

# 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 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

#### New information on authorised medicines

- [Pyramax](#) (*pyronaridine / artesunate*) - change in indication  
Treatment of malaria infection
- [Zutectra](#) (*human hepatitis-B immunoglobulin*) - change in indication  
Prevention of hepatitis B virus re-infection

### Cancer

#### Positive CHMP opinions on new medicines

- [Oncaspar](#) (*pegaspargase*)  
Treatment of leukaemia (blood cancer)
- [Pemetrexed Accord](#) (*pemetrexed*)   
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [Pemetrexed Actavis](#) (*pemetrexed*)  
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- [Spectrila](#) (*asparaginase*)   
Treatment of leukaemia (blood cancer)

#### Communication on prevention of medication errors

- [Farydak](#) (*panobinostat*)  - compliance card to ensure correct use and avoid medication errors  
Treatment of multiple myeloma (cancer of the bone marrow)

## Cardiovascular system

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#### Positive CHMP opinions on new medicines

- [Eptifibatide Accord](#) (*eptifibatide*)   
Prevention of heart attack

## Diabetes

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#### New medicines authorised

- [Ebymect](#) (*dapagliflozin / metformin*)  
Treatment of type 2 diabetes mellitus

#### Negative CHMP opinions on new medicines

- [Solumarv](#) (*insulin human*)   
Intended for the treatment of diabetes

## Haematology

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#### Positive CHMP opinions on new medicines

- [Oncaspar](#) (*pegaspargase*)  
Treatment of leukaemia (blood cancer)
- [Spectrila](#) (*asparaginase*)   
Treatment of leukaemia (blood cancer)

#### New medicines authorised

- [Obizur](#) (*susoctocog alfa*)    
Treatment of bleeding in patients with haemophilia

#### Communication on prevention of medication errors

- [Farydak](#) (*panobinostat*)  - compliance card to ensure correct use and avoid medication errors  
Treatment of multiple myeloma (cancer of the bone marrow)

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#### Key to symbols used

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## HIV

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### Positive CHMP opinions on new medicines

- [Lopinavir/Ritonavir Mylan](#) (*lopinavir/ritonavir*)   
Treatment of HIV infection

## Hormone system

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### New medicines authorised

- [Cinacalcet Mylan](#) (*cinacalcet*)   
Used in patients with hyperparathyroidism (including in patients with kidney disease) and parathyroid carcinoma

## Immune system

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### Positive CHMP opinions on new medicines

- [Benepali](#) (*etanercept*)   
Treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis

### New information on authorised medicines

- [Cimzia](#) (*certolizumab pegol*) - new indication  
Treatment of rheumatoid arthritis

## Nephrology

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### New medicines authorised

- [Cinacalcet Mylan](#) (*cinacalcet*)   
Used in patients with hyperparathyroidism (including in patients with kidney disease) and parathyroid carcinoma

## Nervous system

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### Positive CHMP opinions on new medicines

- [Briviact](#) (*brivaracetam*)  
Treatment of partial-onset epilepsy seizures
- [Wakix](#) (*pitolisant*)   
Treatment of narcolepsy (long-term sleep disorder)

### New medicines authorised

- [Aripiprazole Accord](#) (*aripiprazole*)   
Treatment of schizophrenia and prevention of manic episodes in bipolar I disorder
- [Numient](#) (*levodopa / carbidopa*)  
Treatment of Parkinson's disease

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#### Key to symbols used

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## Respiratory system

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### Positive CHMP opinions on new medicines

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

## Rheumatology

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### Positive CHMP opinions on new medicines

- [Benepali](#) (*etanercept*)   
Treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis

### New information on authorised medicines

- [Cimzia](#) (*certolizumab pegol*) - new indication  
Treatment of rheumatoid arthritis

## Vaccines

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### Safety communication update

- [Human papillomavirus vaccines](#) - CHMP Opinion (EMA confirms evidence does not support that HPV vaccines cause CRPS or POTS)  
Prevention of cancers caused by HPV

## Other medicines

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### Positive CHMP opinions on new medicines

- [Episalvan](#) (*birch bark extract*)  
Treatment of wounds

### New medicines authorised

- [Ionsys](#) (*fentanyl*)  
Treatment of post-operative pain

### Communication on prevention of medication errors

- [Ionsys](#) (*fentanyl*) - measures to ensure correct handling and use  
Treatment of post-operative pain

## Medicines under additional monitoring

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

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### Key to symbols used

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# Other information

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## Guidelines

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### Guidelines open for consultation

- [Draft scientific guidance on post-authorisation efficacy studies](#)  
Deadline for comments: 31 January 2016
- [Draft guideline on clinical investigation of medicinal products for prevention of venous thromboembolism in non-surgical patients \(formerly CPMP/EWP/6235/04 Rev.1\)](#)  
Deadline for comments: 15 May 2016

### Adopted guidelines

- [Reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use](#)
- [Guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis](#)
- [Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products](#)
- [Guideline on non-clinical local tolerance testing of medicinal products](#)

## Scientific committee and working party activities

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- [Medicinal products for human use: monthly figures - October 2015](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP applications for new human medicines: November 2015](#)
- [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](#)

## Other publications

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- [Guido Rasi takes office as head of EMA](#)
- [Safer use of medicines by preventing medication errors](#)
- [Supporting better use of medicines](#)
- [New strategy to fight antimicrobial resistance](#)

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### Key to symbols used

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- EMA-EuropaBio information day – October 2015 - [meeting documents](#)
- Joint BWP/QWP/GMDP IWG – European industry workshop on lifecycle management - October 2015 - [meeting documents](#)
- Second industry stakeholder platform on the operation of the centralised procedure for human medicinal products – November 2015 - [meeting documents](#)
- [Enpr-EMA meeting on rare gastrointestinal and liver diseases](#) - December 2015
- [Emerging medicinal products: from laboratory to patient use](#) - December 2015

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**Key to symbols used**

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## 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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### **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

**E-mail** [info@ema.europa.eu](mailto:info@ema.europa.eu) **Website** [www.ema.europa.eu](http://www.ema.europa.eu)

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