168 Issue 168
April 2023

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

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

- Bimervax (*COVID-19 Vaccine (recombinant, adjuvanted)*)
  Prevention of COVID-19 disease

Antivirals/anti-infectives

New information on authorised medicines

- Tenkasi (previously Orbactiv) (*oritavancin*) - extension of indication
  Treatment of infections of the skin and tissues beneath the skin

Key to symbols used

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

Withdrawal of applications for new medicines

- Garsun (*artesunate*)
  Intended for treatment of severe malaria

Cancer

Positive CHMP opinions on new medicines

- Pedmarqsi (*sodium thiosulfate*)
  Prevention of development of hearing loss caused by cisplatin cancer treatment
- Qaialdo (*spironolactone*)
  Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

New medicines authorised

- Imjudo (*tremelimumab*)
  Treatment of a type of liver cancer

New information on authorised medicines

- Breyanzi (*lisocabtagene maraleucel*) - new indication
  Treatment of lymphomas (cancers of certain types of blood cells)

Direct Healthcare Professional Communication (DHPC)

- Janus kinase inhibitors (JAKi) (*abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib*)
  Updated recommendations to minimize risk of cancer, heart problems and blood clots

Cardiovascular system

Positive CHMP opinions on new medicines

- Dabigatran Etexilate Accord (*dabigatran etexilate*) generic of Pradaxa
  Treatment and prevention of blood clots
- Qaialdo (*spironolactone*)
  Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

New information on authorised medicines

- Neparvis (*sacubitril / valsartan*) - new indication and new pharmaceutical form
  Treatment of chronic heart failure in children
- Entresto (*sacubitril / valsartan*) - new indication and new pharmaceutical form
  Treatment of chronic heart failure in children over one year of age

Direct Healthcare Professional Communication (DHPC)

- Janus kinase inhibitors (JAKi) (*abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib*)
  Updated recommendations to minimize risk of cancer, heart problems and blood clots

Dermatology (skin conditions)

New information on authorised medicines

- Tenkasi (previously Orbactiv) (*oritavancin*) - extension of indication
  Treatment of infections of the skin and tissues beneath the skin

Diabetes

Supply shortages

- Ozempic (*semaglutide*)
  Treatment of diabetes

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Epysqli (*eculizumab*)
  Treatment of paroxysmal nocturnal heamoglobinuria (a rare immune condition in which there is haemoglobin (red pigment) in the urine due to the excessive breakdown of red blood cells.)

New information on authorised medicines

- Ultomiris (*ravulizumab*) - new indication and new pharmaceutical form
  Treatment of paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uraemic syndrome (aHUS), life-threatening blood conditions caused by an overactive immune system

Withdrawal of applications for new medicines

- Feraheme (*ferumoxytol*)
  Intended for treatment of iron deficiency anaemia

Safety update

- Review of Pseudoephedrine-containing medicinal products (*pseudoephedrine*) - review started
  Treatment of nasal congestion

Direct Healthcare Professional Communication (DHPC)

- Janus kinase inhibitors (JAKi) (*abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib*)
  Updated recommendations to minimize risk of cancer, heart problems and blood clots

Hepatology (liver conditions)

Positive CHMP opinions on new medicines

- Qaialdo (*spironolactone*)
  Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

New medicines authorised

- Imjudo (*tremelimumab*)
  Treatment of a type of liver cancer

HIV

Withdrawal of applications for new medicines

- Raltegravir Viatris (*raltegravir potassium*)
  Intended for treatment of HIV type 1 virus

Immune system

Positive CHMP opinions on new medicines

- Epysqli (*eculizumab*)
  Treatment of paroxysmal nocturnal heamoglobinuria (a rare immune condition in which there is haemoglobin (red pigment) in the urine due to the excessive breakdown of red blood cells.)
- Omvoh (mirikizumab)
  Treatment of an inflammation of the large intestine causing ulceration and bleeding

New information on authorised medicines

- Ultomiris (*ravulizumab*) - new indication and new pharmaceutical form
  Treatment of a disease in which the immune system causes damage leading to anaemia, thrombocytopenia (a decrease in the number of platelets, components that help the blood to clot) and kidney failure

Safety update

- Review of Pseudoephedrine-containing medicinal products (*pseudoephedrine*) - review started
  Treatment of nasal congestion

Metabolic disorders

Supply shortages

- Myalepta (*metreleptin*)
  Treatment of abnormal distribution of fat in patients with a condition known as leptin deficiency

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Qaialdo (*spironolactone*)
  Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

New information on authorised medicines

- Ultomiris (*ravulizumab*) - new indication and new pharmaceutical form
  Treatment of a disease in which the immune system causes damage leading to anaemia, thrombocytopenia (a decrease in the number of platelets, components that help the blood to clot) and kidney failure

Nervous system

Positive CHMP opinions on new medicines

- Briumvi (*ublituximab*)
  Treatment of multiple sclerosis
- Lacosamide Adroiq (*lacosamide*) generic of Vimpat
  Treatment of epilepsy
- Sugammadex Adroiq (*sugammadex*) generic of Bridion
  Used to reverse the effect of the muscle relaxants

Safety update

- Review of Pseudoephedrine-containing medicinal products (*pseudoephedrine*) - review started
  Treatment of nasal congestion
- Review of Topiramate (*topiramate*) - review started
  Prevention of epileptic seizures, treatment of epilepsy, prevention of migraine and, in some countries, used in combination with phentermine for body weight reduction

Ophthalmology (eye conditions)

Arbitration procedures

- Gelisia and associated names (*timolol maleate*) - outcome
  Treatment of high pressure inside the eye

Respiratory system

Safety update

- Pholcodine-containing medicinal products (*pholcodine*) - outcome
  Treatment of dry cough (in combination with other active substances for treatment of) symptoms of cold and flu
- Review of Pseudoephedrine-containing medicinal products (*pseudoephedrine*) - review started
  Treatment of nasal congestion

Direct Healthcare Professional Communication (DHPC)

- Pholcodine-containing medicinal products (*pholcodine*)
  Treatment of dry cough (in combination with other active substances for treatment of) symptoms of cold and flu

Rheumatology (immune and inflammatory conditions)

New medicines authorised

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

Withdrawal of applications for new medicines

- Onteeo (*INN*)
  Intended for treatment of various inflammatory conditions and COVID-19

Direct Healthcare Professional Communication (DHPC)

- Janus kinase inhibitors (JAKi) (*abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib*)
  Updated recommendations to minimize risk of cancer, heart problems and blood clots

Other medicines

New information on authorised medicines

- Wegovy (*semaglutide*) - extension of indication
  Treatment of obesity

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Scientific committee and working party activities

- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- 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
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 3 March 2023 - Agenda

Other publications

- DARWIN EU® has completed its first studies and is calling for new data partners
- Public engagement highlights

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Events

- EMA multi-stakeholder workshop on qualification of novel methodologies - 17-18 April 2023
- Fourth Industry Standing Group (ISG) meeting - 21 March 2023 - Agenda
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 15 March 2023
- HMA/EMA multi-stakeholder workshop on shortages - 1-2 March 2023
- Fifth EMA-EFPIA annual bilateral meeting - 7 February 2023 - Agenda

Key to symbols used

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

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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