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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union

IN THIS ISSUE

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

COVID-19 vaccines and treatments

New medicines authorised

- Valneva (COVID-19 Vaccine (*inactivated, adjuvanted*))
  Prevention of coronavirus disease (COVID-19)

New information on authorised medicines

- Nuvaxovid (*COVID-19 Vaccine (recombinant, adjuvanted)*) C - extension of indication
  Prevention of coronavirus disease (COVID-19) in people aged 12 years and older

Antivirals/anti-infectives

- Monkeypox: EMA starts review for Imvanex

Key to symbols used

O Orphan medicine | Generic medicine | Biosimilar medicine | C Conditional approval | E Exceptional circumstances

Cancer

Positive CHMP opinions on new medicines

- Pepaxti (*melphalan flufenamide*) O
  Treatment of multiple myeloma (cancer of the bone marrow)
- Scemblix (*asciminib*) O
  Treatment of Philadelphia chromosome positive chronic myeloid leukaemia (blood cancer)
- Vegzelma (*bevacizumab*)
  Treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and cancer of the cervix

New medicines authorised

- Carvykti (*ciltacabtagene autoleucel*) O C
  Treatment of multiple myeloma (cancer of the bone marrow)
- Lunsumio (*mosunetuzumab*) O C
  Treatment of follicular lymphoma (blood cancer)

New information on authorised medicines

- Enhertu (*trastuzumab deruxtecan)* C *– new indication*
  Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received one or more prior anti HER2 based regimens
- Imbruvica (*ibrutinib*) - extension of indication
  Treatment of chronic lymphocytic leukaemia (blood cancer)

Direct Healthcare Professional Communication (DHPC)

- Imlygic (*talimogene laherparepvec*)
  Treatment of melanoma (skin cancer)

Diabetes

New medicines authorised

- Truvelog Mix 30 (*insulin aspart*)
  Treatment of diabetes mellitus
- Vildagliptin / Metformin hydrochloride Accord (*vildagliptin, metformin hydrochloride*)
  Treatment of diabetes mellitus

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Pepaxti (*melphalan flufenamide*) O
  Treatment of multiple myeloma (cancer of the bone marrow)
- Roctavian (*valoctocogene roxaparvovec*) C O
  Treatment of haemophilia (bleeding disorder caused by lack of factor VIII)

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- Scemblix (*asciminib*)
  Treatment of Philadelphia chromosome positive chronic myeloid leukaemia (blood cancer)

New medicine authorised

- Lunsumio (*mosunetuzumab*)
  Treatment of follicular lymphoma (blood cancer)

New information on authorised medicines

- Imbruvica (*ibrutinib*) - extension of indication
  Treatment of chronic lymphocytic leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

- Sunlenca (*lenacapavir*)
  Treatment of human immunodeficiency virus type 1 (HIV-1)

Immune system

Positive CHMP opinions on new medicines

- Vyvgart (*efgartigimod alfa*)
  Treatment of myasthenia gravis (autoimmune condition that causes muscle weakness)

Safety update

- Review of Janus Kinase inhibitors (JAKi) - scope of the review has been extended
  Treatment of several chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, ulcerative colitis and atopic dermatitis) and alopecia areata

Metabolic disorders

New information on authorised medicines

- Crysvita (*burosumab*) – *new indication*
  Treatment of FGF23-related hypophosphataemia (low levels of phosphate in the blood)

Direct Healthcare Professional Communication (DHPC)

- Ocaliva (*obeticholic acid*)
  Treatment of primary biliary cholangitis (a type of liver disease)

Nervous system

Positive CHMP opinions on new medicines

- Rayvow (*lasmiditan*)
  Treatment of migraine headache

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Ranivisio (*ranibizumab*)
  Treatment of eye problems caused by damage to the retina

Respiratory system

New medicines authorised

- Pirfenidone AET (*pirfenidone*)
  Treatment of idiopathic pulmonary fibrosis (a condition in which the lungs are scarred and damaged)

Rheumatology (immune and inflammatory conditions)

New medicines authorised

- Sondelbay (*teriparatide*)
  Treatment of osteoporosis (a disease that makes the bones fragile)

Safety update

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Other medicines

Direct Healthcare Professional Communication (DHPC)

- Defitelio (*defibrotide*)
  Treatment of hepatic veno-occlusive disease (a condition in which the veins in the liver become blocked)
- Dexmedetomidine-containing products (*dexmedetomidine hydrochloride*)
  Sedation of adults in intensive care units
- Hydroxyethyl starch-containing medicines (HES) (*hydroxyethyl starch*) - suspension of marketing authorisation
  Treatment of low blood volume

Safety update

- Review of amfepramone-containing medicines - PRAC recommendation (withdrawal of marketing authorisations for amfepramone medicines)
  Treatment of obesity

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 - May 2022
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 2022
- 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

Other information on Covid-19

- Start of rolling review for adapted Comirnaty COVID-19 vaccine and for adapted Spikevax COVID-19 vaccine
- List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123
- EMA adopts first list of critical medicines for COVID-19
- COVID-19 vaccines - Safety update: 17 June 2022
- Procedural guidance for variant strain(s) update to vaccines intended for protection against human coronavirus
- Global regulators work towards strengthening collaboration on observational research beyond COVID-19 pandemic

Other publications

- EMA Management Board: highlights of June 2022 meeting
- EMA appoints Chief Medical Officer
- EMA publishes annual report 2021

Events

- Data quality framework for medicines regulation - 7 April 22 - meeting documents
- Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - May 22 - meeting documents
- Big Data Steering Group and industry stakeholders meeting - May 22
- EMA Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - June 22 - meeting documents
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - June 22

Explanation of terms used

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.

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 to generate complete data on the medicine.

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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http://www.ema.europa.eu

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