EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES IN **2025**

An agency of the European Union

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AUTHORISATION OF NEW MEDICINES

Key figures[1] on the European Medicines Agency's (EMA) recommendations for the authorisation of new medicines in 2025:

104

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[1] These figures reflect EMA's recommendations which are sent to the European Commission for the adoption of an EU-wide marketing authorisation.

[2] This figure refers to medicines that had their orphan designation confirmed by 31 December 2025. At the time of approval, orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) to determine whether the information available to date allows maintaining the medicine's orphan status.

[3] Detailed information is available on EMA's website.


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MEDICINES RECOMMENDED FOR APPROVAL[4]

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assesment	Conditional approval	Exceptional circumstances
Cancer / Oncology									
Anktiva	•							•	
Aucatzyl	•	•		•				•	
Aumseqa	•								
Blenrep									
Datroway	•								
Dazublys					•				
Enzalutamide Accordpharma						•			
Ezmekly	•		•					•	
Inluriyo	•								
Itovebi	•								
Lynozyfic	•							•	
Ogsiveo	•		•						
Romvimza	•		•						
Tivdak	•								
Trabectedin Accord						•			
Voranigo	•		•						
Zemcelpro	•	•	•	•				•	
Ziihera	•		•					•	
Cardiovascular									
Macitentan Accord						•			
Macitentan AccordPharma *(duplicate of Macitentan Accord)*						•			
Myqorzo	•								
Rivaroxaban Koanaa						•			
Dermatology									
Vyjuvek	•	•	•	•					
Winlevi	•								
Diagnostic agents									
GalenVita									

[4] Some medicines might fall into more than one therapeutic area but have been reflected only in one.

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assesment	Conditional approval	Exceptional circumstances
Endocrinology									
Acvybra					•				
Bildyos					•				
Bilprevda					•				
Bomyntra					•				
Conexxence					•				
Degevma					•				
Denbrayce					•				
Enwylma					•				
Vevzuo					•				
Yaxwer					•				
Denosumab BBL					•				
Izamby					•				
Junod					•				
Zadenvi					•				
Denosumab Intas					•				
Jubereq					•				
Kefdensis					•				
Kyinsu									
Lynkuet	•								
Oczyesa									
Ondibta					•				
Osqay					•				
Osvyrti					•				
Ponlimsi					•				
Rolcya					•				
Teizeild	•	•							
Tepezza	•								
Xbonzy					•				
Zvogra					•				
Gastroenterology / Hepatology									
Teduglutide Viatris						•			
Haematology / Haemostaseology									
Dyrupeg					•				
Eltrombopag Accord						•			
Imreplys									•
Vivlipeg					•				
Wayrilz	•		•						

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assesment	Conditional approval	Exceptional circumstances
Immunology / Rheumatology / Transplantation									
Deqsiga									
Dawnzera	•								
Ekterly	•		•						
Gobivaz					•				
Gotenfia					•				
Qoyvolma					•				
Usgena					•				
Usrenty					•				
Usymro					•				
Waskyra	•		•	•					
Infections									
Emtricitabine/Tenofovir alafenamide Viatris						•			
Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatris						•			
Enflonsia	•								
Yeytuo							•		
Metabolism									
Aqneursa			•						
Maapliv			•						•
Rezdiffra	•							•	
Sephience	•		•						
Tryngolza	•		•						
Neurology									
Attrogy									
Austedo									
Duvyzat	•		•					•	
Imaavy	•								
Kisunla	•								
Riulvy									
Ophthalmology									
Eyluxvi					•				
Mynzepli					•				
Afiveg *(duplicate of Mynzepli)*					•				
Vgenfli					•				
Eiyzey *(duplicate of Vgenfli)*					•				
Pavblu					•				
Skojoy *(duplicate of Pavblu)*					•				
Ranluspec					•				
Ryjunea									

THERAPEUTIC AREA/ PRODUCT NAME	New active substance	PRIME	Orphan	ATMP	Biosimilar	Generic	Accelerated assesment	Conditional approval	Exceptional circumstances
Pneumology / Allergology									
Alyftrek	•		•						
Brinsupri	•	•					•		
Exdensur	•								
Nintedanib Viatris						•			
Psychiatry									
Zurzuvae	•								
Uro-nephrology									
Xoanacyl									
Vaccines									
Capvaxive	•								
mNexspike	•								
Vacpertagen									
Vimkunya	•	•					•		

EXAMPLES OF IMPORTANT CONTRIBUTIONS TO PUBLIC HEALTH

Authorisation of new medicines is essential to advancing public health as they bring new opportunities to treat certain diseases. Below is a selection of medicines approved in 2025 that represent significant progress in their therapeutic areas:

CANCER / ONCOLOGY

Anktiva (*nogapendekin alfa inbakicept*)
for the treatment of adults with a type of bladder cancer that affects the lining of the bladder (non-muscle invasive bladder cancer, NMIBC) and that is at high risk of growing and spreading. Bladder cancer is one of the most common cancers in the European Union (EU), affecting over 200,000 people each year, with most cases being NMIBC.

Aucatzyl (*obecabtagene autoleucel*)
for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia, a type of cancer of the white blood cells.

Zemcelpro (*dorocubicel / unexpanded umbilical cord cells*)
a stem cell therapy to treat patients with haematological malignancies (blood cancers). This medicine provides an option for patients with blood cancer who need a blood stem cell transplant and have no suitable donor.

DERMATOLOGY

Vyjuvek (*beremagene geperpavec*)
to treat wounds in patients of all ages with dystrophic epidermolysis bullosa, a serious, ultra-rare genetic skin blistering disease caused by mutations in the collagen type VII alpha 1 chain (COL7A1) gene. Vyjuvek is expected to bring substantial therapeutic benefits and improve the quality of life for patients with this skin disorder.

ENDOCRINOLOGY

Teizeild (*teplizumab*)
a first-in-class treatment to delay the onset of stage 3 type 1 diabetes in adults and in children from eight years of age with stage 2 type 1 diabetes.

Tepezza (*teprotumumab*)
for the treatment of adults with moderate-to-severe Thyroid Eye Disease (TED), also known as Graves' Eye Disease, a rare autoimmune disease that triggers inflammation of muscles, fat, and other tissues around and behind the eyes. Treatment options for moderate-to-severe TED are limited, most patients are treated with corticosteroids and some patients need multiple reconstructive surgeries.

IMMUNOLOGY / RHEUMATOLOGY/ TRANSPLANTATION

Waskyra (*etuvetidigene autotemcel*)
the first medicine to treat Wiskott-Aldrich syndrome, a rare, inherited disease, seen almost exclusively in males, that affects blood cells and cells of the immune system.

INFECTIONS

Yeytuo (*lenacapavir*)
for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents at high risk of becoming infected. Yeytuo will facilitate PrEP uptake and compliance because it only has to be administered twice a year via a subcutaneous injection. Lenacapavir was also approved as Lenacapavir Gilead under EU-Medicines for all (EU-M4All).

METABOLISM

Rezdiffra (*resmetirom*)
for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), a serious disease where fat cells accumulate in the liver causing chronic inflammation. This is the first treatment for metabolic dysfunction-associated steatohepatitis in the European Union (EU).

NEUROLOGY

Duvyzat (*givinostat*)
as a treatment for Duchenne muscular dystrophy (DMD) in patients from the age of six who can walk. DMD is a rare, ultimately lethal genetic disease in which the muscles progressively weaken and lose function.

Kisunla (*donanemab*)
for the treatment of early Alzheimer's disease. Patients have to be tested to exclude the presence of two copies of the ApoE ε4 gene.

PNEUMOLOGY / ALLERGOLOGY

Brinsupri (*brensocatib*)
the first treatment for non-cystic fibrosis bronchiectasis, a serious, chronic, progressive lung disease resulting in damaged airways and severe pulmonary dysfunction, often leading to chronic cough and airflow obstruction due to abnormal mucus production.

VACCINES

Vimkunya (*chikungunya vaccine (recombinant, adsorbed)*)
a vaccine to protect young people from 12 years of age and adults against disease caused by the Chikungunya virus.

BIOSIMILARS

In 2025, the CHMP approved **41 biosimilars**, the highest number ever approved.

23 of these biosimilars contain denosumab, a monoclonal antibody to treat conditions in the field of endocrinology, such as osteoporosis, bone loss and skeletal-related events.

Since the establishment of the framework for biosimilars in 2005, the CHMP has assessed 181 applications for marketing authorisation and approved 165 biosimilars.

Biosimilars are interchangeable with reference products, making them a core part of the healthcare system for managing costs and expanding access to essential treatments.

MEDICINES RECOMMENDED FOR USE OUTSIDE THE EUROPEAN UNION

In January 2025, EMA's human medicines committee (CHMP) adopted a positive opinion for **Ivermectin/ Albendazole**[5] (ivermectin/albendazole), for the treatment of infections caused by several types of worm parasites including lymphatic filariasis, a neglected tropical disease.

In June 2025, the CHMP recommended an extension of indication for **Dapivirine Vaginal Ring 25 mg** (dapivirine), a vaginal ring originally approved in July 2020 to reduce the risk of women 18 years and older getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse. The CHMP's opinion extends the indication for this medicine to include its use in women from 16 years of age.

In July 2025, the CHMP adopted a positive opinion for **Lenacapavir Gilead**[6] (lenacapavir) for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents at high risk of becoming infected. This medicine will facilitate PrEP uptake and compliance because it only has to be administered twice a year via a subcutaneous injection.

These three medicines were assessed under a regulatory procedure known as EU-Medicines for all (EU-M4All), in cooperation with the World Health Organization and national regulators in the target countries, to support global regulatory capacity building and contribute to the protection and promotion of public health beyond the EU.

[5] Experts from the national regulatory authorities of Ethiopia, Kenya and Mozambique, also participated in the assessment.

[6] Experts from national regulatory authorities of Uganda, Zambia, Kenya, Nigeria, Zimbabwe, South Africa, Thailand and Vietnam also participated in the assessment.

EARLY ACCESS TO MEDICINES THAT ADDRESS PUBLIC HEALTH NEEDS

ACCELERATED ASSESSMENTS

Three medicines received a recommendation for marketing authorisation following an accelerated assessment. This mechanism is reserved for medicines that are able to address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees (within a maximum of 150 days rather than 210 days).

Infections

Yeytuo (*lenacapavir)*

Pneumology / Allergology

Brinsupri (*brensocatib)*

Vaccines

Vimkunya (*chikungunya vaccine (recombinant, adsorbed))*

PRIORITY MEDICINES (PRIME)

The enhanced development support provided by PRIME aims at helping patients to benefit as early as possible from promising medicines that target an unmet medical need, by optimising the generation of robust data and enabling accelerated assessment. This year, **six PRIME-designated medicines** were recommended for approval:

Cancer / Oncology

Aucatzyl (*obecabtagene autoleucel)*

Zemcelpro (*dorocubicel / unexpanded umbilical cord cells)*

Dermatology

Vyjuvek (*beremagene geperpavec)*

Endocrinology

Teizeild (*teplizumab)*

Pneumology / Allergology

Brinsupri (*brensocatib)*

Vaccines

Vimkunya (*chikungunya vaccine (recombinant, adsorbed))*

Sixteen medicines under development were included in the scheme in 2025:

- Congenital, familial and genetic disorders (**2**)
- Neurology (**2**)
- Pneumology / Allergology (**2**)
- Vaccines (**2**)
- Cardiovascular diseases (**1**)
- Endocrinology / Gynaecology / Fertility / Metabolism (**1**)
- Immunology / Rheumatology / Transplantation (**1**)
- Infectious diseases (**1**)
- Musculoskeletal and connective tissue disorders (**1**)
- Cancer / Oncology (**1**)
- Ophthalmology (**1**)
- Uro-nephrology (**1**)

CONDITIONAL APPROVAL

Eight medicines received a recommendation for a conditional marketing authorisation, one of the possibilities in the EU to give patients early access to new medicines. As these medicines address unmet medical needs the conditional authorisation allows for early approval on the basis of less complete clinical data than normally required. These authorisations are subject to specific post-authorisation obligations to generate complete data on the medicines.

Cancer / Oncology

Anktiva (*nogapendekin alfa inbakicept)*

Aucatzyl (*obecabtagene autoleucel)*

Ezmekly (*mirdametinib)*

Lynozyfic (*linvoseltamab)*

Zemcelpro (*dorocubicel / unexpanded umbilical cord cells)*

Ziihera (*zanidatamab)*

Metabolism

Rezdiffra (*resmetirom)*

Neurology

Duvyzat (*givinostat)*

APPROVAL UNDER EXCEPTIONAL CIRCUMSTANCES

Two medicines were authorised under exceptional circumstances, a route that allows patients' access to medicines that cannot be approved under a standard authorisation as comprehensive data cannot be obtained, either because there are only very few patients with the disease, or the collection of complete information on the efficacy and safety of the medicine would be unethical, or there are gaps in the scientific knowledge. These medicines are subject to specific post-authorisation obligations and monitoring.

Haematology / Haemostaseology

Imreplys (*sargramostim)*

Metabolism

Maapliv (*amino acids)*

MEDICINES FOR RARE DISEASES

The EU framework for orphan medicines aims to encourage the development and marketing of medicines for patients with rare diseases by providing incentives for developers.

In 2025, **16 medicines** had their orphan designation[7] confirmed by the end of the year.

Cancer / Oncology

Ezmekly (*mirdametinib)*

Ziihera (*zanidatamab)*

Ogsiveo (*nirogacestat)*

Romvimza (*vimseltinib)*

Voranigo (*vorasidenib)*

Zemcelpro (*dorocubicel/unexpanded umbilical cord cells)*

Dermatology

Vyjuvek (*beremagene geperpavec)*

Haematology / Haemostaseology

Wayrilz (*rilzabrutinib)*

Immunology / Rheumatology / Transplantation

Ekterly (*sebetralstat)*

Waskyra (*etuvetidigene autotemcel)*

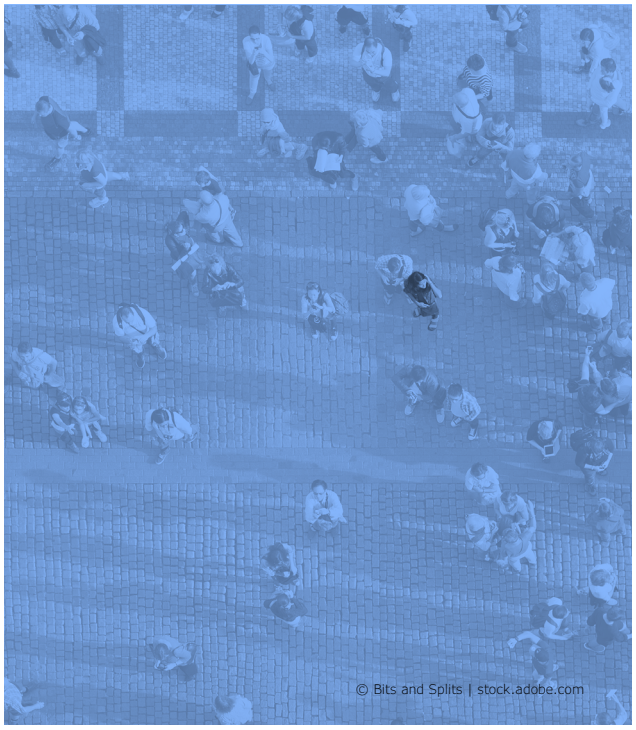
Metabolism

Aqneursa (*levacetylleucine)*

Maapliv (*amino acids)*

Sephience (*sepiapterin)*

Tryngolza (*olezarsen)*



Neurology

Duvyzat (*givinostat)*

Pneumology / Allergology

Alyftrek (*deutivacaftor / tezacaftor / vanzacaftor)*

[7] Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting the medicine ten years of market exclusivity.

NEGATIVE OPINIONS

The Committee for Medical Products for Human Use (CHMP) adopted a negative opinion for **seven medicines** in 2025. When the Committee cannot reach an agreement on a positive benefit-risk balance, it issues a negative opinion on the marketing authorisation application and elaborates on the grounds for this opinion. Applicants have the right to request a re-examination of the negative opinion within 15 days of receipt of the notification.

Atropine sulfate FGK (*atropine*), for the treatment of myopia in children aged three years and older.

Blarcamesine Anavex (*blarcamesine*), for the treatment of Alzheimer's disease.

Elevidys (*delandistrogene moxeparvovec*), for the treatment of Duchenne muscular dystrophy, a rare, ultimately lethal genetic disease in which the muscles progressively weaken and lose function.

Jelrix (*cartilage-forming cells, autologous*), for the treatment of cartilage defects in the knee.

Kinselby (*resminostat*), for the treatment of patients with advanced stage mycosis fungoides and Sezary syndrome, two cancers of blood cells that affect mainly the skin.

Nurzigma (*pridopidine*), for the treatment of adults with Huntington's disease, an inherited condition that worsens over time and causes brain cells to die.

Rezurock (*belumosudil*), for the treatment of chronic graft-versus-host disease, a condition in which donor cells attack the body's organs after a transplant.

NEW USES FOR EXISTING MEDICINES

89 extensions of indication were recommended in 2025, including 40 for paediatric use[8]. The extension of the use of a medicine that is already authorised for marketing in the EU can also offer new treatment opportunities for patients. Extensions of indication included:

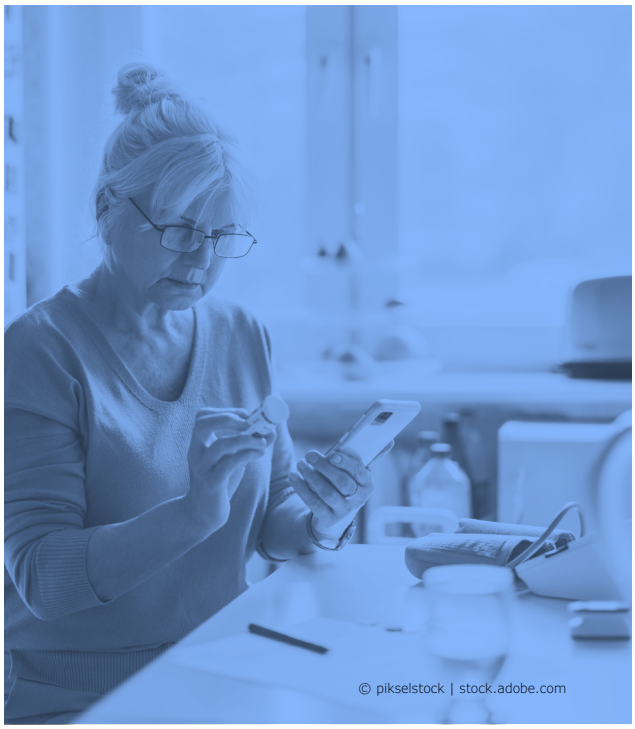
Fabhalta (*iptacopan*), for the treatment of adults with complement 3 glomerulopathy, an ultra-rare kidney disease that previously had no treatment options. Fabhalta was initially approved for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia.

Ixchiq (*chikungunya vaccine (live)*), for active immunisation of adolescents from 12 years of age. This vaccine was initially approved to protect adults against the disease caused by Chikungunya virus. Chikungunya is a viral disease transmitted to humans by infected mosquitoes.

Kaftrio (*ivacaftor/tezacaftor/elexacaftor*) and **Kalydeco** (*ivacaftor*), two cystic fibrosis medicines to be used in combination in patients aged two years and older who have at least one non-class I mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. This extended use for additional, rare mutations allows the treatment of about 95% of all cystic fibrosis patients. Cystic fibrosis is an inherited disease that has severe effects on the lungs, the digestive system and other organs.

Mounjaro (*tirzepatide*), for the treatment of adolescents and children from 10 years of age with insufficiently controlled type 2 diabetes, together with diet and physical activity. Mounjaro was initially approved for use in adults only.

Uplizna (*inebilizumab*), for the treatment of active immunoglobulin G4-related disease, a rare autoimmune disease for which currently there are no authorised medicines in the EU. Uplizna was initially approved for neuromyelitis optica spectrum disorders.



[8] Most paediatric extensions of indication are based on the results of clinical studies agreed in the medicine's paediatric investigation plan (PIP).

KEEPING PATIENTS SAFE

MONITORING IN REAL-LIFE OPTIMISING SAFE AND EFFECTIVE USE

Once a medicine has been authorised, EMA and the EU Member States continuously monitor the quality, safety and the benefit-risk balance of the medicine used in clinical practice. This is to optimise how the medicine is used by patients to achieve its full benefit and to protect patients from avoidable side effects. Regulatory measures range from a change to the product information to the suspension or withdrawal of a medicine or recall of a limited number of batches.

Important new safety advice issued in 2025 included:

Azithromycin
New recommendations on the way azithromycin is used, including the removal of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance.

Caspofungin
New warning against the use of polyacrylonitrile-based membranes during continuous renal replacement therapy in critically ill patients receiving caspofungin.

Clozapine
Recommendation to ease risk minimisation measures based on new scientific evidence showing a markedly reduced risk of severe neutropenia over time; the frequencies of blood monitoring have been reduced, and absolute neutrophil count will now be the sole parameter required, replacing the previous need to also measure white blood cell count.

Crysvita (*burosumab*)
New recommendations to monitor blood calcium levels and parathyroid hormones due to the risk of severe hypercalcaemia, and to add related possible side effects to the product information.

Finasteride and dutasteride tablets
Enhanced measures to minimise the risk of suicidal thoughts alerting patients treated for androgenetic alopecia about the need to seek medical advice if they experience problems with sexual function (such as decreased sex drive or erectile dysfunction) known to contribute to mood alterations and suicidal ideation in some patients. A patient card will be included in the 1 mg finasteride package to remind patients of these risks and to advise them about the appropriate course of action. As a precaution, information about the mood changes seen with finasteride has also been added to the product information for dutasteride because it has the same mechanism of action as finasteride.

Injectable tranexamic acid
A reminder to healthcare professionals to only administer injectable tranexamic acid intravenously (into a vein), and not by other routes, such as intrathecally (into the fluid-filled space between the thin layers that cover the brain and spinal cord), epidurally (into the space between the wall of the spinal canal and the covering of the spinal cord), intraventricularly (into a fluid-filled cavity in the brain) or intracerebrally (into the brain). Syringes containing tranexamic acid should be clearly labelled for intravenous use only and stored separately from local anaesthetics to reduce the risk of medication errors.

Ixchiq (*live attenuated chikungunya vaccine*)
Recommendation to only administer the vaccine when there is a significant risk of chikungunya infection and after careful consideration of the benefits and risks.

Mysimba (*naltrexone / bupropion*)
New measures to minimise potential cardiovascular risks with long-term use and an obligation on the company to provide more information from an ongoing study on the medicine's cardiovascular effects in patients treated for more than one year.

Oxbryta (*voxelotor*)
Recommendation to maintain the marketing authorisation suspended, as recent clinical trials showed more sudden pain episodes and deaths in patients taking Oxbryta. This follows interim measures taken by the committee in September 2024, when it temporarily suspended the medicine to review emerging safety data.

Oxycodone
New black box warning added to the existing warning in the patient leaflet stating that oxycodone is an opioid that can cause dependence and/or addiction. Dependence and addiction are important risks of oxycodone and remain of concern in the EU/EEA. The reporting rate for opioid use disorder-related events for the period 2016 to 2023 increased by around 2-fold as compared with the period from 2012 to 2015 and did not decrease in 2024.

Remsima (*infliximab*)
Instructions to healthcare professionals to confirm patients do not have hereditary fructose intolerance before using a new intravenous formulation, or contraindication of a new intravenous formulation in patients with hereditary fructose intolerance.

Semaglutide
Update of the product information to include non-arteritic anterior ischemic optic neuropathy (NAION) as a very rare side effect and to stop treatment with semaglutide if NAION is confirmed.

Tegretol (*carbamazepine*)
Restriction of the use Tegretol 100 mg/5 mL in neonates because the concentration of the excipient propylene glycol exceeds the recommended threshold.

Varilrix and Varivax (*varicella (chickenpox) vaccines*)
Update to the product information to further describe the severity of the risk of encephalitis. People who receive the vaccine should seek immediate medical attention if they develop signs of infection or inflammation of the brain.

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European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

+31 (0)88 781 6000

www.ema.europa.eu

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