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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

New information on authorised medicines

- Epclusa (*sofosbuvir / velpatasvir*) - extension of indication
  Treatment of chronic hepatitis C virus (HCV) infection in adult patients aged 6 years and older and weighing at least 17 kg.
- Zavicefta (*ceftazidime / avibactam*) - new indication
  Treatment of patients with bacteraemia (bacteria in the blood)

Cancer

Positive CHMP opinions on new medicines

- Aybintio (*bevacizumab*)
  Treatment of different types of cancer

Key to symbols used

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

New medicines authorised

- Sarclisa (*isatuximab*)
  Treatment of multiple myeloma (cancer of the bone marrow)

Safety update

- Review of leuprorelin-containing depot medicinal products - CMDh Position (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system
- Direct healthcare professional communication (DHPC): Fluorouracil (i.v.), capecitabine and tegafur containing products - Pre-treatment testing to identify DPD-deficient patients at increased risk of severe toxicity
- Direct healthcare professional communication (DHPC): Flucytosine - Updated recommendations for the use in patients with dihydropyrimidine dehydrogenase (DPD) deficiency
- Direct healthcare professional communication (DHPC): Tepadina - Risk of defective vials

Cardiovascular system

New medicines authorised

- Nilemdo (*bempedoic acid*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)

Dermatology (skin conditions)

New medicines authorised

- Nepexto (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis (inflammation of the spine causing back pain), axial spondyloarthritis (inflammation of the spine causing back pain), plaque psoriasis and paediatric plaque psoriasis (scaly patches on skin)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and axial spondyloarthritis (inflammation of the spine causing back pain)

Safety update

- Direct healthcare professional communication (DHPC): Fluorouracil (i.v.), capecitabine and tegafur containing products - Pre-treatment testing to identify DPD-deficient patients at increased risk of severe toxicity
- Direct healthcare professional communication (DHPC): Flucytosine - Updated recommendations for the use in patients with dihydropyrimidine dehydrogenase (DPD) deficiency

Gynaecology & Obstetrics (pregnancy and female reproductive)

Withdrawal of authorised medicines

- Fertavid (*follitropin beta)*
  Intended for treatment of infertility

Safety update

- Review of leuprorelin-containing depot medicinal products - CMDh Position (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Haematology (blood conditions)

New medicines authorised

- Deferasirox Mylan (*deferasirox*) generic of Exjade
  Treatment of chronic iron overload due to blood transfusions in patients with blood disorders

Hormone system

Safety update

- Review of leuprorelin-containing depot medicinal products - CMDh Position (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Immune system

Positive CHMP opinions on new medicines

- Idefirix (*imlifidase*) C
  intended for certain patients undergoing kidney transplantation to prevent organ rejection

New medicines authorised

- Atectura Breezhaler / Bemrist Breezhaler (*indacaterol / mometasone furoate*)
  Treatment of asthma
- Nepexto (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis (inflammation of the spine causing back pain), axial spondyloarthritis (inflammation of the spine causing back pain), plaque psoriasis and paediatric plaque psoriasis (scaly patches on skin)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of Plaque psoriasis (scaly patches on skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and axial spondyloarthritis (inflammation of the spine causing back pain)

Key to symbols used

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

- Remsima (infliximab) - extension of indication
  Treatment of Crohn's disease, ulcerative colitis (inflammatory disorders of the gut), ankylosing spondylitis (inflammation affecting the spine) and psoriatic arthritis (inflammation of the joints associated with psoriasis)
- Xolair (omalizumab) - new indication
  Treatment of asthma
- Zavicefta (*ceftazidime / avibactam*) - new indication
  Treatment of patients with bacteraemia (bacteria in the blood)

Metabolic disorders

New medicines authorised

- Nilemdo (*bempedoic acid*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Idefirix (*imlifidase*) C
  intended for certain patients undergoing kidney transplantation to prevent organ rejection

Ophthalmology (eye conditions)

Withdrawal of applications for new medicines

- Xiidra (*lifitegrast*)
  Intended for treatment of dry eye disease

Respiratory system

Positive CHMP opinions on new medicines

- Kaftrio (*elexacaftor / tezacaftor / ivacaftor*)
  Treatment of cystic fibrosis

New medicines authorised

- Atectura Breezhaler / Bemrist Breezhaler (*indacaterol / mometasone furoate*)
  Treatment of asthma

New information on authorised medicines

- Xolair (omalizumab) - new indication
  Treatment of asthma

Negative CHMP opinions on new medicines

- Budesonide SUN (*budesonide*) - CHMP opinion after re-examination
  Intended for treatment of asthma

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Livogiva (*teriparatide*)
  Treatment of osteoporosis (a disease that makes bone fragile)
- Qutavina (*teriparatide*)
  Treatment of osteoporosis (a disease that makes bone fragile)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and axial spondyloarthritis (inflammation of the spine causing back pain)

Withdrawal of applications for new medicines

- Sondelbay (*teriparatide*)
  Intended for the treatment of osteoporosis (a disease that makes bone fragile)

Urology (urinary tract conditions)

Withdrawal of applications for new medicines

- Zemdri (*plazomicin*)
  Intended for treatment of complicated urinary tract infection

Vaccines

Safety update

- Review of Varilrix (*live attenuated varicella virus (OKA strain)*) - review started (Art.30)
  Used for protecting individuals against varicella (chickenpox)

Other Medicines

Positive CHMP opinions on new medicines

- Gencebok (*caffeine citrate*)
  Treatment of primary apnoea (cessation of breathing) of premature newborns
- Methylthioninium chloride Cosmo (*methylthioninium chloride*)
  Intended as a diagnostic agent to help visualize lesions in the colon and rectum
- Vekluri (remdesivir) C
  Treatment of coronavirus disease 2019 (COVID-19)

Negative CHMP opinions on new medicines

- Turalio (*pexidartinib*)
  Intended for the treatment of tenosynovial giant cell tumour (a non-cancerous growth around the joints)

Safety update

- Direct healthcare professional communication (DHPC): Myalepta (metreleptin): inconsistencies in the package leaflet - quality defect
- Direct healthcare professional communication (DHPC): Ondexxya (andexanet alfa): Commercial anti-FXa activity assays are unsuitable for measuring anti-FXa activity following administration of andexanet alfa - safety signal
- Direct healthcare professional communication (DHPC): Suboxone sublingual tablets (buprenorphine / naloxone): inaccurate Braille information on the carton for HU/CZ/SK pack - quality defect

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

- Abiraterone tablets 250 mg and 500 mg product-specific bioequivalence guidance
- Levothyroxine tablets 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg (and additional strengths) and 200 mcg product-specific bioequivalence guidance

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 2020
- 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: June 2020
- PRAC recommendations on safety signals
- PCWP & HCPWP: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint - Virtual meeting - 24 June 2020 - Agenda

COVID-19

- First COVID-19 treatment recommended for EU authorisation
- Global regulators discuss data requirements for phase 3 trials of COVID-19 vaccines
- Patients' and healthcare professionals' organisations updated on EMA's response to COVID-19
- European Commission, EMA and FDA agree new priorities to strengthen their collaboration on medicines
- EMA and Korean Ministry of Food and Drug Safety to share confidential COVID-19 information
- Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19 – update #4
- EMA receives application for conditional authorisation of first COVID-19 treatment in the EU
- EU actions to support availability of medicines during COVID-19 pandemic – update #7
- Leaftlet: Infographic - Fast-track procedures for treatments and vaccines for COVID-19
- International regulators stress value of safe and effective vaccines

Other publications

- Emer Cooke nominated as new EMA Executive Director
- 108th Management Board meeting: 11 June 2020, Amsterdam, the Netherlands - Highlights
- Annual report 2019
- European regulators make recommendations drawing on lessons learnt from presence of nitrosamines in sartan medicines
- Academia developing medicines for rare diseases to receive free EMA scientific advice

Events

- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint - Virtual meeting - 24 June 2020 - Agenda

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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