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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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Emblaveo (*aztreonam / avibactam*)
  Treatment of complicated abdominal and urinary tract infections, hospital-acquired pneumonia and infections due to aerobic Gram-negative organisms

Cancer

Positive CHMP opinions on new medicines

- Wyost (*denosumab*)
  Prevention of bone complications in patients with cancer involving the bones and treatment of giant cell tumours of the bone (a noncancerous bone tumour)

Key to symbols used

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

New information on authorised medicines

- Onivyde pegylated liposomal (previously known as Onivyde) (*irinotecan hydrochloride trihydrate*) O - new indication
  Treatment of pancreatic cancer
- Retsevmo (selpercatinib) C - new indication
  Treatment of certain non-small cell lung cancers, thyroid cancers and other solid tumours
- Xtandi (*enzalutamide*) - new indication
  Treatment of prostate cancer

Withdrawal of applications for new medicines

- Adcetris (*brentuximab vedotin*)
  Treatment of certain lymphomas (cancers of lymphocytes, types of white blood cells)

Supply shortages

- *fludarabine*
  Treatment of chronic lymphocytic leukaemia (type of blood cancer)

Cardiovascular system

Positive CHMP opinions on new medicines

- Neoatricon (*dopamine hydrochloride*)
  Treatment of hypotension (low blood pressure) in children

New information on authorised medicines

- Nilemdo (*bempedoic acid*) - new indication
  Treatment of hypercholesterolemia and dyslipidemias (abnormal levels of fat in the blood)
- Nustendi (*bempedoic acid / ezetimibe*) - new indication
  Treatment of hypercholesterolemia and dyslipidemias (abnormal levels of fat in the blood)

Dermatology (skin conditions)

New information on authorised medicines

- Bimzelx (*bimekizumab*) - new indication
  Treatment of moderate to severe plaque psoriasis (scaly patches on skin)

Diabetes

Positive CHMP opinions on new medicines

- Awiqli (*insulin icodec*)
  Treatment of diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Onivyde pegylated liposomal (previously known as Onivyde) (*irinotecan hydrochloride trihydrate*) O - new indication
  Treatment of pancreatic cancer

Key to symbols used

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Safety update

- Review of Micrazym and associated names - CHMP Opinion
  Treatment of pancreatic insufficiency (when the pancreas does not produce enough enzymes)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Fabhalta (*iptacopan*)
  Treatment of paroxysmal nocturnal haemoglobinuria (a condition in which there is excessive breakdown of red blood cells)

Withdrawal of applications for new medicines

- Adcetris (*brentuximab vedotin*)
  Treatment of certain lymphomas (cancers of lymphocytes, types of white blood cells)

Immune system

Positive CHMP opinions on new medicines

- Omlyclo (*omalizumab*)
  Treatment of asthma, rhinosinusitis (inflammation in nose and sinuses) and urticaria

New information on authorised medicines

- Bimzelx (*bimekizumab*) - new indication
  Treatment of moderate to severe plaque psoriasis (scaly patches on skin)

Withdrawal of applications for extension of indication

- Orencia (*abatacept*)
  Treatment of inflammatory conditions

Nervous system

Positive CHMP opinions on new medicines

- Dimethyl fumarate Accord (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis
- Dimethyl fumarate Mylan (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis
- Dimethyl fumarate Neuraxpharm (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis

Withdrawal of applications for extension of indication

- Ongentys (*opicapone*)
  Treatment of Parkinson's disease

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Lytenava (*bevacizumab*)
  Treatment of neovascular (wet) age-related macular degeneration a disease affecting the central part of the retina, at the back of the eye

Respiratory system

Positive CHMP opinions on new medicines

- Omlyclo (*omalizumab*)
  Treatment of severe persistent allergic asthma, severe chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria

Direct Healthcare Professional Communication (DHPC)

- Paxlovid (*nirmatrelvir / ritonavir*)
  Reminder on the interactions associated with Paxlovid (nirmatrelvir tablets; ritonavir tablets)

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Jubbonti (*denosumab*)
  Treatment of osteoporosis

Other medicines

Positive CHMP opinions on new medicines

- Agilus (*dantrolene sodium, hemiheptahydrate*)
  Treatment of malignant hyperthermia (a high temperature and other reactions to certain medicines used for anaesthesia)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials - Second version
  Deadline for comments: 31 May 2024
- Dabrafenib hard capsule 50 and 75 mg product-specific bioequivalence guidance
  Deadline for comments: 30 June 2024
- Trametinib film-coated tablet 0.5 and 2mg product-specific bioequivalence guidance
  Deadline for comments: 30 June 2024

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: March 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: March 2024
- PRAC recommendations on safety signals
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 2 July
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 3 July

Other publications

- EMA Management Board: highlights of March 2024 meeting
- Accelerating stakeholder collaboration to enhance the clinical trials environment in the EU
- DARWIN EU® continues expanding its capacity to deliver real-world data studies
- Meeting Report of the second Listen and Learn Focus Group (LLFG) meeting of the Quality Innovation Group (QIG)

- Vaccine Monitoring Platform: List of EMA-funded studies
- Note on the HORIZON-JU-IHI-2024-06-two-stage funding call: Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence
- EU recommendations for 2024/2025 seasonal flu vaccine composition
- Regulatory information – adjusted fees for applications to EMA from 1 April 2024

Events

- Training webinar on the use of Scientific Explorer in scientific advice regulatory procedures - 3 April 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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http://www.ema.europa.eu

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European Medicines Agency

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