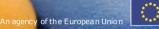


# HUMAN MEDICINES

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.

To receive each new issue of the newsletter, please dick 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 quide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

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# Information on medicines

## COVID-19 vaccines and treatments

#### Ongoing evaluations

- EMA evaluating the use of COVID-19 Vaccine Moderna in young people aged 12 to 17
- COVID-19 Vaccine Janssen: authorities in EU take steps to safeguard vaccine quality
- COVID-19 vaccines: update on ongoing evaluation of myocarditis and pericarditis
- Vaxzevria: EMA advises against use in people with history of capillary leak syndrome

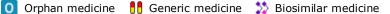
#### Safety update

- COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 18 June 2021
- COVID-19 vaccine safety update for Comirnaty: 18 June 2021
- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 18 June 2021

#### Key to symbols used

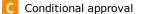














Explanation of terms used 8

COVID-19 vaccine safety update for Spikevax (previously COVID-19 Vaccine Moderna): 18 June 2021

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

- Risk of thrombosis in combination with thrombocytopenia Updated information
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca): contraindication in individuals with previous capillary leak syndrome

## Cancer

#### Positive CHMP opinions on new medicines

- Abecma (idecabtagene vicleucel)
  - Treatment of multiple myeloma (cancer of the bone marrow)
- Abiraterone Mylan (abiraterone acetate) generic of Zytiga Treatment of metastatic prostate cancer
- Minjuvi (tafasitamab)
  - Treatment of relapsed or refractory diffuse large B-cell lymphoma (blood cancer)

#### New medicines authorised

- Inrebic (fedratinib)
  - Treatment of myelofibrosis (a rare form of blood cancer)
- Onureq (azacitidine)
  - Treatment of acute myeloid leukaemia (a cancer of white blood cells)
- Nexpovio (selinexor)
  - Treatment of multiple myeloma (a cancer of the bone marrow)
- Phelinun (melphalan)
  - Treatment of different types of cancer

#### New information on authorised medicines

Opdivo (nivolumab) - new indication

Treatment of several types of cancer

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

Venclyxto - (venetoclax) film coated tablets: Updated recommendations on tumour lysis syndrome

# Dermatology (skin conditions)

#### Positive CHMP opinions on new medicines

Bimzelx (bimekizumab)

Treatment of plaque psoriasis (scaly patches on skin)

#### New medicines authorised

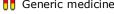
Adtralza (tralokinumab)

Treatment of moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry)

### Key to symbols used













## **Diabetes**

#### New information on authorised medicines

Edistride and Forxiga (dapagliflozin) - new indication Treatment of diabetes mellitus, type 1 and 2

## Gastro-intestinal system

#### Negative CHMP opinions on new medicines

Flynpovi (eflornithine / sulindac) Intended for the treatment of familial adenomatous polyposis (growths in the large intestine that can

## Haematology (blood conditions)

#### Positive CHMP opinions on new medicines

**Evrenzo** (roxadustat) Treatment of anaemia symptoms in patients with chronic kidney disease

#### New medicines authorised

- Inrebic (fedratinib) Treatment of myelofibrosis (a rare form of blood cancer)
- Onureg (azacitidine) Treatment of acute myeloid leukaemia, a cancer of white blood cells

## Hormone system

#### New medicines authorised

- Drovelis (estetrol /drospirenone) Combined contraceptive pill
- Lydisilka (estetrol/drospirenone) Combined contraceptive pill

## Immune system

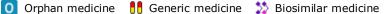
#### New medicines authorised

- Enspryng (satralizumab) Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders that affect mainly the optic nerve which connects the eye to the brain, and the spinal cord)
- Orladeyo (berotralstat) Treatment of hereditary angioedema (swelling beneath the skin)

#### Key to symbols used













#### New information on authorised medicines

- Rinvog (upadacitinib) new indication Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints)
- Xeljanz (tofacitinib) new indication Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints) and psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints)

## Metabolic disorders

#### New information on authorised medicines

Galafold (migalastat) - extension of indication Treatment of Fabry Disease (a rare lysosomal storage disorder)

# Nephrology (kidney conditions)

#### Positive CHMP opinions on new medicines

**Evrenzo** (roxadustat) Treatment of anaemia symptoms in patients with chronic kidney disease

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

INOmax (nitric oxide): Difficulties in closing the cylinder valves after use: precautions for use when disconnecting the cylinders from pressure regulators

## Nervous system

#### Positive CHMP opinions on new medicines

Fingolimod Mylan (fingolimod) generic of Gilenya Treatment of multiple sclerosis

#### New medicines authorised

Ponvory (ponesimod) Treatment of multiple sclerosis

#### Safety update

Review of Stresam (etifoxine) - review started - Art.31 Treatment of anxiety disorders

# Ophthalmology (eye conditions)

#### Positive CHMP opinions on new medicines

Byooviz (ranibizumab) \*\* Treatment of eye problems caused by damage to the retina

## Respiratory system

#### Withdrawal of applications for extension of indication

Esbriet (pirfenidone)

Treatment of idiopathic pulmonary fibrosis (fibrous scar tissue which forms in the lungs, causing persistent cough, frequent lung infections and severe shortness of breath)

## Rheumatology (immune and inflammatory conditions)

#### New information on authorised medicines

- Rinvog (upadacitinib) new indication Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints)
- Xelianz (tofacitinib) new indication Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints) and psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints)

## Other medicines

#### Positive CHMP opinions on new medicines

Voxzogo (vosoritide) Treatment of achondroplasia, a condition that impairs bone growth and causes dwarfism.

#### New medicines authorised

Efmody (hydrocortisone) Treatment of an inherited condition called congenital adrenal hyperplasia

# Medicines under additional monitoring

Updated list of medicines under additional monitoring

# Other information

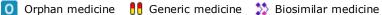
## Guidelines

#### Guidelines open for consultation

- ICH quideline S12 on nonclinical biodistribution considerations for gene therapy products Step 2b Deadline for comments: 24 October 2021
- Concept paper for the revision of residues guidelines to align with the definitions for withdrawal periods provided in Regulation (EU) 2019/6 Deadline for comments: 31 July 2021

Key to symbols used











Draft guideline on data requirements for vaccine antigen master files (VAMF)

Deadline for comments: 30 September 2021

#### **Adopted guidelines**

- Deferasirox, dispersible tablets (125 mg, 250 mg and 500 mg), film-coated tablets (90 mg, 180 mg, and 360 mg) and granules (90 mg, 180 mg and 360 mg) product-specific bioequivalence guidance
- ICH guideline work to advance Patient Focused Drug Development (PFDD)
- ICH quideline E6 on good clinical practice Draft ICH E6 principles

## Scientific committee and working party activities

- Medicinal products for human use: monthly figures May 2021
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- CHMP applications for new human medicines: June 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 statistics: June 2021
- PRAC recommendations on safety signals
- PCWP and HCPWP joint virtual meeting 1 and 2 June 2021- Minutes

## COVID-19

- Additional manufacturing site for COVID-19 Vaccine Janssen
- Additional manufacturing capacity for Moderna's COVID-19 vaccine
- Additional manufacturing capacity for BioNTech/Pfizer's COVID-19 vaccine
- EMA raises awareness of clinical care recommendations to manage suspected thrombosis with thrombocytopenia syndrome
- Advancing international collaboration on COVID-19 real-world evidence and observational studies
- International regulators and WHO address need to boost COVID-19 vaccine confidence



# Other publications

- Deputy Executive Director Noël Wathion retires after 25 years of service
- Highlights of Management Board: June 2021 meeting
- EMA and EUnetHTA take stock of their cooperation
- EU regulators develop recommendations to forecast demand of medicines
- Annual report 2020 published
- Use of antibiotics in animals is decreasing
- Update of EU recommendations for 2021-2022 seasonal flu vaccine composition
- Success rate for marketing authorisation applications from SMEs doubles between 2016 and 2020
- Strengthening Training of Academia in Regulatory Science (STARS) overview
- Report on budgetary and financial management: financial year 2020
- Report on budgetary and financial management: financial year 2019
- Report on budgetary and financial management: financial year 2018

## **Events**

- EMA regular press briefing on COVID-19 Virtual meeting 1 July 2021
- EMA regular press briefing on COVID-19 Virtual meeting 17 June 2021
- Sixth industry stakeholder platform on research and development support Virtual meeting 4 June
- ePI information workshop and exploratory workshop Virtual meeting From 5 July to 8 July 2021 -Agenda 5 July - Agenda 6 - 8 July
- Sixth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines - virtual meeting - 30 June 2021 - 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 <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

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

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