

# 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

#### Withdrawal of application for new medicines

- [Cokiera](#) (*dasabuvir / ombitasvir / paritaprevir / ritonavir*)  
Intended for the treatment of chronic hepatitis C

### Cancer



#### Positive CHMP opinions on new medicines

- [Lartruvo](#) (*olaratumab*)    
Treatment of adults with advanced soft tissue sarcoma
- [Ibrance](#) (*palbociclib*)  
Treatment of breast cancer
- [Ninlaro](#) (*ixazomib*)    
Treatment of multiple myeloma (cancer of the bone marrow)

#### Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances




**New medicines authorised**

- [Zalmoxis](#) (*genetically modified T-cells*)    
Used in patients with blood cancer after bone marrow (blood stem cell) transplantation


## Cardiovascular system

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**Positive CHMP opinions on new medicines**

- [Granpidam](#) (*sildenafil*)   
Treatment of patients with pulmonary arterial hypertension
- [Ivabradine JensonR](#) (*ivabradine*)   
Treatment of angina pectoris (chest pain) and heart failure
- [Ivabradine Zentiva](#) (*ivabradine*)   
Treatment of angina pectoris (chest pain) and heart failure

**Withdrawal of application for extension of indication**

- [Adempas](#) (*riociguat*)   
Intended for the treatment of pulmonary arterial hypertension associated with congenital heart disease

## Diabetes

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**Positive CHMP opinions on new medicines**

- [Glyxambi](#) (*empagliflozin / linagliptin*)  
Treatment of diabetes mellitus

**New information on authorised medicines**

- [NovoRapid](#) (*insulin aspart*) - change in indication  
Treatment of diabetes mellitus

## Gastro-intestinal system

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**New medicines authorised**

- [Truberzi](#) (*eluxadoline*)  
Treatment of irritable bowel syndrome

**New information on authorised medicines**

- [Stelara](#) (*ustekinumab*) - new indication  
Treatment of Crohn's disease

## Haematology

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**Positive CHMP opinions on new medicines**



- [Ninlaro](#) (*ixazomib*)    
Treatment of multiple myeloma (cancer of the bone marrow)

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**Key to symbols used**

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### New medicines authorised

- [Zalmoxis](#) (*genetically modified T-cells*)    
Used in patients with blood cancer after bone marrow (blood stem cell) transplantation

## HIV

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### Positive CHMP opinions on new medicines

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

## Hormone system

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### Positive CHMP opinions on new medicines

- [Parsabiv](#) (*etelcalcetide*)  
Treatment of hyperparathyroidism in patients with chronic kidney disease on haemodialysis therapy

## Immune system

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### New information on authorised medicines

- [Stelara](#) (*ustekinumab*) - new indication  
Treatment of Crohn's disease

### Arbitration procedures

- [Clenil and associated names](#) (*beclometasone dipropionate*) - outcome of procedure  
Treatment of asthma



### New medicines authorised

- [Nordimet](#) (*methotrexate*)  
Treatment of arthritis and psoriasis

## Metabolic system

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### Positive CHMP opinions on new medicines

- [Chenodeoxycholic acid sigma-tau](#) (*chenodeoxycholic acid*)    
Treatment of cerebrotendinous xanthomatosis (abnormal storage of fat in the body)

## Nephrology

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### Positive CHMP opinions on new medicines

- [Parsabiv](#) (*etelcalcetide*)  
Treatment of hyperparathyroidism in patients with chronic kidney disease on haemodialysis therapy

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#### Key to symbols used

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## Nervous system

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### New medicines authorised

- [Sialanar](#) (*glycopyrronium*)  
Treatment of severe drooling in children and adolescents with neurological disorders

### Other information

- [Abilify](#) (*aripiprazole*)  
Treatment of schizophrenia

## Respiratory system

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### New medicines authorised

- [Aerivio Spiromax](#) / [Airexar Spiromax](#) (*salmeterol / fluticasone propionate*)  
Treatment of asthma and chronic obstructive pulmonary disorder (COPD)
- [Cinqaero](#) (*reslizuma*)  
Treatment of asthma

### Arbitration procedures

- [Clenil and associated names](#) (*beclometasone dipropionate*) - outcome of procedure  
Treatment of asthma

## Rheumatology

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### New medicines authorised

- [Nordimet](#) (*methotrexate*)  
Treatment of arthritis and psoriasis

## Other medicines

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### Arbitration procedures

- [Pharmaceutics International Inc.](#) - Outcome of review (supply of non-critical medicines to EU to be stopped due to manufacturing failings)

## 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

- [Concept paper on the revision of the 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation \(bibliographical and mixed applications\) and in applications for simplified registration'](#)

Deadline for comments: 30 Nov 2016

### Adopted guidelines

- [Guideline on the core SmPC for human Anti-D immunoglobulin for intramuscular use](#)
- [Guideline on the core SmPC for human Anti-D immunoglobulin for intravenous use](#)

## Scientific committee and working party activities

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- [CHMP - agendas, minutes and highlights](#)
- [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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- [Paediatric Committee re-elects chair](#)
- [Healthcare professionals' working party elects co-chair](#)
- [EU-US collaboration to boost medicine development for rare diseases](#)
- [Fighting antimicrobial resistance globally](#)
- [Zika virus infection: plasma- and urine-derived medicines safe to use](#)
- [New judicial decisions at odds with EMA's efforts to allow access to documents on medicines](#)
- [EudraVigilance Information Day](#) - Nov 2016
- [Workshop on adaptive pathways - discussing a concept for development of medicines addressing unmet medical needs](#) - Dec 2016

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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

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

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