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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.

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Information on medicines

Cancer

Positive CHMP opinions on new medicines

- Finlee (*dabrafenib*) O
  Treatment of glioma (a type of brain cancer)
- Herwenda (*trastuzumab*)
  Treatment of metastatic and early breast and gastric cancer (stomach cancer)
- Vanflyta (*quizartinib*) O
  Treatment of acute myeloid leukaemia (blood cancer)

New medicines authorised

- Talvey (*talquetamab*) O C
  Treatment of multiple myeloma (a cancer of the bone marrow)

Key to symbols used

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

New information on authorised medicines

- Adcetris (*brentuximab vedotin*) O - extension of indication
  Treatment of stage III Hodgkin lymphoma (a cancers of lymphocytes, a type of white blood cell)
- Enhertu (*trastuzumab deruxtecan*) C - new indication
  Treatment of advanced HER2-mutant non-small cell lung cancer
- Keytruda (*pembrolizumab*) - new indication
  Treatment of non-small cell lung cancer

Withdrawal of authorised medicines

- EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep

Withdrawal of applications for extension of indication

- Iclusig (*ponatinib*)
  Intended for the treatment of adults newly diagnosed with Philadelphia chromosome-positive acute lymphoblastic leukaemia (blood cancer)

Negative CHMP opinions on renewal of conditional marketing authorisation

- EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep (belantamab mafodotin)

Cardiovascular system

Positive CHMP opinions on new medicines

- Aqumeldi (*enalapril maleate*)
  Treatment of heart failure in children

Safety update

- Review of Mysimba (*naltrexone / bupropion*) - review started
  Intended to manage weight in adults who have obesity or are overweight

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Ebglyss (*lebrikizumab*)
  Treatment of moderate to severe atopic dermatitis

New information on authorised medicines

- Nordimet (*methotrexate*) - new indication
  Treatment of moderate psoriasis (a disease causing red, scaly patches on the skin)
- Olumiant (*baricitinib*) - extension of indication
  Treatment of moderate to severe atopic dermatitis

Gynaecology & Obstetrics (pregnancy and female reproductive)

New information on authorised medicines

- Ryeqo (*relugolix / estradiol / norethisterone acetate*) - new indication
  Symptomatic treatment of endometriosis (a condition in which tissue similar to the lining of the womb grows elsewhere in the body)

Withdrawal of applications for new medicines

- Vivjoa (*oteseconazole*)
  Intended for treatment and prevention of vulvovaginal candidiasis (thrush, a fungal infection of the female genital area caused by Candida)

Safety update

- Review of topiramate - PRAC recommendation
  Prevention of epileptic seizures

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Vanflyta (*quizartinib*) O
  Treatment of acute myeloid leukaemia (blood cancer)

New information on authorised medicines

- Adcetris (*brentuximab vedotin*) O - extension of indication
  Treatment of stage III Hodgkin lymphoma (a cancers of lymphocytes, a type of white blood cell)

Withdrawal of applications for extension of indication

- Iclusig (*ponatinib*)
  Intended for the treatment of adults newly diagnosed with Philadelphia chromosome-positive acute lymphoblastic leukaemia (blood cancer)

Safety update

- Review of pseudoephedrine-containing medicinal products - review started
  Treatment of nasal congestion (blocked nose) resulting from a cold, flu or allergy

Hormone system

Positive CHMP opinions on new medicines

- Yorvipath (*palopegteriparatide*) O
  Treatment of chronic hypoparathyroidism (condition where the parathyroid glands, in the neck produce too little parathyroid hormone)

Immune system

Positive CHMP opinions on new medicines

- Ebglyss (*lebrikizumab*)
  Treatment of atopic dermatitis
- Zylbrysq (*zilucoplan*) O
  Treatment of myasthenia gravis (a disease that leads to muscle weakness and tiredness)

New medicines authorised

- Litfulo (*ritlecitinib*)
  Treatment of alopecia areata (a disease causing hair loss of the scalp or other parts of the body)

New information on authorised medicines

- Nordimet (*methotrexate*) - new indication
  Treatment of moderate psoriasis (a disease causing red, scaly patches on the skin)
- Olumiant (*baricitinib*) - extension of indication
  Treatment of moderate to severe atopic dermatitis
- Takhzyro (*lanadelumab*) O - extension of indication
  Prevention of recurrent attacks of hereditary angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs.)

Safety update

- Review of pseudoephedrine-containing medicinal products - review started
  Treatment of nasal congestion (blocked nose) resulting from a cold, flu or allergy

Nervous system

Withdrawal of authorised medicines

- EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna

Safety update

- Review of topiramate - PRAC recommendation
  Prevention of epileptic seizures

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Catiolanze (*latanoprost*)
  Treatment of elevated intraocular (eye) pressure

Respiratory system

New medicines authorised

- Lyfnua (*gefapixant*)
  Treatment of chronic (long-term) cough which is unexplained or for which other treatments have not worked

New information on authorised medicines

- Kaftrio (*ivacaftor / tezacaftor / elexacaftor*) O - new indication
  Treatment of cystic fibrosis
- Kalydeco (*ivacaftor*) - new indication
  Treatment of cystic fibrosis

Safety update

- Review of pseudoephedrine-containing medicinal products - review started
  Treatment of nasal congestion (blocked nose) resulting from a cold, flu or allergy

Vaccines

Positive CHMP opinions on new medicines

- Zoonotic Influenza Vaccine Seqirus (*zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)*)
  Protection against H5N1 subtype of influenza A virus

New medicines authorised

- Abrysvo (*Respiratory syncytial virus vaccines*)
  Protection against lower respiratory tract disease (LRTD; diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV)
- Spikevax: EMA recommends approval of adapted COVID-19 vaccine targeting Omicron XBB.1.5

Withdrawal of applications for new medicines

- Skycovion (*GBP510*)
  Intended for the prevention of coronavirus disease 2019 (COVID-19)

Safety update

- Havrix (*hepatitis A virus (inactivated, adsorbed)*) - review started
  Prevention against hepatitis A virus infection

Direct Healthcare Professional Communication (DHPC)

- Vaxneuvance (*pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)*)
  suspension for injection in pre-filled syringe: Important information regarding the potential for breakage of Vaxneuvance pre-filled syringes

Other medicines

Positive CHMP opinions on new medicines

- Yorvipath (*palopegteriparatide*)
  Treatment of chronic hypoparathyroidism (condition where the parathyroid glands, in the neck produce too little parathyroid hormone)

New information on authorised medicines

- Voxzogo (*vosoritide*) - extension of indication
  Treatment of achondroplasia (a condition that impairs bone growth)

Safety update

- Review concerning the conduct of studies at Synapse Labs Pvt. Ltd, India - review started
  The review covers generic medicines authorised or currently being evaluated on the basis of studies conducted by Synapse Labs Pvt. Ltd, India
- Review of Mysimba (*naltrexone / bupropion*) - review started
  Intended to manage weight in adults who have obesity or are overweight

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- DRAFT Qualification opinion for GFR slope as a Surrogate Endpoint in RCT for CKD
  Deadline for comments: 23 October 2023
- Guideline on clinical investigation of medicinal products in the treatment of depression
  Deadline for comments: 31 March 2024

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - August 2023
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: September 2023
- COMP - agendas, minutes and meetings reports

Other publications

- Towards a permanent collaboration framework for EMA and Health Technology Assessment bodies

Events

- LinkedIn Live interview with Ivo Claassen: Tomorrow's veterinary medicines for healthy animals and humans - 7 September 2023
- Management Board meeting - 7-8 June 2023 – Minutes
- Conversations on Cancer presents "Living with Metastatic Breast Cancer" - 19 October 2023 -
- Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) AI workshop – Smart regulation on a rapidly evolving world - 20 November 2023
- Joint EMA-ECDC press briefing on current state of respiratory diseases and treatments in the EU/EEA - 21 September 2023
- Sixth Industry Standing Group (ISG) meeting - 21 September 2023

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

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