

# HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals  
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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

#### Positive CHMP opinions on new medicines

- [Umbipro](#) (*chlorhexidine digluconate*)  
Prevention of umbilical cord infections in newborn babies
- [Zavicefta](#) (*ceftazidime / avibactam*)  
Treatment of bacterial infections

#### New information on authorised medicines

- [Zinforo](#) (*ceftaroline fosamil*) - change in indication  
Treatment of skin and soft tissue infections and pneumonia

#### Safety communication update

- Review of [fusafungine containing medicinal products](#) for oromucosal and nasal use - CMDh Position (endorses revocation of authorisations for sprays used to treat airway infections)  
Treatment of infections of the upper airways (such as common cold)



#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances


## Cancer

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### New information on authorised medicines

- [Afinitor](#) (*everolimus*) - new indication  
Treatment of neuroendocrine tumours originating in the gut or lungs
- [Avastin](#) (*bevacizumab*) - new indication  
Treatment of non-small cell lung cancer in combination with erlotinib
- [Imbruvica](#) (*ibrutinib*) - change in indication   
Treatment of chronic lymphocytic leukaemia (blood cancer)
- [Gazyvaro](#) (*obinutuzumab*) - new indication   
Treatment of follicular lymphoma (blood cancer)

### New medicines authorised

- [Neofordex](#) (*dexamethasone*)  
Treatment of multiple myeloma (cancer of the bone marrow)
- [Palonosetron Hospira](#) (*palonosetron*)   
Prevention of nausea and vomiting associated with cancer chemotherapy


### Arbitration procedures

- [Novantrone and associated names](#) (*mitoxantrone*) - outcome of review  
Used in the treatment of certain cancers and multiple sclerosis

## Cardiovascular system

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### New medicines authorised

- [Amlodipine / Valsartan Mylan](#) (*amlodipine / valsartan*)   
Treatment of hypertension (high blood pressure)

## Diabetes

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### New information on authorised medicines

- [Victoza](#) (*liraglutide*) - change in indication  
Treatment of type 2 diabetes mellitus

### Safety communication update

- Review of [canagliflozin](#) - review started (after an increase in amputations was observed in an ongoing clinical trial called CANVAS)  
Treatment of diabetes

## Gastro-intestinal system

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### Positive CHMP opinions on new medicines

- [Enzepe](#) (*pancreas powder*)  
Treatment of pancreatic insufficiency

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**New information on authorised medicines**

- [Afinitor](#) (*everolimus*) - new indication  
Treatment of neuroendocrine tumours originating in the gut or lungs


## Haematology

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**New information on authorised medicines**

- [Ferriprox](#) (*deferiprone*) - change in indication  
Treatment of excess iron in the body in patients with thalassaemia
- [Gazyvaro](#) (*obinutuzumab*) - new indication   
Treatment of follicular lymphoma (blood cancer)
- [Imbruvica](#) (*ibrutinib*) - change in indication   
Treatment of chronic lymphocytic leukaemia (blood cancer)

**New medicines authorised**

- [Coagadex](#) (*human coagulation factor X*)   
Treatment and prevention of bleeding episodes in patients with hereditary factor x deficiency

**Communication on prevention of medication errors**

- [Exjade](#) (*deferasirox*)  - educational material to raise awareness of dose variation between different types of tablets  
Treatment of excess iron in the body

## HIV

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**Positive CHMP opinions on new medicines**

- [Odefsey](#) (*emtricitabine / rilpivirine / tenofovir alafenamide*)  
Treatment of HIV-1 infection

**New information on authorised medicines**

- [Reyataz](#) (*atazanafir sulphate*) - change in indication  
Treatment of HIV-1 infection

## Immune system

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**New information on authorised medicines**

- [HyQvia](#) (*human normal immunoglobulin*) - change in indication  
Treatment of primary immunodeficiency syndromes



## Nervous system

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**Positive CHMP opinions on new medicines**




- [Zinbryta](#) (*daclizumab*)  
Treatment of multiple sclerosis

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- [Ongentys](#) (*opicapone*)  
Treatment of Parkinson's disease

#### New medicines authorised

- [Rasagiline Mylan](#) (*rasagiline*)   
Treatment of Parkinson's disease
- [Wakix](#) (*pitolisant*)   
Treatment of narcolepsy (long-term sleep disorder)
- [Zonisamide Mylan](#) (*zonisamide*)   
Treatment of partial seizures

#### Negative CHMP opinions on new medicines

- [Sialanar](#) (*glycopyrronium bromide*)  
Treatment of persistent drooling in children and adolescents with neurological conditions

#### Arbitration procedures

- [Novantrone and associated names](#) (*mitoxantrone*) - outcome of review  
Used in the treatment of certain cancers and multiple sclerosis

## Respiratory system

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#### New information on authorised medicines

- [Afinitor](#) (*everolimus*) - new indication  
Treatment of neuroendocrine tumours originating in the gut or lungs
- [Zinforo](#) (*ceftaroline fosamil*) - change in indication  
Treatment of skin and soft tissue infections and pneumonia

#### Safety communication update

- Review of [fusafungine containing medicinal products](#) for oromucosal and nasal use - CMDh Position (endorses revocation of authorisations for sprays used to treat airway infections)  
Treatment of infections of the upper airways (such as common cold)
- Review of [inhaled corticosteroids](#) for chronic obstructive pulmonary disease - CHMP Opinion (review finds no differences in risk of pneumonia between products)  
Treatment of chronic obstructive pulmonary disease (COPD)

## Vaccines

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- [EU recommendations for composition of 2016/2017 seasonal influenza vaccines](#)

## Other medicines

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#### Positive CHMP opinions on new medicines

- [EndolucinBeta](#) (*lutetium (177 lu) chloride*)  
Radiopharmaceutical precursor

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### Arbitration procedure

- Review on the conduct of studies at [Semler Research Centre Private Ltd](#) - review started (this follows inspections by the FDA and the WHO which raised serious concerns over data generated at Semler's sites)

## Medicines under additional monitoring

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

## Other information

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### Guidelines

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#### Guidelines open for consultation

- [Draft concept paper on an addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements](#)  
Deadline for comments: 31 July 2016
- [Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials](#)  
Deadline for comments: 12 October 2016
- [Draft guideline on the sterilisation of the medicinal product, active substance, excipient and primary container](#)  
Deadline for comments: 13 October 2016
- [Draft guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome](#)  
Deadline for comments: 31 October 2016

#### Adopted guidelines

- [Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man](#)
- [Compilation of individual product-specific guidance on demonstration of bioequivalence \(Revision 3\)](#)
- [Guideline on process validation for the manufacture of biotechnology-derived substances and data to be provided in the regulatory submission](#)

## Scientific committee and working party activities

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- [Medicinal products for human use: monthly figures - March 2016](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP -applications for new human medicines under evaluation: April 2016](#)
- [2016 work plan for the CHMP modelling and simulation working group](#)
- [Mandate, objectives and rules of procedure for the joint CHMP/CVMP Quality Working Party](#)

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#### Key to symbols used

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- [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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- [Listening to the public's views on the safety of medicines](#)
- [Integrating patients' views in clinical studies of anticancer medicines](#)
- [Better safety for patients through EU-funded research](#)
- [Involving general practitioners in regulatory decisions on medicines](#)
- [Collecting high-quality data on antibiotic use in animals in support of the fight against antimicrobial resistance](#)
- [Extrapolation of data from adults to children can facilitate development of paediatric medicines](#)
- [Cooperation between regulators and HTA bodies creates synergies](#)
- Newsletter: [What's new in pharmacovigilance - QPPV Update - Issue 1](#)
- Workshop on the challenges for the approval of anti-cancer immunotherapeutic drugs - April 2016 - [meeting documents](#)
- [2016 annual workshop of the Enpr-EMA](#) - June 2016
- [IMI ADAPT SMART, IMI GetReal and MIT NEW Drug Development ParadIGmS \(NEWDIGS\) "Adaptive Design Laboratory" workshop](#) - June 2016
- [Workshop on measuring the impact of pharmacovigilance activities](#) - December 2016

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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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