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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

Withdrawal of applications for new medicines

- Arikayce (*amikacin*) O
  Treatment of bacterial lung infection

Communication on prevention of medication errors

- Noxafil (*posaconazole*)
  Treatment of fungal infections

Cancer

Positive CHMP opinions on new medicines

- Zalmoxis (*genetically modified T-cells*) C O
  Used in patients with blood cancer after bone marrow (blood stem cell) transplantation

Key to symbols used

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

New medicines authorised

- Palonosetron Accord (*palonosetron*)
  Prevention of nausea and vomiting associated with chemotherapy

New information on authorised medicines

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

Withdrawal of applications for new medicines

- Docetaxel Sun (*docetaxel*)
  Intended for the treatment of various types of cancer

Negative CHMP opinion on extension of indication

- Arzerra (*ofatumumab*)
  Intended as maintenance treatment for chronic lymphocytic leukaemia (blood cancer)

Cardiovascular system

New medicines authorised

- Neparvis (*sacubitril / valsartan*)
  Treatment of chronic heart failure

New information on authorised medicines

- Zontivity (*vorapaxar*) - change in indication
  Prevention of problems caused by blood clots, such as heart attack

Safety communication update

- Adempas (*riociguat*)
  Treatment of pulmonary hypertension

Diabetes

New information on authorised medicines

- Nevanac (*nepafenac*) - new indication
  Reduction in the risk of cataract surgery complications in diabetic patients
- Ryzodeg (*insulin degludec / insulin aspart*) - change in indication
  Treatment of diabetes mellitus

Gastro-intestinal system

New medicines authorised

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

Haematology

Positive CHMP opinions on new medicines

- Zalmoxis (*genetically modified T-cells*)
  Used in patients with blood cancer after bone marrow (blood stem cell) transplantation

New medicines authorised

- Strimvelis (*autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ada) cdna sequence*)
  Treatment of immunodeficiency

Negative CHMP opinion on extension of indication

- Arzerra (*ofatumumab*)
  Intended as maintenance treatment for chronic lymphocytic leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

- Atazanavir Mylan (*atazanavir*)
  Treatment of HIV-1 infection

New medicines authorised

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

Immune system

Positive CHMP opinions on new medicines

- Aerivio Spiromax / Airexar Spiromax (*fluticasone propionate / salmeterol*)
  Treatment of asthma and chronic obstructive pulmonary disorder (COPD)
- Cinqaero (*reslizumab*)
  Treatment of asthma
- Nordimet (*methotrexate*)
  Treatment of arthritis and psoriasis

New medicines authorised

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis
- Strimvelis (*autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ada) cdna sequence*)
  Treatment of immunodeficiency

New information on authorised medicines

- RoActemra (*tocilizumab*) - change in indication
  Treatment of rheumatoid arthritis

Key to symbols used

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Metabolic system

New medicines authorised

- Galafold (*migalastat*)
  Treatment of Fabry disease

Musculoskeletal system

Withdrawal of applications for new medicines

- Kyndrisa (*drisapersen*)
  Intended for the treatment of Duchenne muscular dystrophy

Ophthalmology

New information on authorised medicines

- Nevanac (*nepafenac*) - new indication
  Reduction in the risk of cataract surgery complications in diabetic patients

Respiratory system

Positive CHMP opinions on new medicines

- Aerivio Spiromax / Airexar Spiromax (*fluticasone propionate / salmeterol*)
  Treatment of asthma and chronic obstructive pulmonary disorder (COPD)
- Cinqaero (*reslizumab*)
  Treatment of asthma

New information on authorised medicines

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

Withdrawal of applications for new medicines

- Arikayce (*amikacin*)
  Treatment of bacterial lung infection

Rheumatology

Positive CHMP opinions on new medicines

- Nordimet (*methotrexate*)
  Treatment of arthritis and psoriasis

New medicines authorised

- Flixabi (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

New information on authorised medicines

- Ilaris (*canakinumab*) - change in indication
  Treatment of Still's disease and systemic juvenile idiopathic arthritis
- RoActemra (*tocilizumab*) - change in indication
  Treatment of rheumatoid arthritis

Withdrawal of applications for new medicines

- Alendronic Acid/Colecalciferol Mylan (*alendronic acid/colecalciferol*)
  Intended for the treatment of postmenopausal osteoporosis in women at risk of vitamin D deficiency

Vaccines

New information on authorised medicines

- Cervarix (human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed)) - change in indication
  Prevention against human-papillomavirus (HPV)

New medicines authorised

- Pandemic influenza vaccine H5N1 MedImmune (*pandemic influenza vaccine (H5N1) (live attenuated, nasal*)
  Immunisation against avian flu

Other medicines

Arbitration procedure

- Alkem Laboratories Ltd - CHMP Opinion (studies cannot be used to support medicines approval in the EU)
- Pharmaceutics International Inc. - review started (following an inspection which highlighted shortcomings in relation to good manufacturing practice (GMP))

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on core SmPC and package leaflet for gadoteric acid
  Deadline for comments: 30 Sep. 2016

- Draft guideline on core SmPC and package leaflet for fluorodopa (18F)
  Deadline for comments: 30 Sep. 2016
- Draft guideline on core SmPC and package leaflet for (68Ge/68Ga) generator
  Deadline for comments: 30 Sep 2016

Adopted guidelines

- Reflection paper on viral safety of plasma-derived medicinal products with respect to Hepatitis E virus

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2016
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 2016 (updated)
- 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 Pharmacovigilance Inspectors Working Group for 2016

Other publications

- EMA Management Board: highlights of June 2016 meeting
- Multiannual work programme to 2020
- EMA celebrates ten years of its patients and consumers working party
- EMA's interaction with patients, consumers, healthcare professionals and their organisations - Annual report 2015
- EMA and FDA reinforce collaboration on patient engagement
- EMA stakeholder relations management framework
- First statistics on PRIME are released
- Regulation of advanced therapy medicines
- Single, central platform now mandatory for all periodic safety update reports
- Strengthening interaction with academia
- EMA annual accounts: Financial year 2015
- Joint meeting of the Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) working parties - Mar 2016 - meeting documents

- Enpr-EMA 2016 annual workshop of the Enpr-EMA at the European Medicines Agency - June 2016 - meeting documents
- Targeted consultation on the guideline for development of new medicinal products for the treatment of rheumatoid arthritis - June 2016
- Workshop on single-arm trials in oncology - June 2016
- Follow up information session on the TransCelerate initiative - June 2016
- EMA collaboration with general practitioners/ family physicians (GPs/FPs): Report from a joint EMA workshop with EFPC, UEMO and WONCA-Europe organised on 19 April 2016
- Information Day on Medication Errors - Oct 2016
- Information day on risk management planning and post-authorisation studies - Nov 2016

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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