

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

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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

Safety communication update

- Review of [quinolone- and fluoroquinolone-containing medicinal products](#) - review started (review to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems)
Treatment of bacterial infections

Cancer


Positive CHMP opinions on new medicines

- [Pemetrexed Hospira UK Limited](#) (*pemetrexed*) 
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- [Varuby](#) (*rolapitant*)
Prevention of nausea and vomiting associated with chemotherapy

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Darzalex](#) (*daratumumab*)  - change in indication
Treatment of multiple myeloma (cancer of the bone marrow)
- [Mekinist](#) (*trametinib*) - new indication
Treatment of non-small cell lung cancer
- [Tafinlar](#) (*dabrafenib*) - new indication
Treatment of non-small cell lung cancer

Cardiovascular system

New medicines authorised

- [Ivabradine JensonR](#) (*ivabradine*) 
Treatment of angina pectoris (chest pain) and heart failure

Positive CHMP opinions on new medicines

- [Roteas](#) (*edoxaban*)
Prevention of stroke and treatment and prevention of blood clots

Diabetes

New medicines authorised


- [Fiasp](#) (*insulin aspart*)
Treatment of diabetes mellitus

Safety communication update

- Review of [SGLT2 inhibitors](#) (*canagliflozin, empagliflozin, dapagliflozin, canagliflozin / metformin, empagliflozin / metformin*) - CHMP opinion (increased risk of toe amputation)
Treatment of diabetes mellitus


Gastro-intestinal system

New medicines authorised

- [SomaKit TOC](#) (*edotreotide*) 
Used for the diagnosis of certain tumours originating in the gut or pancreas

Haematology

New information on authorised medicines



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

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

HIV

New medicines authorised

- [Darunavir Mylan](#) (*darunavir*) 
Treatment of HIV infection
- [Emtricitabine / Tenofovir disoproxil Mylan](#) (*emtricitabine / tenofovir disoproxil*) 
Treatment of HIV infection

Positive CHMP opinions on new medicines



- [Emtricitabine / Tenofovir disoproxil Krka d.d.](#) (*emtricitabine / tenofovir disoproxil*) 
Treatment of HIV infection

New information on authorised medicines

- [Truvada](#) (*emtricitabine / tenofovir disoproxil*) - change in indication
Treatment of HIV infection

Hormone system

Positive CHMP opinions on new medicines

- [Natpar](#) (*parathyroid hormone*)  
Treatment of hypoparathyroidism (underactive parathyroid gland)

Metabolic system

Positive CHMP opinions on new medicines

- [Lokelma](#) (*sodium zirconium cyclosilicate*)
Treatment of hyperkalaemia (high levels of potassium in the blood)

Musculoskeletal system

Safety communication update

- Review of [quinolone- and fluoroquinolone-containing medicinal products](#) - review started (review to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems)
Treatment of bacterial infections

Nervous system

Arbitration procedures

- [Saroten and associated names](#) (*amitriptyline*) - outcome of procedure
Treatment of a variety of neurological and psychiatric conditions
- [Haldol and associated names](#) (*haloperidol*) - outcome of procedure
Treatment of a variety of neurological and psychiatric conditions
- [Haldol Decanoate and associated names](#) (*haloperidol*) - outcome of procedure
Treatment of schizophrenia and schizoaffective disorder (schizophrenia with mood disorders)

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety communication update

- Review of [quinolone- and fluoroquinolone-containing medicinal products](#) - review started (review to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems)
Treatment of bacterial infections


Ophthalmology

New medicines authorised

- [Cystadrops](#) (*mercaptamine*) 
Treatment of cystine crystal deposits in the eye

Respiratory system

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- [Mekinist](#) (*trametinib*) - new indication
Treatment of non-small cell lung cancer
- [Tafinlar](#) (*dabrafenib*) - new indication
Treatment of non-small cell lung cancer

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Concept paper on developing a guideline on quality requirements of medicinal products containing a device component for delivery or use of the medicinal product](#)
Deadline for comments: 16 Nov 2017

Adopted guidelines

- [Guideline on core SmPC and package leaflet for nanocolloidal technetium \(99mTc\) albumin - First version](#)
- [ICH S9 Non-clinical evaluation for anticancer pharmaceuticals](#) - updated
- [ICH guideline E17 on general principles for planning and design of multi-regional clinical trials](#) - updated

Key to symbols used

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Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - January 2017](#)
- [CHMP - agendas, minutes and highlights](#)
- [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](#)
- [HMPC work plan 2017](#)
- [PCWP work plan 2017](#)
- [HCPWP work plan 2017](#)

Other publications

- [Minutes of the 94th meeting of the Management Board: 14-15 December 2016](#)
- [EMA mid-year report 2016 from the Executive Director](#)
- [EMA work programme 2017](#)
- [Consultation on revised policy on access to documents](#)
- [Martina Schüssler-Lenz elected as new chair of Committee for Advanced Therapies](#)
- [Over 1,000 studies now recorded in EU register of post-authorisation studies](#)
- [Annual report on the use of the special contribution for orphan medicinal products](#)
- [Advanced therapy medicines: towards increased development and patient access](#)
- [Innovative medicines initiative WEB-RADR workshop report: mobile technologies and social media as new tools in pharmacovigilance](#) - Oct 2017
- [EMA / DIA signal management information day](#) - Oct 2017
- [Report - Patient registries workshop](#) - Oct 2016
- [Adaptive Pathways Workshop - Report on a meeting with stakeholders](#) - Dec 2016
- [Summary report - EMA / EBE fifth annual regulatory conference on optimising the development of advanced therapies to meet patient needs](#) - Dec 2016
- [Seventh Framework Programme \(FP7\) small-population research methods projects and regulatory application workshop](#) - Mar 2017
- [2017 Annual workshop of the Enpr-EMA](#) - May 2017

Key to symbols used

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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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