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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

Positive CHMP opinions on new medicines

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

Cancer

Positive CHMP opinions on new medicines

- Neofordex (*dexamethasone*) O
  Treatment of multiple myeloma (cancer of the bone marrow)
- Portrazza (*necitumumab*)
  Treatment of non-small cell lung cancer
- Tagrisso (*osimertinib*) C
  Treatment of non-small cell lung cancer

Key to symbols used

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

New information on authorised medicines

- Cyramza (*ramucirumab*) O - new indications
  Treatment of non-small cell lung and colorectal cancer
- Tarceva (*erlotinib*) - change in indication
  Treatment of non-small cell lung cancer

New medicines authorised

- Blincyto (*blinatumomab*) O C
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia (blood cancer)
- Cotellic *(cobimetinib)*
  Treatment of melanoma (skin cancer)
- Kyprolis *(carfilzomib)* O
  Treatment of multiple myeloma (cancer of the bone marrow)
- Pemetrexed Hospira (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- Pemetrexed medac (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

Communication on prevention of medication errors

- Blincyto (*blinatumomab*) O C - educational materials to help use the medicine correctly
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia (blood cancer)

Cardiovascular system

New information on authorised medicines

- Brilique (*ticagrelor*) - new indication and change in indication
  Prevention of problems caused by blood clots, such as heart attack

New medicines authorised

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

Diabetes

New medicines authorised

- Edistride *(dapagliflozin)*
  Treatment of type 2 diabetes mellitus

Supply shortages

- Insuman Basal and Comb 25 (*insulin human*)
  Treatment of type 1 and 2 diabetes mellitus

Gastro-intestinal system

Positive CHMP opinions on new medicines

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

Haematology

Positive CHMP opinions on new medicines

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

New medicines authorised

- Blincyto (*blinatumomab*) O C
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia (blood cancer)
- Elocta *(efmoroctocog alfa)* O
  Treatment and prevention of bleeding in haemophilia A
- Praxbind (*idarucizumab*)
  To be used for rapid reversal of the anticoagulant effects of *dabigatran etexilate*

New information on authorised medicines

- Nplate (*romiplostim*) O - change in indication
  Treatment of thrombocytopenic purpura
- Revolade (*eltrombopag*) - change in indication
  Treatment of thrombocytopenic purpura

Communication on prevention of medication errors

- Blincyto (*blinatumomab*) O C - educational materials to help use the medicine correctly
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia (blood cancer)
- Obizur (*susuctocog alfa*) O E - educational materials to help avoid medication errors
  Treatment of bleeding in patients with haemophilia

HIV

New medicines authorised

- Genvoya (*elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide*)
  Treatment of HIV infection

Key to symbols used

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Immune system

New information on authorised medicines

- Nplate (*romiplostim*) O - change in indication
  Treatment of thrombocytopenic purpura
- Revolade (*eltrombopag*) - change in indication
  Treatment of thrombocytopenic purpura

New medicines authorised

- Nucala (*mepolizumab*)
  Treatment of asthma

Metabolic system

Positive CHMP opinions on new medicines

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

New medicines authorised

- Kolbam (*cholic acid*) O
  Treatment of inborn errors in primary bile acid synthesis (defects in bile acid production)
- Ravicti (*glycerol phenylbutyrate*) O
  Treatment of urea cycle disorders

Negative CHMP opinions on new medicines

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

Nervous system

Safety communication update

- Gilenya (*fingolimod*) - new recommendations to minimise risks of the rare brain infection PML and a type of skin cancer
  Treatment of multiple sclerosis

Ophthalmology

Negative CHMP opinions on new medicines

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

Respiratory system

New medicines authorised

- Nucala (*mepolizumab*)
  Treatment of asthma
- Orkambi (*lumacaftor / ivacaftor*)
  Treatment of cystic fibrosis

Rheumatology

Positive CHMP opinions on new medicines

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

Vaccines

Positive CHMP opinions on new medicines

- 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

Medicines under additional monitoring

- Updated list of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the clinical development of medicinal products intended for the treatment of pain
  Deadline for comments: 31 March 2016
- Draft points to consider on frailty: Evaluation instruments for baseline characterisation of clinical trial populations
  Deadline for comments: 31 May 2016

Adopted guidelines

- Guideline on the clinical investigation of medicinal products for the treatment of asthma
- Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy

- Guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2015
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: December 2015
- 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
- Mandate for Enpr-EMA Working Groups
- Work plan for the Biosimilar Medicinal Products Working Party 2016
- Work plan for Biostatistics Working Party 2016
- Work plan for the Cardiovascular Working Party 2016
- Work plan for the Central Nervous System Working Party 2016
- Work plan for the joint CHMP / CVMP Quality Working Party 2016
- Work plan for the Gastroenterology Drafting Group 2016
- Work plan for the Healthcare Professionals' Organisations Working Party 2016
- Work plan for the Infectious Diseases Working Party 2016
- Work plan for the Patients' and Consumers' Organisations Working Party 2016
- Work plan for the Pharmacokinetics Working Party 2016
- Work plan for the Rheumatology-Immunology Working Party 2016
- Work plan for the Safety Working Party 2016
- Work plan for the Vaccines Working Party 2016

Other publications

- End-of-year message by Executive Director, Professor Guido Rasi
- EMA Management Board: highlights of December 2015 meeting
- EMA ready to address challenges ahead
- EU Medicines Agencies Network Strategy to 2020: Working together to improve health

- Increasing access to reports on adverse reactions to medicines
- News bulletin for pharmacovigilance programme update - Issue 6
- PCWP and HCPWP joint meeting: workshop on risk minimisation measures - September 2015 - meeting documents
- PCWP and HCPWP joint meeting - September 2015 - meeting documents
- EMA workshop on extrapolation across age groups - September 2015 - meeting documents
- Demonstrating significant benefit of orphan medicines: concepts, methodology, and impact on access - December 2015 - meeting documents
- Challenges for the approval of anti-cancer immunotherapeutic drugs workshop - February 2016
- EMA public workshop on extrapolation of efficacy and safety in medicine development - May 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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