118 Issue 118
January 2019

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

Positive CHMP opinions on new medicines

- Tobramycin PARI (*tobramycin*)
  Treatment of chronic pulmonary (lung) infections in patients with cystic fibrosis

New medicines authorised

- Vabomere (*meropenem / vaborbactam*)
  Treatment of bacterial infections

Safety communication update

- Review of fosfomycin-containing medicinal products - review started (harmonisation of indication and dosage across the EU)
  Treatment of bacterial infections

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Zirabev (*bevacizumab*) biosimiliar of Avastin
  Treatment of cancers of the colon, breast, lung, kidney, ovaries and cervix

New medicines authorised

- Apealea (*paclitaxel*)
  Treatment of ovarian cancer
- Fulphila (*pegfilgrastim*) biosimiliar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- Pelmeg (*pegfilgrastim*) biosimiliar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients

New information on authorised medicines

- Adcetris (*brentuximab vedotin*) O C - new indication
  Treatment of Hodgkin lymphoma (a type of blood cancer)
- Rubraca (*rucaparib*) O C - new indication
  Treatment of ovarian cancer
- Sprycel (*dasatinib*) O - extension of indication
  Treatment of newly diagnosed Ph+ acute lymphoblastic leukaemia (ALL) in children

Cardiovascular system

Withdrawal of applications for new medicines

- Canakinumab Novartis (*canakinumab*)
  Intended for prevention of stroke and heart attack

Withdrawal of authorised medicines

- Ivabradine JensonR (*ivabradine*) generic of Procolaran
  Treatment of angina and heart failure

Safety communication update

- Review of Omega-3 fatty acid medicines - CHMP Opinion (Omega-3 fatty acid medicines no longer considered effective in preventing heart disease)
  Reducing certain types of blood fats

Dermatology

Withdrawal of applications for new medicines

- Fyzoclad (*adalimumab*) biosimilar of Humira
  Intended for treatment of various inflammatory and autoimmune disorders

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Rizmoic (*naldemedine*)
  Treatment of opioid-induced constipation

New medicines authorised

- Vabomere (*meropenem / vaborbactam*)
  Treatment of bacterial infections

Withdrawal of applications for new medicines

- Fyzoclad (*adalimumab*) biosimilar of Humira
  Intended for treatment of various inflammatory and autoimmune disorders

Gynaecology & Obstetrics

New medicines authorised

- Apealea (*paclitaxel*)
  Treatment of ovarian cancer

New information on authorised medicines

- Rubraca (*rucaparib*) - new indication
  Treatment of ovarian cancer

Haematology

Positive CHMP opinions on new medicines

- Besremi (*ropeginterferon alfa-2b*)
  Treatment of polycythaemia vera (blood disease leading to production of too many red blood cells)
- Fulphila (*pegfilgrastim*) biosimiliar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- Lusutrombopag Shionogi (*lusutrombopag*)
  Treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease undergoing surgery
- Pelmeg (*pegfilgrastim*) biosimiliar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients

New information on authorised medicines

- Adcetris (*brentuximab vedotin*) - new indication
  Treatment of Hodgkin lymphoma (a type of blood cancer)
- Sprycel (*dasatinib*) - extension of indication
  Treatment of newly diagnosed Ph+ acute lymphoblastic leukaemia (ALL) in children

Immune system

Withdrawal of applications for new medicines

- Fyzoclad (*adalimumab*) biosimilar of Humira
  Intended for treatment of various inflammatory and autoimmune disorders

Metabolic disorders

Positive CHMP opinions on new medicines

- Miglustat Dipharma (*miglustat*) generic of Zavesca
  Treatment of type 1 Gaucher disease

Ophthalmology

Withdrawal of applications for new medicines

- Fyzoclad (*adalimumab*) biosimilar of Humira
  Intended for treatment of various inflammatory and autoimmune disorders

Respiratory system

Positive CHMP opinions on new medicines

- Tobramycin PARI (*tobramycin*)
  Treatment of chronic pulmonary (lung) infections in patients with cystic fibrosis

New information on authorised medicines

- Trimbow (*beclometasone / formoterol / glycopyrronium bromide*) - extension of indication
  Maintenance treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

New information on authorised medicines

- Simponi (*golimumab*) - extension of indication
  Treatment of polyarticular juvenile idiopathic arthritis

Withdrawal of applications for new medicines

- Fyzoclad (*adalimumab*) biosimilar of Humira
  Intended for treatment of various inflammatory and autoimmune disorders

Withdrawal of authorised medicines

- Zoledronic acid Teva Pharma (*zoledronic acid*) generic of Aclasta
  Treatment of osteporosis

Vaccines

New medicines authorised

- Dengvaxia (*dengue tetravalent vaccine (live, attenuated)*)
  Prevention of dengue fever

Other medicines

Positive CHMP opinions on new medicines

- Lusutrombopag Shionogi (*lusutrombopag*)
  Treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease undergoing surgery
- Trecondi (*treosulfan*)
  Conditioning treatment prior to blood-stem cell transplantation

New medicines authorised

- Buvidal (*buprenorphine*) generic of Subutex
  Treatment of opioid dependence

New information on authorised medicines

- Rapiscan (*regadenoson*) - new indication Measurement of blood flowing through blocked arteries in the heart

Safety communication update

- Review of metamizole containing medicinal products - CHMP Opinion (harmonisation of maximum dose and use in pregnancy)
  Treatment of severe pain and fever

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on a guideline for allergen products development in moderate to low-sized study populations
  Deadline for comments: 30 June 2019

- Draft cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 4 mg and 80 mg product-specific bioequivalence guidance
  Deadline for comments: 30 June 2019
- Draft ezetimibe tablet 10 mg product-specific bioequivalence guidance
  Deadline for comments: 30 June 2019
- Draft guideline on quality and equivalence of topical products
  Deadline for comments: 30 June 2019

Adopted guidelines

- Aliskiren film-coated tablet 150 mg and 300 mg product-specific bioequivalence guidance
- Pegylated liposomal doxorubicin hydrochloride concentrate for solution 2 mg/ml product-specific bioequivalence guidance
- Guideline on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation
- Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: December 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
- Meeting summary - EMA Human Scientific' Committees Working Party with Healthcare Professionals' Organisations (HCPWP) 26 September 2018

Other publications

- EMA Management Board: highlights of December 2018 meeting - meeting documents
- Minutes of the 101st meeting of the Management Board: 4 October 2018
- Report on the EMA Management Board delegation visit to the future EMA premises
- EMA tracking tool: relocation to Amsterdam - Main milestones
- Responding to emerging health threats in the EU
- Report - Data anonymisation: a key enabler for clinical data sharing

- Enpr-EMA Working group on public-private partnership: Network consultation recommendation
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting - October 2018
- European Medicines Agency stakeholder interaction on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) - December 2018

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

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 to generate complete data on the medicine.

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. These medicines are subject to specific post-authorisation obligations and monitoring.

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

In particular, you may be interested in these links:

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European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Website www.ema.europa.eu

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