s)                                                                | Link to product information                                                                                                                                                                                                           | Date of inclusion |
|--------------------------------------|-----------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Datroway                             | datopotamab deruxtecan      | New active substance, new biological                                                | Daiichi Sankyo Europe GmbH                                                                        | <a href="https://www.ema.europa.eu/en/documents/product-information/datroway-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/datroway-epar-product-information_en.pdf</a>                 | April 2025        |
| Dazublys                             | trastuzumab                 | New biological                                                                      | CuraTeQ Biologics (Malta) Limited                                                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/dazublys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dazublys-epar-product-information_en.pdf</a>                 | July 2025         |
| Dazparda                             | insulin aspart              | New biological                                                                      | <del>Gan &amp; Lee Pharmaceuticals Europe GmbH</del> <span style="color: red;">Sandoz GmbH</span> | <a href="https://www.ema.europa.eu/en/documents/product-information/dazparda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dazparda-epar-product-information_en.pdf</a>                 | May 2026          |
| Daybu                                | efofinetide                 | New active substance                                                                | Acadia Pharmaceuticals (Netherlands) B.V.                                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/daybu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/daybu-epar-product-information_en.pdf</a>                       | September 2026    |
| Dawnzera                             | Donidalorsen                | New active substance                                                                | Otsuka Pharmaceutical Netherlands B.V.                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/dawnzera-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dawnzera-epar-product-information_en.pdf</a>                 | January 2026      |
| Dectova                              | Zanamivir                   | Authorised under exceptional circumstances                                          | GlaxoSmithKline Trading Services Limited                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dectova-epar-product-information_en.pdf</a>                   | May 2019          |
| Defitelio                            | Defibrotide                 | Authorised under exceptional circumstances                                          | Gentium S.p.A.                                                                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/defitelio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/defitelio-epar-product-information_en.pdf</a>               | November 2013     |
| Degevma                              | denosumab                   | New biological                                                                      | Teva GmbH                                                                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/degevma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/degevma-epar-product-information_en.pdf</a>                   | December 2025     |
| Denbrayce                            | denosumab                   | New active substance                                                                | Mabxience Research SL                                                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/denbrayce-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/denbrayce-epar-product-information_en.pdf</a>               | July 2025         |
| Denosumab Ascend                     | denosumab                   | New biological                                                                      | Ascend GmbH                                                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/denosumab-ascend-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/denosumab-ascend-epar-product-information_en.pdf</a> | September 2026    |
| Denosumab Intas                      | denosumab                   | New biological                                                                      | Intas Third Party Sales 2005, S.L.                                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/denosumab-intas-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/denosumab-intas-epar-product-information_en.pdf</a>   | November 2025     |
| Deqsig                               | Human normal Immunoglobulin | New biological                                                                      | Takeda Manufacturing Austria AG                                                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/deqsig-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/deqsig-epar-product-information_en.pdf</a>                     | May 2025          |
| Dovprela (previuosly Pretomanid FGK) | pretomanid                  | New active substance                                                                | Mylan IRE Healthcare Limited                                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/dovprela-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dovprela-epar-product-information_en.pdf</a>                 | August 2020       |
| DUVYZAT                              | givinostat                  | New active substance, conditional marketing authorisation                           | Italfarmaco S.p.A.                                                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/duvyzat-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/duvyzat-epar-product-information_en.pdf</a>                   | June 2025         |
| Dyrupeg                              | Pegfilgrastim               | New biological                                                                      | CuraTeQ Biologics (Malta) Limited                                                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/dyrupeg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/dyrupeg-epar-product-information_en.pdf</a>                   | April 2025        |
| Ebglyss                              | lebrikizumab                | New active substance, new biological                                                | Almirall S.A.                                                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf</a>                   | November 2023     |
| Ebvallo                              | Tabelecleucel               | New active substance and new biological, Authorised under exceptional circumstances | Pierre Fabre Medicament                                                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ebvallo-epar-product-information_en.pdf</a>                   | January 2023      |
| Eiyzey                               | aflibercept                 | New biological                                                                      | Zakłady Farmaceutyczne POLPHARMA S.A.                                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/eiyzey-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eiyzey-epar-product-information_en.pdf</a>                     | September 2025    |
| Ekterly                              | sebetralstat                | New active substance                                                                | KalVista Pharmaceuticals (Ireland) Ltd                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/ekterly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ekterly-epar-product-information_en.pdf</a>                   | September 2025    |
| Eladynos                             | abaloparatide               | New active substance                                                                | Theramex Ireland Limited                                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eladynos-epar-product-information_en.pdf</a>                 | January 2023      |

| Product name                          | Active substance (s)                  | Reason (s) on list                                                                  | Marketing authorisation holder (s)                     | Link to product information                                                                                                                                                                                                            | Date of inclusion |
|---------------------------------------|---------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| ELAHERE                               | mirvetuximab soravtansine             | New biological                                                                      | AbbVie Deutschland GmbH & Co. KG                       | <a href="https://www.ema.europa.eu/en/documents/product-information/elahere-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elahere-epar-product-information_en.pdf</a>                    | November 2024     |
| Elaprase                              | Idursulfase                           | Authorised under exceptional circumstances                                          | Takeda Pharmaceuticals International AG Ireland Branch | <a href="https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elaprase-epar-product-information_en.pdf</a>                  | April 2013        |
| Elfabrio                              | pegunigalsidase alfa                  | New active substance and new biological                                             | Chiesi Farmaceutici S.p.A.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elfabrio-epar-product-information_en.pdf</a>                  | May 2023          |
| ELREXFIO                              | elranatamab                           | New biological, new active substance, conditional marketing authorisation           | Pfizer Europe MA EEIG                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/elrefxio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elrefxio-epar-product-information_en.pdf</a>                  | January 2024      |
| Elucirem                              | gadopiclenol                          | New active substance                                                                | Guerbet                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/elzonris-epar-product-information_en.pdf</a>                  | January 2024      |
| ELZONRIS                              | tagraxofusp                           | New active substance and new biological, Authorised under exceptional circumstances | Stemline Therapeutics B.V.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/enflonsia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enflonsia-epar-product-information_en.pdf</a>                | January 2021      |
| Enflonsia                             | Clesrovimab                           | New active substance, new biological                                                | Merck Sharp & Dohme B.V.                               | <a href="https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf</a>                    | 01 April 2026     |
| Enhertu                               | trastuzumab deruxtecan                | New biological, new active substance, conditional marketing authorisation           | Daiichi Sankyo Europe GmbH                             | <a href="https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enjaymo-epar-product-information_en.pdf</a>                    | January 2021      |
| Enjaymo                               | sutimlimab                            | New active substance, new biological                                                | Recordati Rare Diseases                                |                                                                                                                                                                                                                                        | November 2022     |
| ENOXAPARINE LEDRAXEN                  | enoxaparin sodium                     | New biological                                                                      | VENIPHARM                                              | Not available<br><a href="https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enrylaze-epar-product-information_en.pdf</a> | September 2022    |
| Enrylaze                              | crisantaspase                         | New active substance, new biological                                                | Jazz Pharmaceuticals Ireland Limited                   | <a href="https://www.ema.europa.eu/en/documents/product-information/enwylma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/enwylma-epar-product-information_en.pdf</a>                    | September 2023    |
| Enwylma                               | denosumab                             | New biological                                                                      | Zentiva, k.s.                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/epruvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/epruvy-epar-product-information_en.pdf</a>                      | July 2025         |
| Epruvy (previously Ranibizumab Midas) | ranibizumab                           | New biological                                                                      | Midas Pharma GmbH                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/epysqli-epar-product-information_en.pdf</a>                    | October 2024      |
| Epysqli                               | eculizumab                            | New biological                                                                      | Samsung Bioepis NL B.V.                                | <a href="https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/esperoct-epar-product-information_en.pdf</a>                  | June 2023         |
| Esche Prick Test RX                   | allergen extract from ash tree pollen | New biological                                                                      | Roxall Medizin GmbH                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/etcamah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/etcamah-epar-product-information_en.pdf</a>                    | June 2026         |
| Esperoct                              | Turoctocog alfa pegol                 | PASS <sup>1</sup>                                                                   | Novo Nordisk A/S                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/etcamah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/etcamah-epar-product-information_en.pdf</a>                    | June 2019         |
| Etcamah                               | camizestrant                          | New active substance                                                                | AstraZeneca AB                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf</a>                    | July 2026         |
| Evfraxy                               | denosumab                             | New biological                                                                      | Biosimilar Collaborations Ireland Limited              | <a href="https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evfraxy-epar-product-information_en.pdf</a>                    | July 2025         |
| Evlarco                               | ᄁbicetrapib / ezetimibe               | New active substance                                                                | ᄁ Menarini International Licensing S.A.                | Not available<br><a href="https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf</a>   | September 2026    |
| Evkeeza                               | evinacumab                            | PASS <sup>1</sup> , authorised under exceptional circumstances                      | Ultragenyx Germany GmbH                                |                                                                                                                                                                                                                                        | July 2021         |

| Product name            | Active substance (s)                       | Reason (s) on list                                                                  | Marketing authorisation holder (s)                        | Link to product information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Date of inclusion |
|-------------------------|--------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Evoltra                 | Clofarabine                                | Authorised under exceptional circumstances                                          | Genzyme Europe B.V.                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/evoltra-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | April 2013        |
| Exblifep                | cefepime /<br>enmetazobactam               | New active substance                                                                | ADVANZ PHARMA Limited                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/exblifep-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | April 2024        |
| EXDENSUR                | Depemokimab                                | New active substance, new biological                                                | GlaxoSmithKline Trading Services Limited                  | <a href="https://www.ema.europa.eu/en/documents/product-information/exdensur-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/exdensur-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | February 2026     |
| Eydenzelt               | aflibercept                                | New biological                                                                      | Celltrion Healthcare Hungary Kft.                         | <a href="https://www.ema.europa.eu/en/documents/product-information/eydenzelt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eydenzelt-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                    | February 2025     |
| Eyluxvi                 | aflibercept                                | New biological                                                                      | Biolitec Pharma Limited<br>Zweigniederlassung Jena        | <a href="https://www.ema.europa.eu/en/documents/product-information/eyluxvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/eyluxvi-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | September 2025    |
| Ezmekly                 | mirdametininib                             | New active substance, conditional marketing<br>authorisation, PASS <sup>1</sup>     | Merck Europe B.V.                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/ezmekly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ezmekly-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | July 2025         |
| Fabhalta                | iptacopan                                  | New active substance                                                                | Novartis Europharm Limited                                | <a href="https://www.ema.europa.eu/en/documents/product-information/fabhalta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fabhalta-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | May 2024          |
| Fesilty                 | Human fibrinogen                           | New biological                                                                      | Grifols Worldwide Operations Limited                      | <a href="https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;gripsQuery=STATUS%3DCURRENT+AND+ENR%3D7027299&amp;directdisplay=true">https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;gripsQuery=STATUS%3DCURRENT+AND+ENR%3D7027299&amp;directdisplay=true</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf</a> | September 2026    |
| Filspari                | Sparsentan                                 | New active substance                                                                | Vifor France S.A.                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/filspari-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | May 2024          |
| Fintepla                | fenfluramine                               | PASS <sup>1</sup>                                                                   | UCB Pharma S.A.                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | January 2021      |
| Firdapse                | Amifampridine                              | Authorised under exceptional circumstances                                          | BioMarin Europe Ltd                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/firdapse-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | April 2013        |
| FRUZAQLA                | fruquintinib                               | New active substance                                                                | Takeda Pharmaceuticals International AG<br>Ireland Branch | <a href="https://www.ema.europa.eu/en/documents/product-information/fruzaqla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fruzaqla-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | July 2024         |
| Fubelv                  | etanercept                                 | New biological                                                                      | Biosimilar Collaborations Ireland Limited                 | <a href="https://www.ema.europa.eu/en/documents/product-information/fubelv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fubelv-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                          | May 2026          |
| FYLREVV                 | estetrol                                   | New active substance                                                                | Gedeon Richter Plc.                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/fylrevy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fylrevy-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | April 2026        |
| Fymiskina               | ustekinumab                                | New biological                                                                      | Formycon AG                                               | <a href="https://www.ema.europa.eu/en/documents/product-information/fymiskina-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/fymiskina-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                    | October 2024      |
| Garnele Prick Test RX   | allergen extract from<br>shrimp            | New biological                                                                      | Roxall Medizin GmbH                                       | <a href="https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611921">https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611921</a>                                                                                                                                                                                                                                  | June 2026         |
| Giapreza                | Angiotensin II acetate                     | New active substance                                                                | PAION Pharma GmbH                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/giapreza-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                      | September 2019    |
| Glaskraut Prick Test RX | allergen extract from glass<br>wort pollen | New biological                                                                      | Roxall Medizin GmbH                                       | <a href="https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611872">https://portal.btarm.de/amguitree/am/searchresult.xhtml?accessid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611872</a>                                                                                                                                                                                                                                  | June 2026         |
| GOBIVAZ                 | golimumab                                  | New biological                                                                      | Advanz Pharma Limited                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/gobivaz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gobivaz-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | November 2025     |
| Gohibic                 | vilobelimab                                | New active substance, new biological,<br>authorised under exceptional circumstances | InflaRx GmbH                                              | <a href="https://www.ema.europa.eu/en/documents/product-information/gohibic-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gohibic-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                                        | January 2025      |

| Product name                                                   | Active substance (s)                                                 | Reason (s) on list                                                                              | Marketing authorisation holder (s)             | Link to product information                                                                                                                                                                                                                                                                                             | Date of inclusion |
|----------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Gonasi Set                                                     | Chorionic gonadotrophin                                              | New biological                                                                                  | IBSA Farmaceutici Italia S.r.l.                | Not available                                                                                                                                                                                                                                                                                                           | May 2024          |
| Gotenfia                                                       | golimumab                                                            | New biological                                                                                  | STADA Arzneimittel AG                          | <a href="https://www.ema.europa.eu/en/documents/product-information/gotenfia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/gotenfia-epar-product-information_en.pdf</a>                                                                                                   | February 2026     |
| Grassmuno 6000 SU/ml, 2700 SU/ml, 900 SU/ml                    | allergen extract from 13 types of grass pollen                       | New biological                                                                                  | Bencard Allergie GmbH                          | <a href="https://www.ema.europa.eu/en/documents/product-information/ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=7020744">https://www.ema.europa.eu/en/documents/product-information/ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=7020744</a> | June 2026         |
| Hemgenix                                                       | etranacogene dezaparvovec                                            | New biological, new active substance and Conditional Marketing Authorisation, PASS <sup>1</sup> | CSL Behring GmbH                               | <a href="https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hemgenix-epar-product-information_en.pdf</a>                                                                                                   | March 2023        |
| Hepcludex                                                      | bulevirtide                                                          | New active substance                                                                            | Gilead Sciences Ireland UC                     | <a href="https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hepcludex-epar-product-information_en.pdf</a>                                                                                                 | August 2020       |
| Herwenda                                                       | trastuzumab                                                          | New biological                                                                                  | Sandoz GmbH                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/herwenda-epar-product-information_en.pdf</a>                                                                                                   | November 2023     |
| HETRONIFLY                                                     | serplulimab                                                          | New active substance and new biological                                                         | Accord Healthcare S.L.U.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/hetronifly-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hetronifly-epar-product-information_en.pdf</a>                                                                                               | February 2025     |
| Hund Prick Test RX                                             | allergen extract from dog epithelia                                  | New biological                                                                                  | Roxall Medizin GmbH                            | <a href="https://www.ema.europa.eu/en/documents/product-information/ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611896">https://www.ema.europa.eu/en/documents/product-information/ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611896</a> | June 2026         |
| Hympavzi                                                       | Marstacimab                                                          | New biological, New active substance and PASS <sup>1</sup>                                      | Pfizer Europe MA EEIG                          | <a href="https://www.ema.europa.eu/en/documents/product-information/hympavzi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/hympavzi-epar-product-information_en.pdf</a>                                                                                                   | November 2014     |
| <u>Hydroxyethyl starch (HES)-containing medicinal products</u> | Hydroxyethyl starch                                                  | PASS <sup>1</sup>                                                                               | <u>Various (For full list see Annex V)</u>     | <a href="https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0">https://www.ema.europa.eu/en/medicines/human/referrals/hydroxyethyl-starch-solutions-infusion-0</a>                                                                                                           | January 2014      |
| Idefirix                                                       | imlifidase                                                           | New biological                                                                                  | <del>Hansa-Biopharma AB</del> <b>SERB S.A.</b> | <a href="https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf</a>                                                                                                   | September 2020    |
| ICOTYDE                                                        | Imatukinra hydrochloride                                             | New active substance                                                                            | Janssen-Cilag International N.V.               | <a href="https://www.ema.europa.eu/en/documents/product-information/icotyde-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/icotyde-epar-product-information_en.pdf</a>                                                                                                     | September 2026    |
| Imaavy                                                         | nipocalimab                                                          | New active substance and new biological                                                         | Janssen-Cilag International NV                 | <a href="https://www.ema.europa.eu/en/documents/product-information/imaavy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imaavy-epar-product-information_en.pdf</a>                                                                                                       | December 2025     |
| IMDYLLTRA                                                      | tarlatamab                                                           | New active substance and new biological                                                         | Amgen Europe B.V.                              | <a href="https://www.ema.europa.eu/en/documents/product-information/imdylltra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imdylltra-epar-product-information_en.pdf</a>                                                                                                 | June 2026         |
| IMJUDO                                                         | tremelimumab                                                         | New active substance and new biological                                                         | AstraZeneca AB                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imjudo-epar-product-information_en.pdf</a>                                                                                                       | March 2023        |
| Imreplys                                                       | sargramostim                                                         | New biological, Authorised under exceptional circumstances                                      | Partner Therapeutics Ltd.                      | <a href="https://www.ema.europa.eu/en/documents/product-information/imreplys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imreplys-epar-product-information_en.pdf</a>                                                                                                   | September 2025    |
| Imuldosa                                                       | ustekinumab                                                          | New biological                                                                                  | Accord Healthcare S.L.U.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/imuldosa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imuldosa-epar-product-information_en.pdf</a>                                                                                                   | January 2025      |
| Imvanex                                                        | smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) | Authorised under exceptional circumstances                                                      | Bavarian Nordic A/S                            | <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=WCOB01ac058001d124">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002596/human_med_001666.jsp&amp;mid=WCOB01ac058001d124</a>                                     | September 2013    |
| Inaqovi                                                        | decitabine / cedazuridine                                            | New active substance                                                                            | Otsuka Pharmaceutical Netherlands B.V.         | <a href="https://www.ema.europa.eu/en/documents/product-information/imvanex-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/imvanex-epar-product-information_en.pdf</a>                                                                                                     | September 2023    |
| Incellipan                                                     | Pandemic influenza vaccine (H5N1) (surface antien. inactivated.      | New biological, Conditional Marketing authorisation                                             | Seqirus Netherlands B.V.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/incellipan-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/incellipan-epar-product-information_en.pdf</a>                                                                                               | May 2024          |

| Product name                                                | Active substance (s)       | Reason (s) on list                                               | Marketing authorisation holder (s)                     | Link to product information                                                                                                                                                                                           | Date of inclusion |
|-------------------------------------------------------------|----------------------------|------------------------------------------------------------------|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Increlex                                                    | Mecasermin                 | Authorised under exceptional circumstances                       | Esteve Pharmaceuticals S.A.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/increlex-epar-product-information_en.pdf</a> | April 2013        |
| Inluriyo                                                    | Imlunestrant               | New active substance                                             | Eli Lilly Nederland B.V.                               | <a href="https://www.ema.europa.eu/en/documents/product-information/inluriyo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/inluriyo-epar-product-information_en.pdf</a> | January 2026      |
| Intuniv                                                     | Guanfacine                 | PASS <sup>1</sup>                                                | Takeda Pharmaceuticals International AG Ireland Branch | <a href="https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/intuniv-epar-product-information_en.pdf</a>   | September 2015    |
| Iqirvo                                                      | elafibranor                | New active substance, Conditional marketing authorisation        | Ipsen Pharma                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/iqirvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/iqirvo-epar-product-information_en.pdf</a>     | October 2024      |
| Itovebi                                                     | inavolisib                 | New active substance                                             | Roche Registration GmbH                                | <a href="https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf</a>   | July 2025         |
| Ituxredi                                                    | Rituximab                  | New biological                                                   | Reddy Holding GmbH                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf</a> | October 2024      |
| Itvisma                                                     | onasemnogene abeparvovec   | New biological                                                   | Novartis Europharm Limited                             | <u>Not available</u>                                                                                                                                                                                                  | July 2026         |
| IXCHIQ                                                      | Chikungunya vaccine (live) | New active substance and new biological                          | Valneva Austria GmbH                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/ixchiq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ixchiq-epar-product-information_en.pdf</a>     | July 2024         |
| Izamby                                                      | denosumab                  | New biological                                                   | Mabxience Research SL                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/izamby-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/izamby-epar-product-information_en.pdf</a>     | July 2025         |
| Jascayd Jaydess (also known in some EU countries as Fleree) | nerandomilast              | New active substance                                             | Boehringer Ingelheim International GmbH                | <a href="https://www.ema.europa.eu/en/documents/product-information/jascayd-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jascayd-epar-product-information_en.pdf</a>   | July 2026         |
|                                                             | Levonorgestrel             | PASS <sup>1</sup>                                                | Bayer AB                                               | <a href="https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc">https://docetp.mpa.se/LMF/Jaydess%20intrauterine%20delivery%20system%20ENG%20SmPC.doc</a>                             | November 2013     |
| Jaypirca                                                    | pirtobrutinib              | New active substance, Conditional marketing authorisation        | Eli Lilly Nederland B.V.                               | <a href="https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jaypirca-epar-product-information_en.pdf</a> | November 2023     |
| JEMPERLI                                                    | dostarlimab                | New active substance, new biological                             | GlaxoSmithKline Trading Services Limited               | <a href="https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf</a> | May 2021          |
| JERAYGO                                                     | aprocitentan               | New active substance, PASS <sup>1</sup>                          | Idorsia Pharmaceuticals Deutschland GmbH               | <a href="https://www.ema.europa.eu/en/medicines/human/EPAR/jeraygo#product-info">https://www.ema.europa.eu/en/medicines/human/EPAR/jeraygo#product-info</a>                                                           | July 2024         |
| Jubbonti                                                    | denosumab                  | New biological                                                   | Sandoz GmbH                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/jubbonti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jubbonti-epar-product-information_en.pdf</a> | May 2024          |
| Jubereq                                                     | denosumab                  | New biological                                                   | Accord Healthcare S.L.U.                               | <a href="https://www.ema.europa.eu/en/documents/product-information/jubereq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/jubereq-epar-product-information_en.pdf</a>   | June 2025         |
| Junod                                                       | denosumab                  | New biological                                                   | Gedeon Richter Plc.                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/junod-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/junod-epar-product-information_en.pdf</a>       | July 2025         |
| Joenja                                                      | leniolisib                 | New active substance, Authorised under exceptional circumstances | Pharming Technologies B.V.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/joenja-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/joenja-epar-product-information_en.pdf</a>     | June 2026         |
| Kabeljau Prick Test RX                                      | allergen extract from cod  | New biological                                                   | Roxall Medizin GmbH                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/kabeljau-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kabeljau-epar-product-information_en.pdf</a> | June 2026         |
| Kanuma                                                      | Sebelipase alfa            | PASS <sup>1</sup>                                                | Alexion Europe SAS                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kanuma-epar-product-information_en.pdf</a>     | September 2015    |

| Product name                                                     | Active substance (s)         | Reason (s) on list                                               | Marketing authorisation holder (s)                                   | Link to product information                                                                                                                                                                                                                                                                                                                                                                                                     | Date of inclusion |
|------------------------------------------------------------------|------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Kapruvia                                                         | difelikefalin                | New active substance                                             | Vifor Fresenius Medical Care Renal Pharma France                     | <a href="https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kapruvia-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | May 2022          |
| Kauliv                                                           | teriparatide                 | New biological                                                   | Strides Pharma (Cyprus) Ltd.                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kauliv-epar-product-information_en.pdf</a>                                                                                                                                                                                                               | February 2023     |
| KAVIGALE                                                         | Sipavibart                   | New active substance and new biological                          | AstraZeneca AB                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/kavigale-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kavigale-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | February 2025     |
| KAYFANDA                                                         | Odevixibat                   | Authorized under exceptional circumstances                       | Ipsen Pharma                                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/kayfanda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kayfanda-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | October 2024      |
| Kayshild                                                         | semaglutide                  | New biological and Conditional marketing authorisation           | Novo Nordisk A/S                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/kayshild-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kayshild-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | April 2026        |
| Kefdensis                                                        | denosumab                    | New biological                                                   | STADA Arzneimittel AG                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/kefdensis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kefdensis-epar-product-information_en.pdf</a>                                                                                                                                                                                                         | November 2025     |
| Kerendia<br>Ketoconazole Esteve<br>(previously Ketoconazole HRA) | finerenone                   | New active substance                                             | Bayer AG                                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ketoconazole-hra-epar-product-information_en.pdf</a>                                                                                                                                                                                           | March 2022        |
|                                                                  | Ketoconazole                 | PASS <sup>1</sup>                                                | Esteve Pharmaceuticals S.A.                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kimmtrak-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | December 2014     |
| KIMMTRAK                                                         | tebentafusp                  | New active substance and <i>new biological</i>                   | Immunocore Ireland Limited                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/kisunla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kisunla-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | April 2022        |
| Kisunla                                                          | donanemab                    | New active substance, new biological and PASS <sup>1</sup>       | Eli Lilly Nederland B.V.                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/klisyri-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | October 2025      |
| Klisyri                                                          | Tirbanibulin                 | PASS <sup>1</sup>                                                | Almirall, S.A.                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kostaive-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | July 2021         |
| Kostaive                                                         | zapomieran (mRNA-2105)       | New active substance and new biological                          | <del>Seqirus Netherlands B.V.</del> Acturus Therapeutics Europe B.V. | <a href="https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/koselugo-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | February 2025     |
| Koselugo                                                         | selumetinib                  | Conditional marketing authorisation, PASS <sup>1</sup>           | AstraZeneca AB                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/korjuny-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | June 2021         |
| Korjuny                                                          | catumaxomab                  | New biological                                                   | Atnahs Pharma Netherlands B. V.                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/kygevvvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kygevvvi-epar-product-information_en.pdf</a>                                                                                                                                                                                                           | March 2025        |
| KYGEVVI                                                          | doxycitine / doxribtimine    | New active substance, authorised under exceptional circumstances | UCB Pharma S.A.                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/kyinsu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kyinsu-epar-product-information_en.pdf</a>                                                                                                                                                                                                               | April 2026        |
| Kyinsu                                                           | insulin icodec / semaglutide | New active substance, new biological                             | Novo Nordisk A/S                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | December 2025     |
| Kymriah                                                          | Tisagenlecleucel             | PASS <sup>1</sup>                                                | Novartis Europharm Limited                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/krazati-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/krazati-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | September 2018    |
| Krazati                                                          | adagrasib                    | New active substance, Conditional Marketing Authorisation        | Bristol Myers Squibb Pharma EEIG                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lamzede-epar-product-information_en.pdf</a>                                                                                                                                                                                                             | January 2024      |
| Lamzede                                                          | Velmanase alfa               | Authorised under exceptional circumstances                       | Chiesi Farmaceutici S.p.A.                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf</a>                                                                                                                                                                                     | April 2018        |
| Latex Prick Test RX                                              | allergen extract from latex  | New biological                                                   | Roxall Medizin GmbH                                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf?ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611904">https://www.ema.europa.eu/en/documents/product-information/latex-prick-test-rx-epar-product-information_en.pdf?ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611904</a> | June 2026         |

| Product name | Active substance (s)                                                            | Reason (s) on list                                                           | Marketing authorisation holder (s)                     | Link to product information                                                                                                                                                                                               | Date of inclusion |
|--------------|---------------------------------------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Lazcluze     | lazertinib                                                                      | New active substance                                                         | Janssen-Cilag International NV                         | <a href="https://www.ema.europa.eu/en/documents/product-information/lazcluze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lazcluze-epar-product-information_en.pdf</a>     | February 2025     |
| Lemtrada     | Alemtuzumab                                                                     | PASS <sup>1</sup>                                                            | Sanofi Belgium                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lemtrada-epar-product-information_en.pdf</a>     | January 2020      |
| Leqembi      | Lecanemab autologous CD34+ cell enriched population that contains hematopoietic | New active substance, new biological, PASS <sup>1</sup>                      | Eisai GmbH                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf</a>       | April 2025        |
| Libmeldy     |                                                                                 | PASS <sup>1</sup>                                                            | Orchard Therapeutics (Netherlands) B.V.                | <a href="https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/libmeldy-epar-product-information_en.pdf</a>     | January 2021      |
| Litfulo      | ritlecitinib                                                                    | New active substance                                                         | Pfizer Europe MA EEIG                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/litfulo-epar-product-information_en.pdf</a>       | September 2023    |
| Livmarli     | maralixibat chloride                                                            | New active substance, Authorised under exceptional circumstances             | Mirum Pharmaceuticals International B.V.               | <a href="https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/livmarli-epar-product-information_en.pdf</a>     | January 2023      |
| LIVTENCITY   | maribavir                                                                       | New active substance                                                         | Takeda Pharmaceuticals International AG Ireland Branch | <a href="https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/livtencity-epar-product-information_en.pdf</a> | November 2022     |
| Loargys      | pegzilarginase                                                                  | New active substance, new biological, PASS <sup>1</sup>                      | Immedica Pharma AB                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/loargys-epar-product-information_en.pdf</a>       | January 2024      |
| Locametz     | gozetotide                                                                      | New active substance                                                         | Novartis Europharm Limited                             | <a href="https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/locametz-epar-product-information_en.pdf</a>     | January 2023      |
| Lojuxta      | Lomitapide                                                                      | Authorised under exceptional circumstances                                   | Chiesi Farmaceutici S.p.A.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lojuxta-epar-product-information_en.pdf</a>       | September 2013    |
| LOQTORZI     | toripalimab                                                                     | New biological and New active substance                                      | Topalliance Biosciences Europe Limited                 | <a href="https://www.ema.europa.eu/en/documents/product-information/loqtorzi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/loqtorzi-epar-product-information_en.pdf</a>     | October 2024      |
| LUMYKRAS     | sotorasib                                                                       | New active substance, Conditional marketing authorisation                    | Amgen Europe B.V.                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lumykras-epar-product-information_en.pdf</a>     | January 2022      |
| Lunsumio     | mosunetuzumab                                                                   | New active substance, new biological and conditional marketing authorisation | Roche Registration GmbH                                | <a href="https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lunsumio-epar-product-information_en.pdf</a>     | June 2022         |
| Lupkynis     | voclosporin                                                                     | New active substance                                                         | Otsuka Pharmaceutical Netherlands B.V.                 | <a href="https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lupkynis-epar-product-information_en.pdf</a>     | September 2022    |
| Luxturna     | Voretigene neparvovec                                                           | PASS <sup>1</sup>                                                            | Novartis Europharm Limited                             | <a href="https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/luxturna-epar-product-information_en.pdf</a>     | December 2018     |
| Lyfnua       | gefapixant                                                                      | New active substance                                                         | Merck Sharp & Dohme B.V.                               | <a href="https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lyfnua-epar-product-information_en.pdf</a>         | September 2023    |
| Lynkuet      | elinzanetant                                                                    | New active substance                                                         | Bayer AG                                               | <a href="https://www.ema.europa.eu/en/documents/product-information/lynkuet-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lynkuet-epar-product-information_en.pdf</a>       | December 2025     |
| LYNOZYFIC    | linvoseltamab                                                                   | New active substance, new biological and conditional marketing authorisation | Regeneron Ireland Designated Activity Company (DAC)    | <a href="https://www.ema.europa.eu/en/documents/product-information/lynozyfic-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lynozyfic-epar-product-information_en.pdf</a>   | May 2025          |
| LYROKAUL     | Ārodalcibep                                                                     | New biological and new active substance                                      | ĀB Therapeutics B.V.                                   | <a href="#">Not available</a>                                                                                                                                                                                             | September 2026    |
| Lytenava     | bevacizumab gamma                                                               | New biological                                                               | Outlook Therapeutics NL B.V.                           | <a href="https://www.ema.europa.eu/en/documents/product-information/lytenava-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lytenava-epar-product-information_en.pdf</a>     | June 2024         |

| Product name                 | Active substance (s)                                                    | Reason (s) on list                                                           | Marketing authorisation holder (s)                                         | Link to product information                                                                                                                                                                                               | Date of inclusion |
|------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Lytgobi                      | futibatinib                                                             | New active substance, Conditional marketing authorisation                    | Taiho Pharma Netherlands B.V.                                              | <a href="https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf</a>       | July 2023         |
| Maapliv                      | amino acids                                                             | Authorised under exceptional circumstances                                   | Recordati Rare Diseases                                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/maapliv-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/maapliv-epar-product-information_en.pdf</a>       | September 2025    |
| mCOMBRIAX                    | Influenza and COVID 19, mRNA vaccine                                    | New biological, new active substance                                         | Moderna Biotech Spain S.L.                                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/mcombriax-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mcombriax-epar-product-information_en.pdf</a>   | April 2026        |
| Meerscheinchen Prick Test RX | allergen extract from guinea pig epithelia                              | New biological                                                               | Roxall Medizin GmbH                                                        | <a href="https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mepsevii-epar-product-information_en.pdf</a>     | June 2026         |
| Mepsevii                     | Vestronidase alfa                                                       | Authorized under exceptional circumstances                                   | Ultragenyx Germany GmbH                                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/minjuvi-epar-product-information_en.pdf</a>       | September 2018    |
| Minjuvi                      | Tafasitamab                                                             | New active substance, new biological and conditional marketing authorisation | Incyte Biosciences Distribution B.V.                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/mnexspike-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mnexspike-epar-product-information_en.pdf</a>   | September 2021    |
| mNEXSPIKE                    | COVID-19 mRNA vaccine                                                   | New active substance, new biological                                         | MODERNA BIOTECH SPAIN, S.L.                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf</a>     | February 2026     |
| Mounjaro                     | tirzepatide                                                             | New active substance                                                         | Eli Lilly Nederland B.V.                                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/mresvia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mresvia-epar-product-information_en.pdf</a>       | September 2022    |
| mRESVIA                      | Single-stranded 5' capped mRNA encoding the respiratory syncytial virus | New active substance, new biological                                         | MODERNA BIOTECH SPAIN, S.L.                                                | <a href="https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/myalepta-epar-product-information_en.pdf</a>     | September 2024    |
| Myalepta                     | Metreleptin                                                             | Authorized under exceptional circumstances                                   | Chiesi Farmaceutici S.p.A.                                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/mynzepli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mynzepli-epar-product-information_en.pdf</a>     | September 2018    |
| MYNZEPLI                     | aflibercept                                                             | New biological                                                               | Advanz Pharma Limited                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/myqorzo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/myqorzo-epar-product-information_en.pdf</a>       | September 2025    |
| MYQORZO                      | aficamten                                                               | New active substance                                                         | Cytokinetics (Ireland) Limited                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/mysimba-epar-product-information_en.pdf</a>       | February 2026     |
| Mysimba                      | Naltrexone / bupropion                                                  | PASS <sup>1</sup>                                                            | Orexigen Therapeutics Ireland Limited                                      |                                                                                                                                                                                                                           | April 2015        |
| NADROPARINE CALCIQUE ASPEN   | nadroparin calcium                                                      | New biological                                                               | ASPEN PHARMA TRADING LIMITED                                               | Not available                                                                                                                                                                                                             | September 2022    |
| Nemludio                     | Nemolizumab                                                             | New active substance and new biological                                      | Galderma International                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/nemludio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nemludio-epar-product-information_en.pdf</a>     | February 2025     |
| NEXPOVIO                     | selinexor                                                               | New active substance                                                         | Karyopharm Europe GmbH                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf</a>     | April 2021        |
| Nexviadyme                   | avalglucosidase alfa                                                    | New active substance and new biological                                      | Genzyme Europe B.V.                                                        | <a href="https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nexviadyme-epar-product-information_en.pdf</a> | July 2022         |
| Nezglyal                     | liraglutide                                                             | New active substance, authorised under exceptional circumstances             | Minoryx Therapeutics S.L.                                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/nezglyal-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nezglyal-epar-product-information_en.pdf</a>     | September 2026    |
| Ngenla                       | somatrogon                                                              | New active substance and new biological                                      | Pfizer Europe MA EEIG                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf</a>         | February 2022     |
| NULIBRY                      | fosdenopterin                                                           | New active substance, authorised under exceptional circumstances             | <b>TMC Pharma (EU) Limited</b> <b>Integral Pharma Solutions EU Limited</b> | <a href="https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nulibry-epar-product-information_en.pdf</a>       | September 2022    |

| Product name             | Active substance (s)                                      | Reason (s) on list                                                           | Marketing authorisation holder (s)                  | Link to product information                                                                                                                                                                                                                                                                                             | Date of inclusion |
|--------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Nuvaxovid                | SARS-CoV-2 recombinant spike protein                      | New active substance and new biological                                      | Sanofi Winthrop Industrie                           | <a href="https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf</a>                                                                                                 | January 2022      |
| Obizur                   | Susoctocog alfa                                           | Authorised under exceptional circumstances                                   | Baxalta Innovations GmbH                            | <a href="https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obizur-epar-product-information_en.pdf</a>                                                                                                       | November 2015     |
| Obgemsa                  | Vibegron                                                  | New active substance                                                         | PIERRE FABRE MEDICAMENT                             | <a href="https://www.ema.europa.eu/en/documents/product-information/obgemsa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obgemsa-epar-product-information_en.pdf</a>                                                                                                     | July 2024         |
| Obodence                 | denosumab                                                 | New biological                                                               | Samsung Bioepis NL B.V.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/obodence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/obodence-epar-product-information_en.pdf</a>                                                                                                   | February 2025     |
| Ogsiveo                  | nirogacestat                                              | New active substance                                                         | Merck Europe B.V.                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/ogsiveo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ogsiveo-epar-product-information_en.pdf</a>                                                                                                     | September 2025    |
| Ojemda                   | tovorafenib                                               | New active substance, Conditional marketing authorisation                    | Ipsen Pharma                                        | <a href="https://www.ema.europa.eu/en/documents/product-information/ojemda-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ojemda-epar-product-information_en.pdf</a>                                                                                                       | April 2026        |
| Olivenbaum Prick Test RX | allergen extract from olive tree pollen                   | New biological                                                               | Roxall Medizin GmbH                                 | <a href="https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611864">https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611864</a> | June 2026         |
| Ondexxya                 | Andexanet alfa                                            | New active substance, new biological and conditional marketing authorisation | AstraZeneca AB                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ondexxya-epar-product-information_en.pdf</a>                                                                                                   | May 2019          |
| Ondibta                  | Insulin glargine                                          | New biological                                                               | Sandoz GmbH                                         | <a href="https://www.ema.europa.eu/en/documents/product-information/ondibta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ondibta-epar-product-information_en.pdf</a>                                                                                                     | January 2026      |
| Ontozry                  | cenobamate                                                | New active substance                                                         | Angelini Pharma S.p.A                               | <a href="https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ontozry-epar-product-information_en.pdf</a>                                                                                                     | April 2021        |
| Onswik                   | Insulin efsitora alfa                                     | New active substance, new biological                                         | Eli Lilly Nederland B.V.                            | <a href="#">Not available</a>                                                                                                                                                                                                                                                                                           | September 2026    |
| Omjjara                  | momelotinib                                               | New active substance                                                         | GlaxoSmithKline Trading Services Limited            | <a href="https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf</a>                                                                                                     | February 2024     |
| Omlyclo                  | Omalizumab                                                | New biological                                                               | Celltrion Healthcare Hungary Kft.                   | <a href="https://www.ema.europa.eu/en/documents/product-information/omlyclo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omlyclo-epar-product-information_en.pdf</a>                                                                                                     | June 2024         |
| OmvoH                    | mirikizumab                                               | New active substance, new biological                                         | Eli Lilly Nederland B.V.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/omvoh-epar-product-information_en.pdf</a>                                                                                                         | June 2023         |
| Opdualag                 | nivolumab/relatlimab                                      | New active substance, new biological                                         | Bristol Myers Squibb Pharma EEIG                    | <a href="https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf</a>                                                                                                   | September 2022    |
| Opuviz                   | afibercept                                                | New biological                                                               | Samsung Bioepis NL B.V.                             | <a href="https://www.ema.europa.eu/en/documents/product-information/opuviz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/opuviz-epar-product-information_en.pdf</a>                                                                                                       | November 2024     |
| Ordspono                 | odronextamab                                              | New active substance, new biological and Conditional Marketing authorisation | Regeneron Ireland Designated Activity Company (DAC) | <a href="https://www.ema.europa.eu/en/documents/product-information/ordspono-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ordspono-epar-product-information_en.pdf</a>                                                                                                   | September 2024    |
| Orylmyte                 | Allergen extract from house dust mites (Dermatophagoides) | New biological                                                               | Stallergenes                                        | <a href="https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611864">https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611864</a> | July 2021         |
| Orgovyx                  | relugolix                                                 | New active substance                                                         | Myovant Sciences Ireland Limited                    | <a href="https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf</a>                                                                                                     | May 2022          |
| Orphacol                 | Cholic acid                                               | Authorised under exceptional circumstances                                   | Laboratoires CTRS                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orphacol-epar-product-information_en.pdf</a>                                                                                                   | October 2013      |

| Product name                                                | Active substance (s)                                                      | Reason (s) on list                                        | Marketing authorisation holder (s)    | Link to product information                                                                                                                                                                                                                                                                 | Date of inclusion |
|-------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| ORSERDU                                                     | elacestrant                                                               | New active substance                                      | Stemline Therapeutics B.V.            | <a href="https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/orserdu-epar-product-information_en.pdf</a>                                                                         | September 2023    |
| Osenvelt                                                    | denosumab                                                                 | New biological                                            | Celltrion Healthcare Hungary Kft.     | <a href="https://www.ema.europa.eu/en/documents/product-information/osenvelt-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osenvelt-epar-product-information_en.pdf</a>                                                                       | February 2025     |
| Osvyrti                                                     | denosumab                                                                 | New biological                                            | Accord Healthcare S.L.U.              | <a href="https://www.ema.europa.eu/en/documents/product-information/osvyrti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osvyrti-epar-product-information_en.pdf</a>                                                                         | June 2025         |
| Osqay                                                       | denosumab                                                                 | New biological                                            | Theramex Ireland Limited              | <a href="https://www.ema.europa.eu/en/documents/product-information/osqay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/osqay-epar-product-information_en.pdf</a>                                                                             | January 2026      |
| Oxbryta                                                     | Voxelotor                                                                 | New active substance                                      | Pfizer Europe MA EEIG                 | <a href="https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/oxbryta-epar-product-information_en.pdf</a>                                                                         | February 2022     |
| Otulfi                                                      | ustekinumab                                                               | New biological                                            | Fresenius Kabi Deutschland GmbH       | <a href="https://www.ema.europa.eu/en/documents/product-information/otulfi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/otulfi-epar-product-information_en.pdf</a>                                                                           | October 2024      |
| Padcev                                                      | enfortumab vedotin                                                        | New active substance and <i>new biological</i>            | Astellas Pharma Europe B.V.           | <a href="https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/padcev-epar-product-information_en.pdf</a>                                                                           | April 2022        |
| Palforzia                                                   | defatted powder of Arachis                                                | New biological                                            | Aimmune Therapeutics Ireland Limited  | <a href="https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf</a>                                                                     | November 2022     |
| Palsonify<br>Pandemic influenza vaccine H5N1<br>AstraZeneca | paltusotine<br>Pandemic influenza vaccine (H5N1) (live attenuated, nasal) | New active substance, PASS <sup>1</sup>                   | Crinetics Pharmaceuticals Europe GmbH | <a href="https://www.ema.europa.eu/en/documents/product-information/palsonify-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/palsonify-epar-product-information_en.pdf</a>                                                                     | May 2026          |
|                                                             |                                                                           | Conditional marketing authorisation                       | AstraZeneca AB                        | <a href="https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pandemic-influenza-vaccine-h5n1-astrazeneca-epar-product-information_en.pdf</a> | June 2016         |
| PAVBLU                                                      | aflibercept                                                               | New biological                                            | Amgen Technology (Ireland) UC         | <a href="https://www.ema.europa.eu/en/documents/product-information/pavblu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pavblu-epar-product-information_en.pdf</a>                                                                           | April 2025        |
| Paxlovid                                                    | nirmatrelvir                                                              | New active substance                                      | Pfizer Europe MA EEIG                 | <a href="https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf</a>                                                                       | February 2022     |
| Pemazyre                                                    | pemigatinib                                                               | New active substance, conditional marketing authorisation | Incyte Biosciences Distribution B.V.  | <a href="https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_en.pdf</a>                                                                       | April 2021        |
| Percolozin                                                  | enoxaparin sodium                                                         | New biological                                            | Venipharma                            | <a href="https://www.ema.europa.eu/en/documents/product-information/percolozin-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/percolozin-epar-product-information_en.pdf</a>                                                                   | January 2022      |
| Pferd Prick Test RX                                         | allergen extract from horse epithelia                                     | New biological                                            | Roxall Medizin GmbH                   | <a href="https://www.ema.europa.eu/en/documents/product-information/pferd-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pferd-prick-test-rx-epar-product-information_en.pdf</a>                                                 | June 2026         |
| Piasky                                                      | crovalimab                                                                | New active substance, new biological                      | Roche Registration GmbH               | <a href="https://www.ema.europa.eu/en/documents/product-information/piasky-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/piasky-epar-product-information_en.pdf</a>                                                                           | September 2024    |
| Platane Prick Test RX                                       | allergen extract from plane tree pollen                                   | New biological                                            | Roxall Medizin GmbH                   | <a href="https://www.ema.europa.eu/en/documents/product-information/platane-prick-test-rx-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/platane-prick-test-rx-epar-product-information_en.pdf</a>                                             | June 2026         |
| Pluvicto                                                    | lutetium (177Lu)<br>vipivotide tetraxetan                                 | New active substance                                      | Novartis Europharm Limited            | <a href="https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf</a>                                                                       | January 2023      |
| Poherdy                                                     | pertuzumab                                                                | New biological                                            | N.V. Organon                          | <a href="https://www.ema.europa.eu/en/documents/product-information/poherdy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/poherdy-epar-product-information_en.pdf</a>                                                                         | May 2026          |
| Ponlinsi                                                    | denosumab                                                                 | New biological                                            | Teva GmbH                             | <a href="https://www.ema.europa.eu/en/documents/product-information/ponlinsi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ponlinsi-epar-product-information_en.pdf</a>                                                                       | December 2025     |

| Product name                                                   | Active substance (s)                                                              | Reason (s) on list                         | Marketing authorisation holder (s)                                           | Link to product information                                                                                                                                                                                             | Date of inclusion |
|----------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Pombiliti                                                      | cipaglucosidase alfa                                                              | New active substance, new biological       | Amicus Therapeutics Europe Limited                                           | <a href="https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pombiliti-epar-product-information_en.pdf</a> | April 2023        |
| Prufibry                                                       | Human fibrinogen                                                                  | New biological                             | Biotest Pharma GmbH                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/pylclari-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pylclari-epar-product-information_en.pdf</a>   | January 2026      |
| PyIclari                                                       | piflufolastat (18F)                                                               | New active substance                       | CURIUM PET France                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pyrukynd-epar-product-information_en.pdf</a>   | September 2023    |
| Pyrukynd                                                       | mitapivat                                                                         | New active substance                       | Agios Netherlands B.V.                                                       | <a href="https://www.ema.europa.eu/en/documents/product-information/pyzchiva-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/pyzchiva-epar-product-information_en.pdf</a>   | November 2022     |
| Pyzchiva                                                       | ustekinumab                                                                       | New biological                             | Samsung Bioepis NL B.V.                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/qalsody-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/qalsody-epar-product-information_en.pdf</a>     | May 2024          |
| Qalsody                                                        | tofersen                                                                          | New active substance, PASS <sup>1</sup>    | Biogen Netherlands B.V.                                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/qarziba-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/qarziba-epar-product-information_en.pdf</a>     | June 2024         |
| Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta | Dinutuximab beta                                                                  | Authorised under exceptional circumstances | EUSA Pharma (UK) Limited                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/qdenga-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/qdenga-epar-product-information_en.pdf</a>       | May 2017          |
| Qdenga                                                         | dengue tetravalent vaccine (live, attenuated)                                     | New biological                             | Takeda GmbH                                                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf</a>     | December 2022     |
| QUVIVIQ                                                        | daridorexant                                                                      | New active substance                       | Idorsia Pharmaceuticals Deutschland GmbH                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf</a>     | May 2022          |
| Radelumin (also known as Próstalumin, MAH BIODOSMOS SA)        | (3s,10s,14s)-1-[4-[[[(2s)-4-carboxy-2-[(2s)-4-carboxy-2-(6-[18f] fluoropyridin-3- | New active substance                       | Abx Advanced Biochemical Compounds Biomedizinische Forschungsreagenzien GmbH | Not available                                                                                                                                                                                                           | March 2026        |
| Ragweed Prick Test RX                                          | allergen extract from ragweed                                                     | New biological                             | Roxall Medizin GmbH                                                          | <a href="https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf</a> | June 2026         |
| Ranivisio                                                      | ranibizumab                                                                       | New biological                             | Midas Pharma GmbH                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ranivisio-epar-product-information_en.pdf</a> | September 2022    |
| Ranluspec                                                      | ranibizumab                                                                       | New biological                             | Lupin Europe GmbH                                                            | <a href="https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf</a>       | February 2026     |
| Raxone                                                         | Idebenone                                                                         | Authorised under exceptional circumstances | Chiesi Farmaceutici S.p.A.                                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/raxone-epar-product-information_en.pdf</a>       | September 2015    |
| RAYVOW                                                         | lasmiditan                                                                        | New active substance                       | Eli Lilly Nederland B.V.                                                     | <a href="https://www.ema.europa.eu/en/documents/product-information/redemplo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/redemplo-epar-product-information_en.pdf</a>   | September 2022    |
| Redemplo                                                       | plozasiran                                                                        | New active substance                       | Arrowhead Pharmaceuticals Ireland Limited                                    | <a href="https://www.ema.europa.eu/en/documents/product-information/redemplo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/redemplo-epar-product-information_en.pdf</a>   | July 2026         |
| Refixia                                                        | Nonacog beta pegol                                                                | PASS <sup>1</sup>                          | Novo Nordisk A/S                                                             | <a href="https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf</a>     | June 2017         |
| Relfydess                                                      | Clostridium botulinum neurotoxin type A                                           | New biological                             | Ipsen Pharma                                                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf</a>     | November 2025     |
| REKAMBYS                                                       | rilpivirine                                                                       | PASS <sup>1</sup>                          | Janssen-Cilag International NV                                               | <a href="https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf</a>     | January 2021      |
| Revestive                                                      | Teduglutide                                                                       | PASS <sup>1</sup>                          | Takeda Pharmaceuticals International AG Ireland Branch                       | <a href="https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/refixia-epar-product-information_en.pdf</a>     | April 2013        |

| Product name      | Active substance (s)   | Reason (s) on list                                        | Marketing authorisation holder (s)           | Link to product information                                                                                                                                                                                                                                                                                                                                                                                                                        | Date of inclusion |
|-------------------|------------------------|-----------------------------------------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Revlimid          | Lenalidomide           | PASS <sup>1</sup>                                         | Bristol-Myers Squibb Pharma EEIG             | <a href="https://www.ema.europa.eu/en/documents/product-information/revlimid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/revlimid-epar-product-information_en.pdf</a>                                                                                                                                                                                                                              | June 2014         |
| Rexatilux         | ranibizumab            | New biological                                            | Intas Third Party Sales 2005, S.L.           | <a href="https://www.ema.europa.eu/en/documents/product-information/rexatilux-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rexatilux-epar-product-information_en.pdf</a>                                                                                                                                                                                                                            | July 2026         |
| Rezdiffra         | Resmetirom             | New active substance, Conditional marketing authorisation | Madrigal Pharmaceuticals EU Limited          | <a href="https://www.ema.europa.eu/en/documents/product-information/rezdiffra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rezdiffra-epar-product-information_en.pdf</a>                                                                                                                                                                                                                            | September 2025    |
| REZUROCK          | belumosudil            | New active substance, conditional marketing authorisation | Sanofi Winthrop Industrie                    | <a href="https://www.ema.europa.eu/en/documents/product-information/rezurock-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rezurock-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/rezzayo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rezzayo-epar-product-information_en.pdf</a>       | April 2026        |
| Rezzayo           | Rezafungin             | New active substance                                      | Mundipharma GmbH                             | <a href="https://www.ema.europa.eu/en/documents/product-information/rhapsido-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rhapsido-epar-product-information_en.pdf</a>                                                                                                                                                                                                                              | January 2024      |
| Rhapsido          | remibrutinib           | New active substance                                      | Novartis Europharm Limited                   | <a href="https://www.ema.europa.eu/en/documents/product-information/rhimyrah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rhimyrah-epar-product-information_en.pdf</a>                                                                                                                                                                                                                              | May 2026          |
| Rimmyrah          | ranibizumab            | New biological                                            | QILU PHARMA SPAIN S.L.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/rolcya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rolcya-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                  | January 20247     |
| Rolcya            | denosumab              | New biological                                            | Sandoz GmbH                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/romvimza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/romvimza-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_en.pdf</a>   | July 2025         |
| ROMVIMZA          | vimseltinib            | New active substance                                      | Deciphera Pharmaceuticals (Netherlands) B.V. | <a href="https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf</a>                                                                                                                                                                                                                            | October 2025      |
| Rozlytrek         | entrectinib            | Conditional marketing authorisation                       | Roche Registration GmbH                      | <a href="https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf</a>                                                                                                                                                                                                                              | August 2020       |
| Rybrevant         | Amivantamab            | New active substance, new biological                      | Janssen-Cilag International NV               | <a href="https://www.ema.europa.eu/en/documents/product-information/rytelo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/rytelo-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/ryzneuta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ryzneuta-epar-product-information_en.pdf</a>         | January 2022      |
| Rystiggo          | Rozanolixizumab        | New active substance, new biological                      | UCB Pharma S.A.                              | <a href="https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/scenesse-epar-product-information_en.pdf</a>     | January 2024      |
| Rytelo            | imetelstat             | New active substance                                      | Geron Netherlands B.V.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/seladelpar-gilead-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/seladelpar-gilead-epar-product-information_en.pdf</a>                                                                                                                                                                                                            | March 2025        |
| Ryzneuta          | efbemalenograstim alfa | New active substance and new biological                   | Fisiopharma S.r.l.                           | <a href="https://www.ema.europa.eu/en/documents/product-information/sephience-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sephience-epar-product-information_en.pdf</a>                                                                                                                                                                                                                            | April 2024        |
| Scemblix          | asciminib              | New active substance                                      | Novartis Europharm Limited                   | <a href="https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/skyclarys-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/skyclarys-epar-product-information_en.pdf</a> | September 2022    |
| Scenesse          | Afamelanotide          | Authorised under exceptional circumstances                | Clinuvel UK Limited                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                    | January 2015      |
| Seladelpar Gilead | seladelpar             | New active substance, Conditional marketing authorisation | Gilead Sciences Ireland UC                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                    | March 2025        |
| Sephience         | sepiapterin            | New active substance                                      | PTC Therapeutics International Limited       |                                                                                                                                                                                                                                                                                                                                                                                                                                                    | July 2025         |
| SIILTIBCY         | rdESAT-6 and rCFP-10   | New active substance, new biological                      | Serum Life Science Europe GmbH               |                                                                                                                                                                                                                                                                                                                                                                                                                                                    | January 2025      |
| Skyclarys         | omaveloxolone          | New active substance                                      | Biogen Netherlands B.V.                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                    | February 2024     |

| Product name                                                    | Active substance (s)                                                                     | Reason (s) on list                                                                                 | Marketing authorisation holder (s)                  | Link to product information                                                                                                                                                                                                                                                                   | Date of inclusion |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Sondelbay                                                       | teriparatide                                                                             | New biological                                                                                     | Accord Healthcare S.L.U.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sondelbay-epar-product-information_en.pdf</a>                                                                       | April 2022        |
| SOTYKTU                                                         | deucravacitinib                                                                          | New active substance                                                                               | Bristol Myers Squibb Pharma EEIG                    | <a href="https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf</a>                                                                           | April 2023        |
| Spevigo<br>Spikevax (previously<br>COVID-19 Vaccine<br>Moderna) | spesolimab<br>elasomeran (formally<br>COVID-19 mRNA Vaccine<br>(nucleoside-modified))    | New active substance, new biological and<br>Conditional marketing authorisation                    | LEO Pharma A/S                                      | <a href="https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/spevigo-epar-product-information_en.pdf</a>                                                                           | January 2023      |
| Spitzwegerich Prick Test<br>RX                                  | allergen extract from<br>english plantain                                                | New active substance and new biological                                                            | MODERNA BIOTECH SPAIN, S.L.                         | <a href="https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf</a> | January 2021      |
|                                                                 |                                                                                          | New biological                                                                                     | Roxall Medizin GmbH                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/steqeyma-epar-product-information_en.pdf</a>                                                                         | June 2026         |
| STEQEYMA                                                        | ustekinumab                                                                              | New biological                                                                                     | Celltrion Healthcare Hungary Kft.                   | <a href="https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/stimufend-epar-product-information_en.pdf</a>                                                                       | September 2024    |
| Stimufend                                                       | Pegfilgrastim                                                                            | New biological                                                                                     | Fresenius Kabi Deutschland GmbH                     | <a href="https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/strensiq-epar-product-information_en.pdf</a>                                                                         | April 2022        |
| Strensiq                                                        | Asfotase alfa<br>Autologous CD34+<br>enriched cell fraction that<br>contains CD34+ cells | Authorised under exceptional circumstances                                                         | Alexion Europe SAS                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/strimvelis-epar-product-information_en.pdf</a>                                                                     | September 2015    |
| Strimvelis                                                      |                                                                                          | PASS <sup>1</sup>                                                                                  | Fondazione Telethon ETS                             | <a href="https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf</a>                                                                         | June 2016         |
| Sunlenca                                                        | lenacapavir                                                                              | New active substance                                                                               | Gilead Sciences Ireland UC                          | <a href="https://www.ema.europa.eu/en/documents/product-information/susvimo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/susvimo-epar-product-information_en.pdf</a>                                                                           | September 2022    |
| Susvimo                                                         | ranibizumab                                                                              | New biological                                                                                     | B&Bc Registration GmbH                              | <a href="https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf</a>                                                                           | September 2026    |
| Sylvant                                                         | Siltuximab                                                                               | PASS <sup>1</sup>                                                                                  | EUSA Pharma (Netherlands) B.V.                      | <a href="https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tabrecta-epar-product-information_en.pdf</a>                                                                         | June 2014         |
| Tabrecta                                                        | capmatinib                                                                               | New active substance                                                                               | Novartis Europharm Limited                          | <a href="https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf</a>                                                                             | June 2022         |
| TALVEY                                                          | talquetamab                                                                              | New active substance, new biological and<br>Conditional marketing authorisation                    | Janssen-Cilag International NV                      | <a href="https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tavneos-epar-product-information_en.pdf</a>                                                                           | September 2023    |
| Tavneos                                                         | avacopan                                                                                 | New active substance                                                                               | Vifor Fresenius Medical Care Renal Pharma<br>France | <a href="https://www.ema.europa.eu/en/documents/product-information/tauvid-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tauvid-epar-product-information_en.pdf</a>                                                                             | January 2022      |
| Tauvid                                                          | Flortaucipir (18F)                                                                       | New active substance                                                                               | Eli Lilly Nederland B.V.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf</a>                                                                         | September 2024    |
| Tecartus                                                        | autologous anti-CD19-<br>transduced CD3+ cells                                           | Conditional marketing authorisation / New<br>active substance an new biological/ PASS <sup>1</sup> | Kite Pharma EU B.V.                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecovirimat-siga-epar-product-information_en.pdf</a>                                                         | January 2021      |
| Tecovirimat SIGA                                                | tecovirimat monohydrate                                                                  | Authorised under exceptional circumstances and                                                     | SIGA Technologies Netherlands B.V.                  | <a href="https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tecvayli-epar-product-information_en.pdf</a>                                                                         | January 2022      |
| TECVAYLI                                                        | teclistamab                                                                              | New active substance and new biological                                                            | Janssen-Cilag International NV                      | <a href="https://www.ema.europa.eu/en/documents/product-information/teizeild-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/teizeild-epar-product-information_en.pdf</a>                                                                         | September 2022    |
| Teizeild                                                        | Teplizumab                                                                               | New active substance and new biological                                                            | Sanofi Winthrop Industrie                           |                                                                                                                                                                                                                                                                                               | January 2026      |

| Product name                                                        | Active substance (s)           | Reason (s) on list                                                               | Marketing authorisation holder (s)           | Link to product information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Date of inclusion |
|---------------------------------------------------------------------|--------------------------------|----------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Tepkinly                                                            | epcoritamab                    | New active substance, new biological and conditional marketing authorisation     | AbbVie Deutschland GmbH & Co. KG             | <a href="https://www.ema.europa.eu/en/documents/product-information/tepkinky-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tepkinky-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                      | October 2023      |
| TEPEZZA                                                             | Teprotumumab                   | New active substance and new biological                                          | Amgen Europe B.V.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/tepezza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tepezza-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                        | July 2025         |
| Tevimbra                                                            | tislelizumab                   | New biological                                                                   | BeiGene Ireland Limited                      | <a href="https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                      | September 2023    |
| Tezspire                                                            | tezepelumab                    | New active substance and new biological                                          | AstraZeneca AB                               | <a href="https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                      | September 2022    |
| Thiosix                                                             | Tioguanin                      | Authorised under exceptional circumstances                                       | Teva Nederland B.V.                          | <a href="https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                        | May 2015          |
| Thunfisch Prick Test RX                                             | allergen extract from tuna     | New biological                                                                   | Roxall Medizin GmbH                          | <a href="https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf</a><br><a href="https://www.ema.europa.eu/en/documents/product-information/tibsovo-epar-product-information_en.pdf">ssid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=CURRENT+AND+ENR=2611923</a><br><a href="http://db.cbq-meb.nl/IB-teksten/h114681.pdf">http://db.cbq-meb.nl/IB-teksten/h114681.pdf</a> | June 2026         |
| Tibsovo                                                             | ivosidenib                     | New active substance                                                             | Les Laboratoires Servier                     | <a href="https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tivdak-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                          | May 2023          |
| Tivdak                                                              | Tisotumab vedotin              | New active substance and new biological                                          | Genmab A/S                                   | <a href="https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                    | April 2025        |
| Tofidence                                                           | tocilizumab                    | New biological                                                                   | STADA Arzneimittel AG                        | <a href="https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tofidence-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                    | June 2024         |
| Trivalent Influenza Vaccine                                         | Influenza vaccine (split viric | New biological                                                                   | Sanofi Pasteur                               | Not available<br><a href="https://www.ema.europa.eu/en/documents/product-information/truqap-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/truqap-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                         | May 2019          |
| Truqap                                                              | capivasertib                   | New active substance                                                             | AstraZeneca AB                               | <a href="https://www.ema.europa.eu/en/documents/product-information/tryngolza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tryngolza-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                    | June 2024         |
| Tryngolza<br><u>Topiramate containing medicinal products in the</u> | olezarsen                      | New active substance                                                             | Swedish Orphan Biovitrum AB (publ)           | <a href="https://www.ema.europa.eu/en/medicines/human/referrals/topiramate">https://www.ema.europa.eu/en/medicines/human/referrals/topiramate</a>                                                                                                                                                                                                                                                                                                                                                                                          | September 2025    |
|                                                                     | topiramate                     | PASS <sup>1</sup>                                                                | <u>Various ( for full list see Annex XV)</u> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | May 2024          |
| Tuznue                                                              | trastuzumab                    | New biological                                                                   | Prestige Biopharma Belgium BVBA              | <a href="https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tuznue-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                          | October 2024      |
| Tuyory                                                              | tocilizumab                    | New biological                                                                   | Gedeon Richter Plc.                          | <a href="https://www.ema.europa.eu/en/documents/product-information/tuyory-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tuyory-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                          | May 2026          |
| Tyenne                                                              | tocilizumab                    | New biological                                                                   | Fresenius Kabi Deutschland GmbH              | <a href="https://www.ema.europa.eu/en/documents/product-information/tyenne-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tyenne-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                          | September 2023    |
| Tyruko                                                              | natalizumab                    | New biological                                                                   | Sandoz GmbH                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/tyruko-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                                          | October 2023      |
| Ubeslo                                                              | Obicetrapib                    | New active substance                                                             | Menarini International Licensing S.A.        | <u>Not available</u><br><a href="https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/uplizna-epar-product-information_en.pdf</a>                                                                                                                                                                                                                                                                                                | September 2026    |
| Uplizna                                                             | inebilizumab                   | New active substance, new biological                                             | Amgen Europe B.V.                            | <a href="https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf">https://www.ema.europa.eu/en/documents/product-information/upstaza-epar-product-information_en-0.pdf</a>                                                                                                                                                                                                                                                                                                                    | May 2022          |
| Upstaza                                                             | Eladocagene exuparvovec        | New active substance, new biological, authorised under exceptional circumstances | PTC Therapeutics International Limited       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | July 2022         |

| Product name                                                                                                                                                                  | Active substance (s)                                              | Reason (s) on list                         | Marketing authorisation holder (s)            | Link to product information                                                                                                                                                                                                 | Date of inclusion |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Usgena                                                                                                                                                                        | ustekinumab                                                       | New biological                             | STADA Arzneimittel AG                         | <a href="https://www.ema.europa.eu/en/documents/product-information/usgena-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usgena-epar-product-information_en.pdf</a>           | November 2025     |
| Usrenty                                                                                                                                                                       | ustekinumab                                                       | New biological                             | Biosimilar Collaborations Ireland Limited     | <a href="https://www.ema.europa.eu/en/documents/product-information/usrenty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usrenty-epar-product-information_en.pdf</a>         | October 2025      |
| Usymro                                                                                                                                                                        | ustekinumab                                                       | New biological                             | Gedeon Richter Plc.                           | <a href="https://www.ema.europa.eu/en/documents/product-information/usymro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/usymro-epar-product-information_en.pdf</a>           | September 2025    |
| Uzpruvo                                                                                                                                                                       | ustekinumab                                                       | New biological                             | STADA Arzneimittel AG                         | <a href="https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf</a>         | January 2024      |
| Vabysmo                                                                                                                                                                       | Faricimab                                                         | New active substance, new biological       | Roche Registration GmbH                       | <a href="https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf</a>         | September 2022    |
| VacPertagen                                                                                                                                                                   | Filamentous haemagglutinin                                        | New active substance and new biological    | BioNet Europe                                 | <a href="https://www.ema.europa.eu/en/documents/product-information/vacpertagen-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vacpertagen-epar-product-information_en.pdf</a> | January 2026      |
| Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products) (For full list of products see Annex XIII) | Sodium valproate, valproic acid, valproate semisodium, valpromide | PASS <sup>1</sup>                          | <u>Various (For full list see Annex XIII)</u> | <a href="https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances">https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances</a>                                       | January 2015      |
| Vafseo                                                                                                                                                                        | vadadustat                                                        | New active substance                       | <u>AKEBIA EUROPE Limited</u>                  | <a href="https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vafseo-epar-product-information_en.pdf</a>           | May 2023          |
| VANFLYTA                                                                                                                                                                      | quizartinib                                                       | New active substance                       | <u>Daiichi Sankyo Europe GmbH</u>             | <a href="https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vanflyta-epar-product-information_en.pdf</a>       | November 2023     |
| Vedrop                                                                                                                                                                        | Tocofersolan d-alpha tocopheryl polyethylene glycol succinate     | Authorised under exceptional circumstances | Recordati Rare Diseases                       | <a href="https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vedrop-epar-product-information_en.pdf</a>           | April 2013        |
| VEGZELMA                                                                                                                                                                      | bevacizumab                                                       | New biological                             | Celltrion Healthcare Hungary Kft.             | <a href="https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vegzelma-epar-product-information_en.pdf</a>       | September 2022    |
| Velsipity                                                                                                                                                                     | etrasimod                                                         | New active substance                       | Pfizer Europe MA EEIG                         | <a href="https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/velsipity-epar-product-information_en.pdf</a>     | February 2024     |
| Veozza                                                                                                                                                                        | fezolinetant                                                      | New active substance                       | Astellas Pharma Europe B.V.                   | <a href="https://www.ema.europa.eu/en/documents/product-information/veozza-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/veozza-epar-product-information_en.pdf</a>           | January 2024      |
| Vevzuo                                                                                                                                                                        | denosumab                                                         | New biological                             | Biosimilar Collaborations Ireland Limited     | <a href="https://www.ema.europa.eu/en/documents/product-information/vevzuo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vevzuo-epar-product-information_en.pdf</a>           | July 2025         |
| Vgenfli                                                                                                                                                                       | aflibercept                                                       | New biological                             | Zakłady Farmaceutyczne POLPHARMA S.A.         | <a href="https://www.ema.europa.eu/en/documents/product-information/vgenfli-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vgenfli-epar-product-information_en.pdf</a>         | September 2025    |
| Vijoice                                                                                                                                                                       | alpelisib                                                         | Conditional marketing authorisation        | Novartis Europharm Limited                    | <u>Not available</u>                                                                                                                                                                                                        | July 2026         |
| Vimizim                                                                                                                                                                       | Elosulfase alfa                                                   | PASS <sup>1</sup>                          | BioMarin International Limited                | <a href="https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vimizim-epar-product-information_en.pdf</a>         | June 2014         |
| VIMKUNYA                                                                                                                                                                      | Chikungunya vaccine (recombinant, adsorbed) (PKVX0317)            | New biological, new active substance,      | Bavarian Nordic A/S                           | <a href="https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf</a>       | March 2025        |

| Product name | Active substance (s)     | Reason (s) on list                                                                  | Marketing authorisation holder (s) | Link to product information                                                                                                                                                                                           | Date of inclusion |
|--------------|--------------------------|-------------------------------------------------------------------------------------|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Vislyfa      | ranibizumab              | New biological                                                                      | Ůipin Europe GmbH                  | <a href="https://www.ema.europa.eu/en/documents/product-information/vislyfa-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vislyfa-epar-product-information_en.pdf</a>   | September 2026    |
| VITRAKVI     | Larotrectinib            | Conditional authorisation                                                           | Bayer AG                           | <a href="https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf">https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_en.pdf</a>       | October 2019      |
| Vocabria     | cabotegravir             | PASS <sup>1</sup>                                                                   | ViiV Healthcare BV                 | <a href="https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vocabria-epar-product-information_en.pdf</a> | January 2021      |
| Voranigo     | vorasidenib              | New active substance                                                                | Les Laboratoires Servier           | <a href="https://www.ema.europa.eu/en/documents/product-information/voranigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voranigo-epar-product-information_en.pdf</a> | September 2025    |
| Voraxaze     | glucarpidase             | Authorised under exceptional circumstances, new active substance and new biological | SERB SAS                           | <a href="https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voraxaze-epar-product-information_en.pdf</a> | January 2022      |
| Voxzogo      | vosoritide               | New active substance and new biological                                             | BioMarin International Limited     | <a href="https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voxzogo-epar-product-information_en.pdf</a>   | September 2021    |
| Voydeya      | danicopan                | New active substance                                                                | Alexion Europe SAS                 | <a href="https://www.ema.europa.eu/en/documents/product-information/voydeya-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/voydeya-epar-product-information_en.pdf</a>   | May 2024          |
| Vueway       | gadopiclenol             | New active substance                                                                | Bracco Imaging SPA                 | <a href="https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vueway-epar-product-information_en.pdf</a>     | January 2024      |
| Vydura       | rimegepant               | New active substance                                                                | Pfizer Europe MA EEIG              | <a href="https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vydura-epar-product-information_en.pdf</a>     | May 2022          |
| Vyepti       | eptinezumab              | New biological                                                                      | H. Lundbeck A/S                    | <a href="https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyepti-epar-product-information_en.pdf</a>     | February 2022     |
| Vyjuvek      | Beremagene geperpavec    | New active substance, new biological, PASS <sup>1</sup>                             | Krystal Biotech Netherlands B.V.   | <a href="https://www.ema.europa.eu/en/documents/product-information/vyjuvek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyjuvek-epar-product-information_en.pdf</a>   | May 2025          |
| Vyloy        | zolbetuximab             | New biological                                                                      | Astellas Pharma Europe B.V.        | <a href="https://www.ema.europa.eu/en/documents/product-information/vyloy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyloy-epar-product-information_en.pdf</a>       | October 2024      |
| Vyndaqel     | Tafamidis                | Authorised under exceptional circumstances                                          | Pfizer Europa MA EEG               | <a href="https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyndaqel-epar-product-information_en.pdf</a> | April 2013        |
| Vyvgart      | efgartigimod alfa        | New active substance and new biological                                             | argenx BV                          | <a href="https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/vyvgart-epar-product-information_en.pdf</a>   | September 2022    |
| Wainzua      | eplontersen              | New active substance                                                                | AstraZeneca AB                     | <a href="https://www.ema.europa.eu/en/documents/product-information/wainzua-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wainzua-epar-product-information_en.pdf</a>   | March 2025        |
| Wakix        | Pitolisant hydrochloride | PASS <sup>1</sup>                                                                   | Bioprojet Pharma                   | <a href="https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wakix-epar-product-information_en.pdf</a>       | April 2016        |
| Waskyra      | etuvetidigene autotemcel | New active substance, new biological and PASS <sup>1</sup>                          | Fondazione Telethon ETS            | <a href="https://www.ema.europa.eu/en/documents/product-information/waskyra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/waskyra-epar-product-information_en.pdf</a>   | January 2026      |
| Waylivra     | Volanesorsen             | Conditional marketing authorisation                                                 | Akcea Therapeutics Ireland Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/waylivra-epar-product-information_en.pdf</a> | May 2019          |
| WAYRILZ      | rilzabrutinib            | New active substance                                                                | Sanofi B.V.                        | <a href="https://www.ema.europa.eu/en/documents/product-information/wayrilz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wayrilz-epar-product-information_en.pdf</a>   | January 2026      |
| WELIREG      | belzutifan               | New active substance and conditional marketing authorisation                        | Merck Sharp & Dohme B.V.           | <a href="https://www.ema.europa.eu/en/documents/product-information/welireg-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/welireg-epar-product-information_en.pdf</a>   | February 2025     |

| Product name | Active substance (s)        | Reason (s) on list                                                                  | Marketing authorisation holder (s)        | Link to product information                                                                                                                                                                                                                                                                                               | Date of inclusion |
|--------------|-----------------------------|-------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Wezenla      | ustekinumab                 | New biological                                                                      | Amgen Technology (Ireland) UC             | <a href="https://www.ema.europa.eu/en/documents/product-information/wezenla-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wezenla-epar-product-information_en.pdf</a>                                                                                                       | July 2024         |
| Winlevi      | Clascoterone                | New active substance                                                                | Cassiopea S.p.A.                          | <a href="https://www.ema.europa.eu/en/documents/product-information/winlevi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/winlevi-epar-product-information_en.pdf</a>                                                                                                       | October 2025      |
| Winrevair    | sotatercept                 | New active substance, new biological                                                | Merck Sharp & Dohme B.V.                  | <a href="https://www.ema.europa.eu/en/documents/product-information/winrevair-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/winrevair-epar-product-information_en.pdf</a>                                                                                                   | September 2024    |
| Wyost        | denosumab                   | New biological                                                                      | Sandoz GmbH                               | <a href="https://www.ema.europa.eu/en/documents/product-information/wyost-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/wyost-epar-product-information_en.pdf</a>                                                                                                           | May 2024          |
| Xbonzy       | denosumab                   | New biological                                                                      | Reddy Holding GmbH                        | <a href="https://www.ema.europa.eu/en/documents/product-information/xbonzy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xbonzy-epar-product-information_en.pdf</a>                                                                                                         | November 2025     |
| Xbryk        | denosumab                   | New biological                                                                      | Samsung Bioepis NL B.V.                   | <a href="https://www.ema.europa.eu/en/documents/product-information/xbryk-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xbryk-epar-product-information_en.pdf</a>                                                                                                           | February 2025     |
| Xembify      | Human normal Immunoglobulin | New biological                                                                      | Instituto Grifols S.A.                    | <a href="https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS">https://portal.bfarm.de/amguifree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS</a>                                                   | March 2022        |
| Xenpozyme    | olipudase alfa              | New active substance, new biological                                                | Genzyme Europe B.V.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xenpozyme-epar-product-information_en.pdf</a>                                                                                                   | July 2022         |
| Ximluci      | ranibizumab                 | New biological                                                                      | STADA Arzneimittel AG                     | <a href="https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ximluci-epar-product-information_en.pdf</a>                                                                                                       | November 2022     |
| Xofigo       | Radium Ra 223 dichloride    | PASS <sup>1</sup>                                                                   | Bayer AG                                  | <a href="https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_en.pdf</a>                                                                                                         | December 2013     |
| Xolremdi     | mavorixafor                 | New active substance, Authorised under exceptional circumstances, PASS <sup>1</sup> | Norgine B.V.                              | <a href="https://www.ema.europa.eu/en/documents/product-information/xolremdi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/xolremdi-epar-product-information_en.pdf</a>                                                                                                     | May 2026          |
| Yaxwer       | denosumab                   | New biological                                                                      | Gedeon Richter Plc.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/yaxwer-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yaxwer-epar-product-information_en.pdf</a>                                                                                                         | July 2025         |
| Yesafili     | aflibercept                 | New biological                                                                      | Biosimilar Collaborations Ireland Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yesafili-epar-product-information_en.pdf</a>                                                                                                     | September 2023    |
| Yescarta     | Axicabtagene ciloleucel     | PASS <sup>1</sup>                                                                   | Kite Pharma EU B.V.                       | <a href="https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf</a>                                                                                                     | September 2018    |
| Yesintek     | ustekinumab                 | New biological                                                                      | Biosimilar Collaborations Ireland Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/yesintek-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yesintek-epar-product-information_en.pdf</a>                                                                                                     | February 2025     |
| Yimmugo      | Human normal Immunoglobulin | New biological                                                                      | Biotest Pharma GmbH                       | <a href="https://portal.bfarm.de/amguitree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=C11RRFNT+AND+FNR=700Q1??">https://portal.bfarm.de/amguitree/am/searchresult.xhtml?accesid=amis_off_am_ppv&amp;directdisplay=true&amp;gripsQuery=STATUS=C11RRFNT+AND+FNR=700Q1??</a> | November 2022     |
| Yorvipath    | palopegteriparatide         | New active substance                                                                | Ascendis Pharma Bone Diseases A/S         | <a href="https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yorvipath-epar-product-information_en.pdf</a>                                                                                                   | November 2023     |
| Yselty       | linzagolix choline          | New active substance                                                                | Theramex Ireland Limited                  | <a href="https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/yselty-epar-product-information_en.pdf</a>                                                                                                         | June 2022         |
| ZADENVI      | denosumab                   | New biological                                                                      | Zentiva k.s.                              | <a href="https://www.ema.europa.eu/en/documents/product-information/zadenvi-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zadenvi-epar-product-information_en.pdf</a>                                                                                                       | July 2025         |
| Zandoriah    | teriparatide                | New biological                                                                      | CINNAGEN CO, UNIPESOAL LDA.               | <a href="https://www.ema.europa.eu/en/documents/product-information/zandoriah-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zandoriah-epar-product-information_en.pdf</a>                                                                                                   | May 2026          |
| Zefylti      | Filgrastim                  | New biological                                                                      | CuraTeQ Biologics (Malta) Limited         | <a href="https://www.ema.europa.eu/en/documents/product-information/zefylti-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zefylti-epar-product-information_en.pdf</a>                                                                                                       | February 2025     |

| Product name | Active substance (s)                                                      | Reason (s) on list                                                           | Marketing authorisation holder (s)     | Link to product information                                                                                                                                                                                             | Date of inclusion           |
|--------------|---------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Zemcelpro    | dorocubicel / allogeneic umbilical cord-derived CD34- cells, non-expanded | New active substance, New biological and Conditional marketing authorisation | Cordex Biologics International Limited | <a href="https://www.ema.europa.eu/en/documents/product-information/zemcelpro-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zemcelpro-epar-product-information_en.pdf</a> | September 2025              |
| ZEPZELCA     | lurbinectedin                                                             | New active substance                                                         | Pharma Mar S.A.                        | <a href="https://www.ema.europa.eu/en/documents/product-information/zepezlca-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zepezlca-epar-product-information_en.pdf</a>   | June 2026                   |
| Zercepac     | trastuzumab                                                               | New Biological, New active substance                                         | Accord Healthcare S.L.U.               | <a href="https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zercepac-epar-product-information_en.pdf</a>   | August 2020                 |
| Zilbrysq     | zilucoplan                                                                | New active substance                                                         | UCB Pharma S.A.                        | <a href="https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf</a>   | December 2023               |
| Ziihera      | zanidatamab                                                               | New active substance, New biological and Conditional marketing authorisation | Jazz Pharmaceuticals Ireland Limited   | <a href="https://www.ema.europa.eu/en/documents/product-information/ziihera-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ziihera-epar-product-information_en.pdf</a>     | July 2025                   |
| Zokinvy      | Lonafarnib                                                                | New active substance, authorised under exceptional circumstances             | Integral Pharma Solutions EU Limited   | <a href="https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zokinvy-epar-product-information_en.pdf</a>     | July 2022                   |
| Zokovea      | Ensitrelvir                                                               | New active substance                                                         | Shionogi B.V.                          | <a href="https://www.ema.europa.eu/en/documents/product-information/zokovea-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zokovea-epar-product-information_en.pdf</a>     | September 2026 <sup>9</sup> |
| Zolgensma    | onasemnogene abeparvovec                                                  | New active substance, new biological                                         | Novartis Europharm Limited             | <a href="https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zolgensma-epar-product-information_en.pdf</a> | May 2020                    |
| ZTALMY       | ganaxolone                                                                | New active substance                                                         | Immedica Pharma AB                     | <a href="https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/ztalmy-epar-product-information_en.pdf</a>       | September 2023              |
| Zurzuvae     | Zuranolone                                                                | New active substance                                                         | Biogen Netherlands B.V.                | <a href="https://www.ema.europa.eu/en/documents/product-information/zurzuvae-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zurzuvae-epar-product-information_en.pdf</a>   | October 2025                |
| Zvogra       | denosumab                                                                 | New biological                                                               | STADA Arzneimittel AG                  | <a href="https://www.ema.europa.eu/en/documents/product-information/zvogra-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zvogra-epar-product-information_en.pdf</a>       | November 2025               |
| Zynlonta     | loncastuximab tesirine                                                    | New active substance, new biological and Conditional marketing authorisation | ADC Therapeutics (NL) B.V.             | <a href="https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zynlonta-epar-product-information_en.pdf</a>   | January 2023                |
| ZYNYZ        | retifanlimab                                                              | New active substance, new biological                                         | Incyte Biosciences Distribution B.V.   | <a href="https://www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf</a>         | May 2024                    |

<sup>1</sup> PASS: Post-authorisation safety study. A PASS is defined in Article 1(15) of Directive 2001/83/EC as any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

<sup>2</sup> Product currently suspended following a referral procedure under Article 20 of Regulation (EC) 726/2004.