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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 vaccines authorised

- Nuvaxovid (*NVX-CoV2373*) C

  Prevention of coronavirus disease 2019 (COVID-19)

New medicines authorised

- Xevudy (*sotrovimab*)
  Treatment of coronavirus disease 2019 (COVID-19)

New information on authorised medicines

- Kineret (anakinra) - new indication
  Treatment of coronavirus disease 2019 (COVID-19)

Key to symbols used

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

- RoActemra (*tocilizumab*) - new indication
  Treatment of coronavirus disease 2019 (COVID-19)
- Veklury (remdesivir) - change of indication
  Treatment of coronavirus disease 2019 (COVID-19)

Safety update

- Vaxzevria (previously COVID-19 Vaccine AstraZeneca)
- Comirnaty
- Spikevax (previously COVID-19 Vaccine Moderna)
- COVID-19 Vaccine Janssen

Cancer

Positive CHMP opinions on new medicines

- Padcev (*enfortumab vedotin*)
  Treatment of urothelial cancer (cancer of the bladder and urinary system)
- Tepmetko (*tepotinib*)
  Treatment of non-small cell lung cancer

New medicines authorised

- Brukinsa (*zanubrutinib*)
  Treatment of Waldenstrom macroglobulinemia (a type of blood cancer)

New information on authorised medicines

- Lorviqua (*lorlatinib*) C - new indication
  Treatment of non-small cell lung cancer
- Keytruda (*pembrolizumab*) - extension of indication
  Treatment of melanoma (a type of skin cancer)
- Teysuno (tegafur/gimeracil/oteracil) - new indication
  Treatment of cancers of the stomach and large intestines

Dermatology (skin conditions)

New information on authorised medicines

- Cibinqo (abrocitinib) - new indication
  Treatment of atopic dermatitis (inflammation of the skin)
- Keytruda (*pembrolizumab*) - extension of indication
  Treatment of melanoma (a type of skin cancer)

Diabetes

Positive CHMP opinions on new medicines

- Kerendia (*finerenone*)
  Treatment of chronic kidney disease associated with type 2 diabetes
- Sitagliptin/Metformin hydrochloride Mylan (*metformin hydrochloride / sitagliptin hydrochloride monohydrate*)
  Treatment of type 2 diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Entyvio (*vedolizumab*) - new indication
  Treatment of inflammatory conditions of the gut
- Teysuno (tegafur/gimeracil/oteracil) - new indication
  Treatment of cancers of the stomach and large intestines

Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines

- Yselty (*linzagolix choline*)
  Treatment of symptoms of uterine fibroids

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Oxbryta (Voxelotor)
  Treatment of anemia due to sickle cell disease

New medicines authorised

- Aspaveli (*pegcetacoplan*)
  Treatment of paroxysmal nocturnal haemoglobinuria (blood disorders)

Immune system

New information on authorised medicines

- Cibinqo (abrocitinib) - new indication
  Treatment of atopic dermatitis (inflammation of the skin)
- Entyvio (*vedolizumab*) - new indication
  Treatment of inflammatory conditions of the gut

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Kerendia (*finerenone*)
  Treatment of chronic kidney disease associated with type 2 diabetes

Nervous system

Positive CHMP opinions on new medicines

- Okedi (*risperidone*)
  Treatment of schizophrenia
- Ontilyv (*opicapone*)
  Treatment of Parkinson's disease

Negative CHMP opinions on new medicines

- Aduhelm (*aducanumab*)
  Intended for the treatment of Alzheimer disease

Direct Healthcare Professional Communication (DHPC)

- Briviact® (In Italy: Nubriveo®) (*brivaracetam*)
  Treatment of epilepsy

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Saphnelo (*anifrolumab*)
  Treatment of lupus erythematosus (SLE)

Urology (urinary tract conditions)

Positive CHMP opinions on new medicines

- Padcev (*enfortumab vedotin*)
  Treatment of urothelial cancer (cancer of the bladder and urinary system)

Other medicines

Positive CHMP opinions on new medicines

- Apexxnar (*pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)*)
  Prophylaxis against pneumococcal pneumonia and associated invasive disease
- Ngenla (*somatrogon*) O
  Treatment of growth hormone deficiency (GHD)

- Sapropterin Dipharma (*sapropterin*)
  Treatment of hyperphenylalaninemia (HPA) (high levels of amino acid phenylalanine in the blood)

Withdrawal of applications for new medicines

- Zektayos - Hepjuvo (*obeticholic acid*)
  Intended to treat non-alcoholic steatohepatitis with fibrosis (an inflammatory condition of the liver with scarring)

Direct Healthcare Professional Communication (DHPC)

- LYMPHOSEEK® (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation: temporary extension of shelf life

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics - Questions & answers
- Draft International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline Q9 (R1) on quality risk management - Step 2b
  Deadline for comments: 15 March 2022
- Draft guideline on the acceptability of names for human medicinal products processed through the centralised procedure
  Deadline for comments: 16 March 2022
- Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) - Rev. 6
- Draft enzalutamide soft capsule 40 mg and film-coated tablet 40 mg & 80 mg product-specific bioequivalence guidance
  Deadline for comments: 31 March 2022

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights

- CHMP - applications for new human medicines: December 2021
- 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: December 2021
- PRAC recommendations on safety signals

Other information on COVID-19

- EMA and ECDC recommendations on heterologous vaccination courses against COVID-19
- EMA recommends approval for use of RoActemra in adults with severe COVID-19
- ICMRA and WHO map out flexibilities used by regulators to respond to the COVID-19 pandemic
- EMA starts rolling review of Valneva's COVID-19 vaccine (VLA2001)
- Increase in manufacturing capacity for COVID-19 vaccine from AstraZeneca
- EMA reviewing new data on effectiveness of Lagevrio (molnupiravir) for the treatment of COVID-19
- International regulators stress continued need for COVID-19 therapeutics
- Report: Heterologous primary and booster COVID-19 vaccination - Evidence based regulatory considerations
- Increase in manufacturing capacity for COVID-19 vaccines from Janssen, Moderna and BioNTech/Pfizer
- COVID-19 Vaccine Janssen: EMA recommendation on booster dose
- International regulators' reflections on remote approaches to GCP and GMP regulatory oversight during COVID-19 pandemic
- EMA issues advice on use of Paxlovid (PF-07321332 and ritonavir) for the treatment of COVID-19: rolling review starts in parallel

Other publications

- EMA Management Board: highlights of December 2021 meeting
- Emer Cooke's end-of-year message
- Financial advantages of SME status
- Highlights - 16th industry stakeholder platform - operation of European Union (EU) pharmacovigilance
- News bulletin for small and medium-sized enterprises - Issue 54
- Newsletter: Clinical Trials Information System (CTIS) highlights - December 2021
- Getting started with CTIS: Sponsor quick guide
- Newsletter: Enpr-EMA newsletter 2021
- European Medicines Regulatory Network Data Standardisation Strategy

- Report: European Medicines Agency-Nuclear Medicines Europe meeting
- Note on European Medicines Agency's involvement in HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment
- Report: EU Big Data Stakeholder Forum 2021
- EMA framework of interaction with healthcare professionals: 10 years of implementation

Events

- DADI webinar - Introducing DADI: The digital application dataset integration network project to replace electronic application forms, virtual meeting, 18 January 2022 - Agenda
- Digital application dataset integration (DADI) webinar - common factors in the Fast Healthcare Interoperability Resources (FHIR) data standard for Article 57(2) and electronic application forms (eAF), virtual meeting, 25 January 2022 - Agenda
- EMA regular press briefing on COVID-19, virtual meeting, 09 December 2021
- ICMRA high-level meeting on global health emergencies and regulatory approaches
- Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - virtual meeting, 17 February 2022
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - virtual meeting, 14 to 16 February 2022
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - virtual meeting, 02 to 04 May 2022
- Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - virtual meeting, 05 May 2022
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - virtual meeting, 27 June to 29 June 2022
- Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - virtual meeting, 30 June 2022
- CTIS sponsor user training programme - virtual meeting, 24 January to 27 January 2022
- Regulatory science research needs launch event - virtual meeting, 18 January 2022 - Agenda
- EMA regular press briefing on COVID-19 - virtual meeting, 21 December 2021

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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