

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

Antivirals/anti-infectives	1
Cancer	1
Cardiovascular system	2
Dermatology	3
Diabetes	3
Haematology	3
HIV	3
Immune system	4
Metabolic system	4
Musculoskeletal system	4
Nephrology	4
Nervous system	5
Ophthalmology	5
Respiratory system	5
Rheumatology	5
Other medicines	6
Medicines under additional monitoring	6
Guidelines	6
Scientific committee and working party activities	6
Other publications	7
Explanation of terms used	8

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

Other information

- Review of [vancomycin-containing medicines](#) - CHMP Opinion (changes to prescribing information)
Treatment of serious bacterial infections


Cancer

Positive CHMP opinions on new medicines




- [Blitzima](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)
- [Ritemvia](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma (blood cancer), granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Tuxella \(rituximab\)](#)  Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)

New medicines authorised

- [Dinutuximab beta Apeiron \(dinutuximab beta\)](#)   Treatment of neuroblastoma (cancer of the nerve cells)
- [Pemetrexed Hospira UK Limited \(pemetrexed\)](#)  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- [Varuby \(rolapitant\)](#) Prevention of nausea and vomiting associated with cancer chemotherapy

New information on authorised medicines

- [Zykadia \(ceritinib\)](#) - new indication  Treatment of non-small cell lung cancer

Withdrawal of applications for new medicines

- [Qinprezo \(vosaroxin\)](#) Intended for the treatment of leukaemia (blood cancer)

Negative CHMP opinions on new medicines

- [Adlumiz \(anamorelin hydrochloride\)](#) Intended for the treatment of anorexia, cachexia (wasting) or unintended weight loss in patients with non-small cell lung cancer
- [Human IgG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech](#) Intended for the treatment of symptoms of advanced colorectal cancer

Arbitration procedures

- [Cardioxane \(dexrazoxane\)](#) - outcome of procedure
Treatment of breast cancer

Cardiovascular system

New information on authorised medicines

- [Uptravi \(selexipag\)](#) - new contraindication
Treatment of pulmonary arterial hypertension
- **New medicines authorised**
[Roteas \(edoxaban\)](#)
Prevention of stroke (blood clots in brain) and systemic embolism (blood clots in other organs) and treatment of deep-vein thrombosis ((DVT) a blood clot in a deep vein) and prevention of DVT and pulmonary embolism from re-occurring
- **Withdrawal of authorised medicines**
[Imprida \(amlodipine / valsartan\)](#)
Treatment of hypertension (high blood pressure)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances


Dermatology

Positive CHMP opinions on new medicines

- [Kyntheum](#) (*brodalumab*)
Treatment of psoriasis (scaly patches on skin)

Diabetes

Positive CHMP opinions on new medicines




- [Insulin lispro Sanofi](#) (*insulin lispro*) 
Treatment of diabetes mellitus

New information on authorised medicines

- [Komboglyze](#) (*saxagliptin / metformin hydrochloride*) - change in indication
Treatment of diabetes mellitus
- [Onglyza](#) (*saxagliptin*) - change in indication
Treatment of diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- [Blitzima](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)
- [Ritemvia](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma (blood cancer), granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)
- [Tuxella](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)

Withdrawal of applications for new medicines

- [Qinprezo](#) (*vosaroxin*)
Intended for the treatment of leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

- [Efavirenz / Emtricitabine / Tenofovir disoproxil Zentiva](#) (*efavirenz/emtricitabine/tenofovir disoproxil*) 
Treatment of HIV infection

New information on authorised medicines

- [Isentress](#) (*raltegravir*) - new strength
Treatment of HIV infection

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- **Withdrawal of authorised medicines**


Vitekta (*elvitegravir*)
Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- [Kyntheum](#) (*brodalumab*)
Treatment of psoriasis (scaly patches on skin)

Negative CHMP opinions on new medicines

- [Masipro](#) (*masitinib*) 
Intended for the treatment of mastocytosis (excess mast cells, a type of white blood cell)

Metabolic system

Positive CHMP opinions on new medicines

- [Veltassa](#) (*patiromer*)
Treatment of hyperkalaemia (high levels of potassium)

New medicines authorised

[Chenodeoxycholic acid sigma-tau](#) (*chenodeoxycholic acid*) 

Treatment of inborn errors of primary bile acid synthesis synthesis (defects in bile acid production)

New information on authorised medicines

- [Renvela](#) (*sevelamer carbonate*) - new indication
Control of hyperphosphataemia (high levels of phosphate in the blood) in kidney disease
- [Sevelamer carbonate Zentiva](#) (*sevelamer carbonate*) - new indication
Control of hyperphosphataemia (high levels of phosphate in the blood) in kidney disease

Musculoskeletal system

Positive CHMP opinions on new medicines






- [Spherox](#) (*spheroids of human autologous matrix-associated chondrocytes*)
Treatment of knee cartilage defects

Nephrology

New information on authorised medicines

- [Renvela](#) (*sevelamer carbonate*) - new indication
Control of hyperphosphataemia (high levels of phosphate in the blood) in kidney disease
- [Sevelamer carbonate Zentiva](#) (*sevelamer carbonate*) - new indication
Control of hyperphosphataemia (high levels of phosphate in the blood) in kidney disease

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Nervous system

Positive CHMP opinions on new medicines

- [Reagila](#) (*cariprazine*)
Treatment of schizophrenia

Ophthalmology

Positive CHMP opinions on new medicines

- [Oxervate](#) (*cenegermin*) 
Treatment of neurotrophic keratitis (inflammation of the cornea)

New information on authorised medicines


- [Izba](#) (*travoprost*) - new indication
Decrease of elevated intraocular pressure in children

Respiratory system


Positive CHMP opinions on new medicines

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

New medicines authorised




- [Pemetrexed Hospira UK Limited](#) (*pemetrexed*) 
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- [Zykadia](#) (*ceritinib*) - new indication 
Treatment of non-small cell lung cancer

Rheumatology

Positive CHMP opinions on new medicines

- [Blitzima](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)
- [Ritemvia](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma (blood cancer), granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)
- [Tuxella](#) (*rituximab*) 
Treatment of non-Hodgkin's lymphoma, lymphocytic leukaemia (blood cancers) and granulomatosis with polyangiitis and microscopic polyangiitis (disease affecting the blood vessels)

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Other medicines

Arbitration procedures

- [Paracetamol/Ibuprofen 500 mg/150 mg film-coated tablets](#) - outcome of procedure
Treatment of pain

Medicines under additional monitoring

- [Updated list of medicines under additional monitoring](#)

Other information

Guidelines

Guidelines open for consultation

- [Concept paper on a guideline on the evaluation of medicinal products indicated for treatment of influenza](#)
Deadline for comments: 31 July 2017
- [Concept paper on the revision of the guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population](#)
Deadline for comments: 31 July 2017
- [Draft guideline for the notification of serious breaches of Regulation \(EU\) No 536/2014 or the clinical trial protocol](#)
Deadline for comments: 22 August 2017

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - March 2017](#)
- [Medicinal products for human use: monthly figures - April 2017](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines under evaluation: May 2017](#)
- [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](#)
- [CAT work plan 2017](#)






Key to symbols used

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Other publications

- [Minutes of the 95th meeting of the Management Board: 16 March 2017](#)
- [EMA 2016 annual report published: Progress on science, medicines and health](#)
- [Biosimilars in the EU - Information guide for healthcare professionals](#)
- [Involving patients in discussions on benefits and risks of medicines](#)
- [Green light given for new EudraVigilance system for collection and monitoring of suspected adverse reactions](#)
- [New action plan to support SMEs as drivers of pharmaceutical innovation](#)
- [Regulatory guidance for industry to prepare for the UK's withdrawal from the EU](#)
- [East African Community looks to EMA as model for future regional agency](#)
- PCWP and HCPWP joint workshop on personalised medicines - Mar 2017 - [meeting documents](#)
- [Joint EMA/ DIA information day on measuring the impact of pharmacovigilance activities](#) - Nov 2017

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.

Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

<http://www.ema.europa.eu>

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