

# 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.

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## Information on medicines

### Antivirals/anti-infectives

#### New medicines authorised

- [Zinforo](#) (*ceftaroline fosamil*)  
Treatment of complicated skin and soft tissue infections and community-acquired pneumonia

#### Arbitration procedures

- [Tavanic](#) (*levofloxacin*)  
Treatment of various infections

### Cancer

#### Positive CHMP opinions on new medicines

- [Capecitabine Medac](#) (*capecitabine*)   
Treatment of colon, colorectal, gastric and breast cancer

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [Ibandronic acid Accord](#) (*ibandronic acid*)   
Prevention of bone complications in patients with breast or bone cancer and treatment of tumour-induced hypercalcaemia

#### New medicines authorised

- [Inlyta](#) (*axitinib*)  
Treatment of advanced renal cell carcinoma
- [Zoledronic acid Mylan](#) (*zoledronic acid*)   
Prevention of bone complications in cancer patients and treatment of hypercalcaemia caused by tumours

#### New information on authorised medicines

- [Avastin](#) (*bevacizumab*) - new indication  
Treatment of ovarian, fallopian-tube or primary peritoneal cancer

#### Withdrawal of applications for extension of indication

- [Erbbitux](#) (*cetuximab*)  
Intended to include the treatment of non-small-cell lung cancer

## Cardiovascular system

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#### New information on authorised medicines

- [Multaq](#) (*dronedarone*) - new contraindication  
Treatment of atrial fibrillation
- [Eliquis](#) (*apixaban*) - new indication, change to an existing indication and new contraindications  
Prevention of venous thromboembolic events

#### Withdrawal of authorised medicines

- [Riprazo HCT](#) (*aliskiren and hydrochlorothiazide*)  
Treatment of essential hypertension

#### Arbitration procedures

- [Flolan](#) (*epoprostenol*)  
Prevention of blood clotting during haemodialysis and treatment of pulmonary arterial hypertension

## Dermatology

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#### Positive CHMP opinions on new medicines

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

#### New medicines authorised

- [Zyclara](#) (*imiquimod*)   
Treatment of actinic keratosis

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#### Key to symbols used

## Diabetes

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### New information on authorised medicines

- [Jalra](#), [Xiliarx](#) and [Galvus](#) (*vildagliptin*) - new indication  
Treatment of type 2 diabetes
- [Zomarist](#), [Icandra](#) and [Eucreas](#) (*vildagliptin and metformin*) - new indication  
Treatment of type 2 diabetes
- [Komboglyze](#) (*saxagliptin and metformin*) - new indication  
Treatment of type 2 diabetes

## Gastro-intestinal system

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### Positive CHMP opinions on new medicines

- [Constella](#) (*linaclotide*)  
Treatment of irritable bowel syndrome

### Withdrawal of applications for new medicines

- [SecreFlo](#) (*secretin human*)  
Intended for the diagnosis of pancreatitis

## Immune system

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### New medicines authorised

- [Desloratadine ratiopharm](#) (*desloratadine*)   
Treatment of allergic rhinitis or urticaria

## Respiratory system

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### New medicines authorised

- [Eklira Genuair](#) and [Bretaris Genuair](#) (*acclidinium bromide*)  
Treatment of chronic obstructive pulmonary disease

## Urology

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### New information on authorised medicines

- [Votubia](#) (*everolimus*) - new indication  
Treatment of renal angiomyolipoma associated with tuberous sclerosis complex

## Other medicines

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### New medicines authorised

- [Cuprymina](#) (*copper (<sup>64</sup>Cu) chloride*)  
For radiolabelling use

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# Other information

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## Guidelines

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### Guidelines open for consultation

- [Concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis](#)  
Deadline for comments: 15 December 2012
- [Concept paper on the involvement of children and young people at the Paediatric Committee \(PDCO\)](#)  
Deadline for comments: 19 November 2012
- [Draft guideline on quality of transdermal patches](#)  
Deadline for comments: 15 March 2013
- [Draft guideline on quality of oral modified-release products](#)  
Deadline for comments: 15 March 2013

## Scientific committee activities

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- CHMP  
[Applications for new human medicines for evaluation by the CHMP](#)  
[Start of Community reviews](#)  
[Scientific advice and protocol assistance](#)
- COMP  
[Meeting report on the review of applications for orphan designation](#)  
[Election of new chair and vice-chair](#)
- PDCO  
[Monthly report of opinions on paediatric investigation plans and other activities](#)  
[Minutes of the 15-17 August 2012 meeting](#)
- PRAC  
[Minutes - inaugural plenary meeting 19-20 July 2012](#)  
[Election of chair and vice-chair](#)

## Other publications

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- [Medicinal products for human use: Monthly figures - August 2012](#)
- [Minutes of the 76th meeting of the Management Board](#)
- [Questions and answers on implementation of pharmacovigilance legislation](#)
- [Dr Tomas Salmonson elected new chair of the Committee for Medicinal Products for Human Use \(CHMP\)](#)
- [EMA seeks views on involvement of children and young people in Paediatric Committee](#)
- [Standard operating procedure for evaluation of conflicts of interests of experts for involvement in European Medicines Agency activities](#)

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- [Working arrangement between the European Medicines Agency and the European Monitoring Centre for Drugs and Drug Addiction](#)
- [Reporting requirements of individual case safety reports applicable to marketing-authorisation holders during the interim period](#)
- [Over 1000 SMEs now registered with European Medicines Agency SME office](#)
- [News bulletin for small and medium-sized enterprises - Issue 21](#)
- [Questions and answers on biosimilar medicines \(similar biological medicinal products\)](#)
- [EMA to accept biosimilar reference medicines sourced outside European Economic Area](#)
- [EMA seeking participants for website user-experience research](#)
- [European Union regulatory workshop in ophthalmology - Summary and report](#)
- [FDA / EMA orphan-product designation and grant workshop](#), FDA, United States, 12 Oct 2012
- [EMA excellence in pharmacovigilance: Clinical trials and post-marketing](#), London, 1-5 Oct 2012
- [EudraVigilance information day](#), EMA, London, 5 Oct 2012
- [EMA workshop on pharmacogenomics: from science to clinical care](#), EMA, London, 8-9 Oct 2012
- [World Alzheimer's Month: September 2012](#)
- [Speakers confirmed for European Medicines Agency workshop on clinical-trial data and transparency](#)

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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.

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

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