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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 medicines authorised

- Caspofungin Accord (*caspofungin*)
  Treatment of fungal infections

### Arbitration procedures

- Vancomycin-containing medicines - start
  Treatment of bacterial infections

### Safety communication update

- Review of direct-acting antivirals for hepatitis C - review started (to investigate possible hepatitis B re-activation)
  Treatment of hepatitis C

**Key to symbols used**

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

# Cancer

### Positive CHMP opinions on new medicines

- Darzalex (*daratumumab*)
  Treatment of multiple myeloma
- Palonosetron Accord (*palonosetron*)
  Prevention of nausea and vomiting associated with chemotherapy

### New information on authorised medicines

- Halaven (*eribulin*) - new indication
  Treatment of liposarcoma (a cancer of fat tissues)
- Opdivo (*nivolumab*) - change in indication
  Treatment of melanoma (skin cancer)

### Safety communication update

- Review of Zydelig (*idelalisib)* - review started (concerns over serious adverse events in ongoing clinical trials)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (types of cancers)

# Cardiovascular system

### Positive CHMP opinions on new medicines

- Neparvis (*sacubitril / valsartan*)
  Treatment of chronic heart failure

# Dermatology

### New information on authorised medicines

- Opdivo (*nivolumab*) - change in indication
  Treatment of melanoma (skin cancer)

# Diabetes

### Withdrawal of authorised medicines

- Paglitaz (*pioglitazone*)
  Treatment of type 2 diabetes mellitus

# Gastro-intestinal system

### Positive CHMP opinions on new medicines

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

### New information on authorised medicines

- Humira (*adalimumab*) - change in indication
  Treatment of Crohn's disease

### New medicines authorised

- Feraccru (*ferric maltol*)
  Treatment of iron deficiency anaemia in patients with inflammatory bowel disease

### Arbitration procedures

- Symbioflor 2 (*Escherichia coli bacteria (cells and autolysate)*) - start
  Treatment of diseases affecting the stomach and gut including irritable bowel syndrome

# Haematology

### Positive CHMP opinions on new medicines

- Strimvelis (*autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ada) cdna sequence*) O
  Treatment of severe combined immunodeficiency
- Darzalex (*daratumumab*) O C
  Treatment of multiple myeloma

### New medicines authorised

- Feraccru (*ferric maltol*)
  Treatment of iron deficiency anaemia in patients with inflammatory bowel disease
- Iblias (*octocog alfa*) / Kovaltry (*octocog alfa*)
  Treatment and prevention of bleeding in patients with haemophilia A

### Safety communication update

- Review of Zydelig (*idelalisib*) - review started (concerns over serious adverse events in ongoing clinical trials)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (types of cancers)

# Immune system

### Positive CHMP opinions on new medicines

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis
- Strimvelis (*autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ada) cdna sequence*) O
  Treatment of severe combined immunodeficiency

# Metabolic system

**Positive CHMP opinions on new medicines**

- Galafold (*migalastat*)
  Treatment of Fabry disease

# Nervous system

**Safety communication update**

- Review of gadolinium-containing contrast agents - review started (to consider evidence on gadolinium accumulation in brain tissue)
  Diagnostic agent

# Ophthalmology

**Negative CHMP opinions on new medicines - re-examination**

- Dropcys (*mercaptamine*)
  Intended for the treatment and prevention of cystinosis (build-up of the amino acid cysteine) affecting the eye

# Respiratory system

**Safety communication update**

- Review of inhaled corticosteroids containing medicinal products indicated in the treatment of chronic obstructive pulmonary disease - PRAC recommendation (PRAC review finds no differences in risk of pneumonia between products)
  Treatment of chronic obstructive pulmonary disease

# Rheumatology

**Positive CHMP opinions on new medicines**

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

**New medicines authorised**

- Zurampic (*lesinurad*)
  Treatment of gout (inflammation in the joints)

# Vaccines

### Positive CHMP opinions on new medicines

- Pandemic influenza vaccine H5N1 MedImmune (*pandemic influenza vaccine (H5N1) (live attenuated, nasal*)
  Immunisation against avian influenza

### Withdrawal of authorised medicines

- Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics (*prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)*
  Immunisation against H5N1 subtype of influenza A virus

# Other medicines

### Arbitration procedure

- Alkem BE: A good clinical practice (GCP) inspection of this site raised concerns regarding study data used to support the marketing authorisation applications of some medicines in the EU

### Safety communication update

- Review of gadolinium-containing contrast agents - review started (to consider evidence on gadolinium accumulation in brain tissue)
  Diagnostic agent

# Medicines under additional monitoring

- Updated list of medicines under additional monitoring

# Other information

# Guidelines

### Guidelines open for consultation

- Draft guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder
  Deadline for comments: 31 August 2016
- Draft guideline on evaluation of anticancer medicinal products in man
  Deadline for comments: 15 September 2016

### Adopted guidelines

- Reflection paper on assessment of cardiovascular safety profile of medicinal products
- Guideline on epidemiological data on blood transmissible infections (Rev.1)

- Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 (Revision 1)
- Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to Article 14(9) of Regulation (EC) No 726/2004
- Questions and answers: Positions on specific questions addressed to the Pharmacokinetics Working Party

# Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines under evaluation: March 2016
- CAT - agendas, minutes and reports
- CAT work plan 2016
- 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
- Work plan for the CHMP Respiratory Drafting Group for 2016 - updated
- Work plan of the CHMP Blood Products Working Party for 2016

# Other publications

- EMA Management Board: highlights of March 2016 meeting
- Work programme of the EMA 2016
- Launch of PRIME – Paving the way for promising medicines for patients
- 10th anniversary of EMA's Patients' and Consumers' Working Party (PCWP)
- Early dialogue with regulators and HTA bodies
- EMA welcomes Italy's Minister of Health Beatrice Lorenzin
- Guidance for the publication of clinical data
- Enpr-EMA newsletter: January 2016
- Workshop on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products - Nov 2015 - meeting documents
- Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins - March 2016 - meeting documents
- EudraVigilance information day - June 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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http://www.ema.europa.eu

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