64 Issue 64
June 2014

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

Positive CHMP opinions on new medicines

- Vantobra (*tobramycin*) O
  Treatment of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis
- Daklinza (*daclatasvir*)
  Treatment of chronic (long-term) hepatitis C virus

New medicines authorised

- Olysio (*simeprevir*)
  Treatment of chronic (long-term) hepatitis C virus
- Ebilfumin *(oseltamivir)*
  Treatment or prevention of influenza

Withdrawal of applications for new medicines

- Faldaprevir Boehringer Ingelheim (*faldaprevir*)
  Intended for the treatment of chronic (long-term) hepatitis C virus

Key to symbols used

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

Cancer

New information on authorised medicines

- Avastin (*bevacizumab*)- new indication
  Treatment of ovarian, fallopian tube, peritoneal (abdomen lining) cancer, in addition to colon or rectal, breast, lung and renal (kidney) cell cancer
- Stivarga (*regorafenib*)- new indication
  Treatment of gastrointestinal stromal tumors (digestive cancer), in addition to colon or rectal cancer

Withdrawal of applications for new medicines

- Folcepri *(etarfolatide)* O
  Intended as a diagnostic medicine used when scanning for ovarian cancer cells
- Neocepri *(folic acid)* O
  Intended as a diagnostic medicine used when scanning for ovarian cancer cells
- Vynfinit *(vintafolide)* O
  Intended for the treatment of ovarian cancer

Withdrawal of applications for a new indication

- Tasigna *(nilotinib)* O
  Intended for the treatment of Philadelphia-chromosome-positive chronic myelogenous leukaemia (white blood cell cancer)

Safety communication update

- Supply of stolen medicines (Herceptin, Remicade and Amilta) - update on investigation

Cardiovascular system

Positive CHMP opinions on new medicines

- Clopidogrel / Acetylsalicylic acid Teva *(clopidogrel and acetylsalicylic acid)*
  Prevention of atherothrombotic events (blood clots)

New information on authorised medicines

- Eliquis (*apixaban*)- new indication
  Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), including prevention of recurrent DVT and PE, in addition to prevention of VTE after hip or knee replacement surgery and prevention of stroke and systemtic embolism in patients with non-valvular atrial fibrillation

Safety communication update

- Review of ibuprofen and dexibuprofen-containing medicines - review started (concerns over possible cardiovascular side effects with high doses taken over long periods)
  Treatment of pain and inflammation

Endocrinology

Arbitration procedures

- Sandostatin and associated names and Sandostatin LAR and associated names (*octreotide*) - outcome
  Various uses, including treatment of agromegaly (excess of growth hormone), digestive tumours, prevention of pancreatic surgery complications, and bleeding veins in the oesophagus or stomach

Diabetes

Positive CHMP opinions on new medicines

- Abasria (*insulin glargine*)
  Treatment of diabetes mellitus

New medicines authorised

- Jardiance *(empagliflozin)*
  Treatment of type-2 diabetes mellitus

Safety communication update

- Assessment report of non-compliance with Good Manufacturing Pratice at Ranbaxy, Toansa (Enyglid, Repaglinide Krka, Repaglinide Teva): no risk to public health
  Treatment of type-2 diabetes mellitus

Gastro-intestinal system

New medicines authorised

- Entyvio *(vedolizumab)*
  Treatment of ulcerative colitis or Crohn's disease

Gynaecology & Obstetrics

Arbitration procedures

- Seasonique and associated names (*levonorgestrel and ethinylestradiol*) - outcome
  Combined hormonal contraceptive

HIV

Positive CHMP opinions on new medicines

- Triumeq *(dolutegravir / abacavir / lamivudine)*
  Treatment of HIV-1 infection

Safety communication update

- Assessment report of non-compliance with Good Manufacturing Pratice at Ranbaxy, Toansa (Nevirapine Teva): no risk to public health
  Treatment of HIV-1 infection

New information on authorised medicines

- Isentress (*raltegravir*) - new indication
  Treatment of HIV infection in toddlers and infants from the age of 4 weeks, in addition to adults, adolescents, and children

Metabolic system

New medicines authorised

- Vimizim *(elosulfase alfa)* O
  Treatment of mucopolysaccharidosis type IVA

Nervous system

Positive CHMP opinions on new medicines

- Vizamyl *(flutemetamol)*
  Diagnosis of Alzheimer's disease and other causes of cognitive impairment

Ophthalmology

New information on authorised medicines

- Eylea *(aflibercept)* - new indication
  Treatment of visual impairment due to diabetic macular oedema, in addition to neovascular (wet) age-related macular degeneration and visual impairment due to macular oedema secondary to central retinal vein occlus

Respiratory system

Positive CHMP opinions on new medicines

- Vantobra (*tobramycin*) O
  Treatment of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis
- Kalydeco *(ivacaftor)* O
  Treatment of cystic fibrosis

New medicines authorised

- Anoro and Laventair *(umeclidinium bromide / vilanterol)*
  Relief of the symptoms of chronic obstructive pulmonary disease
- Revinty Ellipta *(fluticasone furoate / vilanterol)*
  Treatment of asthma

Safety communication update

- Review of codeine containing medicinal products for the treatment of cough or cold in paediatric patients - review started (concerns over the increase of morphine levels in blood)

Rheumatology

New information on authorised medicines

- Enbrel (*etanercept*) - new indication
  Treatment of axial spondyloarthritis, in addition to rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, adult and paediatric plaque psoriasis

Other medicines

New medicines authorised

- Sylvant *(siltuximab)*
  Treatment of multicentric Castleman's disease

Safety communication update

- Review of ibuprofen- and dexibuprofen-containing medicines - review started (concerns over the increase of cardiovascular side effects with high doses taken over long periods)
  Treatment of pain and inflammation

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Public consultation on EMA's draft guide on monitoring of medical literature
  Deadline for comments: 27 July 2014
- Concept paper on qualification and reporting of physiologically based pharmacokinetic (PBPK) modelling and analyses
  Deadline for comments: 30 September 2014
- Draft reflection paper on classification of advanced-therapy medicinal products
  Deadline for comments: 31 October 2014
- Revised guidance on advanced-therapy classification for public consultation
  Deadline for comments: 31 October 2014
- Draft reflection paper on the use of patient reported outcome (PRO) measures in oncology studies
  Deadline for comments: 30 November 2014
- Questions and answers on benzalkonium chloride in the context of the revision of the guideline on excipients in the label and package leaflet of medicinal products for human use
  Deadline for comments: 30 November 2014

Adopted guidelines

- Final guideline on influenza vaccines – Quality module
- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1)
- Regulatory information – revised guideline on acceptability of names for human medicines is published
- Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- Applications for new human medicines under evaluation by the CHMP: June 2014
- 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
- PRAC meeting dates 2014 and 2015
- Good Clinical Practice Inspectors Working Group 2013 - Annual report
- EMA modelling and simulation Working Group for 2014 - Work plan and Activity report

Other publications

- Organisation chart of the European Medicines Agency
- EMA Management Board re-elects Sir Kent Woods as chair
- Management Board meeting dates 2015
- EMA agrees policy on publication of clinical trial data with more user-friendly amendments
- EMA selects first two medicines to be included in its adaptive licensing pilot project
- EMA welcomes publication of pharmacovigilance fee Regulation in Official Journal of the EU
- Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014
- Criteria to be fulfilled by patients' and consumers' organisations involved in EMA activities
- News bulletin for small and medium-sized enterprises - Issue 28
- European Commission launches logo for online pharmacies to protect patients from falsified medicines
- Outcome report on first European collaboration between regulators and HTA organisations: improving the contribution of regulatory assessment reports to health technology assessment

Key to symbols used

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

- Reinforcing communication with patients and healthcare professionals - 23 July 2014 - Serbia
- Advanced-therapy-medicinal-product classification
- Falsified medicines
- Sixth annual workshop of the European network of paediatric research at the EMA (Enpr-EMA) - Agenda
- Workshop on advanced-therapy medicinal products: How to bring cell-based medicinal products successfully to the market
- Course - Introduction to Pharmacovigilance and rules for expedited reporting of Individual Case Safety Reports (ICSRs) in Europe, EMA: 14 October 2014 and 04 November 2014
- EudraVigilance training on the electronic reporting of ICSRs in the EEA, EMA:01-03 October; 15-17 October; 05-07 November; 17-19 November; 03-05 December
- EMA excellence in Pharmacovigilance: Clinical trials and post-marketing training course, EMA: 13-17 October 2014
- EMA/EFPIA workshop on the importance of dose finding and dose selection for the successful development, licensing and lifecycle management of medicinal products: 4-5 December 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

In particular, you may be interested in these links:

About us

Patients and carers

Healthcare professionals

European public assessment reports

European Medicines Agency

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union