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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

- Fluad Tetra *(influenza vaccine (surface antigen, inactivated, adjuvanted))*
  Vaccine against influenza virus
- Pretomanid FGK (*pretomanid*)
  Treatment of tubercolosis

Safety update

- Review of fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - PRAC recommendations on screening methods to identify patients at risk of severe side effects (Art.31)
  Treatment of various skin conditions and fungal infections
- Review of fosfomycin-containing medicinal products - CHMP Opinion (Art.31)
  Treatment of a range of bacterial infections

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

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

New medicines authorised

- Ivozall (*clofarabine*) generic of Evoltra
  Treatment of acute lymphoblastic leukaemia (blood cancer)

New information on authorised medicines

- Adcetris (*brentuximab vedotin*)- new indication
  Treatment of Hodgkin's lymphoma (a type of blood cancer)

Withdrawal of applications for new medicines

- Doxorubicin Hydrochloride Tillomed (*doxorubicin*)
  Intended for treatment of breast and ovarian cancer, multiple myeloma and AIDS-related Kaposi's sarcoma
- Rituximab Mabion (*rituximab*)
  Intended for treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (blood cancers) and certain inflammatory diseases (severe rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis)

Safety update

- Review of cyproterone-containing medicinal products - CMDh Position (meningioma risk with cyproterone medicines) (Art. 31)
  Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne
- Review of Ifosfamide - review started (Art. 31)
  Treatment of different types of cancers, including various solid tumours and blood cancers such as lymphomas (cancer of white blood cells)
- Review of leuprorelin-containing depot medicinal products - under evaluation (Art. 31)
  Treatment of prostate cancer, breast cancer and conditions that affect the female reproductive system

Cardiovascular system

Other information

- No change is needed in use of direct oral anticoagulants following EMA-funded study

Dermatology

Positive CHMP opinions on new medicines

- Nepexto (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on the skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and ankylosing spondylitis (nflammation and pain in the joints of the spine)

Withdrawal of authorised medicines

- Public Statement: Kromeya - Withdrawal of the marketing authorisation in the European Union

Safety update

- Review of fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - PRAC recommendations on screening methods to identify patients at risk of severe side effects (Art.31)
  Treatment of various skin conditions and fungal infections

Gastro-intestinal system

New information on authorised medicines

- Jorveza (*budesonide*) O - extension of indication
  Treatment of eosinophilic oesophagitis (inflammation of the oesophagus, the food-pipe that leads from the mouth to the stomach)

Gynaecology & Obstetrics

Withdrawal of applications for new medicines

- Doxorubicin Hydrochloride Tillomed (*doxorubicin*)
  Intended for treatment of breast and ovarian cancer, multiple myeloma and AIDS-related Kaposi's sarcoma

Safety update

- Review of cyproterone-containing medicinal products - CMDh Position (meningioma risk with cyproterone medicines) (Art. 31)
  Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne
- Review of leuprorelin-containing depot medicinal products - under evaluation Art. 31
  Treatment of prostate cancer, breast cancer and conditions that affect the female reproductive system
- Review of ulipristal acetate - review started (Art 31)
  Treatment for uterine fibrosis
- Direct Healthcare Professional Communication: ulipristal acetate 5 mg for uterine fibroids not to be used during ongoing review of liver injury risk

Haematology

New medicines authorised

- Deferasirox Accord (*deferasirox*) generic of Exjade
  Treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia and other anaemias

Key to symbols used

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

- Ivozall (*clofarabine*) generic of Evoltra
  Treatment of acute lymphoblastic leukaemia (blood cancer)

Withdrawal of applications for new medicines

- Rituximab Mabion (*rituximab*)
  Intended for treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (blood cancers) and certain inflammatory diseases (severe rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis)

Hepatology

Safety update

- Review of ulipristal acetate - review started (Art 31)
  Treatment for uterine fibrosis
- Direct Healthcare Professional Communication: ulipristal acetate 5 mg for uterine fibroids not to be used during ongoing review of liver injury risk

HIV

New information on authorised medicines

- Intelence (*etravirine*) - extension of indication
  Treatment of HIV

Withdrawal of applications for new medicines

- Doxorubicin Hydrochloride Tillomed (*doxorubicin*)
  Intended for treatment of breast and ovarian cancer, multiple myeloma and AIDS-related Kaposi's sarcoma

Hormone system

Safety update

- Review of cyproterone-containing medicinal products - CMDh Position (meningioma risk with cyproterone medicines) (Art. 31)
  Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne
- Review of leuprorelin-containing depot medicinal products - under evaluation (Art. 31)
  Treatment of prostate cancer, breast cancer and conditions that affect the female reproductive system

Immune system

Positive CHMP opinions on new medicines

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

- Nepexto (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis

New medicines authorised

- Rinvoq (*upadacitinib*)
  Treatment of rheumatoid arthritis (inflammation in joints)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on the skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and ankylosing spondylitis (nflammation and pain in the joints of the spine)
- Kineret (*anakinra*) - new indication
  Treatment of Familial Mediterranean Fever
- Ruconest (*conestat alfa*) - extension of indication
  Treatment of acute angioedema in patients with hereditary angioedema (swelling beneath the skin)

Arbitration procedures

- Budesonide SUN (*budesonide*) - outcome
  Intended to treat Asthma

Withdrawal of authorised medicines

- Public Statement: Kromeya - Withdrawal of the marketing authorisation in the European Union

Metabolic disorders

New medicines authorised

- Givlaari (*givosiran*)
  Treatment of acute hepatic porphyria (a rare genetic condition in which patients lack certain enzymes needed to produce haem, a basic structure of haemoglobin)

Musculoskeletal system

Positive CHMP opinions on new medicines

- Zolgensma (*onasemnogene abeparvovec*)
  Treatment of babies and young children who have a rare, serious inherited condition called spinal muscular atrophy

Nervous system

Positive CHMP opinions on new medicines

- Zeposia (*ozanimod*)
  Treatment of relapsing remitting multiple sclerosis
- Zolgensma (*onasemnogene abeparvovec*)
  Treatment of babies and young children who have a rare, serious inherited condition called spinal muscular atrophy

Safety update

- Review of methocarbamol / paracetamol-containing medicinal products - CHMP Opinion (Art. 31)
  Treatment of painful muscle spasms

Ophthalmology

Withdrawal of authorised medicines

- Public Statement: Kromeya - Withdrawal of the marketing authorisation in the European Union

Respiratory system

Positive CHMP opinions on new medicines

- Atectura Breezhaler (*indacaterol / mometasone furoate*)
  Treatment of asthma
- Bemrist Breezhaler (*indacaterol / mometasone furoate*)
  Treatment of asthma
- Pretomanid FGK (*pretomanid*)
  Treatment of tubercolosis

Arbitration procedures

- Budesonide SUN (*budesonide*) - outcome
  Intended for treatment of asthma

Rheumatology

New medicines authorised

- Rinvoq (*upadacitinib*)
  Treatment of rheumatoid arthritis (inflammation in joints)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on the skin), psoriatic arthritis (inflammation of the joints associated with psoriasis) and ankylosing spondylitis (nflammation and pain in the joints of the spine)
- Kineret (*anakinra*) - new indication
  Treatment of Familial Mediterranean Fever

Withdrawal of authorised medicines

- Public Statement: Kromeya - Withdrawal of the marketing authorisation in the European Union
  Treatment of various inflammatory conditions

Vaccines

Positive CHMP opinions on new medicines

- Fluad Tetra (*influenza vaccine (surface antigen, inactivated, adjuvanted)*)
  Vaccine against influenza virus

Other medicines

Safety update

- Review of methocarbamol / paracetamol-containing medicinal products - CHMP Opinion (Art.31)
  Treatment of painful muscle spasms

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Implications of coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials
  Deadline for comments: 25/04/2020

Adopted guidelines

- ICH guideline Q12 on technical and regulatory considerations for pharmaceutical product lifecycle management
- Note on EU implementation of ICH Q12 (guideline on technical and regulatory considerations for pharmaceutical product lifecycle management)
- ICH guideline Q12 on technical and regulatory considerations for pharmaceutical product lifecycle management - annexes

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - February 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: March 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: March 2020
- PRAC recommendations on safety signals

Other publications

- Update on treatments and vaccines against COVID-19 under development
- COVID-19: Beware of falsified medicines from unregistered websites
- EMA advises continued use of medicines for hypertension, heart or kidney disease during COVID-19 pandemic
- EMA gives advice on the use of non-steroidal anti-inflammatories for COVID-19
- Addressing the potential impact of novel coronavirus disease (COVID-19) on medicines supply in the EU
- Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic
- Call to pool research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on COVID-19 treatments
- COVID-19: developers of medicines or vaccines to benefit from free scientific advice
- Global regulators map out data requirements for phase 1 COVID-19 vaccine trials
- COVID-19: EMA meetings with delegates and experts will be held virtually until end April 2020
- EMA to issue electronic certificates for medicines
- Advancing regulatory science in the EU – new strategy adopted
- Update on nitrosamines in EU medicines
- EMA Management Board – highlights of March 2020 meeting
- 106th meeting of the Management Board: 18-19 December 2019, Amsterdam, The Netherlands - Minutes
- Notice to Stakeholders: Withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products
- Orientation guide for Patient Representatives and Healthcare Professionals
- EMA organisational changes come into effect

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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Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

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