128 **Issue 128**
November 2019

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

Antivirals/anti-infectives	1
Cancer	2
Cardiovascular system	2
Dermatology	2
Diabetes	2
Gastro-intestinal system	3
Gynaecology & Obstetrics	3
Haematology	3
HIV	3
Immune system	3
Musculoskeletal system	4
Nervous system	4
Respiratory system	4
Rheumatology	5
Vaccines	5
Other medicines	5
Medicines under additional monitoring	5
Scientific committee and working party activities	5
Other publications	6
Events	6
Explanation of terms used	7

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

- Ervebo (*Ebola Zaire Vaccine [rVSVΔG-ZEBOV-GP, live]*)
  Prevention of Zaire Ebola virus disease
- Quofenix (*delafloxacin*)
  Treatment of bacterial infections of the skin and skin structures

New medicines authorised

- Trogarzo (*ibalizumab*)
  Treatment of HIV

New information on authorised medicines

- Evotaz (*atazanavir / cobicistat*) - new contraindication
  Treatment of HIV

Key to symbols used

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

Withdrawal of applications for new medicines

- Nuzyra (*omadacycline*)
  Intended for the treatment of pneumonia (lung infection) and bacterial infections of the skin and skin structures

Cancer

New medicines authorised

- Vitrakvi (*larotrectinib*) C
  Treatment of solid tumours with a specific gene mutation

New information on authorised medicines

- Darzalex (*daratumumab*) - extension of existing indication
  Treatment of multiple myeloma (cancer of the bone marrow)
- Keytruda (*pembrolizumab*) - new indication
  Treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC)

Negative CHMP opinions on new medicines

- Vanflyta (*quizartinib*) O
  Intended for the treatment of acute myeloid leukaemia (blood cancer)

Cardiovascular system

New medicines authorised

- Giapreza (*angiotensin II*)
  Treatment of dangerously low blood pressure (a condition known as shock)

Dermatology

Positive CHMP opinions on new medicines

- Quofenix (*delafloxacin*)
  Treatment of bacterial infections of the skin and skin structures

New medicines authorised

- Nuceiva (*botulinum toxin type a*)
  Temporary improvement of vertical lines between the eyebrows

Diabetes

Positive CHMP opinions on new medicines

- Baqsimi (*glucagon*)
  Treatment of severe hypoglycaemia (low blood sugar) in patients with diabetes

New information on authorised medicines

- Toujeo (previously Optisulin) (*insulin glargine*) - change of existing indication
  Treatment of diabetes mellitus

Gastro-intestinal system

Safety update

- Review Xeljanz (*tofacitinib*) - PRAC recommendation (restrictions in patients at high risk of blood clots)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Gynaecology & Obstetrics

Safety update

- Review of estradiol containing medicinal products (0.01% w/w) - PRAC recommendation (Four-week limit for use of high-strength estradiol creams)
  Treatment of vaginal atrophy

Haematology

New medicines authorised

- Deferasirox Mylan (*deferasirox*) generic of Exjade
  Treatment of chronic iron overload due to blood transfusions in patients with blood disorders

Withdrawal of applications for new medicines

- Xyndari (*glutamine*)
  Intended for the treatment of sickle cell disease (genetic blood disorder)

HIV

New medicines authorised

- Trogarzo (*ibalizumab*)
  Treatment of HIV

New information on authorised medicines

- Evotaz (*atazanavir / cobicistat*) - new contraindication
  Treatment of HIV

Immune system

Positive CHMP opinions on new medicines

- Pegfilgrastim Mundipharma (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of a type of white blood cell) due to chemotherapy

Key to symbols used

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

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

Safety update

- Review Xeljanz (*tofacitinib*) - PRAC recommendation (restrictions in patients at high risk of blood clots)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Musculoskeletal system

Withdrawal of applications for new medicines

- Ekesivy (*diclofenamide*) O
  Intended for the treatment of muscle disorders called periodic paralysis

Nervous system

Positive CHMP opinions on new medicines

- Spravato (*esketamine*)
  Treatment of major depressive disorder

New medicines authorised

- Epidyolex (*cannabidiol*) O
  Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS)

Safety update

- Review of Lemtrada (*alemtuzumab*) - PRAC recommendation (restrictions due to risk of immune and circulatory system disorders)
  Treatment of multiple sclerosis

Respiratory system

New information on authorised medicines

- Kalydeco (*ivacaftor*) O new strength and extension of existing indication
  Treatment of cystic fibrosis

Withdrawal of applications for new medicines

- Nuzyra (*omadacycline*)
  Intended for the treatment of pneumonia (lung infection) and bacterial infections of the skin and skin structures

Arbitration procedures

- Flurbiprofen Geiser (*flurbiprofen*) - outcome
  Treatment of sore throat

Rheumatology

Positive CHMP opinions on new medicines

- Evenity (*romosozumab*)
  Treatment of severe postmenopausal osteoporosis (reduction in bone strength)
- Rinvoq (*upadacitinib*)
  Treatment of rheumatoid arthritis (inflammation in joints)

Withdrawal of applications for new medicines

- Ekesivy (*diclofenamide*)
  Intended for the treatment of muscle disorders called periodic paralysis

Safety update

- Review Xeljanz (*tofacitinib*) - PRAC recommendation (restrictions in patients at high risk of blood clots)
  Treatment of rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers in the lining of the gut)

Vaccines

Positive CHMP opinions on new medicines

- Ervebo (*Ebola Zaire Vaccine* [*rVSVΔG-ZEBOV-GP, live*])
  Prevention of Zaire Ebola virus disease

Other medicines

Negative CHMP opinions on new medicines

- Hopveus (*sodium oxybate*)
  Intended for the treatment of alcohol dependence

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2019
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights

Key to symbols used

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

- CHMP - applications for new human medicines: October 2019
- 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: November 2019
- PRAC recommendations on safety signals

Other publications

- Management Board meeting: 3 October 2019 - Highlights
- Management Board meeting: 12-13 June 2019 - Minutes
- EMA tracking tool: relocation to Amsterdam - Main milestones (updated)
- First vaccine to protect against Ebola
- Biosimilars in the EU - Information guide for healthcare professionals - available in 23 official EU languages
- The role of members representing patients' and healthcare professionals' organisations on EMA scientific committees
- Enhancing consistency in wording of therapeutic indications to support healthcare decision-making
- European countries increase commitment to responsible antibiotic use in animals
- How to ensure that novel analytic methods are fit for decision-making
- Dialogue with Chinese authorities on medicine regulation
- EMA/EUnetHTA meeting - 4 July 2019 - Minutes
- PCWP meeting - 24 September 2019 - Meeting documents
- HCPWP meeting - 24 September 2019 - Meeting documents
- EMA Joint PCWP and HCPWP meeting - 25 September 2019 - Meeting documents

Events

- Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for human medicines) - 18-19 November 2019
- Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features - 29 November 2019

Key to symbols used

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

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.

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:

About us

Patients and carers

Healthcare professionals

European public assessment reports

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

European Medicines Agency

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Website www.ema.europa.eu **Telephone** +31 (0)88 871 6000

An agency of the European Union