107 Issue 107
February 2018

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

- Shingrix (*herpes zoster vaccine (recombinant, adjuvanted)*)
  Prevention of herpes zoster

New medicines authorised

- Darunavir Krka d.d. (*darunavir*) generic of Prezista
  Treatment of HIV infection
- Prevymis (*letermovir*)
  Prevention of cytomegalovirus (CMV) reactivation (viral infection)

Cancer

New medicines authorised

- Lutathera (*lutetium (177Lu) oxodotreotide*)
  Treatment of gastroenteropancreatic neuroendocrine tumours (cancer of the gut or pancreas)

Key to symbols used

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

- Mvasi (*bevacizumab*) biosimilar of Avastin
  Treatment of cancers of the colon, breast, lung, kidney, ovaries and cervix
- Ontruzant (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast cancer and stomach cancer

Withdrawal of applications for new medicines

- Balimek (*binimetinib*)
  Intended for the treatment of melanoma (skin cancer)

Withdrawal of applications for extension of indication

- Opdivo (*nivolumab*)
  Intended for the treatment of colorectal cancer (bowel cancer)

Diabetes

Positive CHMP opinions on new medicines

- Segluromet (*ertugliflozin / metformin*)
  Treatment of type 2 diabetes
- Semglee (*insulin glargine*) biosimilar of Lantus
  Treatment of diabetes (type 1 and 2)
- Steglatro (*ertugliflozin*)
  Treatment of type 2 diabetes
- Steglujan (*ertugliflozin / sitagliptin*)
  Treatment of type 2 diabetes

Gastro-intestinal system

New medicines authorised

- Jorveza (*budesonide*)
  Treatment of eosinophilic oesophagitis (inflammation of the oesophagus)
- Ontruzant (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast cancer and stomach cancer

Haematology

Positive CHMP opinions on new medicines

- Hemlibra (*emicizumab*)
  Treatment and prevention of bleeding in patients with haemophilia A who have factor VIII inhibitors

Safety communication update

- Review of hydroxyethyl starch (HES) containing medicinal products - CMDh Position (to be suspended due to serious risks of kidney injury and death in certain patient populations)
  Used for hypovolaemia (low blood volume) caused by acute (sudden) blood loss

HIV

New medicines authorised

- Darunavir Krka d.d. (*darunavir*) generic of Prezista
  Treatment of HIV infection

Hormone system

Negative CHMP opinions on new medicines

- EnCyzix (*enclomifene*)
  Intended for the treatment of hypogonadotropic hypogonadism in men (reduced testicular function)

Immune system

New medicines authorised

- Tacforius (*tacrolimus*) generic of Advagraf
  Used for prevention and treatment of transplant rejection

New information on authorised medicines

- Relvar Ellipta / Revinty Ellipta (*fluticasone furoate / vilanterol*) - extension of indication
  Treatment of asthma

Metabolic disorders

Positive CHMP opinions on new medicines

- Lamzede (*velmanase alfa*)
  Treatment of alpha-mannosidosis (rare inherited enzyme disorder)
- Lokelma (*sodium zirconium cyclosilicate*)
  Treatment of hyperkalaemia (high levels of potassium in the blood)

Nervous system

New medicines authorised

- Ocrevus (*ocrelizumab*)
  Treatment of multiple sclerosis

New information on authorised medicines

- Hizentra (*human normal immunoglobulin (SCIg)*) - new indication
  Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) (inflammatory disease of the nerves)

Withdrawal of applications for new medicines

- Rotigotine Mylan (*rotigotine*) generic of Neupro
  Intended for the treatment of Parkinson's disease and restless-leg syndrome

Safety communication update

- Buccolam: Defect with Buccolam oral syringes
  Used to stop prolonged, acute (sudden) convulsive seizures (fits) in children and adolescents with epilepsy

Respiratory system

New medicines authorised

- Elebrato Ellipta (*fluticasone furoate / umeclidinium / vilanterol*)
  Treatment of chronic obstructive pulmonary disease (COPD)

New information on authorised medicines

- Relvar Ellipta / Revinty Ellipta (*fluticasone furoate / vilanterol*) - extension of indication
  Treatment of asthma

Other medicines

New medicines authorised

- VeraSeal (*human fibrinogen / human thrombin*)
  Used as a sealant during surgery
- Zubsolv (*buprenorphine / naloxone*)
  Treatment of opioid dependence

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft qualification opinion on molecular neuroimaging of the dopamine transporter as biomarker to identify patients with early manifest Parkinsonism in Parkinson's disease
  Deadline for comments: 07 March 2018
- Draft guideline on core summary of product characteristics (SmPC) and package leaflet for technetium (99mTc) macrosalb
  Deadline for comments: 31 March 2018

- Draft ledipasvir/sofosbuvir film-coated tablet 90 mg/400 mg product-specific bioequivalence guidance
  Deadline for comments: 30 April 2018
- Draft posaconazole gastro-resistant tablet 100 mg product-specific bioequivalence guidance
  Deadline for comments: 30 April 2018
- Draft agomelatine oral tablet 25 mg product-specific bioequivalence guidance
  Deadline for comments: 30 April 2018
- Draft vismodegib hard capsule 150 mg product-specific bioequivalence guidance
  Deadline for comments: 30 April 2018
- Draft cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance
  Deadline for comments: 30 April 2018

Adopted guidelines

- Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs
- Overview of comments received on 'Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs
- Guideline on clinical investigation of medicinal products for the treatment of rheumatoid arthritis

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- Autologous stromal vascular fraction
- Autologous human mesenchymal stem cells present in bone marrow cells suspension
- Autologous ex vivo expanded polyclonal CD4+CD25+CD127lo/-FOXP3+ regulatory T cells
- Viable autologous adipose-derived regenerative cells
- Pro-inflammatory dendritic cells
- DNA plasmid encoding for the extracellular domain of human TNFα p55 receptor linked to the human IgG1 Fc domain
- Recombinant adeno-associated virus serotype 2/1 vector encoding human β-hexosaminidase alpha and beta subunits
- Cultured dental pulp stem cells
- Autologous dental pulp stem cells
- Freshly isolated autologous CD34+
- Allogenic adipose-derived stem cells differentiated in vitro towards the cardiovascular lineage
- Adeno-associated viral vector serotype 8 containing the human low-density lipoprotein receptor (LDLR) gene
- Full-thickness human skin substitute composed of an epidermal layer of fully-stratified human keratinocytes and a collagen-rich dermal equivalent containing human dermal fibroblasts

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - December 2017
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: January 2018
- 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
- Mandate, objectives and rules of procedure of the Scientific Advice Working Party (SAWP) - updated
- Work plan of the CHMP Blood Products Working Party for 2018 - updated
- Work plan for the Biosimilar Medicinal Products Working Party 2018 - updated
- Work plan for the Infectious Diseases Working Party 2018 - updated
- Work plan for the CHMP Respiratory Drafting Group for 2018 - updated
- Work plan for the Cardiovascular Working Party 2018 - updated
- Work plan for the CHMP Oncology Working Party for 2018
- Work plan for the Pharmacogenomics Working Party 2018
- Work plan for the Gastroenterology Drafting Group 2018
- Work plan for the Rheumatology-Immunology Working Party 2018
- Work plan for the Pharmacokinetics Working Party 2018
- Work plan for the Central Nervous System Working Party 2018
- Work plan for the CHMP Excipients Drafting Group (ExcpDG) for the revision of the EC guideline 'Excipients in the labelling and package leaflet of medicinal products for human use' for 2018

Other publications

- EMA Management Board meeting - December 2017 - report: EMA budget for 2018
- Statement by Executive Director Guido Rasi in The Hague - press conference with Dutch authorities
- Human medicines: highlights of 2017 - interactive report
- Why EMA matters to European citizens - video animations
- How to better apply the paediatric legislation to boost development of medicines for children
- Chair of EMA's committee for orphan medicines receives award for outstanding patient engagement
- Is an orphan medicine still an orphan once it gets on the market?

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

- Orphan medicines figures 2000-2017 - PowerPoint presentation
- EMA surveys pharma companies on their preparedness for Brexit
- A common data model in Europe? – Why? Which? How? - December 2017 - meeting documents

Events

- Chimeric antigen receptor (CAR) T-cell therapy registries workshop - February 2018
- Second international awareness session for international regulators, academia and non-governmental organisations - March 2018
- Multi-stakeholder workshop to further improve implementation of Paediatric Regulation - March 2018

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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