

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

Arbitration procedures

- [Tobramycin VVB and associated names](#) - outcome
Treatment of lung infection in patients with cystic fibrosis

Cancer

Positive CHMP opinions on new medicines


- [Empliciti \(elotuzumab\)](#) 
Treatment of multiple myeloma (cancer of the bone marrow)

New medicines authorised


- [Oncaspar \(pegaspargase\)](#)
Treatment of leukaemia (blood cancer)
- [Spectrila \(asparaginase\)](#)
Treatment of leukaemia (blood cancer)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

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

New information on authorised medicines



- [Revlimid](#) (*lenalidomide*)  - new indication
Treatment of mantle cell lymphoma

Withdrawal of authorised medicines


- [Nivolumab BMS](#) (*nivolumab*)
Treatment of non-small cell lung cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- [Amlodipine-Valsartan Mylan](#) (*amlodipine / valsartan*) 
Treatment of hypertension (high blood pressure)
- [Uptravi](#) (*selexipag*) 
Treatment of high blood pressure in arteries of the lungs

New medicines authorised

- [Eptifibatide Accord](#) (*eptifibatide*) 
Prevention of heart attack



Diabetes

Arbitration procedures

- [Metformin-containing medicines](#) - start
Treatment of type 2 diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- [Coagadex](#) (*human coagulation factor X*) 
Treatment and prevention of bleeding episodes in patients with hereditary factor X deficiency
- [Empliciti](#) (*elotuzumab*) 
Treatment of multiple myeloma (cancer of the bone marrow)


New medicines authorised

- [Oncaspar](#) (*pegaspargase*)
Treatment of leukaemia (blood cancer)
- [Spectrila](#) (*asparaginase*)
Treatment of leukaemia (blood cancer)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Revlimid](#) (*lenalidomide*) - new indication 
Treatment of mantle cell lymphoma

Immune system

New medicines authorised



- [Benepali](#) (*etanercept*) 
Treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis

New information on authorised medicines

- [Revolade](#) (*eltrombopag*) - change in indication
Treatment of thrombocytopenic purpura

Nervous system


Positive CHMP opinions on new medicines

- [Rasagiline Mylan](#) (*rasagiline*) 
Treatment of Parkinson's disease
- [Zonisamide Mylan](#) (*zonisamide*) 
Treatment of partial seizures

New medicines authorised


- [Briviact](#) (*brivaracetam*)
Treatment of partial-onset seizures

Withdrawal of application for new medicine

- [Aripiprazole Mylan](#) (*aripiprazole*) 
Intended for the treatment of schizophrenia and the treatment and prevention of manic episodes in patients with bipolar I disorder

Respiratory system

New medicines authorised

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

Arbitration procedures


- [Tobramycin VVB and associated names](#) - outcome
Treatment of lung infection in patients with cystic fibrosis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Rheumatology

New medicines authorised

- [Benepali](#) (*etanercept*) 
Treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Draft concept paper on the revision of the reflection paper on non-clinical and clinical development of similar biological medicinal products containing recombinant interferon alpha or pegylated recombinant interferon alpha](#)
Deadline for comments: 31 March 2016

Adopted guidelines

- [Lessons learned from the review of the labelling of centrally authorised pandemic vaccines](#)
- [Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance \(NAS\) status of chemical substances](#)
- [Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance \(NAS\) status of chemical substances](#)

Scientific committee and working party activities

- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: January 2016](#)
- [CAT - agendas, minutes and reports](#)
- [COMP - agendas, minutes and meetings reports](#)
- [COMP work plan 2016](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)

Key to symbols used





-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [PRAC recommendations on safety signals](#)
- [Work plan for the CHMP Biologics Working Party 2016](#)
- [Work plan for the GMP/GDP Inspectors Working Group 2016](#)

Other publications

- [News bulletin for small and medium-sized enterprises - Issue 34](#)
- Expert meeting on paediatric development of fixed-dose combinations for the treatment of the human immunodeficiency virus (HIV) - Nov 2015 - [meeting documents](#)
- Workshop the role of pharmacokinetic and pharmacodynamic measurements in the use of direct oral anticoagulants (DOACs) - Nov 2015 - [meeting documents](#)
- Enpr-EMA meeting on rare gastrointestinal and liver diseases - Dec 2015 - [meeting documents](#)
- [Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins](#) - Mar 2016

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.

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.

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.

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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