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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

Positive CHMP opinions on new medicines

- Sovaldi (*sofosbuvir*)
  Treatment of hepatitis C virus infection
- Para-aminosalicylic acid Lucane (*para-aminosalicylic acid*) O
  Treatment of multidrug-resistant tuberculosis
- Deltyba (*delamanib*) O C
  Treatment of multidrug-resistant tuberculosis

Other information

- Daclatasvir - compassionate use
  Treatment of hepatitis C virus infection

Cancer

Positive CHMP opinions on new medicines

Key to symbols used

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

- Zoledronic Acid Accord (*zoledronic acid*)
  Prevention of bone complications and treatment of hypercalcaemia caused by tumours

New medicines authorised

- Xofigo (*radium-223 dichloride*)
  Treatment of prostate cancer

New information on authorised medicines

- Abraxane (*paclitaxel*) - new indication
  Treatment of pancreatic cancer
- Erbitux (*cetuximab*) - change in indication
  Treatment of metastatic colorectal cancer
- Velcade (*bortezomib*) - change in indication
  Treatment of progressive multiple myeloma

Negative CHMP opinions on new medicines

- Masican (*masitinib*)
  Treatment of gastrointestinal stromal tumour (a cancer of the stomach and bowel)

Safety communication update

- Iclusig (*ponatinib*) - changes in use in order to minimise risk of blood clots
  Treatment of leukaemia

Cardiovascular system

New information on authorised medicines

- Pradaxa (*dabigatran etexilate*) - change in indication
  Prevention of stroke and blood clots
- Corlentor and Procoralan (*ivabradine*) - change in contraindication (extended to women of child-bearing potential not using appropriate contraceptive measures)
  Treatment of symptoms of long-term stable angina

Safety communication update

- Review of substances related to nicotinic acid (acipimox) - PRAC recommendation
  Possible increased risk of painful muscle damage when used together with a statin

Diabetes

Positive CHMP opinions on new medicines

- Xigduo (*dapagliflozin and metformin*)
  Treatment of type 2 diabetes
- New medicines authorised
- Invokana (*canagliflozin*)
  Treatment of type 2 diabetes

Gynaecology & Obstetrics

Safety communication update

- Review of combined hormonal contraceptives (*desogestrel, gestodene, norgestimate, etonogestrel, drospirenone, dienogest, chlormadinone, nomegestrol, norelgestromin)* - CHMP Opinion
  Risk of venous thromboembolism (VTE or blood clots in veins)

HIV

Positive CHMP opinions on new medicines

- Tivicay (*dolutegravir*)
  Treatment of HIV infection

New medicines authorised

- Vitekta (*elvitegravir*)
  Treatment of HIV-1 infection

Haematology

Positive CHMP opinions on new medicines

- Velcade (*bortezomib*)
  Treatment of progressive multiple myeloma

New medicines authorised

- Grastofil (*filgrastim*)
  Treatment of neutropenia (low levels of white blood cells)

Safety communication update

- Iclusig (*ponatinib*) - changes in use in order to minimise risk of blood clots
  Treatment of leukaemia

Metabolic system

Positive CHMP opinions on new medicines

- Cholic Acid FGK (*cholic acid*)
  Treatment of inborn errors of primary bile acid synthesis

Safety communication update

- Review of substances related to nicotinic acid (acipimox) - PRAC recommendation
  Possible increased risk of painful muscle damage when used together with a statin

Nervous system

New medicines authorised

- Abilify Maintena (*aripiprazole*)
  Treatment of schizophrenia
- Levodopa/Carbidopa/Entacapone Sandoz (*levodopa, carbidopa and entacapone*)
  Treatment of Parkinson's disease and end-of-dose motor fluctuations

Rheumatology

Positive CHMP opinions on new medicines

- Zoledronic Acid Accord (*zoledronic acid*)
  Prevention of bone complications and treatment of hypercalcaemia caused by tumours

Safety communication update

- Review of thiocolchicoside-containing medicines by mouth or injection - restriction in use
  Only to be used at low doses for additional short-term relief of painful muscle contractures
- Review of diacerein-containing medicines - PRAC recommendation
  Risk of severe diarrhoea and potentially harmful effects on the liver

Other medicines

New medicines authorised

- Lidocaine/Prilocaine Plethora (*lidocaine and prilocaine*)
  Treatment of premature ejaculation

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Second draft guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation
  Deadline for comments: 15 January 2014
- Draft telithromycin product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft voriconazole product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft repaglinide product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014

- Draft posaconazole product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft oseltamivir product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft miglustat product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft memantine product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft imatinib product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft erlotinib product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft emtricitabine/tenofovir disoproxil product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft sirolimus product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft sorafenib product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft tadalafil product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft carglumic acid product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft capecitabine product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft dasatinib product-specific bioequivalence guidance
  Deadline for comments: 15 February 2014
- Draft guideline on the adventitious agent safety of urine-derived medicinal products
  Deadline for comments: 31 May 2014

Adopted guidelines

- Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

Scientific committee and working party activities

- CAT monthly report - November meeting
- CHMP highlights - November meeting
- CHMP - applications for new human medicines under evaluation - November meeting
- CHMP - adopted scientific advice and protocol assistance - November meeting
- CHMP - start of Community reviews - November meeting

Key to symbols used

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

- COMP agenda - December meeting
- COMP report - November meeting
- COMP minutes - October meeting
- HMPC meeting report - November meeting
- HMPC agenda - November meeting
- HMPC minutes - September meeting
- European Medicines Agency's Committee on Herbal Medicinal Products elects new chair and vice-chair
- PDCO agenda - December meeting
- PDCO monthly report - November meeting
- PDCO agenda - November meeting
- PDCO minutes - October meeting
- PDCO Rules of procedure
- PRAC highlights - November meeting
- PRAC recommendations on signals adopted at the November meeting
- PRAC agenda - November meeting
- PRAC minutes - October meeting
- PCWP meeting with all eligible organisations
- Mandate, objectives and rules of procedure for the GCP Inspectors Working Group (GCP IWG)

Other publications

- Training session for patients and consumers involved in European Medicines Agency activities
- European Medicines Agency updates on development of its policy on publication and access to clinical-trial data
- New EMA guidance on development of antibacterials to help in the fight against multidrug-resistant pathogens
- Early dialogue between regulators and health technology assessment bodies key to medicines development
- EMA-HTA workshop on parallel scientific advice in drug development
- European Medicines Agency and EUnetHTA agree joint work plan
- Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem
- Minutes of the workshop on methods for efficacy studies in the everyday practice
- Workshop on biosimilars
- European SME Week – early dialogue with the EMA is key to success
- Risk based quality management in clinical trials workshop
- Launch of European project for monitoring benefits and risks of vaccines throughout their lifecycle

- European Medicines Agency finalises review of medicines concerned by Roche pharmacovigilance inspection
- Regulatory information - EMA encourages companies to submit quality type-I variations for 2013 by end of November
- European Medicines Agency launches public catalogue of medicine shortages assessed by the Agency
- European Medicines Agency and US Food and Drug Administration release further guidance on quality-by-design approach
- EMA promotes consistent development of bioequivalence studies through product-specific guidance
- Mitigating risk aversion in medicines regulation in the interest of public health
- World AIDS Day 2013 – Revised guidance to facilitate development of new medicines
- European Antibiotic Awareness Day 2013: 'Everyone is responsible'
- World Diabetes Day – more treatment options to meet needs of growing patient numbers
- European Medicines Agency closed 23 December 2013 to 2 January 2014
- European Medicines Agency meeting and holiday dates 2014
- The annual European Medicines Agency review of the year and outlook for 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.

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http://www.ema.europa.eu

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