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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

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

New information on authorised medicines

- Rezolsta (*darunavir / cobicistat*)- extension of indication
  Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)
- Tybost (*cobicistat*) - extension of indication
  Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)

Cancer

Positive CHMP opinions on new medicines

- Arsenic trioxide Mylan (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (APL), a blood cancer
- Azacitidine betapharm (*azacitidine*)
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)

Key to symbols used

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

- Azacitidine Mylan (azacitidine)
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)
- Cinacalcet Accordpharma (*cinacalcet*)
  Treatment of secondary hyperparathyroidism, parathyroid carcinoma and primary hyperparathyroidism
- Nubeqa (*darolutamide*)
  Treatment of prostate cancer
- Ruxience (*rituximab*)
  Treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and Pemphigus vulgaris (PV)

New medicines authorised

- Polivy (*polatuzumab vedotin*)
  Treatment of large B-cell lymphoma (DLBCL), a blood cancer

New information on authorised medicines

- MabThera (*rituximab*)- new indication
  Treatment of blood cancers and inflammatory conditions
- Venclyxto (*venetoclax*) - extension of indication
  Treatment of blood cancer known as chronic lymphocytic leukaemia (CLL)

Withdrawal of applications for new medicines

- Idhifa (*enasidenib*)
  Intended to treat acute myeloid leukaemia (a cancer of white blood cells)

Withdrawal of applications for extension of indication

- Keytruda (*Ipembrolizumab*)
  Intended for treatment of cancer of the aesophagus (food pipe)

Negative CHMP opinions on new medicines

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

Cardiovascular system

Positive CHMP opinions on new medicines

- Nilemdo (*bempedoic acid*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- Nustendi (*bempedoic acid / ezetimibe*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- Trepulmix (*treprostinil sodium*)
  Treatment of chronic thromboembolic pulmonary hypertension (CTEPH), high blood pressure in the lungs

New medicines authorised

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

Dermatology

Positive CHMP opinions on new medicines

- Staquis (*crisaborole*)
  Treatment of atopic dermatitis (itchy, red skin)

New information on authorised medicines

- Ameluz (*5-aminolevulinic acid hydrochloride*) - extension of indication
  Treatment of mild to moderate actinic keratoses (skin growths caused by exposure to sunlight which can lead to skin cancer)

Diabetes

Positive CHMP opinions on new medicines

- Liumjev (*insulin lispro*)
  Treatment of diabetes mellitus
- Rybelsus (*semaglutide*)
  Treatment of type 2 diabetes

New information on authorised medicines

- Suliqua (*insulin glargine / lixisenatide*) - change of indication
  Treatment of adults with type 2 diabetes

Gynaecology & Obstetrics

Safety update

- Review of estradiol containing medicinal products (0.01% w/w) - CMDh Position (Four-week limit for use of high-strength estradiol creams)
  Treatment of vaginal atrophy in post-menopausal women

Haematology

Positive CHMP opinions on new medicines

- Arsenic trioxide Mylan (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (APL), a blood cancer
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  Prevention of atherothrombotic events (problems caused by blood clots and hardening of the arteries)

New information on authorised medicines

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Negative CHMP opinions on new medicines

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HIV

New information on authorised medicines

- Rezolsta (*darunavir / cobicistat*) - extension of indication
  Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)
- Tybost (*cobicistat*) - extension of indication
  Treatment of HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS)

Immune system

Positive CHMP opinions on new medicines

- Budesonide / Formoterol Teva Pharma B.V. (*budesonide / formoterol fumarate dihydrate*)
  Treatment of asthma and chronic obstructive pulmonary disease (COPD), a lung disease
- Ruxience (*rituximab*)
  Treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and Pemphigus vulgaris (PV)
- Staquis (*crisaborole*)
  Treatment of atopic dermatitis

Metabolic disorders

Positive CHMP opinions on new medicines

- Nilemdo (*bempedoic acid*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)
- Nustendi (*bempedoic acid / ezetimibe*)
  Treatment of primary hypercholesterolaemia and mixed dyslipidaemia (blood fat disorders)

Nervous system

New medicines authorised

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

Respiratory system

Positive CHMP opinions on new medicines

- Budesonide / Formoterol Teva Pharma B.V. (*budesonide / formoterol fumarate dihydrate*)
  Treatment of asthma and chronic obstructive pulmonary disease (COPD), a lung disease
- Trepulmix (*treprostinil sodium*) O
  Treatment of chronic thromboembolic pulmonary hypertension (CTEPH), high blood pressure in the lungs

Withdrawal of applications for new medicines

- Linhaliq (*ciprofloxacin*)
  Intended for treating and preventing flare-ups of bronchiectasis in patients with long-term lung infection

Vaccines

Positive CHMP opinions on new medicines

- Vaxchora (*Cholera vaccine (recombinant, live, oral)*)
  Prophylaxis against disease caused by Vibrio cholerae

Other medicines

Positive CHMP opinions on new medicines

- Givlaari (*givosiran*) O
  Treatment of acute hepatic porphyria (a rare genetic condition in which patients lack certain enzymes needed to produce haem, a basic structure of haemoglobin)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

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Other information

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - December 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: January 2020
- 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: January 2020
- PRAC recommendations on safety signals

Other publications

- Human medicines: highlights of 2019
- Court of Justice upholds EMA's approach to transparency
- UK withdrawal from the EU on 31 January 2020
- Ten recommendations to unlock the potential of big data for public health in the EU
- Electronic product information for human medicines in the EU - Key principles
- Mandatory use of international standard for the reporting of side effects to improve safety of medicines
- Categorisation of antibiotics used in animals promotes responsible use to protect public and animal health
- Responsible use of antibiotics protects animals and people
- Martina Schüssler-Lenz re-elected as chair of Committee for Advanced Therapies
- EMA welcomes new Head of Information Management Division
- Privacy Statement concerning Public Hearings at the European Medicines Agency
- Privacy Statement for the EMA individual experts' stakeholder database
- Privacy Statement regarding the Experts database and the handling of competing interests of scientific committees' members and experts

Events

- European Medicines Agency EORTC workshop on novel PRO and QoL approaches in cancer clinical research - 12 - 13 March 2020 - EMA, Amsterdam, the Netherlands
- 2020 European Union Good Clinical Practice Inspectors Working Group workshop—30 September-02 October 2020— Seeheim-Jugenheim, Germany

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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