

# 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

Cancer	1
Dermatology	2
Diabetes	2
HIV	2
Haematology	2
Respiratory system	3
Rheumatology	3
Vaccines	3
Other medicines	3
Guidelines	4
Scientific committee activities	4
Other publications	4
Explanation of terms used	6

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

### Cancer

#### New marketing authorisation

- [Adcetris](#) (*brentuximab vedotin*)    
Treatment of Hodgkin lymphoma and systemic anaplastic large cell lymphoma
- [Capecitabine Medac](#) (*capecitabine*)   
Treatment of colon cancer, colorectal cancer, gastric cancer and breast cancer
- [Xalkori](#) (*crizotinib*)   
Treatment of lung cancer
- [Zoledronic Acid Hospira](#) (*zoledronic acid*)   
Prevention of bone complications and treatment of hypercalcaemia caused by tumours; treatment of osteoporosis

#### Positive CHMP opinions on new medicine

- [Zaltrap](#) (*aflibercept*)  
Treatment of colorectal cancer

#### Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

**Negative CHMP opinions on new medicines**

- [Istodax](#) (*romidepsin*)  
Intended to treat peripheral T-cell lymphoma

**Withdrawal of applications for new medicines**

- [Jenzyl](#) (*ridaforolimus*)  
Intended to treat soft-tissue or bone sarcoma

**New information on authorised medicines**

- [Zytiga](#) (*abiraterone*) - new indication and new contraindication  
Treatment of prostate cancer

## Dermatology

---

**New medicines authorised**

- [Picato](#) (*ingenol mebutate*)  
Treatment of actinic keratosis

## Diabetes

---

**Positive CHMP opinions on new medicines**

- [Lyxumia](#) (*lixisenatide*)  
Treatment of type-2 diabetes

**Withdrawal of applications for new medicines**

- [Solumarv, Isomarv and Combimarv](#) (*human insulin*)   
Intended to treat diabetes mellitus

## HIV

---

**New information on authorised medicines**

- [Intelence](#) (*etravine*) - new indication  
Treatment of human immunodeficiency virus type-1

## Haematology

---

**New information on authorised medicines**

- [Exjade](#) (*deferasirox*) - new indication  
Treatment of chronic iron overload

**Safety updates**

- [Review of protamine-containing medicines](#) - started  
Treatment of bleeding

---

**Key to symbols used**

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Respiratory system

---

### Safety updates

- [Review of almitrine-containing medicines](#) - started  
Treatment of chronic respiratory diseases

## Rheumatology

---

### New marketing authorisation

- [Zoledronic Acid Hospira](#) (zoledronic acid)   
Prevention of bone complications and treatment of hypercalcaemia caused by tumours; treatment of osteoporosis

### Safety updates

- [Review of calcitonin-containing medicines](#) - started  
Prevention of calcium loss in bones
- [Review of diacerein-containing medicines](#) - started  
Treatment of osteoarthritis and other joint diseases

## Vaccines

---

### Positive CHMP opinions on new medicines

- [Bexsero](#) (meningococcal group-B vaccine)  
Prevention of meningitis B

### New information on authorised medicines

- [Prevenar-13](#) (pneumococcal polysaccharide conjugate vaccine) - change in indication  
Prevention of invasive disease, pneumonia and acute otitis

### Safety updates

- [Assessment report for immunological differences of pandemic vaccines \(review of hypothesis on Pandemrix and development of narcolepsy\)](#)

## Other medicines

---

### New information on authorised medicines

- [TachoSil](#) (human fibrinogen/human thrombin) - new contraindication  
Used as a sealant during surgery to help reduce bleeding

### Safety updates

- [Review of codeine-containing medicines](#) - started  
Treatment of pain
- [Evicel and Quixil](#) (fibrin)  
Used as a sealant during surgery to help reduce bleeding

---

### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [Review of short-acting beta agonists](#) - started  
Treatment of premature labour
- [Review of solutions for infusion containing hydroxyethyl starch](#) - started  
Used to replace lost fluids in the blood

## Other information

---

### Guidelines

---

#### Guidelines open for consultation

- [Concept paper on the revision of the guideline on the development of medicinal products for the treatment of ulcerative colitis](#)  
Deadline for comments: 15 February 2013
- [Concept paper on the need of a guideline for clinical investigation of medicinal products for the treatment of chronic constipation](#)  
Deadline for comments: 15 February 2013
- [Concept paper on the revision of the guideline on the development of new medicinal products for the treatment of Crohn's disease](#)  
Deadline for comments: 15 February 2013

#### Adopted guidelines

- [Reflection paper on consideration given to designation of a single stereo isometric form \(enantiomer\), a complex, a derivative, or a different salt or ester as new active substance in relation to the relevant reference active substance](#)
- [Guideline on clinical investigation of medicinal products in the treatment of chronic obstructive pulmonary disease](#)

### Scientific committee activities

---

- [CHMP November meeting highlights](#)
- [COMP October meeting minutes](#) and [COMP November meeting report on the review of applications for orphan designation](#)
- [PDCO Agendas, meeting and reports](#)
- [CAT November monthly report](#)
- [PRAC October meeting minutes](#) and [PRAC November meeting highlights](#)

### Other publications

---

- [EMA increases transparency of ongoing applications for human medicines](#)
- [Overview of the allowable interests for the EMA scientific activities](#)

---

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [European Commission public consultation on phasing-in of 'black symbol' for medicines under additional monitoring](#)
- [Quality Review of Documents human product-information annotated template \(English\) version 8 \(revision 2\) - highlighted](#)
- [Patients' and Consumers' Working Party \(PCWP\) and Healthcare Professionals' Working Group \(HCPWG\) joint meeting minutes](#)
- [Workshop on access to clinical-trial data and transparency kicks off process towards proactive publication of data](#)
- [EMA workshop on pharmacogenomics: from science to clinical care \(workshop report\)](#)
- [Joint European Medicines Agency / Food and Drug Administration workshop for paediatric Gaucher disease type I: exploring the way forward \(workshop minutes and outcomes\)](#)
- [EMA supports the European Antibiotic Awareness Day: 18 November 2012](#)
- [EMA supports the World Diabetes Day: 14 November 2012](#)

---

**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>

In particular, you may be interested in these links:

[About us](#)

[Patients and carers](#)

[Healthcare professionals](#)

[European public assessment reports](#)

### European Medicines Agency

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416

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

An agency of the European Union

