

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

- [Harvoni](#) (*ledipasvir / sofosbuvir*)
Treatment of hepatitis C

New medicines authorised

- [Daklinza](#) (*daclatasvir*)
Treatment of hepatitis C

Cancer

Positive CHMP opinions on new medicines

- [Cyramza](#) (*ramucirumab*) 
Treatment of cancer of the stomach or of the junction between the stomach and gullet

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Egranli](#) (*balugrastim*)
Prevention of chemotherapy-induced neutropenia (low level of white blood cells)
- [Lymphoseek](#) (*tilmanocept*)
Diagnostic agent for locating sentinel lymph nodes in breast cancer, skin cancer and mouth cancer
- [Vargatef](#) (*nintedanib*)
Treatment of non-small cell lung cancer

Negative CHMP opinions on extension of indication

- [Javlor](#) (*vinflunine*)
Intended for the treatment of breast cancer

Negative CHMP opinions on extension of indication (re-examination)

- [Avastin](#) (*bevacizumab*)
Intended for the treatment of glioblastoma (a brain cancer)

Cardiovascular system

New medicines authorised

- [Clopidogrel/Acetylsalicylic acid Teva](#) (*clopidogrel / acetylsalicylic acid*)
Prevention of problems caused by blood clots, such as heart attack

Diabetes

Positive CHMP opinions on new medicines

- [Trulicity](#) (*dulaglutide*)
Treatment of type 2 diabetes mellitus

Withdrawal of authorised medicines

- [Pioglitazone Krka](#) (*pioglitazone*) 
Treatment of type 2 diabetes mellitus

Gastro-intestinal system

Positive CHMP opinions on new medicines

- [Cynamza](#) (*ramucirumab*) 
Treatment of cancer of the stomach or of the junction between the stomach and gullet

HIV

Positive CHMP opinions on new medicines

- [Rezolsta](#) (*darunavir / cobicistat*)
Treatment of HIV-1 infection

Key to symbols used

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New information on authorised medicines

- [Prezista](#) (*darunavir*) - change in indication
Treatment of HIV-1 infection

Haematology

Positive CHMP opinions on new medicines

- [Egranli](#) (*balugrastim*)
Prevention of chemotherapy-induced neutropenia (low level of white blood cells)

Hormone system

Positive CHMP opinions on new medicines

- [Ketoconazole HRA](#) (*ketoconazole*) 
Treatment of Cushing's syndrome

New information on authorised medicines

- [Signifor](#) (*pasireotide*) - new indication 
Treatment of acromegaly (excess growth of body tissues due to excessive growth hormone)

Immune system

Positive CHMP opinions on new medicines

- [Budesonide/Formoterol Teva Pharma B.V.](#) (*budesonide / formoterol*)
Treatment of asthma

Musculoskeletal system

New medicines authorised

- [Translarna](#) (*ataluren*)  
Treatment of Duchenne muscular dystrophy

Nervous system

New medicines authorised

- [Vizamyl](#) (*flutemetamol (18F)*)
Diagnosis of Alzheimer's disease and other causes of cognitive impairment

Safety communication update

- [Valdoxan/Thymanax](#) (*agomelatine*) - CHMP Opinion (confirms positive benefit-risk with further measures introduced to minimise risk of liver toxicity)
Treatment of depression

Key to symbols used

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Respiratory system

Positive CHMP opinions on new medicines

- [Brimica Genuair](#) / [Duaklir Genuair](#) (*aclidinium / formoterol*)
Treatment of chronic obstructive pulmonary disease
- [Budesonide/Formoterol Teva](#) / [Vylaer Spiromax](#) (*budesonide / formoterol*)
Treatment of asthma and chronic obstructive pulmonary disease
- [Budesonide/Formoterol Teva Pharma B.V.](#) (*budesonide / formoterol*)
Treatment of asthma

Other medicines

Positive CHMP opinions on new medicines

- [Moventig](#) (*naloxegol*)
Treatment of constipation
- [Tadalafil Mylan](#) (*tadalafil*) 
Treatment of erectile dysfunction

Other information

- [Maci](#) (*matrix-applied characterised autologous cultured chondrocytes*) - CHMP Opinion (suspension of the marketing authorisation following closure of manufacturing site)
Used for the repair of cartilage defects of the knee

Arbitration procedure

- [EMLA cream and associated names](#) (*lidocaine / prilocaine*) - outcome
Local anaesthesia

Medicines under additional monitoring

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

Other information

Guidelines

Adopted guidelines

- [Guideline on good pharmacovigilance practices: Module III – Pharmacovigilance inspections](#) rev 1
- [Guideline on good pharmacovigilance practices: Module VI – Management and reporting of adverse reactions to medicinal products](#) rev 1
- [Guideline on bioanalytical method validation](#) rev 1 Corr.

Key to symbols used

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- [Guideline on assessment and control of DNA reactive \(mutagenic\) impurities in pharmaceuticals to limit potential carcinogenic risk - Step 4](#)
- [Guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - August 2014](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: September 2014](#)
- [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

- [Patients to discuss benefit-risk evaluation of medicines with the CHMP](#)
- [Ebola outbreak: EMA to review experimental medicines to support treatment decisions](#)
- [Medicines regulators to work together internationally to find innovative solutions to facilitate evaluation of and access to potential new medicines to counter Ebola outbreaks](#)
- [Avoiding duplication of clinical trials in children](#)
- [Evaluation of financial information from patients' consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility'](#)
- [Small and medium-sized enterprises: driving innovation in medicines](#)
- Review in relation to findings of GCP non-compliance at [GVK Biosciences](#) site - review started (concerns raised about study data used to support the marketing authorisation applications of generic medicines)
- Eighth stakeholders forum on the implementation of the pharmacovigilance legislation: Building on two years of operation - [meeting documents](#)
- [Joint EFGCP / DIA / EMA: Better medicines for children conference](#) - September 2014
- EU clinical trials portal and Union database: meetings with stakeholders - [September](#), [October](#) and [December](#) 2014

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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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