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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

Antivirals/anti-infectives

New information on authorised medicines

- Zinforo (*ceftaroline fosamil*) - extension of indication
  Treatment of skin and soft tissue infections and pneumonia

Safety update

- Review of Bacterial lysate medicines - CHMP Opinion (effectiveness in reducing the number and severity of respiratory infections)
  Intended for the prevention of recurrent respiratory tract infections with the exception of pneumonia

Cancer

Positive CHMP opinions on new medicines

- Azacitidine Celgene (*azacitidine*)
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukemia

Key to symbols used

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

New medicines authorised

- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy
- Lorviqua (*orlatinib*)
  Treatment of non-small cell lung cancer (NSCLC)
- Vizimpro (*dacomitinib*)
  Treatment of advanced non small cell lung cancer (NSCLC)

New information on authorised medicines

- Cyramza (ramucirumab) - new indication
  Treatment of hepatocellular carcinoma (liver cancer)
- Imbruvica (*ibrutinib*) - change of indication
  Treatment of mantle cell lymphoma (MCL)
- Tecentriq (*atezolizumab*) - extension of indication
  Treatment of urothelial carcinoma (UC) a cancer of the bladder

Safety update

- Review of Leuprorelin-containing depot medicinal products - review started (problems preparing and giving the medicines, resulting in too low a dose being given)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Cardiovascular system

Positive CHMP opinions on new medicines

- Giapreza (*angiotensin II*)
  Treatment of refractory hypotension in adults with septic or other distributive shock

New medicines authorised

- Ondexxya (*andexanet alfa*)
  Antidote to the anticoagulant (clot-preventing) medicines apixaban and rivaroxaban

Dermatology

New medicines authorised

- Skyrizi (*risankizumab*)
  Treatment of psoriasis

New information on authorised medicines

- Dupixent (*dupilumab*)- extension of indication
  Treatment of atopic dermatitis
- Zinforo (*ceftaroline fosamil*) - extension of indication
  Treatment of skin and soft tissue infections and pneumonia

Withdrawal of applications for new medicines

- ABP 710 (*infliximab*)
  Intended for the treatment of inflammatory diseases

Diabetes

New information on authorised medicines

- Ebymect (*dapagliflozin / metformin*) - change of indication
  Treatment of insufficiently controlled type 2 diabetes
- Edistride (*dapagliflozin*) - change of indication
  Treatment of insufficiently controlled type 2 diabetes
- Fiasp (*insulin aspart*) - extension of indication
  Treatment of diabetes
- Forxiga (*dapagliflozin*) - change of indication
  Treatment of diabetes
- Victoza (*liraglutide*) - change of indication
  Treatment of insufficiently controlled type 2 diabetes
- Xigduo (*dapagliflozin*) - change of indication
  Treatment of insufficiently controlled type 2 diabetes

Gastro-intestinal system

Withdrawal of applications for new medicines

- ABP 710 (*infliximab*)
  Intended for the treatment of inflammatory diseases

Gynaecology & Obstetrics

Safety update

- Review of Leuprorelin-containing depot medicinal products - review started (problems preparing and giving the medicines, resulting in too low a dose being given)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Haematology

Positive CHMP opinions on new medicines

- Azacitidine Celgene (*azacitidine*)
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukemia

New medicines authorised

- Doptelet (*avatrombopag*)
  Treatment of thrombocytopenia (low levels of platelets, a component that helps blood clot) in patients with liver disease
- Esperoct (*turoctocog alfa pegol*)
  Treatment and prevention of bleeding
- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy
- Zynteglo (*autologous CD34+ cells encoding βA-T87Q-globin gene*)
  Treatment of beta thalassaemia, a type of blood disorder

New information on authorised medicines

- Cyramza (*ramucirumab*) - new indication
  Treatment of hepatocellular carcinoma

Negative CHMP opinions on extension of indication

- Revolade (*eltrombopag*)
  Intended for the treatment of previously untreated patients with severe aplastic anaemia

Immune system

New medicines authorised

- Dectova (*zanamivir*)
  Treatment of severe flu infection
- Grasustek (*pegfilgrastim*) *biosimilar of Neulasta*
  Prevention of neutropenia (low levels of neutrophils, a type of white blood) in patients treated with chemotherapy

New information on authorised medicines

- Flebogamma DIF (previously Flebogammadif) (*human normal immonogloubulin*) - change of indication
  Replacement therapy in Primary immunodeficiency syndromes (PID) and Secondary immunodeficiencies (SID)

Musculoskeletal system

Negative CHMP opinions on extension of indication

- Translarna (*ataluren*)
  Intended to extend treatment of patients with Duchenne muscular dystrophy who are no longer able to walk

Withdrawal of applications for new medicines

- ABP 710 (*infliximab*)
  Intended for the treatment of inflammatory diseases

Nervous system

Positive CHMP opinions on new medicines

- Lacosamide UCB (*lacosamide*)
  Treatment of partial-onset seizures with or without secondary generalisation

Respiratory system

New medicines authorised

- Vizimpro (*dacomitinib*)
  Treatment of advanced non small cell lung cancer (NSCLC)
- Lorviqua (*orlatinib*) C
  Treatment of non-small cell lung cancer (NSCLC)

New information on authorised medicines

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Safety update

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Rheumatology

Negative CHMP opinions on new medicines

- Evenity (*romosozumab*)
  Treatment of osteoporosis

Withdrawal of applications for new medicines

- ABP 710 (*infliximab*)
  Intended for the treatment of inflammatory diseases

Urology

New information on authorised medicines

- Tecentriq (*atezolizumab*) - extension of indication
  Treatment of urothelial carcinoma (UC) a cancer of the bladder

Safety update

- Review of Leuprorelin-containing depot medicinal products - review started (problems preparing and giving the medicines, resulting in too low a dose being given)
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Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on quality requirements for medical devices in combination products
  Deadline for comments: 31 August 2019
- Draft qualification opinion of Multiple sclerosis clinical outcome assessment (MSCOA)
  Deadline for comments: 20 September 2019
- Draft qualification opinion of clinically interpretable treatment effect measures based on recurrent event endpoints that allow for efficient statistical analyses
  Deadline for comments: 09 October 2019

Adopted guidelines

- Detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Addendum 1
- COMP guidance - Points to consider on the estimation and reporting on the prevalence of a condition for the purpose of orphan designation

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2019
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 2019
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals

Other publications

- Final programming document 2019-2021

- EMA activities, other than the highest priority activities (category 1 activities), that will continue in 2019 - Annex 1
- Strengthening engagement between EMA and general practitioners
- European Medicines Agency stakeholder interaction on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) - Report published
- Small and medium-sized enterprise (SME) Office annual report 2018
- Three additional countries to benefit from EU-US mutual recognition agreement for inspections: Germany, Luxembourg and the Netherlands
- Rules for reimbursement of expenses for delegates attending meetings with effect from 14 June 2019

Events

- European Medicines Agency (EMA) and European Union (EU) payer community meeting, 18 June 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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European Medicines Agency

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