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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

- Posaconazole Accord / Posaconazole AHCL (*posaconazole*) generics of Noxafil
  Treatment and prevention of fungal infections

New medicines authorised

- Atazanavir Krka (*atazanavir*) generic of Reyataz
  Treatment of HIV infection

Cancer

New medicines authorised

- Pazenir (*paclitaxel*) generic of Abraxane
  Treatment of metastatic breast cancer and non-small cell lung cancer (NSCLC)

Key to symbols used

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

Negative CHMP opinions on new medicines

- Doxolipad (*doxorubicin*)
  Intended for the treatment of breast and ovarian cancer

Cardiovascular system

Withdrawal of applications for new medicines

- Ambrisentan Zentiva (*ambrisentan*) generic of Volibris
  Intended for the treatment of pulmonary arterial hypertension (high blood pressure in the arteries of the lungs)

Diabetes

New medicines authorised

- Zynquista (*sotagliflozin*)
  Treatment of type 1 diabetes

Gastro-intestinal system

Safety update

- Review of Xeljanz (*tofacitinib*) - review started (restrictions in use while EMA reviews risk of blood clots in lungs)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Haematology

New medicines authorised

- Besremi (*ropeginterferon alfa-2b*) O
  Treatment of polycythaemia vera (blood disease leading to production of too many red blood cells)

Negative CHMP opinions on new medicines

- Xyndari (*glutamine*) O
  Intended for the treatment of sickle cell disease (genetic disease in which red blood cells become rigid and crescent-shaped)

HIV

New medicines authorised

- Atazanavir Krka (*atazanavir*) generic of Reyataz
  Treatment of HIV infection

Immune system

Safety update

- Review of Xeljanz (*tofacitinib*) - review started (restrictions in use of the medicine while EMA reviews risk of blood clots in lungs)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Metabolic disorders

Positive CHMP opinions on new medicines

- Cufence (*trientine dihydrochloride*) O
  Treatment of Wilson's disease (a condition in which excessive amounts of copper accumulate in the body)

New medicines authorised

- Miglustat Dipharma (*miglustat*) generic of Zavesca
  Treatment of type 1 Gaucher disease (a condition in which a fat called glucocerebrosidase accumulates in the body)
- Palynziq (*pegvaliase*) O
  Treatment of phenylketonuria (inability to break down the amino acid phenylalanine, which then builds up in the blood and brain)
- Waylivra (*volanesorsen*) O
  Treatment of familial chylomicronaemia syndrome (FCS, an inherited disorder of fat metabolism which results in high risk for pancreatitis)

Nephrology

Positive CHMP opinions on new medicines

- LysaKare (*arginine / lysine*)
  Used to protect the kidneys against radiation during radioactive therapy with lutetium (177Lu) oxodotreotide

Nervous system

Withdrawal of applications for new medicines

- Radicava (*edaravone*) O
  Intended for the treatment of amyotrophic lateral sclerosis (ALS), a degenerative neurological condition

Safety update

- Review of methocarbamol / paracetamol-containing medicinal products - review started (review of the effectiveness of medicines)
  Treatment of painful muscle spasms

Key to symbols used

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

Respiratory system

New medicines authorised

- Pazenir (*paclitaxel*) generic of Abraxane
  Treatment of metastatic breast cancer and non-small cell lung cancer (NSCLC)

Safety update

- Review of fenspiride-containing medicinal products - CMDh Position (withdrawal of marketing authorisations)
  Used to relieve cough resulting from lung diseases

Rheumatology

Safety update

- Review of Xeljanz (*tofacitinib*) - review started (restrictions in use of the medicine while EMA reviews risk of blood clots in lungs)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft etonogestrel and ethinylestradiol vaginal delivery system product-specific bioequivalence
  Deadline for comments: 28 October 2019

Adopted guidelines

- Qualification opinion on stride velocity 95th centile as a secondary endpoint in Duchenne Muscular Dystrophy measured by a valid and suitable wearable device

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - April 2019
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 2019

- CAT - agendas, minutes and reports
- 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 2019
- PRAC recommendations on safety signals
- Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP)
- Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP)
- Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

Other publications

- EMA annual report 2018 published
- Working together for safe medicines in the EU
- EMA facilitates early engagement with medicine developers to combat antimicrobial resistance
- Update of EU recommendations for 2019–2020 seasonal flu vaccine composition

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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