75 Issue 75
May 2015

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

- Orbactiv (*oritavancin*)
  Treatment of acute bacterial skin infections

Supply shortages

- Tygacil (*tigecycline*)
  Treatment of skin and soft skin infections

Cancer

Positive CHMP opinions on new medicines

- Bortezomib Accord (*bortezomib*)
  Treatment of multiple myeloma and mantle cell lymphoma
- Keytruda (*pembrolizumab*)
  Treatment of skin cancer

Key to symbols used

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

- Nivolumab BMS (*nivolumab*)
  Treatment of squamous non-small-cell lung cancer
- Unituxin (*dinutuximab*) O
  Treatment of neuroblastoma (cancer of the nerve cells)

New information on authorised medicines

- Imbruvica (*ibrutinib*) O - new indication
  Treatment of Waldenström's macroglobulinaemia (a rare blood cell cancer)

Withdrawal of authorised medicines

- Provenge (*autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor (sipuleucel-T)*)
  Used in the treatment of prostate cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Repatha (*evolocumab*)
  Treatment to reduce blood cholesterol levels

Safety communication update

- Review of ibuprofen- and dexibuprofen-containing medicines - CMDh Position (small cardiovascular risk with daily doses at or above 2,400 mg)
  Treatment of pain and inflammation

Dermatology

New medicines authorised

- Orbactiv (*oritavancin*)
  Treatment of acute bacterial skin infections

New information on authorised medicines

- Stelara (*ustekinumab*) - new indication
  Treatment of plaque psoriasis in children

Supply shortages

- Tygacil (*tigecycline*)
  Treatment of skin and soft skin infections

Diabetes

New information on authorised medicines

- Xultophy (*insulin degludec / liraglutide*) - new indication
  Treatment of type-2 diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- Bortezomib Accord (*bortezomib*)
  Treatment of multiple myeloma and mantle cell lymphoma

New information on authorised medicines

- Imbruvica (*ibrutinib*) O - new indication
  Treatment of Waldenström's macroglobulinaemia (a rare blood cell cancer)

HIV

Positive CHMP opinions on new medicines

- Evotaz (*atazanavir / cobicistat*)
  Treatment of HIV-1 infection

Hormone system

Withdrawal of applications for new medicines

- Corluxin (*mifepristone*) O
  Intended for the treatment of Cushing's syndrome

Immune system

New information on authorised medicines

- Stelara (*ustekinumab*) - new indication
  Treatment of plaque psoriasis in children
- Simponi (*golimumab*) - new indication
  Treatment of axial spondyloarthritis (inflammatory rheumatic diseases that cause arthritis)

Metabolic system

Positive CHMP opinions on new medicines

- Repatha (*evolocumab*)
  Treatment to reduce blood cholesterol levels

New information on authorised medicines

- Kuvan (*sapropterin*) O - change in indication
  Treatment of hyperphenylalaninaemia in patients of all ages with phenylketonuria

Nervous system

Positive CHMP opinions on new medicines

- Pregabalin Mylan (*pregabalin*)
  Treatment of epilepsy and generalised anxiety disorder
- Pregabalin Sandoz GmbH (*pregabalin*)
  Treatment of epilepsy and generalised anxiety disorder
- Pregabalin Zentiva (*pregabalin*)
  Treatment of epilepsy and generalised anxiety disorder

New information on authorised medicines

- Fycompa (*perampanel*) - new indication
  Treatment of primary generalised tonic-clonic seizures

Withdrawal of applications for new medicines

- Aripiprazole Mylan (*aripiprazole*)
  Intended for the treatment of schizophrenia and prevention of manic episodes in patients with bipolar I disorder

Safety communication update

- Review of Tysabri (*natalizumab*) - review started (to assess whether the risk of progressive multifocal leukoencephalopathy should be revised)
  Treatment of multiple sclerosis

Ophthalmology

Positive CHMP opinions on new medicines

- Omidria (*phenylephrine hydrochloride / ketorolac trometamol*)
  Maintenance of pupil dilation during lens replacement surgery and prevention of pain

New medicines authorised

- Ikervis (*ciclosporin*)
  Treatment of severe keratitis (inflammation of the cornea) in patients with dry eye disease

Respiratory system

Safety communication update

- Review of codeine-containing medicines - CMDh Position (not to be used in children below 12 years for cough and cold)
  Treatment of cough and cold in children
- Review of inhaled corticosteroids containing medicines - review started (known risk of pneumonia to be examined in detail)
  Treatment of chronic obstructive pulmonary disease

Rheumatology

New information on authorised medicines

- Simponi (*golimumab*) - new indication
  Treatment of axial spondyloarthritis (inflammatory rheumatic diseases that cause arthritis)

Safety communication update

- Review of ibuprofen- and dexibuprofen-containing medicines - CMDh Position (small cardiovascular risk with high doses)
  Treatment of pain and inflammation

Other medicines

New medicines authorised

- Raplixa (*human fibrinogen / human thrombin*)
  Treatment to stop bleeding in patients undergoing surgery

Safety communication update

- Review of ibuprofen- and dexibuprofen-containing medicines - CMDh Position (small cardiovascular risk with high doses)
  Treatment of pain and inflammation

Other information

- GVK Biosciences: EMA confirms recommendation to suspend medicines over flawed studies

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on new guidance for importers of medicinal products
  Deadline for comments: 29 August 2015
- Draft guideline on the quality, non-clinical and clinical aspects of gene therapy medicinal products
  Deadline for comments: 31 August 2015
- Draft guideline on clinical development of fixed combination medicinal products
  Deadline for comments: 15 Nov 2015

Adopted guidelines

- Guideline adventitious agent safety of urine-derived medicinal products

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 2015
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- COMP work plan 2015
- 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 Pharmacovigilance Inspectors Working Group for 2015

Other publications

- 2014 annual report on EudraVigilance for the European Parliament, the Council and the Commission
- Minutes of the 87th meeting of the Management Board
- EMA tightens rules on 'revolving door' for committee members and experts
- Safety monitoring of medicines: EMA to screen medical literature for 400 active substance groups
- Update of EMA recommendations for 2015/2016 seasonal flu vaccine composition
- Workshop on the therapeutic use of bacteriophages - June 2015
- EMA workshop on the development of new medicinal products for the treatment of ulcerative colitis and Crohn's disease - June 2015
- PCWP meeting, PCWP and HCPWP joint meeting, and HCPWP meeting - June 2015
- Applying regulatory science to neonates: launch of the International Neonatal Consortium (INC) - May 2015
- EMA-industry stakeholders platform meeting on paediatric medicines - May 2015
- EMA/EGA joint workshop on the impact of the revised EMA guideline on the pharmacokinetic and clinical evaluation of modified-release dosage forms - April 2015 - meeting documents

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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