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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.

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Information on medicines

Antivirals/anti-infectives

Safety communication update

- Review of quinolone- and fluoroquinolone-containing medicinal products - CHMP Opinion (long-lasting effects mainly affecting musculoskeletal and nervous systems)
  Treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Erleada (*apalutamide*)
  Treatment of prostate cancer

New medicines authorised

- Alunbrig (*brigatinib*)
  Treatment of non-small cell lung cancer

Key to symbols used

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

New information on authorised medicines

- Blincyto (*blinatumomab*) O - new indication
  Treatment of acute lymphoblastic leukaemia (ALL)
- Kisqali (*ribociclib*) - change in indication
  Treatment of breast cancer
- Opdivo (*nivolumab*) and Yervoy (*ipilimumab*) - extension of indication
  Combination treatment of renal cell carcinoma (kidney cancer)

Withdrawal of applications for extension of indication

- Tecentriq (*atezolizumab*)
  Intended for treatment of renal cell carcinoma (kidney cancer)

Cardiovascular system

Safety communication update

- Review of sartan medicines - Valsartan from Mylan laboratories in India can no longer be used in EU medicines due to NDEA impurity
  Treatment of high blood pressure, recent heart attack and heart failure

Haematology

New information on authorised medicines

- Blincyto (*blinatumomab*) O - new indication
  Treatment of acute lymphoblastic leukaemia (ALL)
- MabThera (*rituximab*) - extension of indication
  Treatment of granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Hormone system

Positive CHMP opinions on new medicines

- Macimorelin Aeterna Zentaris (*macimorelin*)
  Diagnosis of growth hormone deficiency

Metabolic disorders

New information on authorised medicines

- Ravicti (*glycerol phenylbutyrate*) O - change in indication
  Treatment of urea cycle disorders

Nervous system

Positive CHMP opinions on new medicines

- Fexinidazole Winthrop (*fexinidazole*) - Article 58
  Treatment of human African trypanosomiasis (sleeping sickness)

New medicines authorised

- Rxulti *(brexpiprazole)*
  Treatment of schizophrenia

Withdrawal of authorised medicines

- Trobalt (*retigabine*)
  Treatment of epilepsy

Respiratory system

New medicines authorised

- Alunbrig (*brigatinib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Orkambi (*lumacaftor/ivacaftor*) - extension of indication
  Treatment of cystic fibrosis in children from 2 years of age

Rheumatology

New information on authorised medicines

- MabThera (*rituximab*) - extension of indication
  Treatment of granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Urology

Positive CHMP opinions on new medicines

- Silodosin Recordati (*silodosin*) generic of Urorec
  Treatment of prostatic hyperplasia (enlarged prostate)

Other medicines

Withdrawal of authorised medicines

- Ionsys (*fentanyl*)
  Management of post-operative pain (pain after surgery)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for a paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease
  Deadline for comments: 31 January 2019
- Draft guideline on the quality of water for pharmaceutical use
  Deadline for comments: 15 May 2019
- Concept paper on the need for revision of the Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease - Revision 1
  Deadline for comments: 30 June 2019
- Draft guideline on the non-clinical requirements for radiopharmaceuticals - First version
  Deadline for comments: 30 June 2019
- Draft guideline on the environmental risk assessment of medicinal products for human use - Revision 1
  Deadline for comments: 30 June 2019
- Draft guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products - Revision 3
  Deadline for comments: 30 June 2019
- Draft guideline on clinical investigation of recombinant and human plasma-derived factor IX products - Revision 2
  Deadline for comments: 30 June 2019
- Reflection paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH)
  Deadline for comments: 31 August 2019
- Reflection paper on the qualification of non-genotoxic impurities
  Deadline for comments: 30 September 2019
- CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products - Revision 3
  Deadline for comments: 31 October 2019

Adopted guidelines

- Guideline on the clinical evaluation of medicinal products indicated for the prophylaxis or treatment of respiratory syncytial virus (RSV) disease - First version
- Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract - Revision 1

- Guideline on good pharmacovigilance practices (GVP): Product- or Population-Specific Considerations IV: Paediatric population
- Guideline on quality aspects included in the product information for vaccines for human use - Revision 1
- Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials - Revision 1
- Questions and answers on bovine spongiform encephalopathies (BSE) and vaccines - Revision 1
- Questions and answers on the haemagglutination inhibition (HI) test for qualification of influenza vaccine (inactivated) seed preparations - First version
- Questions and answers on sodium laurilsulfate used as an excipient in medicinal products for human use

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: November 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
- EMA Human Scientific' Committees Working Party with Patients' and Consumers' Organisations (PCWP) and with Healthcare Professionals' Organisations (HCPWP) - September 2018 - meeting documents
- EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) - September 2018 - meeting documents
- EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) - September 2018 - meeting documents
- Good Clinical Practice Inspectors Working Group 2017 - annual report

Other publications

- European Commission-DG Health and Food Safety and EMA action plan on advanced therapy medicinal products (ATMPs)
- Use of patient disease registries for regulatory purposes – methodological and operational considerations - discussion paper
- Data from patient registries to replace clinical trials in previously untreated haemophilia patients
- Guidance on the format of the risk management plan (RMP) in the EU – in integrated format
- Five additional countries to benefit from EU-US mutual recognition agreement for inspections

Key to symbols used

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- First EMA workshop on non-animal approaches in support of medicinal product development – challenges and opportunities for use of micro-physiological systems - October 2017 - meeting report
- 15th Joint EMA / European network for Health Technology Assessment dialogue meeting - July 2018 - minutes
- Multi-stakeholder workshop to launch consultation on EMA human regulatory science to 2025 - October 2018 - video and meeting documents
- EMA / Heads of Medicines Agencies (HMA) / European Commission (EC) workshop on electronic product information (ePI) - November 2018 - agenda

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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