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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.

To receive an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

New information on authorised medicines

- Ecalta (*anidulafungin*) - change in indication
  Treatment of invasive candidiasis
- Baraclude (*entecavir*) - new indication
  Treatment of chronic hepatitis B virus in children

Cancer

Positive CHMP opinions on new medicines

- Imbruvica (*ibrutinib*) O
  Treatment of mantle cell lymphoma and chronic lymphocytic leukaemia
- Zydelig (*idelalisib*)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma

Key to symbols used

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

New medicines authorised

- Mekinist (*trametinib*)
  Treatment of melanoma

New information on authorised medicines

- Xgeva (*denosumab*) - new indication
  Treatment of giant cell tumour of bone

Withdrawal of applications for new medicines

- Neofordex (*dexamethasone*)
  Intended for the treatment of multiple myeloma

Cardiovascular system

Safety communication update

- Review of bromocriptine-containing medicines - PRAC recommendation (restricted use due to risk of side effects, particularly cardiovascular, neurological and psychiatric effects)
  Prevention and suppression of lactation

Diabetes

Positive CHMP opinions on new medicines

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

Gynaecology & Obstetrics

Safety communication update

- Review of bromocriptine-containing medicines - PRAC recommendation (restricted use due to risk of side effects, particularly cardiovascular, neurological and psychiatric effects)
  Prevention and suppression of lactation

Haematology

Positive CHMP opinions on new medicines

- Accofil (*filgrastim*)
  Treatment of neutropenia

Hormone system

Safety communication update

- Review of emergency contraceptives (*levonorgestrel, ulipristal acetate*) - CHMP concluded that these remain suitable emergency contraceptives for all women, regardless of bodyweight
  Prevention of unintended pregnancy following unprotected sexual intercourse or contraceptive failure

Immune system

New medicines authorised

- Envarsus (*tacrolimus*)
  Prevention of transplant rejection

New information on authorised medicines

- Humira (*adalimumab*) - new indication
  Treatment of enthesitis-related arthritis
- RoActemra *(tocilizumab)* - new indication
  Treatment of rheumatoid arthritis in adults not previously treated with methotrexate

Withdrawal of application for line extension of authorised medicines

- Simponi (*golimumab*) - intended line extension
  Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis

Nervous system

New medicines authorised

- Plegridy (*peginterferon beta-1a*)
  Treatment of multiple sclerosis

Withdrawal of authorised medicines

- Olanzapine Cipla (previously Olanzapine Neopharma) *(olanzapine)*
  Used for the treatment of schizophrenia

Safety communication update

- Review of bromocriptine-containing medicines - PRAC recommendation (restricted use due to risk of side effects, particularly cardiovascular, neurological and psychiatric effects)
  Prevention and suppression of lactation

Ophthalmology

New medicines authorised

- Simbrinza (*brinzolamide / brimonidine tartrate*)
  Treatment of elevated intraocular pressure

New information on authorised medicines

- Ozurdex (*dexamethasone*) - new indication
  Treatment of visual impairment due to diabetic macular oedema

Rheumatology

Positive CHMP opinions on new medicines

- RoActemra *(tocilizumab)* - new indication
  Treatment of rheumatoid arthritis in adults not previously treated with methotrexate

Key to symbols used

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New information on authorised medicines

- Humira (*adalimumab*) - new indication
  Treatment of enthesitis-related arthritis

Withdrawal of authorised medicines

- Preotact (*parathyroid hormone*)
  Intended for the treatment of osteoporosis in postmenopausal women

Withdrawal of application for line extension of authorised medicines

- Simponi (*golimumab*) - intended line extension
  Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis

Other medicines

Positive CHMP opinions on new medicines

- Busulfan Fresenius Kabi (*busulfan*)
  Conditioning treatment prior to blood-stem cell transplantation

New information on authorised medicines

- Busilvex (*busulfan*) - new indication
  To be used following fludarabine as conditioning treatment prior to blood-stem cell transplantation

Safety communication update

- Review of oral methadone medicines containing providone - CMD(h) Position (suspension and reformulation of solutions containing high molecular weight povidone due to risks associated with misuse by injection)
  Used in rehabilitation programs in patients dependent on opioids

Supply shortages

- Maci (*matrix-applied characterised autologous cultured chondrocytes*)
  Repair of cartilage defects of the knee

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolic risk in non-surgical patients
  Deadline for comments: 15 October 2014

- Concept paper on transferring quality control methods validated in collaborative trials to a product/ laboratory specific context
  Deadline for comments: 31 October 2014
- Draft reflection paper on the use of cocrystals and other solid state forms of active substances in medicinal products
  Deadline for comments: 31 October 2014
- Draft guideline on core SmPC and package leaflet for sodium fluoride (18F)
  Deadline for comments: 31 October 2014
- Draft guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency
  Deadline for comments: 01 January 2015
- Draft guideline on clinical evaluation of medicinal products used in weight control
  Deadline for comments: 31 January 2015
- Draft guideline on influenza vaccines: non-clinical and clinical module
  Deadline for comments: 31 January 2015

Adopted guidelines

- ICH guideline Q4B annex 6 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on uniformity of dosage units – general chapter - step 5
- ICH guideline E2B (R3) on electronic transmission of individual case safety reports (ICSRs) - implementation guide - data elements and message specification - step 5
- Guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation
- Guideline on quality of oral modified release products

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2014
- Medicinal products for human use: monthly figures - June 2014
- CHMP - applications for new human medicines - July 2014
- CHMP - agendas, minutes and highlights
- 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 and objectives for the EMA Working Party on Quality Review of Documents (QRD)
- PCWP/HCPWP joint meeting and workshop on benefit-risk communication - September 2014

Key to symbols used

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Other publications

- EMA launches public consultation on rules of procedures for public hearings
- Management Board delays formal adoption of EMA publication of clinical trial data policy to October 2014
- EMA publishes first public summaries of Paediatric Committee evaluations of paediatric investigation plans
- EMA recommends approval of two new treatment options for rare cancers
- EMA invites comments on new overarching guidance for the development of influenza vaccines
- EMA recommends 39 medicines for human use for marketing authorisation in first half of 2014
- Guide on methodological standards in pharmacoepidemiology revised to include pharmacogenetic studies
- World Hepatitis Day – EMA uses regulatory tools to facilitate patient access to innovative medicines - July 2014
- Workshop on clinical trials designs in neuromyelitis optica and spectrum disorders - October 2014
- Workshop on viral safety of plasma-derived medicinal products with respect to hepatitis E virus - October 2014

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.

Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

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