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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

Safety update

- COVID-19 vaccines - Safety update: 12 May 2022

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Ertapenem SUN (*ertapenem*) generic of Invanz
  Treatment of bacterial infection and prevention of infection following colorectal surgery

New medicines authorised

- Apexxnar (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed))
  Vaccine to prevent against pneumonia (infection of the lungs) and invasive diseases caused by the bacterium *Streptococcus pneumoniae*

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

Cancer

New medicines authorised

- Breyanzi (*lisocabtagene maraleucel*)
  Treatment of different types of blood cancers
- Padcev (*enfortumab vedotin*)
  treatment of urothelial cancer (a cancer of the bladder and urinary tract)
- Tepmetko (*tepotinib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Keytruda (*pembrolizumab*) - extension of indication
  Treatment of different types of cancer
- Nexpovio (*selinexor*) - new indication
  Treatment of multiple myeloma (cancer of the bone marrow)

Withdrawal of applications for new medicines

- Sitoiganap (*autologous glioma tumor cell lysates (inactivated) / allogeneic glioma tumor cell lysates (inactivated) / allogeneic glioma tumor cells (inactivated) / autologous glioma tumor cells (inactivated)*)
  Intended to treat malignant glioma (a type of brain cancer)

Negative CHMP opinions on new medicines

- Hervelous (*trastuzumab*)
  Intended for the treatment of certain forms of breast cancer and gastric (stomach) cancer
- Tuznue (*trastuzumab*)
  Intended for the treatment of certain forms of breast cancer and gastric (stomach) cancer

Safety update

- Review of Daruph and Anafezyn (*dasatinib (anhydrous)*) - CHMP Opinion
  Treatment of chronic myeloid leukaemia and acute lymphoblastic leukaemia (blood cancer)

Direct Healthcare Professional Communication (DHPC)

- Rubraca (*rucaparib*): Interim data from Study CO-338-043 (ARIEL4) show a decrease in overall survival compared to standard of care

Diabetes

Positive CHMP opinions on new medicines

- Sitagliptin / Metformin hydrochloride Accord (*sitagliptin/metformin hydrochloride*) generic of Janumet
  Treatment of type 2 diabetes mellitus

Gastro-intestinal system

Positive CHMP opinions on new medicines

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  Treatment of bacterial infection and prevention of infection following colorectal surgery

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Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines

- Ganirelix Gedeon Richter (*ganirelix*) generic of Orgalutran
  Intended for the prevention of premature ovulation in women receiving fertility treatment and who are having ovarian stimulation

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Cevenfacta *(Eptacog beta (activated))*
  Treatment of bleeding episodes

New medicines authorised

- Breyanzi (*lisocabtagene maraleucel*)
  Treatment of different types of blood cancers

Withdrawal of applications for new medicines

- HemAryo (*eptacog alfa (activated)*)
  Intended for treating bleeding episodes and for preventing bleeding after surgical procedures in patients with clotting disorders

Hormone system

Supply shortages

- Natpar (*parathyroid hormone)*
  Treatment of under-active parathyroid glands, a condition known as hypoparathyroidism

Immune system

New medicines authorised

- Amifampridine SERB (*amifampridine*) generic of Firdapse
  Treatment of the symptoms of Lambert-Eaton myasthenic syndrome (an autoimmune disease leading to muscle weakness)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA), ankylosing spondylitis and non-radiographic axial spondyloarthritis (inflammatory conditions)

- Olumiant (*baricitinib*) - new indication
  Treatment of alopecia areata, rheumatoid arthritis and atopic dermatitis (inflammatory conditions)
- Rinvoq (*upadacitinib*) - new indication
  Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, atopic dermatitis and ulcerative colitis (inflammatory conditions)
- Xeljanz (*tofacitinib*) - new indication
  Treatment of ankylosing spondylitis, rheumatoid arthritis and psoriatic arthritis (inflammatory conditions)

Metabolic disorders

Positive CHMP opinions on new medicines

- Zokinvy (*lonafarnib*) O E
  Treatment of a genetically confirmed diagnosis of Hutchinson-Gilford progeria syndrome or progeroid laminopathies (premature aging conditions)

Musculoskeletal system

Positive CHMP opinions on new medicines

- Sugammadex Fresenius Kabi (*sugammadex*) generic of Bridion
  Treatment to reverse neuromuscular blockade induced by rocuronium or vecuronium

New medicines authorised

- Amifampridine SERB (*amifampridine*) generic of Firdapse
  Treatment of the symptoms of Lambert-Eaton myasthenic syndrome (an autoimmune disease leading to muscle weakness)

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Kinpeygo (*budesonide*) O C
  Treatment of primary immunoglobulin A nephropathy (an inflammatory disease of the kidneys)

Nervous system

Positive CHMP opinions on new medicines

- Xenpozyme (*olipudase alfa*) O
  Treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (a disease in which fat builds up within cells)

New medicines authorised

- Amifampridine SERB (*amifampridine*) generic of Firdapse
  Treatment of the symptoms of Lambert-Eaton myasthenic syndrome (a disease leading to muscle weakness)

- Dimethyl fumarate Mylan (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis
- Dimethyl fumarate Neuraxpharm (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis
- Dimethyl fumarate Polpharma (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis
- Quviviq (*daridorexant*)
  Treatment of insomnia (difficulty sleeping)

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA), ankylosing spondylitis and non-radiographic axial spondyloarthritis (inflammatory disorders)
- Xeljanz (*tofacitinib*) - new indication
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- Rinvoq (*upadacitinib*) - new indication
  Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, atopic dermatitis and ulcerative colitis (inflammatory disorders)

Urology (urinary tract conditions)

New medicines authorised

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

Vaccines

New medicines authorised

- Apexxnar (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed))
  Vaccine to prevent against pneumonia (infection of the lungs) and invasive diseases (caused by the bacterium *Streptococcus pneumoniae*

Other medicines

Positive CHMP opinions on new medicines

- Upstaza (*eladocagene exuparvovec*) O E
  Treatment of aromatic L-amino acid decarboxylase deficiency (genetic condition affecting the nervous system)

Safety update

- Synchron Research Service: suspension of medicines over flawed studies - CHMP Opinion

Direct Healthcare Professional Communication (DHPC)

- Lymphoseek (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation: temporary extension of shelf life - medicine shortage

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Lanreotide acetate, prolonged-release solution for injection in prefilled syringe 60, 90 and 120 mg product specific bioequivalence guidance
  Deadline for comments: 31 August 2022
- Public consultation concerning the physical attendance and the location of personal residency of the qualified person
  Deadline for comments: 13 June 2022

Adopted guidelines

- Reflection paper on data required in confirmatory studies of medicinal products for the treatment of type 2 diabetes - Revision 2

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - April 2022
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 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 statistics: May 2022

- PRAC recommendations on safety signals

Other information on COVID-19

- International regulators and WHO: support healthcare professionals to enhance public confidence in COVID-19 vaccines

Other publications

- Stakeholder engagement highlights 2021
- Key performance indicators (KPIs) to monitor the European clinical trials environment
- EMA guidance supports development of new antibiotics
- Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to EMA
- Gerrit Johan Schefferlie elected new Chair of EMA Committee for Veterinary Medicinal Products (CVMP)
- Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 16-19 May 2022

Events

- Webinar on submissions of parallel distribution notifications for centrally authorised products (CAPs), 9 June 2022, 16:00-17:30
- Methodology for the establishment of lists of "main therapeutic groups" in crisis preparedness and of the lists of "critical medicines1" in the context of a major event and/or public health emergency
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , 11 May 2022, 10:00-11:30
- Ad-hoc meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), 25 May 2022, 10:00-11:00
- EMA regular press briefing on COVID-19, 2 June 2022, 14:30-15:00
- EMA and European Infrastructure for Translational Research (EATRIS) webinar on Scientific Advice for Advanced Therapy Medicinal Products (ATMPs): what and when to ask, 10 June 2022, 13:00-14:00

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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