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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

Arbitration procedures

- Cymeven (*ganciclovir*) - outcome
  Treatment or prevention of infection with cytomegalovirus

Safety communication update

- Review of fusafungine containing medicinal products for oromucosal and nasal use - PRAC recommendation (nose and mouth sprays are no longer marketed)
  Treatment of infections of the upper airways (such as common cold)

Cancer

Positive CHMP opinions on new medicines

- Lonsurf (*trifluridine / tipiracil)*
  Treatment of colorectal cancer

Key to symbols used

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

- Palonosetron Hospira (*palonosetron*)
  Prevention of nausea and vomiting associated with cancer chemotherapy

New medicines authorised

- Imlygic (*talimogene laherparepvec)*
  Treatment of melanoma (skin cancer)
- Tagrisso (*osimertinib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Giotrif (*afatinib*) - new indication
  Treatment of squamous non-small cell lung cancer after platinum-based chemotherapy
- Opdivo (*nivolumab*) - new indication and change in indication
  Treatment of renal cell cancer and non-small cell lung cancer
- Zydelig (*idelalisib*) - change in indication
  Treatment of chronic lymphocytic leukaemia

Cardiovascular system

Other information

- Xarelto (*rivaroxaban*)
  Treatment of blood clots in veins after hip or knee surgery

Dermatology

Safety communication update

- Review of medicines containing dienogest and ethinylestradiol - review started (concerns regarding efficacy in the treatment of acne and the risk of VTE (blood clots in veins))
  Oral contraceptives used for the treatment of moderate acne in women

Diabetes

Safety communication update

- Review of SGLT2 inhibitors (*canagliflozin, dapagliflozin, empagliflozin*) - CHMP Opinion (EMA confirms recommendations to minimise ketoacidosis risk with SGLT2 inhibitors for diabetes)
  Treatment of type 2 diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- Alprolix (*eftrenonacog alfa*)
  Prevention and treatment of bleeding in patients with haemophilia B
- Idelvion (*albutrepenonacog alfa*)
  Prevention and treatment of bleeding in patients with haemophilia B

Key to symbols used

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New information on authorised medicines

- Zydelig (*idelalisib*) - change in indication
  Treatment of chronic lymphocytic leukaemia

HIV

Positive CHMP opinions on new medicines

- Descovy (*emtricitabine / tenofovir alafenamide*)
  Treatment of HIV infection

New medicines authorised

- Lopinavir/Ritonavir Mylan (*lopinavir / ritonavir*)
  Treatment of HIV infection

New information on authorised medicines

- Telzir (*fosamprenavir*) - new contraindication
  Treatment of HIV infection

Hormone system

Safety communication update

- Review of medicines containing dienogest and ethinylestradiol - review started (concerns regarding efficacy in the treatment of acne and the risk of VTE (blood clots in veins))
  Oral contraceptives used for the treatment of moderate acne in women

Immune system

Positive CHMP opinions on new medicines

- Taltz (*ixekizumab*)
  Treatment of psoriasis

New information on authorised medicines

- Humira (*adalimumab*) - change in indication
  Treatment of psoriasis
- Ruconest (*conestat alfa*) - change in indication
  Treatment of hereditary angioedema (swelling beneath the skin)

Nephrology

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication and change in indication
  Treatment of renal cell cancer and non-small cell lung cancer

Nervous system

New information on authorised medicines

- TachoSil (*human fibrinogen / human thrombin*) - new indication
  Used during neurosurgery to prevent leakage of cerebrospinal fluid

Safety communication update

- Review of Tysabri (*natalizumab*) - CHMP Opinion (confirms recommendations to minimise risk of the brain infection progressive multifocal leukoencephalopathy)
  Treatment of multiple sclerosis

Respiratory system

Safety communication update

- Review of fusafungine containing medicinal products for oromucosal and nasal use - PRAC recommendation (nose and mouth sprays are no longer marketed)
  Treatment of infections of the upper airways (such as common cold)

Vaccines

New medicines authorised

- Vaxelis (*diphtheria, tetanus, pertussis (acellular, component), hepatitis B (Rdna), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (absorbed)*)
  Prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type B

Other medicines

New medicines authorised

- Episalvan (*birch bark extract*)
  Treatment of wounds

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the core SmPC for human Anti-D immunoglobulin for intramuscular use
  Deadline for comments: 30 April 2016
- Draft guideline on the core SmPC for human Anti-D immunoglobulin for intravenous use
  Deadline for comments: 30 April 2016
- Draft guideline on core SmPC and package leaflet for nanocolloidal technetium (99mTc) albumin
  Deadline for comments: 30 April 2016
- Draft guideline on core SmPC and package leaflet for gadopentetate dimeglumine
  Deadline for comments: 30 April 2016
- ICH guideline E18 on genomic sampling and management of genomic data - Step 3
  Deadline for comments: 31 May 2016
- Guideline on GVP 3 - Module V - Risk management systems (Rev 2)
  Deadline for comments: 31 May 2016
- Draft guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias
  Deadline for comments: 31 July 2016
- Draft guideline on clinical investigation of medicinal products for the treatment of chronic heart failure
  Deadline for comments: 31 August 2016

Adopted guidelines

- Evaluation of anticancer medicinal products in man - Appendix 4: Condition specific guidance (Rev.2)
- Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products
- Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products
- Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function
- ICH guideline E14: the clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs (R3) questions and answers - Step 5 (updated)

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 2016
- CHMP work plan 2016
- CAT - agendas, minutes and reports

- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- HMPC work plan 2016
- HMPC Quality Drafting Group work plan 2016
- MLWP work plan 2016
- PDCO - agendas, minutes and meeting reports
- PDCO work plan 2016 (updated)
- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals
- PRAC work plan 2016
- ORGAM work plan 2016
- GCP Inspectors Working Group work plan 2016
- Oncology Working Party work plan 2016
- Pharmacogenomics Working Party work plan 2016 (updated)
- Radiopharmaceuticals Drafting Group work plan 2016

Other publications

- EMA sets up task force on Zika virus
- Measures to help protect patients from falsified medicines
- How to facilitate development of cancer immunotherapies
- EMA consultation on the proposal of a collaboration framework with Academia
- Advice on the impact on public health and animal health of the use of antibiotics in animals (colistin) following the recent discovery of the first mobile colistin resistance gene (mcr-1)
- Training session for patients and consumers - Nov 2015 - meeting documents
- PCWP meeting with all eligible organisations - Nov 2015 - meeting documents
- PCWP and HCPWP joint meeting: session on communication and information on medicines - March 2016
- PCWP and HCPWP joint meeting - March 2016
- DIA information day on medication errors - October 2016

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease.

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.

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.

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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