



# 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.

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

#### New medicines authorised

- [Dovato](#) (*dolutegravir / lamivudine*)  
Treatment of HIV

### Cancer

#### Positive CHMP opinions on new medicines



- [Arsenic trioxide Accord](#) (*arsenic trioxide*)  generic of Trisenox  
Treatment of acute promyelocytic leukaemia (blood cancer)
- [Bortezomib Fresenius Kabi](#) (*bortezomib*)  generic of Velcade  
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- [Ivozall](#) (*clofarabine*)  generic of Evoltra  
Treatment of acute lymphoblastic leukaemia (blood cancer)

#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [Xospata](#) (*gilteritinib*)  
Treatment of acute myeloid leukaemia (AML) with a FLT3 mutation (blood cancer)

#### New information on authorised medicines

- [Bavencio](#) (*avelumab*)   - new indication  
Treatment of metastatic Merkel cell carcinoma (skin cancer)
- [Docetaxel Zentiva](#) (*docetaxel*) - extension to an existing indication  
Treatment of metastatic hormone-sensitive prostate cancer
- [Taxotere](#) (*docetaxel*) - extension to an existing indication  
Treatment of metastatic hormone-sensitive prostate cancer


#### Safety update

- Review of [Picato](#) (*ingenol mebutate*) - review started (data on skin cancer to be evaluated)  
Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)

## Dermatology

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#### New information on authorised medicines

- [Bavencio](#) (*avelumab*)   - new indication  
Treatment of metastatic Merkel cell carcinoma (skin cancer)

#### Safety update

- Review of [Picato](#) (*ingenol mebutate*) - review started (data on skin cancer to be evaluated)  
Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)

## Diabetes

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#### Positive CHMP opinions on new medicines

- [Otrilmet](#) (*metformin hydrochloride / saxagliptin / dapagliflozin*)  
Treatment of diabetes mellitus

#### New information on authorised medicines

- [Trulicity](#) (*dulaglutide*) - change to the existing indication  
Treatment of diabetes mellitus

## Gastro-intestinal system

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#### Safety update

- Review of [ranitidine medicines](#) - review started (tests showed that some products contained an impurity called N-nitrosodimethylamine (NDMA))  
Used to treat and prevent conditions caused by excess acid in the stomach such as heartburn and stomach ulcers

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#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Haematology

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### Positive CHMP opinions on new medicines

- [Arsenic trioxide Accord](#) (*arsenic trioxide*)  generic of Trisenox  
Treatment of acute promyelocytic leukaemia (blood cancer)
- [Bortezomib Fresenius Kabi](#) (*bortezomib*)  generic of Velcade  
Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- [Ivozall](#) (*clofarabine*)  generic of Evoltra  
Treatment of acute lymphoblastic leukaemia (blood cancer)

## HIV

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### New medicines authorised

- [Dovato](#) (*dolutegravir / lamivudine*)  
Treatment of HIV

## Immune system

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### New information on authorised medicines

- [Dupixent](#) (*dupilumab*) - new indication  
Treatment of chronic rhinosinusitis with nasal polyposis (inflammation in the nose and sinuses)
- [Remsima](#) (*infliximab*)  biosimilar of Remicade - new route of administration, strength and pharmaceutical form  
Treatment of rheumatoid arthritis

## Nervous system

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### New medicines authorised

- [Inbrija](#) (*levodopa*)  
Treatment of Parkinson's disease
- [Lacosamide UCB](#) (*lacosamide*)  
Treatment of epilepsy

## Ophthalmology

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### Positive CHMP opinions on new medicines

- [Rhokiinsa](#) (*netarsudil*)  
Treatment of glaucoma or ocular hypertension (increased pressure in the eye)

### New information on authorised medicines

- [Lucentis](#) (*ranibizumab*) - extension to the existing indication  
Treatment of proliferative diabetic retinopathy (diabetes complication that affects eyes)

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### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Respiratory system

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### New medicines authorised

- [Temybric Ellipta](#) (*fluticasone furoate / umeclidinium / vilanterol*)  
Treatment of chronic obstructive pulmonary disease (condition causing difficulty in breathing)

## Rheumatology

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### New information on authorised medicines

- [Benlysta](#) (*belimumab*) - extension to the existing indication  
Treatment of autoantibody- positive systemic lupus erythematosus (SLE) (condition causing inflammation and organ damage)
- [Remsima](#) (*infliximab*)  biosimilar of Remicade - new route of administration, strength and pharmaceutical form  
Treatment of rheumatoid arthritis

## Other medicines

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### Positive CHMP opinions on new medicines

- [Senstend](#) (*lidocaine / prilocaine*)  
Treatment of premature ejaculation

## Other information

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- Review of [presence of nitrosamines in human medicines](#) - outcome of Art 5 (3)

## Medicines under additional monitoring

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

## Other information

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## Scientific committee and working party activities

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- [Medicinal products for human use: monthly figures - August 2019](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: August 2019](#)
- [COMP - agendas, minutes and meetings reports](#)

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### Key to symbols used

-  Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC statistics: September 2019](#)
- [PRAC recommendations on safety signals](#)
- [PCWP meeting: 24 September 2019 - Agenda](#)
- [HCPWP meeting: 24 September 2019 - Agenda](#)
- [PCWP and HCPWP joint meeting: 25 September 2019 - Agenda](#)

## Other publications

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- [Preparedness of medicines' clinical trials in paediatrics: Recommendations by the Enpr-EMA working group on trial preparedness](#)
- [Working parties for healthcare professionals and for patients and consumers elect new co-chairs](#)
- [EMA advises companies on steps to take to avoid nitrosamines in human medicines](#)






## Events

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- [Workshop on the use of registries for tumour histology-independent cancer therapies](#) - 29 November 2019 - [Agenda](#)

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### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Explanation of terms used

### **O** Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

### **G** 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')

### **B** 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)

### **C** 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 to generate complete data on the medicine.

### **E** 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. These medicines are subject to specific post-authorisation obligations and monitoring.

### **Medicines assessed under Article 58**

Article 58 of Regulation (EC) No 726/2004 allows the [CHMP](#) to give opinions, in co-operation with the World Health Organization, on [medicinal products](#) that are intended exclusively for markets outside of the European Union.

### **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](#)

If you have a question relating to the content of this Newsletter, please send it via [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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