

# HUMAN MEDICINE

Key information for patients, consumers and healthcare professionals Published monthly by the European Medicines Agency



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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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

# Information on medicines

# Antivirals/anti-infectives

#### Positive CHMP opinions on new medicines

<u>Dovato</u> (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



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

Treatment of cancer, various skin conditions and fungal infections

Review of <u>Lartruvo</u> (olaratumab) - 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

<u>Libtayo</u> (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
- <u>Ultomiris</u> (ravulizumab)

Treatment of paroxysmal nocturnal haemoglobinuria (PNH)

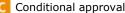












Xromi (hydroxycarbamide)

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
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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)
- <u>Temybric Ellipta</u> (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













# 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

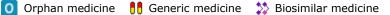
## Other publications

- 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**





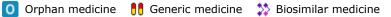




European Medicines Agency's privacy statement for selection and recruitment

## **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 0

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** E

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.

#### Visit our website

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http://www.ema.europa.eu

In particular, you may be interested in these links:

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If you have a question relating to the content of this Newsletter, please send it via <u>www.ema.europa.eu/contact</u>

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