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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

- Dovato (*dolutegravir, lamivudine*)
  Treatment of HIV infection

New medicines authorised

- Tobramycin PARI (*tobramycin*)
  Treatment of chronic pulmonary (lung) infections in patients with cystic fibrosis

Withdrawal of authorised medicines

- Silgard (*human papillomavirus vaccine*)
  Protection against conditions caused by specific types of human papillomavirus (HPV)

Safety update

- Review of Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - review started (risk of neutropenia, neurotoxicity, severe diarrhoea and stomatitis)
  Treatment of cancer, various skin conditions and fungal infections

Key to symbols used

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

- Review of Fosfomycin containing medicinal products - review started (risk of increasing resistance to antibiotics)
  Treatment of a range of infections

Cancer

Positive CHMP opinions on new medicines

- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy
- Talzenna (*talazoparib*)
  Treatment of locally advanced or metastatic breast cancer

Withdrawal of authorised medicines

- Silgard (*human papillomavirus vaccine*)
  Protection against conditions caused by specific types of human papillomavirus (HPV)

Negative CHMP opinions on new medicines

- Cabazitaxel Teva (*cabazitaxel*)
  Treatment of prostate cancer

Safety update

- Review of Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - review started (risk of neutropenia, neurotoxicity, severe diarrhoea and stomatitis)
  Treatment of cancer, various skin conditions and fungal infections
- Review of Lartruvo (*olaratumab*) O C - CHMP Opinion (CHMP recommends revocation of marketing authorisation)
  Treatment of advanced soft tissue sarcoma (cancer that affects the soft, supportive tissues of the body such as muscles, blood vessels and fat tissue)

Cardiovascular system

Positive CHMP opinions on new medicines

- Ambrisentan Mylan (*ambrisentan*)
  Treatment of pulmonary arterial hypertension (PAH)

Dermatology

Positive CHMP opinions on new medicines

- Libtayo (*cemiplimab*)
  Treatment of advanced cutaneous squamous cell carcinoma, a type of skin cancer
- Nuceiva (*botulinum toxin type a*)
  Temporary improvement of vertical lines between the eyebrows when psychological impact on the person

New medicines authorised

- Idacio (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders
- Kromeya (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders

Safety update

- Review of Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - review started (risk of neutropenia, neurotoxicity, severe diarrhoea and stomatitis)
  Treatment of cancer, various skin conditions and fungal infections

Gastro-intestinal system

New medicines authorised

- Idacio (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders
- Kromeya (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders

Gynaecology & Obstetrics

Withdrawal of authorised medicines

- Silgard (*human papillomavirus vaccine*)
  Protection against conditions caused by specific types of human papillomavirus (HPV)

Safety update

- Review of Estradiol containing (0.01% w/w) medicinal products - review started (risk of estradiol being absorbed systemically)
  Treating vaginal atrophy through menopause

Haematology

Positive CHMP opinions on new medicines

- Doptelet (*avatrombopag*)
  Treatment of thrombocytopenia (low levels of platelets, a component that helps blood clot) in patients with liver disease
- Esperoct (*turoctocog alfa pegol*)
  Treatment and prevention of bleeding
- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy
- Ultomiris (*ravulizumab*)
  Treatment of paroxysmal nocturnal haemoglobinuria (PNH)

- Xromi (*hydroxycarbamide*)
  Prevention of vaso-occlusive complications of sickle cell disease

HIV

Positive CHMP opinions on new medicines

- Dovato (*dolutegravir, lamivudine*)
  Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy

New medicines authorised

- Idacio (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders
- Kromeya (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders

Withdrawal of authorised medicines

- Silgard (*human papillomavirus vaccine*)
  Protection against conditions caused by specific types of human papillomavirus (HPV)

Safety update

- Review of Fosfomycin containing medicinal products - review started (risk of increasing resistance to antibiotics)
  Treatment of a range of infections

Nervous system

Positive CHMP opinions on new medicines

- Striascan (*ioflupane (123i)*)
  Intended for the diagnosis of Parkinson's disease and other related diseases and dementia

New medicines authorised

- Ajovy (*fremanezumab*)
  Prevention of migraine

Safety update

- Review of Lemtrada (*alemtuzumab*) - review started (risks of body's defence system not working properly and problems with the heart and blood vessels)
  Treatment of multiple sclerosis

Ophthalmology

New medicines authorised

- Idacio (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders
- Kromeya (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders

Respiratory system

Positive CHMP opinions on new medicines

- Ambrisentan Mylan (*ambrisentan*)
  Treatment of pulmonary arterial hypertension (PAH)
- Temybric Ellipta (*fluticasone furoate / umeclidinium / vilanterol*)
  Treatment of chronic obstructive pulmonary disease

New medicines authorised

- Tobramycin PARI (*tobramycin*)
  Treatment of chronic pulmonary (lung) infections in patients with cystic fibrosis

Rheumatology

New medicines authorised

- Idacio (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders
- Kromeya (*adalimumab*) *biosimilar of Humira*
  Treatment of various inflammatory and autoimmune disorders

Vaccines

Withdrawal of authorised medicines

- Silgard (*human papillomavirus vaccine*)
  Protection against conditions caused by specific types of human papillomavirus (HPV)

Other medicines

Positive CHMP opinions on new medicines

- Sixmo (*buprenorphine*)
  Substitution treatment of opioid dependence

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

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Other information

Guidelines

Adopted guidelines

- Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract - Revision 1

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - March 2019
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: April 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 recommendations on safety signals

Other publications

- European authorities working to avoid shortages of medicines due to Brexit – Questions and answers
- European Medicines Agency policy on publication of clinical data for medicinal products for human use
- Questions and answers on the European Medicines Agency policy on publication of clinical data for medicinal products for human use
- The role of regulators in establishing added benefit of novel therapies
- EU recommendations for 2019/2020 seasonal flu vaccine composition and Update of EU recommendations for 2019/2020 seasonal flu vaccine composition
- Questions and answers on the impact of mutual recognition agreement between the European Union and the United States as of 30 April 2019
- EMA tracking tool: relocation to Amsterdam - Main milestones
- Decision of the Executive Director on rules governing the secondment of national experts to the European Medicines Agency
- Regulatory information – 1.7% increase of fees from 1 April 2019
- European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members

Key to symbols used

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

- European Medicines Agency's privacy statement for selection and recruitment

Events

- European Immunization Week 2019: statement by Executive Director Guido Rasi
- EMA regrets to learn of the passing of Dr Eric Abadie, former CHMP Chair

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

In particular, you may be interested in these links:

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European Medicines Agency

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