178 Issue 178
March 2024

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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Celldemic (*influenza vaccine (surface antigen, inactivated, prepared in cell cultures)*)
  Immunisation against the H5N1 subtype of Influenza A virus
- Incellipan (*influenza vaccine (surface antigen, inactivated, prepared in cell cultures)*) C
  Immunisation against influenza in an officially declared pandemic

Cancer

Positive CHMP opinions on new medicines

- Tizveni (*tislelizumab*)
  Treatment of locally advanced or metastatic non-small cell lung cancer

Key to symbols used

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

Positive CHMP opinions on new medicines

- Zynyz (*retifanlimab*)
  Treatment of Merkel cell carcinoma, an agressive, life-threatening skin cancer

New medicines authorised

- Naveruclif (*paclitaxel*) generic of Abraxane
  Treatment of different types of cancers

New information on authorised medicines

- Carvykti (*ciltacabtagene autoleucel*) - extension of indication
  Treatment of relapsed and refractory multiple myeloma (cancer of the bone marrow)
- Keytruda (*pembrolizumab*) - new indication
  Treatment of several types of cancer

Supply shortages

- Eldisine (*vindesine*)
  Treatment of different types of blood cancers, as well as certain solid tumours, such as cancer of the breast, oesophagus (the tube that connects the mouth to the stomach), upper aerodigestive tract (airways of the head and neck) and lungs.

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Apremilast Accord (*apremilast*) generic of Otezla
  Treatment of psoriatic arthritis, psoriasis and Behcet's disease, a rare type of inflammatory disease which affects many parts of the body
- Pyzchiva (*ustekinumab*)
  Treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease
- Zynyz (*retifanlimab*)
  Treatment of Merkel cell carcinoma, an agressive, life-threatening skin cancer

New information on authorised medicines

- Cibinqo (*abrocitinib*) - extension of indication
  Treatment of moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Pyzchiva (*ustekinumab*)
  Treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease

New medicines authorised

- Velsipity (*etrasimod*)
  Treatment of ulcerative colitis (a disease causing inflammation and ulcers in the lining of the bowel)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Voydeya (*danicopan*) O
  Add-on therapy to ravulizumab or eculizumab for the treatment of residual haemolytic anaemia in adult patients with paroxysmal nocturnal haemoglobinuria, rare genetic disorder and potentially life-threatening blood disease leading to the premature destruction of red blood cells (haemolytic anaemia) by the immune system

New information on authorised medicines

- Carvykti (*ciltacabtagene autoleucel*) O C - extension of indication
  Treatment of relapsed and refractory multiple myeloma (cancer of the bone marrow)
- Reblozyl (*luspatercept*) - extension of indication
  Treatment of anaemia (low red blood cell counts)
- Xromi (*hydroxycarbamide*) - extension of indication
  Treatment of sickle cell disease

Immune system

Positive CHMP opinions on new medicines

- Apremilast Accord (*apremilast*) generic of Otezla
  Treatment of psoriatic arthritis, psoriasis and Behcet's disease, a rare type of inflammatory disease which affects many parts of the body
- Pyzchiva (*ustekinumab*)
  Treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease

New information on authorised medicines

- Cibinqo (*abrocitinib*)- extension of indication
  Treatment of moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry)

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Filspari (*sparsentan*) O C
  Treatment of primary immunoglobulin A nephropathy, a disease where the kidneys gradually stop working and eventually fail, requiring patients to undergo dialysis or have a kidney transplant

Nervous system

Positive CHMP opinions on new medicines

- Qalsody (*tofersen*) E
  Treatment of a type of amyotrophic lateral sclerosis, a rare and often fatal disease that causes muscles to become weak and leads to paralysis

Respiratory system

Positive CHMP opinions on new medicines

- Nintedanib Accord (*nintedanib*)
  Treatment of idiopathic pulmonary fibrosis, other chronic fibrosing interstitial lung diseases with a progressive phenotype, and systemic sclerosis associated interstitial lung disease
- Tizveni (*tislelizumab*)
  Treatment of locally advanced or metastatic non-small cell lung cancer

New information on authorised medicines

- Kalydeco (*ivacaftor*)- extension of indication /new pharmaceutical form
  Treatment of cystic fibrosis, an inherited disease that has severe effects on the lungs, the digestive system and other organs

Direct Healthcare Professional Communication (DHPC)

- Pseudoephedrine-containing medicinal products
  Nasal decongestants for systemic use

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Apremilast Accord (*apremilast*) generic of Otezla
  Treatment of psoriatic arthritis, psoriasis and Behcet's disease, a rare type of inflammatory disease which affects many parts of the body
- Pyzchiva (*Ustekinumab*)
  Treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease

Vaccines

Positive CHMP opinions on new medicines

- Celldemic (*influenza vaccine (surface antigen, inactivated, prepared in cell cultures)*)
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- Incellipan (*influenza vaccine (surface antigen, inactivated, prepared in cell cultures)*) C
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Other medicines

Safety update

- EMA recommends refusal of authorisation for Ibuprofen NVT (ibuprofen, 400 mg, soft capsules) - review concluded
  Painkiller and anti-inflammatory medicine

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper for the development of a reflection paper on a tailored clinical approach in biosimilar development
  Deadline for comments: 30 April 2024
- Non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the prevention and treatment of COVID-19 - Scientific guideline
  Deadline for comments: 30 April 2024
- Non-inferiority and equivalence comparisons in clinical trials - Scientific guideline
  Deadline for comments: 31 May 2024

Adopted guidelines

- Reflection paper on investigation of pharmacokinetics in the obese population

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - January 2024
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 2024
- 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: February 2024
- PRAC recommendations on safety signals
- Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 27 and 28 February
- Oncology Working Party (ONCWP) work plan: Priorities for 2024
- Non-clinical domain work plan: Priorities for 2024

- Consolidated 3-year work plan for the Rheumatology and Immunology Working Party (RIWP) 2024-2026
- 3-year work plan for the joint CHMP/CVMP Quality Working Party 2024-2026
- 3-year work plan for the Quality Innovation Group 2024-2026
- 3-year work plan for Biosimilar Medicinal Products Working Party (BMWP) 2024-2026
- 3-year work plan for the Biologics Working Party (BWP) 2024-2026
- Methodology European Specialised Expert Community (ESEC) - membership

Other publications

- Progress update on pilot for academic and non-profit developers of advanced therapy medicines
- European Medicines Agency's Data Protection Notice for the Antimicrobials Sales and Use platform
- EMA/ECDC/EFSA fourth joint report on the integrated analysis of the antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA
- Simplified summary - EMA/ECDC/EFSA fourth joint report on the integrated analysis of the antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA
- Report of Cancer medicines forum meeting - 4 December 2023
- Launch of new HMA-EMA catalogues of real-world data sources and studies

Events

- SPOR Status Update webinar - 10 April 2024
- Eighth Industry Standing Group (ISG) meeting - 25 March 2024
- Clinical Trials Information System Webinar: Last Year of Transition - 25 March 2024
- Third European Medicines Agency (EMA) and MedTech Europe bilateral meeting - 18 March 2024
- Multi-stakeholder webinar on the HMA-EMA Catalogues of real-world data sources and studies - 4 March 2024
- Sixth European Medicines Agency (EMA) and EFPIA bilateral meeting - 6 February 2024

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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