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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 each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

Information on medicines

Antivirals/anti-infectives

Safety communication update

- Review of direct-acting antivirals for hepatitis C - CHMP Opinion (recommendation to screen all patients for hepatitis B before starting treatment for hepatitis C)
  Treatment of hepatitis C

Cancer

Positive CHMP opinions on new medicines

- Alecensa (*alectinib*) C
  Treatment of non-small cell lung cancer
- Ledaga (*chormethine*) O
  Treatment of mycosis fungoides-type cutaneous T-cell lymphoma (type of skin cancer)

Key to symbols used

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

- Truxima (*rituximab*)
  Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

New information on authorised medicines

- Ameluz (*5-aminolevulinic acid hydrochloride*) - new indication
  Treatment of basal cell carcinoma (skin cancer)
- Keytruda (*pembrolizumab*) - new indication
  Treatment of non-small cell lung cancer

Withdrawal of applications for new medicines

- Graspa (*eryaspase*)
  Intended for the treatment of leukaemia (blood cancer)

Withdrawal of application - extension of indication

- Arzerra (*ofatumumab*)
  Intended for the treatment of leukaemia (blood cancer)

Withdrawal of authorised medicines

- Capecitabine SUN (*capecitabine*)
  Treatment of colon, colorectal, gastric and breast cancers

Cardiovascular system

Arbitration procedures

- Lovenox and associated names - outcome of procedure
  Treatment and prevention of conditions related to blood clots

Dermatology

Positive CHMP opinions on new medicines

- Ledaga (*chormethine*)
  Treatment of mycosis fungoides-type cutaneous T-cell lymphoma (type of skin cancer)

New information on authorised medicines

- Ameluz (*5-aminolevulinic acid hydrochloride*) - new indication
  Treatment of basal cell carcinoma (skin cancer)

Diabetes

New information on authorised medicines

- Jardiance (*empagliflozin*) - change in indication
  Treatment of diabetes mellitus
- Jentadueto (*linagliptin / metformin hydrochloride*) - change in indication
  Treatment of diabetes mellitus

- Trajenta (*linagliptin*) - change in indication
  Treatment of diabetes mellitus

Gastro-intestinal system

Withdrawal of authorised medicines

- Capecitabine SUN (*capecitabine*)
  Treatment of colon, colorectal, gastric and breast cancers

Haematology

Positive CHMP opinions on new medicines

- Truxima (*rituximab*)
  Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)
- Vihuma (*simoctocog alfa*)
  Prevention and treatment of bleeding in patients with haemophilia A

Withdrawal of applications for new medicines

- Cavoley (*pegfilgrastim*)
  Intended for the treatment of neutropenia (low level of white blood cells)
- Efgratin (*pegfilgrastim*)
  Intended for the treatment of neutropenia (low level of white blood cells)
- Graspa (*eryaspase*)
  Intended for the treatment of leukaemia (blood cancer)

Withdrawal of application - extension of indication

- Arzerra (*ofatumumab*)
  Intended for the treatment of leukaemia (blood cancer)

HIV

New information on authorised medicines

- Tivicay (*dolutegravir*) - change in indication
  Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- Lifmior (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis

- Olumiant (*baricitinib*)
  Treatment of rheumatoid arthritis
- Truxima (*rituximab*)
  Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

New information on authorised medicines

- Cinryze (*C1 inhibitor (human)*) - change in indication
  Treatment and prevention of angioedema attacks (swelling beneath the skin)
- Ilaris (*canakinumab*) - new indications
  Treatment of various inflammatory syndromes

Metabolic system

New information on authorised medicines

- Repatha (*evolocumab*) - new strength
  Treatment of hypercholesterolaemia and mixed dyslipidaemia (high levels of fat in blood)

Musculoskeletal system

Withdrawal of applications for new medicines

- Kepnetic (*aceneuramic acid*)
  Intended for the treatment of GNE myopathy (muscle disease)

Nervous system

Positive CHMP opinions on new medicines

- Pregabalin Zentiva k.s (*pregabalin*)
  Treatment of epilepsy, neuropathic pain and generalised anxiety disorder

New information on authorised medicines

- Votubia *(everolimus)* - new indication
  Treatment of partial-onset seizures

Respiratory system

Positive CHMP opinions on new medicines

- Alecensa (*alectinib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Treatment of non-small cell lung cancer

Rheumatology

Positive CHMP opinions on new medicines

- Lifmior (*etanercept*)
  Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis
- Olumiant (*baricitinib*)
  Treatment rheumatoid arthritis
- Truxima (*rituximab*)
  Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Vaccines

Withdrawal of authorised medicines

- Celvapan (*influenza vaccine (H1N1)v (whole virion, inactivated, prepared in cell culture*))
  Immunisation against influenza virus

Other medicines

Other information

- Micro Therapeutics Research Labs: Start of review concerning the conduct of studies at two sites in India

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft crizotinib hard capsules 200 mg and 250 mg product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017
- Draft elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil film-coated tablets 150 mg/150 mg/200 mg/ 245 mg product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017
- Draft elvitegravir 85 mg & 150 mg film-coated tablets product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017

- Draft emtricitabine/rilpivirine/tenofovir disoproxil, film-coated tablets, 200 mg/25 mg/245 mg product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017
- Draft vortioxetine hydrobromide, 5 mg, 10 mg, 15 mg and 20 mg immediate release tablets, vortioxetine lactate, oral drops solution 20 mg/ml product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017
- Draft dabigatran etexilate, hard capsules, 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance
  Deadline for comments: 31 Mar 2017
- Draft guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)
  Deadline for comments: 31 Mar 2017
- Draft guideline on core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg)
  Deadline for comments: 31 Mar 2017

Adopted guidelines

- ICH guideline Q3C (R5) on impurities: guideline for residual solvents - Step 5
- Guideline on the clinical development of medicinal products intended for the treatment of pain - First version
- Scientific guidance on post-authorisation efficacy studies - First version
- Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches
- Clinical development of medicinal products intended for the treatment of pain
- ICH Q3C (R6) Residual solvents
- ICH E6 (R2) Good clinical practice

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- Applications for new human medicines under evaluation by the CHMP: December 2016
- 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
- Work plan for the Biologics Working Party for 2017
- Work plan for the Biosimilar Medicinal Products Working Party for 2017

- Work plan for the Central Nervous System Working Party for 2017
- Work plan for the Cardiovascular Working Party for 2017
- Work plan of the Blood Products Working Party for 2017
- Work plan for the CHMP Excipients Drafting Group for 2017
- Work plan for the Oncology Working Party for 2017
- Work plan for the Respiratory Drafting Group for 2017
- Work plan for the Gastroenterology Drafting Group for 2017
- Work plan for the Pharmacogenomics Working Party for 2017
- Work plan for the Pharmacokinetics Working Party for 2017
- Work plan for the Rheumatology-Immunology Working Party for 2017
- Work plan for the Vaccine Working Party for 2017
- Kaisa Immonen elected as new co-chair of Patients' and Consumers' Working Party
- Revised framework for interaction between the European Medicines Agency and healthcare professionals and their organisations
- Training session for patients and consumers interested in EMA activities - meeting documents - Nov 2016

Other publications

- EMA Management Board: highlights of December 2016 meeting
- EMA budget for 2017
- Tailored scientific advice to support step-by-step development of new biosimilars
- Simpler website navigation for regulatory information on human medicines
- External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use
- EMA policy on access to EudraVigilance data for medicinal products for human use - Revision 3
- Workshop on qualification and reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation - Nov 2016 - meeting documents
- Workshop on measuring the impact of pharmacovigilance activities - Dec-2016 - meeting documents
- EMA / European Biopharmaceutical Enterprises (EBE) fifth annual regulatory conference on optimising the development of advanced therapies to meet patient needs - Dec 2016 - 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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http://www.ema.europa.eu

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30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
E-mail info@ema.europa.eu **Website** www.ema.europa.eu