

HUMAN MEDICINES

Key information for patients, consumers and healthcare professionals Published monthly by the European Medicines Agency



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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

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

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
- Pelmeq (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)
- Rubraca (rucaparib) new indication Treatment of ovarian cancer
- Sprycel (dasatinib) extension of indication Treatment of newly diagnosed Ph+ acute lymphoblastic leukaemia (ALL) in children

Cardiovascular system

Withdrawal of applications for new medicines

<u>Canakinumab Novartis</u> (canakinumab) Intended for prevention of stroke and heart attack

Withdrawal of authorised medicines

<u>Ivabradine JensonR</u> (*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*) O C - 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
- <u>Lusutrombopag Shionogi</u> (*lusutrombopag*) Treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease undergoing
- 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

<u>Trimbow</u> (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) qeneric 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

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

New medicines authorised

Buvidal (buprenorphine) qeneric of Subutex Treatment of opioid dependence

New information on authorised medicines

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

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

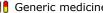
Guidelines

Guidelines open for consultation

Concept paper on a guideline for allergen products development in moderate to low-sized study

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 quidance
- 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

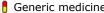
- Medicinal products for human use: monthly figures November 2018
- CHMP agendas, minutes and highlights
- CHMP applications for new human medicines: December 2018
- CAT agendas, minutes and reports
- COMP agendas, minutes and meetings reports
- HMPC agendas, minutes and meetings reports
- PDCO agendas, 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

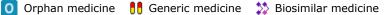
Other publications

- 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





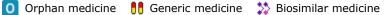




- Enpr-EMA Working group on public-private partnership: Network consultation recommendation
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting - October 2018
- European Medicines Agency stakeholder interaction on the development 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.

6 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.

E 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

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