

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

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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-infective






New medicines authorised

- [Tigecycline Accord](#) (*tigecycline*)  
Treatment of complicated skin and soft tissue infections (cSSTI) and complicated intra-abdominal infections (cIAI)

New information on authorised medicines

- [Ecalta](#) (*anidulafungin*)- extension of indication
Treatment of invasive candidiasis (a fungal infection caused by a yeast called Candida)
- [Harvoni](#) (*ledispavir / sofosbuvir*)- extension of indication
Treatment of chronic (long-term) hepatitis C, an infectious disease that affects the liver caused by the hepatitis C virus
- [Sovaldi](#) (*sofosbuvir*) - extension of indication
Treatment of chronic (long-term) hepatitis C, an infectious disease that affects the liver caused by the hepatitis C virus

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety update




- Review of [fluorouracil and fluorouracil related substances \(capecitabine, tegafur and flucytosine\) containing medicinal products](#) - CHMP opinion on screening methods to identify patients at risk of severe side effects (Art.31)
Treatment of various skin conditions and fungal infections

Cancer



Positive CHMP opinions on new medicines

- [Cabazitaxel Accord](#) (*cabazitaxel*)
Treatment of prostate cancer
- [Daurismo](#) (*glasdegib*)
Treatment of acute myeloid leukaemia (blood cancer)

New medicines authorised

- [Azacitidine betapharm](#) (*azacitidine*) 
Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)
- [Cinacalcet Accordpharma](#) (*cinacalcet*) 
Treatment of cancer of the parathyroid glands (glands found behind the thyroid) and hyperthyroidism (over active parathyroid glands).
- [Nubeqa](#) (*darolutamide*)
Treatment of prostate cancer
- [Ruxience](#) (*rituximab*) 
Treatment of blood cancers and inflammatory conditions


New information on authorised medicines

- [Braftovi](#) (*encorafenib*) - new indication
Treatment of melanoma (a skin cancer)
- [Carmustine Obvius](#) (*carmustine*)  - extension of indication
Treatment of brain tumours, Hodgkin's lymphoma and non-Hodgkin's lymphomas (cancers that originate from white blood cells)
- [Darzalex](#) (*daratumumab*)  - new pharmaceutical form
Treatment of multiple myeloma (a cancer of the bone marrow)

Safety update


- Review of [cyproterone-containing medicinal products](#) - CMDh Position (meningioma risk with cyproterone medicines)
Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne
- Review of [Picato](#) (*ingenol mebutate*) - CHMP opinion (data on skin cancer to be evaluated)
Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)
- Direct healthcare professional communication (DHPC): [Restrictions in use of cyproterone acetate due to risk of meningioma](#)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Cardiovascular system

New medicines authorised


- [Nilemdo](#) (*bempedoic acid*)
Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- [Nustendi](#) (*bempedoic acid / ezetimibe*)
Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- [Trepulmix](#) (*treprostinil sodium*) 
Treatment of chronic thromboembolic pulmonary hypertension (CTEPH), high blood pressure in the lungs

New information on authorised medicines

- [Cabliivi](#) (caplacizumab)  - extension of indication
Treatment of acquired thrombotic thrombocytopenic purpura (aTTP), a blood clotting disorder

Dermatology (skin conditions)

New medicines authorised

- [Staquis](#) (*crisaborole*)
Treatment of atopic dermatitis (itchy, red skin)
- [Tigecycline Accord](#) (*tigecycline*) 
Treatment of complicated skin and soft tissue infections (cSSTI) and complicated intra-abdominal infections (cIAI)

New information on authorised medicines

- [Taltz](#) (*ixekizumab*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)

Safety update

- Review of [fluorouracil and fluorouracil related substances \(capecitabine, tegafur and flucytosine\)](#) - CHMP opinion on screening methods to identify patients at risk of severe side effects (Art.31)
Treatment of various skin conditions and fungal infections
- Review of [Picato](#) (*ingenol mebutate*) - CHMP opinion (data on skin cancer to be evaluated)
Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)

Diabetes


Positive CHMP opinions on new medicines

- [Insulin aspart Sanofi](#) (*insulin aspart*)
Treatment of diabetes mellitus

New medicines authorised

- [Liumjev](#) (*insulin lispro*)
Treatment of diabetes mellitus

Key to symbols used

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Gastro-intestinal system

Safety update

- Review of [ranitidine medicines](#) - CHMP opinion (tests showed that some products contained an impurity called N-nitrosodimethylamine (NDMA))
Used to treat and prevent conditions caused by excess acid in the stomach such as heartburn and stomach ulcers

Gynaecology & Obstetrics (pregnancy and female reproductive system)

New information on authorised medicines

- [Ecalta](#) (*anidulafungin*) - extension of indication
Treatment of invasive candidiasis (a fungal infection caused by a yeast called Candida)

Safety update

- Review of [ulipristal acetate](#) - under evaluation (assessment of risk of liver injury)
Treatment for uterine fibrosis

Haematology (blood conditions)


Positive CHMP opinions on new medicines

- [Daurismo](#) (*glasdegib*)
Treatment of acute myeloid leukaemia (blood cancer)
- [Reblozyl](#) (*luspatercept*)
Treatment of anaemia caused by myelodysplastic syndromes (MDS) or beta-thalassaemia (a type of blood disorder)

New medicines authorised

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

New information on authorised medicines


- [Carmustine Obvius](#) (*carmustine*)  - extension of indication
Treatment of brain tumours, Hodgkin's lymphoma and non-Hodgkin's lymphomas (cancers that originate from white blood cells)
- [Ultomiris](#) (*ravulizumab*) - new indication
Treatment of paroxysmal nocturnal haemoglobinuria (PNH) (a life-threatening disease including excessive breakdown of red blood cells)

Hepatology (liver conditions)

Safety update

- Review of [ulipristal acetate](#) - under evaluation (assessment of risk of liver injury)
Treatment for uterine fibrosis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Hormone system

Safety update

- Review of [cyproterone-containing medicinal products](#) - CMDh Position (meningioma risk with cyproterone medicines)
Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne

Immune system

New medicines authorised

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

New information on authorised medicines

- [Taltz](#) (*ixekizumab*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)

Metabolic disorders

New medicines authorised

- [Nilemdo](#) (*bempedoic acid*)
Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- [Nustendi](#) (*bempedoic acid / ezetimibe*)
Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)

Nervous system

Positive CHMP opinions on new medicines

- [Fingolimod Accord](#) (*fingolimod*)
Treatment of relapsing-remitting multiple sclerosis with high disease activity
- [Paliperidone Janssen-Cilag International](#) (*paliperidone*)
Treatment of schizophrenia






Withdrawal of authorised medicines

- [Numient](#) (*levodopa / carbidopa*)
Intended for treatment of Parkinson's disease

Arbitration procedures

- [Carbamazepin Tillomed](#) (*carbamazepine*) - outcome
Treatment of epilepsy, prevention of psychosis (altered sense of reality) and treatment of facial pain caused by disrupted function of the trigeminal nerve in the face

Key to symbols used


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Respiratory system

Positive CHMP opinions on new medicines

- [Enerzair Breezhaler](#) / [Zimbus Breezhaler](#) (*indacaterol / glycopyrronium / mometasone*)
Treatment of asthma

New medicines authorised

- [Budesonide/Formoterol Teva Pharma B.V.](#) (*budesonide / formoterol fumarate dihydrate*)
Treatment of asthma
- [Trepulmix](#) (*treprostinil sodium*) 
Treatment of chronic thromboembolic pulmonary hypertension (CTEPH), high blood pressure in the lungs

New information on authorised medicines

- [Kalydeco](#) (*ivacaftor*) - change of indication
Treatment of cystic fibrosis

Vaccines

New medicines authorised

- [Vaxchora](#) (*Cholera vaccine (recombinant, live, oral)*)
Prevention of cholera (infectious disease that causes severe diarrhea)

Other medicines

New information on authorised medicines

- [Suboxone](#) (*buprenorphine / naloxone*)- new pharmaceutical form
Treatment of dependence on opioid (narcotic) drugs such as heroin or morphine






Negative CHMP opinions on new medicines

- [Hopveus](#) re-examination (*sodium oxybate*)
Intended for the treatment of alcohol dependence

Medicines under additional monitoring

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

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Other information


Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - March 2020](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: April 2020](#)
- [COMP - agendas, minutes and meetings reports](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC statistics: April 2020](#)
- [PRAC recommendations on safety signals](#)

Other publications



- [EMA starts rolling review of remdesivir for COVID-19](#)
- [Reporting suspected side effects of medicines in patients with COVID-19](#)
- [COVID-19: chloroquine and hydroxychloroquine only to be used in clinical trials or emergency use programmes](#)
- [COVID-19: reminder of risk of serious side effects with chloroquine and hydroxychloroquine](#)
- [Launch of enhanced monitoring system for availability of medicines used for treating COVID-19](#)
- [Regulatory information - 1.6% increase in fees from 1 April 2020](#)
- [EU recommendations for 2020/2021 seasonal flu vaccine composition](#)
- [International regulators discuss available knowledge supporting COVID-19 medicine development](#)
- [EMA provides recommendations on compassionate use of remdesivir for COVID-19](#)
- [EU authorities agree new measures to support availability of medicines used in the COVID-19 pandemic](#)
- [Global regulators discuss observational studies of real world data for COVID-19 medicines](#)
- [Global regulators stress need for robust evidence on COVID-19 treatments](#)
- [Meeting highlights from ICMRA global regulatory workshop on COVID-19 observational studies and real world data](#)
- [EMA establishes task force to take quick and coordinated regulatory action related to COVID-19 medicines](#)
- [Update on EU actions to support availability of medicines during COVID-19 pandemic](#)

Key to symbols used

-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [EU actions to support availability of medicines during COVID-19 pandemic – update #2](#)
- [EU actions to support availability of medicines during COVID-19 pandemic – update #3](#)
- [EU actions to support availability of medicines during COVID-19 pandemic – update #4](#)
- [Guidance on regulatory requirements in the context of the COVID-19 pandemic](#)
- [Update to guidance on regulatory expectations in the context of COVID-19 pandemic](#)
- [International regulators pledge collective support to combat COVID-19 pandemic](#)
- [Report of the workshop on the use of registries in the monitoring of cancer therapies based on tumours' genetic and molecular features - 29 November 2019](#)
- [EMA's governance during COVID-19 pandemic](#)
- [Public-health advice during COVID-19 pandemic](#)
- Report: [Meeting summary - PCWP/HCPWP joint meeting on 3-4 March 2020](#)

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Explanation of terms used

O Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

I 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')

B 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)

C 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 to generate complete data on the medicine.

E 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. These medicines are subject to specific post-authorisation obligations and monitoring.

Medicines assessed under Article 58

Article 58 of Regulation (EC) No 726/2004 allows the [CHMP](#) to give opinions, in co-operation with the World Health Organization, on [medicinal products](#) that are intended exclusively for markets outside of the European Union.

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.

Visit our website

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<http://www.ema.europa.eu>

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