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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

- Maviret (*glecaprevir / pibrentasvir*)
  Treatment of chronic hepatitis C

Cancer

New medicines authorised

- Blitzima (*rituximab*) / Rituzena (previously Tuxella) (*rituximab*): biosimilars of MabThera
  Treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)
- Kisqali (*ribociclib*)
  Treatment of breast cancer

Key to symbols used

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

- Ritemvia (*rituximab*): biosimilar of MabThera
  Treatment of non-Hodgkin's lymphoma (blood cancer) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Dermatology

New medicines authorised

- Imraldi (*adalimumab*): biosimilar of Humira
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (scaly patches on skin with inflammation of joints), rheumatoid arthritis, axial spondyloarthritis (inflammation of spine), Crohn's disease (inflammation of the gut), ulcerative colitis (inflammation of the gut), polyarticular juvenile idiopathic and enthesitis-related arthritis (both inflammations of the joints), hidradenitis suppurativa (a skin disease) and non-infectious uveitis (inflammation in the eye)
- Kyntheum (*brodalumab*)
  Treatment of plaque psoriasis (scaly patches on skin)

Haematology

New medicines authorised

- Blitzima (*rituximab*) / Rituzena (previously Tuxella) (*rituximab*): biosimilars of MabThera
  Treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)
- Refixia (*nonacog beta pegol*)
  Treatment and prevention of bleeding in patients with haemophilia B
- Ritemvia (*rituximab*): biosimilar of MabThera
  Treatment of non-Hodgkin's lymphoma (blood cancer) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Immune system

New medicines authorised

- Imraldi (*adalimumab*): biosimilar of Humira
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (scaly patches on skin with inflammation of joints), rheumatoid arthritis, axial spondyloarthritis (inflammation of spine), Crohn's disease (inflammation of the gut), ulcerative colitis (inflammation of the gut), polyarticular juvenile idiopathic and enthesitis-related arthritis (both inflammations of the joints), hidradenitis suppurativa (a skin disease) and non-infectious uveitis (inflammation in the eye)
- Kyntheum (*brodalumab*)
  Treatment of plaque psoriasis (scaly patches on skin)

Metabolic system

New medicines authorised

- Veltassa (*patiromer*)
  Treatment of hyperkalaemia (high levels of potassium in the blood)

Ophthalmology

New medicines authorised

- Imraldi (*adalimumab*): biosimilar of Humira
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (scaly patches on skin with inflammation of joints), rheumatoid arthritis, axial spondyloarthritis (inflammation of spine), Crohn's disease (inflammation of the gut), ulcerative colitis (inflammation of the gut), polyarticular juvenile idiopathic and enthesitis-related arthritis (both inflammations of the joints), hidradenitis suppurativa (a skin disease) and non-infectious uveitis (inflammation in the eye)

Respiratory system

New medicines authorised

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

Rheumatology

New medicines authorised

- Blitzima (*rituximab*) / Rituzena (previously Tuxella) (*rituximab*): biosimilars of MabThera
  Treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)
- Imraldi (*adalimumab*): biosimilar of Humira
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis (scaly patches on skin with inflammation of joints), rheumatoid arthritis, axial spondyloarthritis (inflammation of spine), Crohn's disease (inflammation of the gut), ulcerative colitis (inflammation of the gut), polyarticular juvenile idiopathic and enthesitis-related arthritis (both inflammations of the joints), hidradenitis suppurativa (a skin disease) and non-infectious uveitis (inflammation in the eye)
- Ritemvia (*rituximab*): biosimilar of MabThera
  Treatment of non-Hodgkin's lymphoma (blood cancer) and granulomatosis with polyangiitis and microscopic polyangiitis (inflammatory conditions of the blood vessels)

Supply shortages

- Inductos (*dibotermin alfa*) - shortage resolved
  Implant used to help new bone develop in patients with spinal disc problems and leg fractures

Other information

Guidelines

Guidelines open for consultation

- Draft tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance - Revision 1
  Deadline for comments: 31 October 2017
- Draft prasugrel hydrochloride film-coated tablets 5 mg and 10 mg product-specific bioequivalence guidance - Revision 1
  Deadline for comments: 31 October 2017
- Draft dimethyl fumarate gastro-resistant capsules 120 mg and 240 mg product-specific bioequivalence guidance
  Deadline for comments: 31 October 2017
- Draft Ibuprofen 200 - 800 mg oral use, immediate release formulations product-specific bioequivalence guidance
  Deadline for comments: 31 October 2017
- Concept paper on the development of guidance on the non-clinical evaluation of radiopharmaceuticals - First version
  Deadline for comments: 31 October 2017
- Draft guideline on non-clinical documentation in applications for marketing authorisation/registration of well-established and traditional herbal medicinal products - Revision 1
  Deadline for comments: 30 November 2017
- Reflection paper on the pharmaceutical development of medicines for use in the older population - First version
  Deadline for comments: 31 January 2018
- Draft ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials, step 2b - Revision 1
  Deadline for comments: 28 February 2018
- Draft ICH S5 (R3) guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals, step 2b - Revision 3
  Deadline for comments: 28 February 2018

Adopted guidelines

- Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action - First version
- Guideline on manufacture of the finished dosage form - Revision 1
- Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat pulmonary disease due to Mycobacterium tuberculosis
- Scientific recommendation on classification of ATMPs: Allogeneic human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord

- Scientific recommendation on classification of ATMPs: Autologous adipose derived mesenchymal stem cells, freshly isolated
- Scientific recommendation on classification of ATMPs: Cultured allogenic Wharton's jelly derived mesenchymal stem cells
- Scientific recommendation on classification of ATMPs: Cultured autologous adipose derived mesenchymal stem cells
- Scientific recommendation on classification of ATMPs: Cultured autologous adipose derived regenerative mesenchymal stem cells
- Scientific recommendation on classification of ATMPs: Cultured autologous Wharton's jelly derived mesenchymal stem cells
- Scientific recommendation on classification of ATMPs: Replication incompetent adenoviral vector encoding Interleukin 12 with activator ligand
- Scientific recommendation on classification of ATMPs: Autologous human adipose perivascular stromal cells genetically modified to secrete soluble TRAIL ligand
- Scientific recommendation on ATMPs: Allogeneic haptenized, stimulated and irradiated non-proliferative colorectal tumour whole cells derived from 3 colorectal cell lines
- Scientific recommendation on classification of ATMPs: Resorbable, viscoelastic matrix
- Scientific recommendation on classification of ATMPs: Human cultured dermal fibroblasts and human epidermal keratinocytes
- Scientific recommendation on classification of ATMPs: Human autologous adipose-derived stromal/stem Cells (ADSCs)
- Scientific recommendation on classification of ATMPs: Human autologous stromal vascular fraction (SVF)
- Scientific recommendation on classification of ATMPs: Recombinant adeno-associated virus (AAV) pseudotyped with viral capsid from serotype 5 which holds a construct that contains two guide ribonucleic acids (gRNAs) sequences (CEP290-64 and CEP290-323) driven by human U6 promoter elements and the clustered regularly interspaced short palindromic repeats (CRISPR)-associated protein 9 (Cas9) gene
- Scientific recommendation on classification of ATMPs: Allogeneic suspension of unexpanded and uncultured human amniotic fluid-derived cells

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2017
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: August 2017
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports

Key to symbols used

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

- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals

Other publications

- Minutes of the 96th meeting of the Management Board: 14-15 June 2017
- Science and innovation for better medicines
- EMA encourages tailored development of medicines for older people
- EMA supports regulatory harmonisation in East Africa
- Better veterinary medicines for healthier animals and people
- EMA prepares for Brexit
- Strengthening EU-US cooperation in medicine inspections
- The new EudraVigilance system – Public communications plan for EMA and National Competent Authorities in the EEA: overview of the planned public communication milestones
- Launch of the new EudraVigilance system: questions and answers from stakeholders

Events

- Eleventh stakeholder forum on the pharmacovigilance legislation - September 2017

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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