129 Issue 129
December 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

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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

- Ervebo (*rVSVΔG-ZEBOV-GP*)
  Protection against Ebola virus disease

Cancer

Positive CHMP opinions on new medicines

- Polivy (*polatuzumab vedotin*) O
  Treatment of diffuse large B-cell lymphoma (DLBCL), a type of blood cancer, in combination with bendamustine and rituximab

New medicines authorised

- Arsenic trioxide Accord (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (APL), a rare form of leukaemia (cancer of the white blood cells)

Key to symbols used

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

- Bortezomib Fresenius Kabi (*bortezomib*)
  Treatment of multiple myeloma, a type of blood cancer
- Ivozall (*clofarabine*)
  Treatment of acute lymphoblastic leukaemia (ALL), a cancer of the lymphocytes (type of white blood cell)
- Xospata (*gilteritinib*)
  Treatment of acute myeloid leukaemia (AML), a type of blood cancer

New information on authorised medicines

- Kadcyla (*trastuzumab emtansine*) - extension of indication
  Treatment of early breast cancer (EBC)
- Revlimid (*lenalidomide*) - new indication
  Treatment of follicular lymphoma and multiple myeloma (types of blood cancer)

Withdrawal of applications for new medicines

- Luxceptar (*viable T-cells*)
  Intended for the treatment of patients with blood cancers who are receiving a type of blood stem cell transplant

Safety update

- Review of cyproterone-containing medicinal products - review started (risk of meningioma) Intended
  Treatment of a range of conditions, including excessive hair growth, prostate cancer and acne, and use in hormone replacement therapy

Cardiovascular system

Positive CHMP opinions on new medicines

- Clopidogrel/Acetylsalicylic acid Mylan (*clopidogrel/acetylsalicylic acid*)
  Secondary prevention of atherothrombotic events (problems caused by blood clots and hardening of the arteries)

Safety update

- Review of Xeljanz (*tofacitinib*) - CHMP Opinion (to be used with caution in patients at high risk of blood clots)
  Treatment of rheumatoid arthritis, a disease that causes inflammation of the joints

Gynaecology & Obstetrics

New information on authorised medicines

- Kadcyla (*trastuzumab emtansine*) - extension of indication
  Treatment of early breast cancer (EBC)

Haematology

Positive CHMP opinions on new medicines

- Clopidogrel/Acetylsalicylic acid Mylan (*clopidogrel/acetylsalicylic acid*)
  Secondary prevention of atherothrombotic events (problems caused by blood clots and hardening of the arteries)
- Deferasirox Accord (*deferasirox*)
  Treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia and other anaemias
- Polivy (*polatuzumab vedotin*)
  Treatment of diffuse large B-cell lymphoma (DLBCL), a type of blood cancer, in combination with bendamustine and rituximab
- Tavlesse (*fostamatinib*)
  Treatment of primary immune thrombocytopenia (ITP), a disorder characterised by destruction of platelets and impaired platelet production

New medicines authorised

- Arsenic trioxide Accord (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (APL), a rare form of leukaemia (cancer of the white blood cells)
- Bortezomib Fresenius Kabi (*bortezomib*)
  Treatment of multiple myeloma, a type of blood cancer
- Ivozall (*clofarabine*)
  Treatment of acute lymphoblastic leukaemia (ALL), a cancer of the lymphocytes (type of white blood cell)
- Xospata (*gilteritinib*)
  Treatment of acute myeloid leukaemia (AML), a type of blood cancer

New information on authorised medicines

- Revlimid (*lenalidomide*) - new indication
  Treatment of follicular lymphoma and multiple myeloma (types of blood cancer)

Withdrawal of applications for new medicines

- Luxceptar (*viable T-cells*)
  Intended for the treatment of patients with blood cancers who are receiving a type of blood stem cell transplant

Hormone system

Positive CHMP opinions on new medicines

- Isturisa (*osilodrostat*)
  Treatment of the Cushing's syndrome

Safety update

- Review of cyproterone-containing medicinal products - review started (risk of meningioma)
  Treatment of a range of conditions, including excessive hair growth, prostate cancer and acne, and use in hormone replacement therapy

Immune system

Positive CHMP opinions on new medicines

- Tavlesse (*fostamatinib*)
  Treatment of primary immune thrombocytopenia (ITP), a disorder characterised by destruction of platelets and impaired platelet production

Nervous system

Positive CHMP opinions on new medicines

- Mayzent (*siponimod*)
  Treatment of secondary progressive multiple sclerosis (SPMS), a condition that affects the nerves

Safety update

- Review of Lemtrada (*alemtuzumab*) - CHMP Opinion (restriction of its use due to reports of rare but serious side effects)
  Treatment of multiple sclerosis, a condition that affects the nerves

Respiratory system

Withdrawal of applications for new medicines

- Linhaliq (*ciprofloxacin*)
  Intended for the treatment and prevention of flare-ups of bronchiectasis (damage to the airways) in patients with lung infection caused by *Pseudomonas aeruginosa* bacteria

Withdrawal of applications for extension of indication

- Opsumit (*macitentan*)
  Intended for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH), a condition that causes high blood pressure in the lungs

Rheumatology

Safety update

- Review of Xeljanz (*tofacitinib*) - CHMP Opinion (to be used with caution in patients at high risk of blood clots)
  Treatment of rheumatoid arthritis, a disease that causes inflammation of the joints

Vaccines

Positive CHMP opinions on new medicines

- Ervebo (*rVSVΔG-ZEBOV-GP*)
  Protection against Ebola virus disease

Other medicines

Positive CHMP opinions on new medicines

- Sunosi (*solriamfetol*)
  Treatment of narcolepsy (a sleep disorder that causes a person to fall asleep suddenly and unexpectedly) and obstructive sleep apnoea (interruption of breathing)

New medicines authorised

- Senstend (*lidocaine/prilocaine*)
  Treatment of primary (lifelong) premature ejaculation

Negative CHMP opinions on new medicines

- Hopveus (*sodium oxybate*)
  Treatment of alcohol dependence

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Guideline on Clinical investigation of medicinal products for the treatment of gout

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2019
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: November 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: December 2019
- PRAC recommendations on safety signals
- PCWP Plenary meeting, 24 September - Meeting summary
- HCPWP Plenary meeting, 24 September - Meeting summary
- Joint PCWP HCPWP meeting, 25 September - Meeting summary
- Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations, 20 November 2019

Other publications

- European Medicines Agency mid-year report 2019 from the Executive Director
- Regulators' advice can make a difference for faster patient access to highly innovative therapies
- European Medicines Agency second response to European Ombudsman regarding pre-submission activities
- Leaflet: World AIDS Day – Communities make the difference
- Leaflet: Responsible use of antibiotics: what's your role?
- Leaflet: Ebola vaccine development 2014-2019
- Report: Dashboard created for visual representation of the scoring of the included data sources

Key to symbols used

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

- Report: Inventory of registries
- Report: Bioanalytical Omics - Subgroup report
- Report: Clinical Trial and Imaging - Subgroup report
- Report: Data Analytics - Subgroup report
- Report: Genomics, Genetics, Transcriptomics and Epigenetics - Subgroup report
- Report: Observational data (Real World Data) - Subgroup report
- Report: Social Media and M-Health Data - Subgroup report
- Report: Spontaneous Adverse Drug Reactions - Subgroup report

Events

- Dutch authorities hand over final building to EMA in Amsterdam
- Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for human medicines), 18 and 19 November 2019
- Tripartite meeting held between the EMA, Food and Drug Administration (FDA) and Pharmaceuticals and Medical Devices Agency (PMDA) to discuss regulatory approaches for the evaluation of antibacterial agents, Tokyo, Japan, 24 and 25/09/2019
- Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features, 29 November 2019

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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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 www.ema.europa.eu/contact

European Medicines Agency

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