89 Issue 89
July 2016

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

Positive CHMP opinions on new medicines

- Tenofovir disoproxil Zentiva (*tenofovir disoproxil*)
  Treatment of HIV-1 infection and chronic hepatitis B

New medicines authorised

- Epclusa *(sofosbuvir / velpatasvir)*
  Treatment of hepatitis C
- Zepatier (*elbasvir / grazoprevir*)
  Treatment of hepatitis C
- Zavicefta (*ceftazidime / avibactam*)
  Treatment of bacterial infections

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Cabometyx (*cabozantinib*)
  Treatment of renal cell carcinoma (kidney cancer)
- Kisplyx (*lenvatinib*)
  Treatment of renal cell carcinoma (kidney cancer)
- Onivyde (*irinotecan*) O
  Treatment of cancer of the pancreas

New medicines authorised

- Bortezomib Hospira (*bortezomib*)
  Treatment of multiple myeloma (cancer of the bone marrow)
- Pemetrexed Fresenius Kabi (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- Imbruvica (*ibrutinib*) O - change in indication
  Treatment of mantle cell lymphoma, chronic lymphocytic leukaemia and Waldenström's macroglobulinaemia (blood cancers)
- Xalkori (*crizotinib*) C - new indication
  Treatment of non-small cell lung cancer

Safety communication update

- Review of Zydelig (*idelalisib*) - CHMP Opinion (Zydelig benefits outweigh its risks)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)

Cardiovascular system

Positive CHMP opinions on new medicines

- Inhixa (*enoxaparin sodium*)
  Prevention and treatment of various disorders related to blood clots
- Thorinane (*enoxaparin sodium*)
  Prevention and treatment of various disorders related to blood clots

Dermatology

New information on authorised medicines

- Ameluz (*5-aminolevulinic acid hydrochloride*) - change in indication
  Treatment of actinic keratosis (abnormal skin growths caused by over exposure to sunlight)

Safety communication update

- Review of retinoid-containing medicinal products - review started (measures for pregnancy prevention and minimising possible risk of neuropsychiatric disorders)
  Treatment of several skin conditions

Key to symbols used

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

Diabetes

New medicines authorised

- Qtern (*saxagliptin / dapagliflozin*)
  Treatment of diabetes mellitus

Safety communication update

- Review of SGLT2 inhibitors (previously only canagliflozin) (*canagliflozin, empagliflozin, dapagliflozin*) - review started (following increase in amputations in ongoing clinical trial)
  Treatment of diabetes

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Truberzi (*eluxadoline*)
  Treatment of irritable bowel syndrome

New medicines authorised

- Enzepi (*pancreas powder*)
  Treatment of pancreatic insufficiency

Haematology

New medicines authorised

- Bortezomib Hospira (*bortezomib*)
  Treatment of multiple myeloma (cancer of the bone marrow)

New information on authorised medicines

- Imbruvica (*ibrutinib*) O - change in indication
  Treatment of mantle cell lymphoma, chronic lymphocytic leukaemia and Waldenström's macroglobulinaemia (blood cancers)

Safety communication update

- Review of Factor VIII - start of review (to evaluate the risk of developing inhibitor proteins)
  Treatment of haemophilia A
- Review of Zydelig (*idelalisib*) - CHMP Opinion (Zydelig benefits outweigh its risks)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)

HIV

New medicines authorised

- Odefsey *(emtricitabine / rilpivirine / tenofovir alafenamide)*
  Treatment of HIV-1 infection

Key to symbols used

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

New information on authorised medicines

- Truvada (*emtricitabine / tenofovir disoproxil*) - new indication
  Prevention of sexually-acquired HIV-1 infection

Hormone system

Safety communication update

- Review of retinoid-containing medicinal products - review started (measures for pregnancy prevention and minimising possible risk of neuropsychiatric disorders)
  Treatment of several skin conditions

Immune system

New information on authorised medicines

- Orencia (*abatacept*) - new indication
  Treatment of rheumatoid arthritis

Withdrawal of applications for new medicines

- Begedina (*begelomab*)
  Intended for graft-versus-host disease (when transplanted cells attack host tissues)

Nephrology

Positive CHMP opinions on new medicines

- Cabometyx (*cabozantinib*)
  Treatment of renal cell carcinoma (kidney cancer)
- Kisplyx (*lenvatinib*)
  Treatment of renal cell carcinoma (kidney cancer)

Nervous system

Positive CHMP opinions on new medicines

- Sialanar (*glycopyrronium bromide*)
  Treatment of severe drooling in children and adolescents with neurological disorders

New medicines authorised

- Ongentys (*opicapone*)
  Treatment of Parkinson's disease
- Zinbryta (*daclizumab*)
  Treatment of multiple sclerosis

Safety communication update

- Review of retinoid-containing medicinal products - review started (on measures for pregnancy prevention and for minimising possible risk of neuropsychiatric disorders)
  Treatment of several skin conditions

Key to symbols used

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

Respiratory system

New medicines authorised

- Pemetrexed Fresenius Kabi (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- Xalkori (*crizotinib*) C - new indication
  Treatment of non-small cell lung cancer

Rheumatology

New information on authorised medicines

- Orencia (*abatacept*) - new indication
  Treatment of rheumatoid arthritis

Other medicines

New medicines authorised

- EndolucinBeta (*lutetium (177 Lu) chloride*)
  Radiopharmaceutical precursor

Arbitration procedures

- Diclofenac epolamine 50 mg tablets (*diclofenac*) - outcome of procedure
  Used for the relief of pain and inflammation
- Durogesic and associated names (*fentanyl*) - outcome of procedure
  Used to relieve severe long-term pain
- Review on the conduct of studies at Semler Research Centre - outcome of procedure

Safety communication update

- Review of paracetamol-modified release (*paracetamol*) - start of review (measures to minimise risk and reduce harm of overdose to be considered)
  Used to relieve pain and fever

Medicines under additional monitoring

- Updated list of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Proposals to revise guidance on first-in-human clinical trials
  Deadline for comments: 30 September 2016
- Draft review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken
  Deadline for comments: 31 October 2016
- Concept paper on the need for revision of the note for guidance on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder
  Deadline for comments: 31 October 2016
- Draft concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus
  Deadline for comments: 31 October 2016
- Draft guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials
  Deadline for comments: 31 December 2016
- Draft guideline on the clinical investigation of medicinal products for the treatment of axial spondyloarthritis - Revision 1
  Deadline for comments: 31 December 2016
- Draft guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis
  Deadline for comments: 31 December 2016
- ICH guideline E17 on general principles for planning and design of multi-regional clinical trials - Step 2b
  Deadline for comments: 28 January 2017
- ICH S9 guideline on nonclinical evaluation for anticancer 4 pharmaceuticals - questions and answers - Step 2b
  Deadline for comments: 28 January 2017
- Draft guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs
  Deadline for comments: 31 January 2017
- Draft guideline on the qualification and reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation
  Deadline for comments: 31 January 2017

Adopted guidelines

- Influenza vaccines - non-clinical and clinical module

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use topic E 2 B (R5): Questions and answers: Data elements for transmission of individual case safety reports - Step 5
- ICH M4E (R2) Common technical document for the registration of pharmaceuticals for human use - efficacy - Step 5
- Guideline on the clinical development of medicinal products for the treatment of HIV infection
- Guideline on clinical investigation of medicinal products in the treatment of lipid disorders
- Guideline on clinical investigation of medicinal products in the treatment of hypertension
- Guideline on clinical evaluation of medicinal products used in weight management
- Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antimicrobial medicinal products

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - June 2016
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: July 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
- Annual report of the Pharmacovigilance Inspectors Working Group for 2015

Other publications

- Minutes of the 92nd meeting of the EMA Management Board
- Work programme of the EMA 2016 (updated)
- Second annual scientific workshop at EMA: Applying regulatory science to neonates - Sep 2016
- PCWP and HCPWP joint meeting: Workshop on social media - Sep 2016
- PCWP and HCPWP joint meeting - Sep 2016
- Joint DIA/EFGCP/EMA better medicines for children conference 2016 on optimisation of drug development for the benefit of children - Oct 2016
- Spinal muscular atrophy workshop - Nov 2016
- Recommendations on eligibility to PRIME scheme
- Infringement procedure against Roche – EMA update

Key to symbols used

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

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

In particular, you may be interested in these links:

About us

Patients and carers

Healthcare professionals

European public assessment reports

European Medicines Agency

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