

# HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union



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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 an e-mail alert when each new issue of the newsletter is published, send a request to: [HMHnewsletter@ema.europa.eu](mailto:HMHnewsletter@ema.europa.eu)

## Information on medicines

### Antivirals/anti-infectives

#### Suspension of authorised medicines

- [Vibativ](#) (*telavancin*)  
Treatment of nosocomial pneumonia

### Cancer

#### New medicines authorised

- [Zoledronic acid Teva](#) (*zoledronic acid*)   
Prevention of bone complications in cancer patients and treatment of hypercalcaemia

#### Withdrawal of authorised medicines

- [MabCampath](#) (*alemtuzumab*)  
Treatment of leukaemia

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

**Safety communication update**

- [DepoCyte](#) (*cytarabine*)  
Treatment of lymphomatous meningitis

## Cardiovascular system

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**Withdrawal of authorised medicines**

- [Sprimeo HCT](#) (*aliskiren / hydrochlorothiazide*)  
Treatment of hypertension

## Diabetes

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**New medicines authorised**

- [Jentadueto](#) (*linagliptin / metformin hydrochloride*)  
Treatment of type-2 diabetes

## Hormone system

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**Withdrawal of authorised medicines**

- [Valtropin](#) (*somatropin*)   
Treatment of growth hormone deficiency

## Metabolic system

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**Refusal of marketing authorisation**

- [Orphacol](#) (*cholic acid*)   
Intended for treatment of inborn errors in primary bile acid synthesis

## Musculoskeletal system

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**New medicines authorised**

- [Zoledronic Acid Teva Pharma](#) (*zoledronic acid*)   
Treatment of osteoporosis and Paget's disease

## Nervous system

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**New medicines authorised**

- [Fycompa](#) (*perampanel*)  
Treatment of epilepsy

**Withdrawal of authorised medicines**

- [Exalief](#) (*eslicarbazepine acetate*)  
Treatment of epilepsy

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## Respiratory system

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### New medicines authorised

- [Kalydeco](#) (*ivacaftor*)   
Treatment of cystic fibrosis

## Other medicines

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### Withdrawal of authorised medicines

- [Teslascan](#) (*mangafodipir*)  
For diagnostic use
- [Regranex](#) (*becaplermin*)  
Healing of neuropathic ulcers

### Suspension of authorised medicines

- [Luminity](#) (*perflutren*)  
For diagnostic use

## Other information

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## Guidelines

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### Guidelines open for consultation

- [Draft guideline on core Summary of Products Characteristics and package leaflet for technetium \(<sup>99m</sup>Tc\) sestamibi](#)  
Deadline for comments: 30 November 2012
- [Draft guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation](#)  
Deadline for comments: 15 January 2013

### Adopted guidelines

- [Guideline on core summary of product characteristics and package leaflet for fludeoxyglucose \(18F\)](#)
- [Guideline on clinical investigation of medicinal products in the treatment of chronic obstructive pulmonary disease \(COPD\)](#)

## Scientific committee activities

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- [PDCO August monthly report](#)
- [PDCO minutes of the 4-6 July 2012 meeting](#)
- [PDCO agenda of the 5-7 September 2012 meeting](#)

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## Other publications

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- [Ensuring safe and effective medicines for an ageing population: Workshop Proceedings](#)
- [European Medicines Agency starts consultation on inventory of needs for children's medicines](#)
- [EMA publishes public assessment reports for ancillary medicinal substances included in medical devices](#)
- [Minutes of the Healthcare Professionals' Working Group meeting of 8 May 2012](#)
- [EMA explains EU incident management plan for human medicines](#)
- [Workshop on clinical trials data and transparency, EMA London, 22 November 2012](#)
- [EMA phasing out follow-up measures](#)
- [EMA standard operating procedure on preparation of the publication of the web reports on the "European database of suspected adverse drug reaction reports" website](#)

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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>

In particular, you may be interested in these links:

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