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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

New medicines authorised

- Juluca (*dolutegravir / rilpivirine*)
  Treatment of HIV infection

Safety communication update

- Juluca (*dolutegravir / rilpivirine*) / Triumeq (*abacavir sulfate / dolutegravir sodium / lamivudine*) / Tivicay (*dolutegravir*): while review is ongoing, dolutegravir should not be used in women seeking to become pregnant
  Treatment of HIV infection

Cancer

Positive CHMP opinions on new medicines

- Trazimera (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer

Key to symbols used

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

New medicines authorised

- Herzuma (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer
- Kanjinti (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer
- Mylotarg (*gemtuzumab ozogamicin*)
  Treatment of acute myeloid leukaemia (AML) (blood cancer)
- Rubraca (*rucaparib*)
  Treatment of ovarian cancer

Safety communication update

- Keytruda (*pembrolizumab*) / Tecentriq (*atezolizumab*): restrict the use of these medicines as first line-treatments for urothelial (bladder) cancer
  Treatment of various cancers

Cardiovascular system

New medicines authorised

- Prasugrel Mylan (*prasugrel*) generic of Efient
  Prevention of problems caused by blood clots, such as heart attack

Dermatology

Positive CHMP opinions on new medicines

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Diabetes

New medicines authorised

- Semglee (*insulin glargine*) biosimilar of Lantus
  Treatment of diabetes (type 1 and 2)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Trazimera (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer
- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
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New medicines authorised

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- Kanjinti (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer

New information on authorised medicines

- Xeljanz (*tofacitinib*) - new strength and new indication
  Treatment of ulcerative colitis (inflammation of large intestine)

Gynaecology & Obstetrics

New medicines authorised

- Rubraca (*rucaparib*)
  Treatment of ovarian cancer

Safety communication update

- Review of Esmya (*ulipristal acetate*) - CHMP opinion (new measures to minimise risk of rare but serious liver injury)
  Treatment of uterine fibroids (non-cancerous tumours of the womb)

HIV

New medicines authorised

- Juluca (*dolutegravir / rilpivirine*)
  Treatment of HIV infection

Safety communication update

- Juluca (*dolutegravir / rilpivirine*) / Triumeq (*abacavir sulfate / dolutegravir sodium / lamivudine*) / Tivicay (*dolutegravir*): while review is ongoing, dolutegravir should not be used in women seeking to become pregnant
  Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

New information on authorised medicines

- Xeljanz (*tofacitinib*) - new strength and new indication
  Treatment of ulcerative colitis (inflammation of large intestine)

Metabolic disorders

Positive CHMP opinions on new medicines

- Myalepta (*metreleptin*)
  Treatment of fat disorders

- Nityr (*nitisinone*)
  Treatment of hereditary tyrosinemia type 1 (inability to breakdown an amino acid)
- Tegsedi (*inotersen*) O
  Treatment of transthyretin amyloidosis (abnormal build up of proteins, particularly around nerves)

Musculoskeletal system

New information on authorised medicines

- Translarna (*ataluren*) - extension to existing indication (to include children aged below 5 years)
  Treatment of Duchenne muscular dystrophy

Negative CHMP opinions on new medicines

- Exondys (*eteplirsen*) O
  Intended for the treatment of Duchenne muscular dystrophy

Nervous system

Positive CHMP opinions on new medicines

- Aimovig (*erenumab*)
  Prevention of migraine
- Rxulti (*brexpiprazole*)
  Treatment of schizophrenia
- Tegsedi (*inotersen*) O
  Treatment of transthyretin amyloidosis (abnormal build up of proteins, particularly around nerves)

New information on authorised medicines

- Briviact (*brivaracetam*) - extension to existing indication (to include children aged below 16 years)
  Treatment of epilepsy

Safety communication update

- Review of Zinbryta (*daclizumab*) - confirmation of previous PRAC recommendation (medicine no longer authorised, it poses a risk of serious and potentially fatal immune reactions affecting the brain, liver and other organs)
  Treatment of multiple sclerosis

Ophthalmology

Positive CHMP opinions on new medicines

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Withdrawal of applications for new medicines

- Restaysis (*ciclosporin*)
  Intended for the treatment of moderate dry eye disease

Respiratory system

New medicines authorised

- Trydonis (*beclometasone / formoterol / glycopyrronium bromide*)
  Treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

Positive CHMP opinions on new medicines

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Other medicines

Safety communication update

- Review of metamizole containing medicinal products (*metamizole*) - review started (review prompted by inconsistent doses and contraindications)
  Treatment of severe pain and fever
- Review of Scandonest and associated names (*mepivacaine*) - CHMP Opinion (changes to the prescribing information in order to harmonise the way the medicine is used in the EU)
  Used to block sensation and pain in part of the body during medical procedures

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use in accordance with good clinical practice and good manufacturing practice
  Deadline for comments: 31 August 2018

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - April 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 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
- Work plan for the Pharmacovigilance Inspectors Working Group for 2018
- Committee for Medicinal Products for Human Use (CHMP): Work Plan 2018 (updated)

Other publications

- EMA 2017 annual report published - report - annexes
- Construction of new EMA building in Amsterdam on track
- Two years of PRIME - report
- Two more EU Member States benefit from EU-US mutual recognition agreement for inspections
- EC-DG Health and Food Safety and EMA action plan on advanced therapy medicinal products (ATMPs) (updated)
- Chimeric antigen receptor (CAR) T-cell therapy registries workshop - February 2018 - report
- Working together for people with rare and complex disease
- Development of antibiotics for children - towards a global approach
- Supporting medicines for children in the European Union - Factsheet - Video
- Multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation - March 2018 - report
- Registry initiative - April 2018 - presentation
- EMA / RD-ACTION / DG SANTE workshop: how European Reference Networks can add value to clinical research - May 2018 - meeting documents
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting - June 2018 - meeting documents
- Haemophilia registries workshop - June 2018 - meeting documents
- Workshop on the development of antimicrobial medicinal products for paediatric patients - 21-22 June 2018

Key to symbols used

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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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