

# 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

Antivirals/anti-infectives	1
Cancer	1
Cardiovascular system	2
Diabetes	3
Gastro-intestinal system	3
Gynaecology & Obstetrics	3
Haematology	3
Immune system	4
Nervous system	4
Ophthalmology	4
Respiratory system	4
Rheumatology	4
Medicines under additional monitoring	5
Guidelines	5
Scientific committee and working party activities	6
Other publications	6
Explanation of terms used	7

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

#### Positive CHMP opinions on new medicines

- [Epclusa](#) (*sofosbuvir / velpatasvir*)  
Treatment of hepatitis C
- [Zepatier](#) (*elbasvir / grazoprevir*)  
Treatment of hepatitis C



### Cancer

#### Positive CHMP opinions on new medicines





- [Bortezomib Hospira](#) (*bortezomib*)   
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- [Bortezomib Sun](#) (*bortezomib*)   
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)

#### Key to symbols used




 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

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


#### New medicines authorised

- [Ciambra](#) (*pemetrexed*)    
Treatment of malignant pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- [Darzalex](#) (*daratumumab*)    
Treatment of multiple myeloma (cancer of the bone marrow)
- [Empliciti](#) (*elotuzumab*)  
Treatment of multiple myeloma (cancer of the bone marrow)
- [Lonsurf](#) (*trifluridine / tipiracil*)  
Treatment of colorectal cancer

#### New information on authorised medicines

- [Kyprolis](#) (*carfilzomib*)  - change in indication  
Treatment of multiple myeloma (cancer of the bone marrow)
- [Adecetris](#) (*brentuximab vedotin*) - new indication    
Treatment of Hodgkin Lymphoma

#### Withdrawal of applications for new medicines

- [Xegafri](#) (*rociletinib*)   
Intended for the treatment of non-small cell lung cancer

#### Negative CHMP opinions on new medicines

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


#### Supply shortages

- [Taxotere](#) (*docetaxel*)  
Treatment of breast cancer; non-small-cell lung cancer; prostate cancer; adenocarcinoma (a type of stomach cancer) and head and neck cancers.


## Cardiovascular system

---

#### New medicines authorised

- [Uptravi](#) (*selexipag*)   
Treatment of high blood pressure in arteries of the lungs

#### Communication on prevention of medication errors

- [Uptravi](#) (*selexipag*)   
Treatment of high blood pressure in arteries of the lungs

---

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Diabetes

---


### New medicines authorised

- [Otern](#) (*saxagliptin / dapagliflozin*)  
Treatment of type 2 diabetes

## Gastro-intestinal system

---

### New information on authorised medicines

- [Revestive](#) (*teduglutide*)  - change in indication  
Treatment of short bowel syndrome

## Gynaecology & Obstetrics

---



### Arbitration procedures

- [Levonelle 1500 microgram tablets and associated names](#) (*levonorgestrel*) - outcome of procedure  
Emergency contraception





## Haematology

---


### Positive CHMP opinions on new medicines

- [Bortezomib Hospira](#) (*bortezomib*)   
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- [Bortezomib Sun](#) (*bortezomib*)   
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)

### New medicines authorised

- [Alprolix](#) (*eftrenonacog alfa*)   
Prevention and treatment of bleeding in patients with haemophilia B
- [Darzalex](#) (*daratumumab*)    
Treatment of multiple myeloma (cancer of the bone marrow)
- [Empliciti](#) (*elotuzumab*)  
Treatment of multiple myeloma (cancer of the bone marrow)
- [Idelvion](#) (*albutrepenonacog alfa*)   
Prevention and treatment of bleeding in patients with haemophilia B

### New information on authorised medicines






- [Kyprolis](#) (*carfilzomib*)  - change in indication  
Treatment of multiple myeloma (cancer of the bone marrow)

### Negative CHMP opinions on new medicines

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

---

### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Immune system

---

### New medicines authorised

- [Taltz](#) (*ixekizumab*)  
Treatment of psoriasis

## Nervous system

---

### New information on authorised medicines

- [Tysabri](#) (*natalizumab*) - change in indication  
Treatment of multiple sclerosis

## Ophthalmology

---

### New information on authorised medicines

- [Humira](#) (*adalimumab*) - new indication  
Treatment of uveitis (inflammation in the eye)


### Withdrawal of applications for new medicines

- [Opsiria](#) (*sirolimus*)  
Intended for the treatment of non-infectious uveitis (inflammation in the eye)


## Respiratory system

---

### Positive CHMP opinions on new medicines

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

### New medicines authorised

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

### Withdrawal of applications for new medicines

- [Xegafri](#) (*rociletinib*)   
Intended for the treatment of non-small cell lung cancer

## Rheumatology

---

### New information on authorised medicines

- [Simponi](#) (*golimumab*) - new indication  
Treatment of juvenile idiopathic arthritis

---

### Key to symbols used

-  Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Medicines under additional monitoring

---

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

## Other information

---

### Guidelines

---

#### Guidelines open for consultation

- [Draft Everolimus tablets 0.25, 0.5, 0.75 and 1mg; 2.5, 5 and 10mg, dispersible tablets 0.1 and 0.25mg; 2, 3 and 5mg product-specific bioequivalence guidance](#)  
Deadline for comments: 31 July 2016
- [Draft Fingolimod capsules 0.5mg product-specific bioequivalence guidance](#)  
Deadline for comments: 31 July 2016
- [Draft Paliperidone prolonged-release tablet 1.5mg, 3mg, 6mg, 9mg and 12mg product-specific bioequivalence guidance](#)  
Deadline for comments: 31 July 2016
- [Draft Pazopanib film-coated tablet 200mg and 400mg product-specific bioequivalence guidance](#)  
Deadline for comments: 31 July 2016
- [Draft Levodopa/Carbidopa/Entacapone film-coated tablet 200mg/50mg/200mg, 175mg/43.75mg/200mg, 150mg/37.5mg/200mg, 125mg/31.25mg/200mg, 100mg/25mg/200mg, 75mg/18.75mg/200mg and 50mg/12.5mg/200mg product-specific bioequivalence guidance](#)  
Deadline for comments: 31 July 2016
- [Draft information in the package leaflet for fragrances containing allergens in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' \(CPMP/463/00 Rev. 1\)](#)  
Deadline for comments: 03 August 2016
- [Draft information in the package leaflet for fructose and sorbitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' \(CPMP/463/00 Rev. 1\)](#)  
Deadline for comments: 03 August 2016
- [Draft information in the package leaflet for aspartame in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' \(CPMP/463/00 Rev. 1\)](#)  
Deadline for comments: 03 August 2016
- [Draft reflection paper on the dissolution specification for generic oral immediate release products](#)  
Deadline for comments: 13 August 2016
- [ICH guideline S3A: Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies - questions and answers](#)  
Deadline for comments: 31 August 2016
- [Draft reflection paper on the dissolution specification for generic oral immediate release products](#)  
Deadline for comments: 13 August 2016

---

#### Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Draft guideline on good pharmacogenomic practice](#)  
Deadline for comments: 16 September 2016
- [Concept paper on the revision of the 'Guideline on the environmental risk assessment of medicinal products for human use'](#)  
Deadline for comments: 31 October 2016

## Scientific committee and working party activities

---

- [Medicinal products for human use: monthly figures - April 2016](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP applications for new human medicines under evaluation: May 2016](#)
- [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

---

- [Can regulators influence the affordability of medicines?](#)
- [Progress in science, medicine and health](#)
- [Improving safety of first-in-human clinical trials](#)
- [Accessing key EMA information on human medicines](#)
- [Supporting innovative SMEs as major drivers of new pharmaceutical developments](#)
- [European expert group proposes reduction of use in animals of last resort antibiotic colistin to manage risk of resistance](#)
- [EMA public workshop on extrapolation of efficacy and safety in medicine development - May 2016 - meeting documents](#)
- [Multi-stakeholder advanced therapy medicinal products \(ATMPs\) expert meeting: exploring solutions to foster ATMPs' development and patient access in Europe - May 2016](#)
- [Targeted consultation on the guideline for development of new medicinal products for the treatment of rheumatoid arthritis - June 2016](#)
- [Workshop on single-arm trials \(SAT\) in oncology - June 2016](#)

---

### 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

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)

An agency of the European Union

