

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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This newsletter is addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the European Medicines Agency.



Information is selected based on recommendations from consulted patients, consumers and healthcare professionals, and does not necessarily cover all relevant information published by the Agency.

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Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines


- [Entecavir Accord](#) (entecavir) 
Treatment of chronic hepatitis B
- [Entecavir Mylan](#) (entecavir) 
Treatment of chronic hepatitis B

New information on authorised medicines

- [Sovaldi](#) (sofosbuvir) - change in indication
Treatment of chronic hepatitis C




Cancer

Positive CHMP opinions on new medicines




- [Bavencio](#) (avelumab) 
Treatment of Merkel cell carcinoma (skin cancer)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Lutathera](#) (*lutetium (¹⁷⁷Lu) oxodotreotide*) 
Treatment of gastroenteropancreatic neuroendocrine tumours (cancer of the gut or pancreas)
- [Rydapt](#) (*midostaurin*) 
Treatment of myeloid leukaemia (blood cancer)
- [Tecentriq](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the urinary system) and non-small cell lung cancer
- [Xermelo](#) (*telotristat ethyl*) 
Treatment of diarrhoea in patients with carcinoid syndrome (a condition caused by certain tumours in the gut)

New medicines authorised

- [Besponsa](#) (*inotuzumab ozogamicin*) 
Treatment of acute lymphoblastic leukaemia (blood cancer)
- [Rixathon](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions
- [Riximyo](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions

New information on authorised medicines

- [Gazyvaro](#) (*obinutuzumab*) - new indication 
Treatment of follicular lymphoma (blood cancer)
- [Keytruda](#) (*pembrolizumab*) - new indication
Treatment of urothelial carcinoma (cancer of the urinary system)

Negative CHMP opinions on new medicines

- [Onzeald](#) (*etirinotecan pegol*)
Intended for the treatment of breast cancer

Supply shortages

- [Trisenox](#) (*arsenic trioxide*)
Treatment of acute promyelocytic leukaemia (blood cancer)

Cardiovascular system

New information on authorised medicines

- [RoActemra](#) (*tocilizumab*) - new indication
Treatment of giant cell arteritis (inflammatory disease of blood vessels in the brain)

Supply shortages


- [Arixtra](#) (*fondaparinux sodium*)
Prevention and treatment of problems caused by blood clots, such as heart attack

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Dermatology

Positive CHMP opinions on new medicines

- [Bavencio](#) (*avelumab*) 
Treatment of Merkel cell carcinoma (skin cancer)
- [Dupixent](#) (*dupilumab*)
Treatment of atopic dermatitis (inflammation of the skin)

New medicines authorised

- [Skilarence](#) (*dimethyl fumarate*)
Treatment of plaque psoriasis (scaly patches on skin)



Diabetes

New information on authorised medicines

- [Bydureon](#) (*exenatide*) - change in indication
Treatment of diabetes mellitus

Gastro-intestinal system

Positive CHMP opinions on new medicines


- [Lutathera](#) (*lutetium (177Lu) oxodotreotide*) 
Treatment of gastroenteropancreatic neuroendocrine tumours (cancer of the gut or pancreas)
- [Xermelo](#) (*telotristat ethyl*) 
Treatment of diarrhoea in patients with carcinoid syndrome (a condition caused by certain tumours in the gut)

Withdrawal of authorised medicines




- [Enzepti](#) (*pancreas powder*)
Treatment of exocrine pancreatic insufficiency (a condition where patients lack enzymes to digest food)

Haematology

Positive CHMP opinions on new medicines

- [Rydapt](#) (*midostaurin*) 
Treatment of myeloid leukaemia (blood cancer)


New medicines authorised

- [Besponsa](#) (*inotuzumab ozogamicin*) 
Treatment of acute lymphoblastic leukaemia (blood cancer)
- [Rixathon](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions
- [Riximyo](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Gazyvaro](#) (*obinutuzumab*) - new indication 
Treatment of follicular lymphoma (blood cancer)

Supply shortages

- [Trisenox](#) (*arsenic trioxide*)
Treatment of acute promyelocytic leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

- [Symtuza](#) (*darunavir / cobicistat / emtricitabine / tenofovir alafenamide*)
Treatment of HIV infection

Hormone system

New information on authorised medicines



- [Signifor](#) (*pasireotide*) - change in indication 
Treatment of Cushing's disease (overproduction of hormones from the pituitary gland)

Immune system

Positive CHMP opinions on new medicines

- [Dupixent](#) (*dupilumab*)
Treatment of atopic dermatitis (inflammation of the skin)


New medicines authorised

- [Rixathon](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions
- [Riximyo](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions
- [Skilarence](#) (*dimethyl fumarate*)
Treatment of plaque psoriasis (scaly patches on skin)

New information on authorised medicines

- [RoActemra](#) (*tocilizumab*) - new indication
Treatment of giant cell arteritis (inflammatory disease of blood vessels in the brain)

Withdrawal of authorised medicines

- [Repsol](#) (*leflunomide*) 
Treatment of rheumatoid and psoriatic arthritis

Safety communication update

- Review of [methylprednisolone injections containing lactose](#) (*methylprednisolone*) - CMDh Position (not to be used in patients allergic to cow's milk proteins)
Treatment of symptoms of severe allergic reactions and other inflammatory conditions

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances



Musculoskeletal system

New medicines authorised

- [Spherox](#) (*spheroids of human autologous matrix-associated chondrocytes*)
Repair defects to the cartilage in the knee

Nervous system

Positive CHMP opinions on new medicines

- [Lacosamide Accord](#) (*lacosamide*) 
Treatment of partial-onset seizures in patients with epilepsy

New information on authorised medicines

- [Vimpat](#) (*lacosamide*) - change in indication
Treatment of partial-onset seizures in patients with epilepsy

Negative CHMP opinions on new medicines

- [Fanaptum](#) (*iloperidone*)
Intended for the treatment of schizophrenia

Safety communication update


- Review of [gadolinium-containing contrast agents](#) (*gadobenic acid / gadobutrol / gadodiamide / gadopentetic acid / gadoteric acid / gadoteridol / gadoversetamide / gadoxetic acid*) - CHMP Opinion (EMA scientific review confirms deposition in brain and other tissues)
Used as contrast enhancers to improve image quality with body scans
- Review of [Zinbryta](#) (*daclizumab*) - PRAC recommendation (provisionally restricted use of the medicine)
Treatment of multiple sclerosis

Public Hearing


- Review of [Valproate](#) (*sodium valproate / valproate magnesium / valproate semisodium / valproic acid / valpromide*) - Review started (use of the medicine in women and girls)
Treatment of epilepsy, bipolar disorder and in some countries, migraine

Ophthalmology

Positive CHMP opinions on new medicines

- [Verkazia](#) (*ciclosporin*) 
Treatment of vernal keratoconjunctivitis (chronic eye allergy)

New medicines authorised

- [Oxervate](#) (*cenegermin*) 
Treatment of neurotrophic keratitis (eye condition causing damage to the cornea)

New information on authorised medicines

- [Humira](#) (*adalimumab*) - new indication
Treatment of uveitis (inflammation in the eye)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Respiratory system

Positive CHMP opinions on new medicines



- [Tecentrig](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the urinary system) and non-small cell lung cancer

Withdrawal of applications for new medicines


- [Infinia](#) (*alpha-1-antitrypsin*) 
Treatment of lung disease due to deficiency of alpha-1-antitrypsin

Rheumatology

New medicines authorised

- [Rixathon](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions
- [Riximyo](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions

Withdrawal of authorised medicines

- [Repsol](#) (*leflunomide*) 
Treatment of rheumatoid and psoriatic arthritis

Urology

Positive CHMP opinions on new medicines

- [Tecentrig](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the urinary system) and non-small cell lung cancer

New information on authorised medicines

- [Keytruda](#) (*pembrolizumab*) - new indication
Treatment of urothelial carcinoma (cancer of the urinary system)

Other medicines

New medicines authorised

- [Axumin](#) (*fluciclovine* (¹⁸F))
Diagnostic medicine (used with a body scan to check whether prostate cancer has returned)

Safety communication update

- Review of [gadolinium-containing contrast agents](#) (*gadobenic acid / gadobutrol / gadodiamide / gadopentetic acid / gadoteric acid / gadoteridol / gadoversetamide / gadoxetic acid*) - CHMP Opinion (EMA scientific review confirms deposition in brain and other tissues)
Used as contrast enhancers to improve image quality with body scans

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- Review of [paracetamol-modified release](#) (*paracetamol*) - review started (risk of overdose with modified- and prolonged-release paracetamol, and whether any additional measures need to be taken)
Treatment of pain and fever

Medicines under additional monitoring

- [Updated list of medicines under additional monitoring](#)

Other information

Guidelines

Guidelines open for consultation

- [Concept paper on an addendum on terms and concepts of pharmacogenomic features related to metabolism to the Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products \(EMA/CHMP/37646/2009\)](#)
Deadline for comments: 10 October 2017
- [Draft reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health](#)
Deadline for comments: 31 October 2017
- [Draft Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance](#)
Deadline for comments: 31 October 2017
- [Draft dolutegravir film-coated tablets 10 mg, 25 mg and 50 mg product-specific bioequivalence guidance - First version](#)
Deadline for comments: 31 October 2017
- [Draft dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance - First version](#)
Deadline for comments: 31 October 2017
- [Draft paracetamol oral use, immediate release formulations product-specific bioequivalence guidance - First version](#)
Deadline for comments: 31 October 2017
- [Concept paper on the revision of the guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells](#)
Deadline for comments: 31 October 2017
- [Concept paper on development and lifecycle of personalised medicines and companion diagnostics](#)
Deadline for comments: 15 November 2017
- [Concept paper on predictive biomarker-based assay development in the context of drug development and lifecycle](#)
Deadline for comments: 15 November 2017

Adopted guidelines

- [Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products](#)

Key to symbols used

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- [Crizotinib hard capsules 200 mg and 250 mg product-specific bioequivalence guidance](#) (updated)
- [Elvitegravir 85 mg & 150 mg film-coated tablets product-specific bioequivalence guidance](#) (updated)
- [Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil film-coated tablets 150 mg / 150 mg / 200 mg / 245 mg product-specific bioequivalence guidance](#) (updated)
- [Vortioxetine hydrobromide, 5 mg, 10 mg, 15 mg, and 20 mg immediate release tablets, vortioxetine lactate, oral drops solution 20 mg / ml product-specific bioequivalence guidance](#) (updated)
- [Emtricitabine / rilpivirine / tenofovir disoproxil, film-coated tablets, 200 mg / 25 mg / 245 mg product-specific bioequivalence guidance](#) (updated)
- [Guideline on Influenza vaccines – Quality module Revision 1](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - June 2017](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - Applications for new human medicines under evaluation by the CHMP: July 2017](#)
- [CAT - agendas, minutes and reports](#)
- [COMP - agendas, minutes and meetings reports](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC recommendations on safety signals](#)
- [2017 Work plan for the Blood Product Working Party](#) - updated
- [2017 Work plan for the Safety Working Party](#) - updated
- PCWP and HCPWP joint meeting - documents - [meeting documents](#) - March 2017

Other publications

- [EMA seeks views of public during its safety review of valproate](#)
- [EMA annual accounts: Financial year 2016](#)
- [Involving young people in EMA activities](#)
- [Patients, consumers, healthcare professionals key figures - 2016](#)
- [EMA and FDA encourage use of innovative approaches in the development of medicines for Gaucher disease](#)
- [EU report: more evidence on link between antibiotic use and antibiotic resistance](#)
- [EMA and EUnetHTA step up interaction to align data requirements](#)
- [List of products granted eligibility to PRIME](#)

Key to symbols used






 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Launch of the new EudraVigilance system: questions and answers from stakeholders](#)
- [Call for independent scientific experts to join EMA's Pharmacovigilance Risk Assessment Committee](#)
- [Implementation plan for the introduction of the safety features on the packaging of centrally authorised medicinal products for human use](#) (updated)
- [EMA improves its guidance for post-authorisation activities](#)
- 2017 annual workshop of the European network of paediatric research at the EMA - May 2017 - [meeting documents](#)
- EMA meeting with stakeholders - First anniversary of PRIME - May 2017 - [meeting report](#)
- Eleventh industry stakeholder platform on the operation of pharmacovigilance in the EU - June 2017- [meeting documents](#)

Events

- [The EU medicines regulatory system and the European Medicines Agency: an introduction for international regulators and non-governmental organisations](#) - September 2017
- [EudraVigilance information day](#) - September 2017
- [EMA / DIA signal management information day](#) - October 2017
- [Joint Biologics Working Party / Quality Working Party workshop with stakeholders in relation to prior knowledge and its use in regulatory applications](#) - November 2017

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease.

Generic medicine

A medicine that is essentially the same as one that has already been authorised for use. (The latter is known as the 'reference medicine')

Biosimilar medicine

A biological medicine that is similar to another biological medicine which has already been authorised for use. (Biosimilar medicines are also known as 'similar biological' medicines)

Conditional approval

A medicine that fulfils an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorisation on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorisation holder.

Exceptional circumstances

A medicine may be approved in some cases where the applicant cannot provide comprehensive data on the safety or efficacy of the medicine under normal conditions of use, due to exceptional circumstances such as ethical issues or the rarity of the disease concerned.

Note on the centralised authorisation procedure

To obtain a single marketing authorisation (licence) for a medicine that is valid in all Member States of the European Union (EU) – via a process known as the 'centralised procedure' – the company or person developing the medicine must submit an application to the European Medicines Agency.

The Agency's Committee for Medicinal Products for Human Use (CHMP) carries out a scientific evaluation of the information contained in the application and prepares an opinion (scientific recommendation). The Agency transmits this (positive or negative) opinion to the European Commission, which then issues a Decision granting or refusing the marketing authorisation.

When the CHMP adopts a positive opinion on a medicine, the Agency publishes on its website a 'summary of opinion', in the first instance, followed by more detailed information in a 'European public assessment report (EPAR)' after the marketing authorisation has been granted.

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