

# HUMAN MEDICINES

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.

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# Information on medicines

## COVID-19 vaccines and treatments

#### Ongoing evaluations

- COVID-19 treatments: under evaluation
- EMA starts review of VIR-7831 for treating patients with COVID-19
- EMA starts evaluating use of Olumiant in hospitalised COVID-19 patients requiring supplemental oxygen

#### Safety update

- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 22 April 2021
- COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

#### Key to symbols used

AstraZeneca's COVID-19 vaccine: EMA to provide further context on risk of very rare blood clots with low blood platelets

#### **Direct Healthcare Professional Communication (DHPC)**

- Direct healthcare professional communication (DHPC): COVID-19 Vaccine Janssen: link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia
- Direct healthcare professional communication (DHPC): Vaxzevria (previously COVID-19 Vaccine AstraZeneca): link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia

## Antivirals/anti-infectives

#### New information on authorised medicines

Maviret (glecaprevir / pibrentasvir) - extension of indication Treatment of chronic hepatitis C in children aged 3 years and older

### Cancer

#### Positive CHMP opinions on new medicines

- Abiraterone Krka (abiraterone acetate) generic of Zytiga Treatment of prostate cancer
- Onureq (azacitidine) Treatment of acute myeloid leukemia (blood cancer)

#### New medicines authorised

Oyavas (bevacizumab) \*\*

Treatment of colon or rectum cancer, breast cancer, non-small cell lung cancer, renal cell cancer, ovarian cancer, fallopian tube cancer, primary peritoneal cancer and cervical cancer

Sunitinib Accord (sunitinib) generic of Sutent Treatment of metastatic cancers of the breast, kidneys and pancreas

#### New information on authorised medicines

- Opdivo (nivolumab) new indication Treatment of pleural mesothelioma (cancer of the lung lining)
- Tagrisso (osimertinib) new indication Treatment of non-small cell lung cancer
- Venclyxto (venetoclax) new indication Treatment of acute myeloid leukaemia (blood cancer)
- Yervoy (ipilimumab) new indication Treatment of pleural mesothelioma (cancer of the lung lining)

# Cardiovascular system

#### Positive CHMP opinions on new medicines

Evkeeza (evinacumab)

Treatment of high levels of cholesterol (a type of fat in the blood)

#### New medicines authorised

Vazkepa (icosapent ethyl)

Prevention of cardiovascular events, such as heart attack and stroke

## Dermatology (skin conditions)

#### Positive CHMP opinions on new medicines

Adtralza (tralokinumab)

Treatment of atopic dermatitis (inflammation of the skin)

# Haematology (blood conditions)

#### Positive CHMP opinions on new medicines

Onureq (azacitidine)

Treatment of acute myeloid leukemia (blood cancer)

#### New information on authorised medicines

Venclyxto (venetoclax) - new indication

Treatment of acute myeloid leukaemia (blood cancer)

## Immune system

#### Positive CHMP opinions on new medicines

Enspryng (satralizumab)

Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)

Adtralza (tralokinumab)

Treatment of atopic dermatitis (inflammation of the skin)

Jayempi (azathioprine)

Prevention of transplant rejection

#### New medicines authorised

BroPair Spiromax and Seffalair Spiromax (salmeterol / fluticasone propionate)

Treatment of asthma

#### New information on authorised medicines

BiResp Spiromax and DuoResp Spiromax (budesonide / formoterol) - extension of indication Treatment of asthma in adolescents (12 years and older)



Nulojix (belatacept) - extension of indication Prevention of kidney transplant rejection

## Metabolic disorders

#### New medicines authorised

Sogroya (somapacitan) Treatment of growth hormone deficiency

# Nephrology (kidney conditions)

Nulojix (belatacept) - extension of indication Prevention of kidney transplant rejection

## Nervous system

#### Positive CHMP opinions on new medicines

- Enspryng (satralizumab) Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)
- Koselugo (selumetinib) Treatment of children with neurofibromatosis (disorder of the nervous system affecting development of nerve cell tissues)
- Celsunax (ioflupane (123I)) Diagnostic agent for parkinsonian syndromes and dementia

#### New medicines authorised

Ontozry (cenobamate) Treatment of epilepsy

#### New information on authorised medicines

Aubagio (teriflunomide) - extension of indication Treatment of multiple sclerosis

# Ophthalmology (eye conditions)

#### Positive CHMP opinions on new medicines

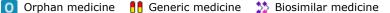
Enspryng (satralizumab) Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)

#### **Direct Healthcare Professional Communication (DHPC)**

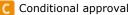
Direct healthcare professional communication (DHPC): Eylea 40 mg/mL (aflibercept solution for intravitreal injection): Higher risk of intraocular pressure increase with the pre-filled syringe













# Respiratory system

#### New medicines authorised

BroPair Spiromax and Seffalair Spiromax (salmeterol / fluticasone propionate) Treatment of asthma

#### New information on authorised medicines

- BiResp Spiromax and DuoResp Spiromax (budesonide / formoterol) extension of indication Treatment of asthma in adolescents (12 years and older)
- Opdivo (nivolumab) new indication Treatment of pleural mesothelioma (cancer of the lung lining)
- Tagrisso (osimertinib) new indication Treatment of non-small cell lung cancer
- Yervoy (ipilimumab) new indication Treatment of pleural mesothelioma (cancer of the lung lining)

## Other medicines

#### New medicines authorised

Byfavo (remimazolam) Used for sedation

# Medicines under additional monitoring

Updated list of medicines under additional monitoring

# Other information

# Guidelines

#### Adopted guidelines

Dasatinib product-specific bioequivalence quidance

## Other scientific recommendations

Classification of advanced therapy medicinal products (ATMs)





## Scientific committee and working party activities

- Medicinal products for human use: monthly figures March 2021
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- CHMP applications for new human medicines: April 2021
- 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

## COVID-19

- EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe
- Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from BioNTech/Pfizer and **Moderna**
- AstraZeneca's COVID-19 vaccine: benefits and risks in context

# Other publications

- Academia collaboration matrix action plan 2021-2023
- Clinical Trials Information System reaches major milestone towards go-live and application of the **Clinical Trial Regulation**
- Stakeholder engagement highlights 2020

## **Events**

- EMA press briefing to update on analysis of data on Vaxzevria, the COVID-19 vaccine from AstraZeneca
  - Virtual meeting 23 April 2021
- Risk management information day 2021
  - Virtual meeting 15 June 2021

Key to symbols used

## 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 <u>CHMP</u> to give opinions, in co-operation with the World Health Organization, on <u>medicinal products</u> 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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