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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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.

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Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Supemtek (*quadrivalent influenza vaccine (recombinant, prepared in cell culture)*)
  Vaccine to prevent influenza

New information on authorised medicines

- Deltyba (*delamanid*) O C - extension of indication
  Treatment of multi-drug resistant tuberculosis
- Direct healthcare professional communication (DHPC): Prevymis (letermovir) concentrate for solution for infusion - Essential to administer through sterile 0.2 micron or 0.22 micron polyethersulfone (PES) in-line filter

Key to symbols used

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

- Zavicefta (*ceftazidime / avibactam*) - extension of indication
  Treatment of pneumonia, bacterial soft tissue infections and urinary tract infections

Cancer

Positive CHMP opinions on new medicines

- Nyvepria (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- Phelinun (*melphalan*)
  Treatment of blood and bone marrow cancers and for preparing patients for blood stem cell transplants

New medicines authorised

- Aybintio (*bevacizumab*) biosimilar of Avastin
  Treatment of different types of cancer
- Ayvakyt (*avapritinib*) C O
  Treatment of gastrointestinal stromal tumours (cancer of stomach and bowel)
- Blenrep (*belantamab mafodotin*) C O
  Treatment of multiple myeloma (blood cancer)
- Rozlytrek (*entrectinib*)
  Treatment of solid tumours and non-small cell lung cancer

New information on authorised medicines

- Lynparza (*olaparib*) - new indication and extension of indication
  Treatment of ovarian, breast, pancreatic and prostate cancers
- Opdivo (*nivolumab*) - extension of indication
  Treatment of different kinds of cancers
- Tecentriq (*atezolizumab*) - new indication
  Treatment of urothelial cancer (cancer of the bladder and urinary system), lung cancer and breast cancer
- Yervoy (*ipilimumab*) - new indication
  Treatment of advanced melanoma (a type of skin cancer) and advanced renal cell carcinoma (a kidney cancer)
- Zejula (*niraparib*) O - extension of indication
  Treatment of ovarian cancer

Re-examination request following negative CHMP opinions on new medicines

- Elzonris (*tagraxofusp*)
  Intended for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare and aggressive type of blood cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Rivaroxaban Accord (*rivaroxaban*)
  Treatment and prevention of blood clots

Key to symbols used

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Dermatology (skin conditions)

New information on authorised medicines

- Olumiant (*baricitinib*) - new indication
  Treatment of atopic dermatitis (eczema) and rheumatoid arthritis (a disease causing inflammation of the joints)

Gastro-intestinal system

Safety update

- Review of ranitidine medicines - re-examination of CHMP Opinion in relation of presence of impurity
  Used to treat and prevent conditions caused by excess acid in the stomach such as heartburn and stomach ulcers

Gynaecology & Obstetrics (pregnancy and female reproductive)

Safety update

- Review of Ulipristal acetate 5mg medicinal products - PRAC recommendation (Art.31)
  Treatment of uterine fibrosis

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Nyvepria (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- Rivaroxaban Accord (*rivaroxaban*)
  Treatment and prevention of blood clots

New medicines authorised

- Blenrep (*belantamab mafodotin*) C O
  Treatment of multiple myeloma (blood cancer)

Re-examination request following negative CHMP opinions on new medicines

- Elzonris (*tagraxofusp*)
  Intended for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare and aggressive type of blood cancer

Hepatology (liver conditions)

Safety update

- Review of Ulipristal acetate 5mg medicinal products - PRAC recommendation (Art.31)
  Treatment of uterine fibrosis

Key to symbols used

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Immune system

Re-examination request following negative CHMP opinions on new medicines

- Gamifant *(emapalumab)*
  Intended for treatment of haemophagocytic lymphohistiocytosis (a rare disease in which patients have an overactive immune system)

Nephrology (kidney conditions)

New information on authorised medicines

- Velphoro (*mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches*) - new indication and new pharmaceutical form
  Treatment of long-term kidney disease

Supply shortages

- Direct healthcare professional communication (DHPC): Nulojix (belatacept): Extension of the temporary restriction in supply up until 4Q 2021 (initiated in March 2017)

Nervous system

New information on authorised medicines

- Fycompa (*perampanel*) - extension of indication
  Treatment of partial-onset seizures (epileptic fits)

Withdrawal of applications for new medicines

- Upkanz (*deferiprone*)
  Intended for the treatment of pantothenate kinase-associated neurodegeneration (a disease that causes brain damage

Respiratory system

New medicines authorised

- Kaftrio (*elexacaftor / tezacaftor / ivacaftor*)
  Treatment of cystic fibrosis
- Zimbus Breezhaler (*indacaterol / glycopyrronium / mometasone*)
  Treatment of asthma

New information on authorised medicines

- Kalydeco (*ivacaftor*) - extension of indication
  Treatment of cystic fibrosis
- Symkevi (*tezacaftor / ivacaftor*) - extension of indication
  Treatment of cystic fibrosis
- Zavicefta (*ceftazidime / avibactam*) - extension of indication
  Treatment of pneumonia, bacterial soft tissue infections and urinary tract infections

Urology (urinary tract conditions)

New information on authorised medicines

- Zavicefta (*ceftazidime / avibactam*) - extension of indication
  Treatment of pneumonia, bacterial soft tissue infections and urinary tract infections

Vaccines

Positive CHMP opinions on new medicines

- MenQuadfi (*meningococcal group A, C, W and Y conjugate vaccine*)
  Prophylaxis against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W and Y
- Supemtek (*quadrivalent influenza vaccine (recombinant, prepared in cell culture)*)
  Vaccine to prevent influenza

New information on authorised medicines

- Flucelvax Tetra (*influenza vaccine surface antigen inactivated prepared in cell cultures*) - extension of indication
  Prevention against influenza

Other medicines

Positive CHMP opinions on new medicines

- Exparel (*bupivacaine*)
  Treatment of post-operative pain
- Obiltoxaximab SFL (*obiltoxaximab*)
  Treatment or prevention of inhalational anthrax

New information on authorised medicines

- Orfadin (*nitisinone*) - new indication
  Treatment of alkaptonuria (a rare metablolic disease)

Communication on prevention of medication errors

- Peyona (previously Nymusa)(*caffeine*)
  Treatment of apnoea of prematurity, a condition in which babies born prematurely stop breathing for longer than 20 seconds

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Title: Guideline on registry-based studies - launch of public consultation

  Deadline for comments: 31 December 2020

Scientific committee and working party activities

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

COVID-19

- EMA receives application for marketing authorisation of Dexamethasone Taw for COVID-19

Other publications

- Extraordinary meeting of the Management Board for the nomination of the Executive Director - Amsterdam, The Netherlands, 25 June 2020 - Minutes
- 109th Management Board meeting - Amsterdam, The Netherlands, 1 October 2020 - Agenda
- 108th Management Board meeting - Amsterdam, The Netherlands, 11 June 2020 - Minutes
- How incidents with medicines are managed in the EU – a ten-year analysis
- Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21

Events

- Workshop on the draft guideline on registry-based studies - Virtual meeting, 19 October 2020 - Agenda
- Workshop on support for orphan medicines development - Virtual meeting, 30 November 2020
- Online training: How to submit Initial and Follow-up Scientific Advice applications (human) using IRIS - Virtual meeting, 13 October 2020
- Workshop on the General Data Protection Regulation (GDPR) and secondary use of data for medicines and public health purposes - 29 September 2020 - Virtual meeting - Agenda
- EMA 25th anniversary symposium: New approaches in patient - focused cancer drug development - Virtual meeting, 29 October 2020 - Agenda
- Online training: how to register for access to IRIS; what research product identifiers (RPI) are and how we use them - Virtual meeting, 24 September 2020
- Workshop on benefit-risk of medicines used during pregnancy and breastfeeding - Virtual meeting, 22 September 2030 - Agenda

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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