



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-infectives

Positive CHMP opinions on new medicines

- [Arikayce liposomal](#) (*amikacin*)
Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC)
- [Dapivirine Vaginal Ring 25 mg](#) (*Dapivirine*) - article 58
Intended to reduce the risk of contracting HIV infection through vaginal intercourse

New medicines authorised

- [Veklury](#) (remdesivir) 
Treatment of coronavirus disease 2019 (COVID-19)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Prezista](#) (*darunavir*) - extension of indication
Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)
- [Reyataz](#) (*atazanavir sulphate*) - new contraindication
Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)
- [Shingrix](#) (*herpes zoster vaccine (recombinant, adjuvanted)*) - extension of indication
Vaccine used to protect adults aged 50 years and over against shingles (herpes zoster) and post-herpetic neuralgia (long-lasting nerve pain following shingles)

Cancer

Positive CHMP opinions on new medicines

- [Arsenic trioxide medac](#) (*arsenic trioxide*) 
Treatment of acute promyelocytic leukaemia (blood cancer)
- [Ayvakyt](#) (*avapritinib*) 
Treatment of unresectable or metastatic gastrointestinal stromal tumours (cancer of stomach and bowel)
- [Blenrep](#) (*belantamab mafodotin*) 
Treatment of relapsed and refractory multiple myeloma (blood cancer)
- [Calquence](#) (*acalabrutinib*) 
Treatment of chronic lymphocytic leukaemia (blood cancer)
- [Equidacent](#) (*bevacizumab*) 
Treatment of several types of cancers

New medicines authorised

- [Daurismo](#) (*glasdegib*) 
Treatment of acute myeloid leukaemia (blood cancer)
- [Pigray](#) (*alpelisib*)
Treatment of locally advanced or metastatic breast cancer
- [Zercepac](#) (*trastuzumab*)
Treatment of breast and stomach cancers

New information on authorised medicines

- [Imbruvica](#) (*ibrutinib*)  - extension of indication
Treatment of blood cancers
- [Imfinzi](#) (*durvalumab*)  - extension of indication
Treatment of a type of lung cancer called non-small cell lung cancer

Negative CHMP opinions on new medicines

- [Elzonris](#) (*tagraxofusp*)
Intended for treatment of blastic plasmacytoid dendritic cell neoplasm, a rare and aggressive type of acute myeloid leukaemia (blood cancer)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety update

- Review of [Yondelis](#) (*trabectedin*) - CHMP Opinion (Art.20)
Treatment of ovarian cancer and soft tissue sarcoma (a type of cancer that develops from the soft, supporting tissues of the body)

Other information

- [Votubia](#) (*everolimus*)
Treatment the benign (non-cancerous) tumours caused by the genetic disease tuberous sclerosis

Diabetes

New medicines authorised

- [Insulin aspart Sanofi](#) (*insulin aspart*)
Treatment of diabetes mellitus
- Direct Healthcare Professional Communication: [Insuman Implantable 400 IU/ml insulin solution for infusion: no new patients should be started due to discontinuation of MiniMed Implantable Pump](#)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- [Avyakyt](#) (*avapritinib*) 
Treatment of unresectable or metastatic gastrointestinal stromal tumours (cancer of stomach and bowel)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- [Adakveo](#) (*crizanlizumab*)
Prevention of recurrent vaso-occlusive crises in patients with sickle cell disease
- [Arsenic trioxide medac](#) (*arsenic trioxide*) 
Treatment of acute promyelocytic leukaemia (blood cancer)
- [Calquence](#) (*acalabrutinib*) 
Treatment of chronic lymphocytic leukaemia (blood cancer)

New medicines authorised

- [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 information on authorised medicines

- [Crysvita](#) (*burosumab*)   - change and extension of indication
Treatment of X-linked hypophosphataemia, a disorder that can lead to weak bones and rickets

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Imbruvica](#) (*ibrutinib*)  - extension of indication
Treatment of blood cancers
- [NovoThirteen](#) (*catridecacog*)- extension of indication
Prevention of bleeding in patients with inherited blood clotting disorder

Negative CHMP opinions on new medicines

- [Gamifant](#) (*emapalumab*)
Intended for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a disorder that results in an overactive immune system

HIV

Positive CHMP opinions on new medicines

- [Dapivirine Vaginal Ring 25 mg](#) (*Dapivirine*) - article 58
Intended to reduce the risk of contracting HIV infection through vaginal intercourse

New information on authorised medicines

- [Prezista](#) (*darunavir*)- extension of indication
Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)
- [Reyataz](#) (*atazanavir sulphate*) - new contraindication
Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)

Immune system

Positive CHMP opinions on new medicines

- [Jyseleca](#) (*filgotinib*)
Treatment of rheumatoid arthritis

New information on authorised medicines

- [HyQvia](#) (*human normal immunoglobulin*) - extension of indication
Treatment of patients with immunodeficiency syndromes

Negative CHMP opinions on new medicines

- [Gamifant](#) (*emapalumab*)
Intended for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a disorder that results in an overactive immune system

Musculoskeletal system

New information on authorised medicines

- [Crysvita](#) (*burosumab*)   - change and extension of indication
Treatment of X-linked hypophosphataemia, a disorder that can lead to weak bones and rickets

Key to symbols used

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Nervous system

Positive CHMP opinions on new medicines

- [Fampridine Accord](#) (*fampridine*) 
Treatment to improve walking of adult patients suffering from multiple sclerosis with walking disability

New medicines authorised

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

New information on authorised medicines

- [Latuda](#) (*lurasidone*) - extension of indication
Treatment of schizophrenia

Withdrawal of applications for new medicines

- [Abilify MyCite](#) (*aripiprazole*)
Intended for treatment of schizophrenia and bipolar I disorder

Ophthalmology (eye conditions)

Withdrawal of applications for new medicines

- [Rayoqta](#) (*abicipar pegol*)
Intended for treatment of the 'wet' form of age-related macular degeneration (AMD), a disease affecting the retina, the light sensitive part of the eye

Respiratory system

Positive CHMP opinions on new medicines

- [Arikayce liposomal](#) (*amikacin*)
Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by *Mycobacterium avium* Complex (MAC)

New medicines authorised

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

New medicines authorised

- [Veklury](#) (*remdesivir*) 
Treatment of coronavirus disease 2019 (COVID-19)

New information on authorised medicines

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

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- [Jyseleca](#) (*filgotinib*)
Treatment of rheumatoid arthritis

Vaccines

New medicines authorised

- [Mvabea](#) (rDNA, replication-incompetent)
Vaccine to protect against Ebola virus disease caused by Zaire ebolavirus
- [Zabdeno](#) (*Ebola vaccine (rDNA, replication-incompetent)*)
Vaccine to protect against Ebola virus disease caused by Zaire ebolavirus

New information on authorised medicines

- [Shingrix](#) (*herpes zoster vaccine (recombinant, adjuvanted)*) - extension of indication
Vaccine used to protect adults aged 50 years and over against shingles (herpes zoster) and post-herpetic neuralgia (long-lasting nerve pain following shingles)

Other medicines

Positive CHMP opinions on new medicines

- [Zynrelef](#) (*bupivacaine / meloxicam*)
Treatment of post-operative pain

New information on authorised medicines

- [Fortacin](#) (*lidocaine / prilocaine*) - change in prescription status
Treatment of men with primary (lifelong) premature ejaculation

Arbitration procedures

- [Panexcell Clinical Laboratories Priv. Ltd](#) - outcome (Art. 31)

Safety update

- Review of [Ibuprofen Kabi 400 mg Infusionslösung and associated names](#) - CHMP Opinion (disagreement between member states regarding a marketing authorisation on the grounds of a potential serious risk to public health) - Art 29 (4)
Active substance used as a painkiller and anti-inflammatory medicine

Medicines under additional monitoring

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

Key to symbols used

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Other information

Guidelines

Adopted guidelines

- [Guideline on the quality of water for pharmaceutical use](#)
- [ICH guideline M7 on assessment and control of DNA reactive \(mutagenic\) impurities in pharmaceuticals to limit potential carcinogenic risk - questions & answers](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - June 2020](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: July 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: July 2020](#)
- [PRAC recommendations on safety signals](#)

COVID-19

- [EMA starts review of dexamethasone for treating adults with COVID-19 requiring respiratory support](#)
- [COVID-19: EMA sets up infrastructure for real-world monitoring of treatments and vaccines](#)
- [International regulators provide guiding principles for COVID-19 clinical trials](#)
- [International regulators align positions on phase 3 COVID-19 vaccine trials](#)
- [Global regulatory workshop on COVID-19 real-world evidence and observational studies](#)
- [Global regulatory workshop on COVID-19 therapeutics #2: agreement on acceptable endpoints for clinical trials](#)

Other publications

- [Launch of public consultation on joint network strategy to 2025](#)
- [EMA finalises opinion on presence of nitrosamines in medicines](#)

Key to symbols used

-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Rules of engagement for patients' organisations and their representatives in repurposing activities and impact on involvement in EMA activities](#)
- Leaflet: [Infographic: Medicines for use outside the EU – EU-M4all](#)
- [Panexcell Clinical Laboratories: suspension of medicines over flawed studies](#)

Events

- [Workshop on benefit-risk of medicines used during pregnancy and breastfeeding](#) - Virtual meeting - 22 September 2020
- [Workshop on the application of the General Data Protection Regulation \(GDPR\) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes](#) - Virtual meeting - 23 September 2020
- [Workshop on the General Data Protection Regulation \(GDPR\) and secondary use of data for medicines and public health purposes](#) - [Agenda](#) - Virtual meeting - 29 September 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.

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