

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


Positive CHMP opinions on new medicines

- [Alpivab](#) (*peramivir*)
Treatment of influenza

New medicines authorised

- [Darunavir Krka](#) (*darunavir*)  generic of Prezista
Treatment of HIV infection

New information on authorised medicines


- [Efavirenz/Emtricitabine/Tenofovir disoproxil Krka](#) (*efavirenz / emtricitabine / tenofovir disoproxil*)  generic of Atripla
Treatment of HIV infection
- [Isentress](#) (*raltegravir*) - extension to existing indication
Treatment of HIV infection

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Cancer



Positive CHMP opinions on new medicines

- [Mylotarg](#) (*gemtuzumab ozogamicin*) 
Treatment of myeloid leukaemia (blood cancer)

New medicines authorised

- [Fulvestrant Mylan](#) (*fulvestrant*)  generic of Faslodex
Treatment of breast cancer

New information on authorised medicines

- [Bosulif](#) (*bosutinib*) - extension to existing indication 
Treatment of chronic myelogenous leukaemia (blood cancer)
- [Lynparza](#) (*olaparib*) - new presentation and new strengths 
Treatment of ovarian cancer
- [Xgeva](#) (*denosumab*) - extension to existing indication
Prevention of bone complications of advanced cancers

Withdrawal of applications for extension of indication

- [Zydeliq](#) (*idelalisib*)
Intended to be used in combination with rituximab and bendamustine to treat chronic lymphocytic leukaemia (CLL) (blood cancer)

Negative CHMP opinions on new medicines

- [Nerlynx](#) (*neratinib*)
Intended for the treatment of breast cancer

Negative CHMP opinions on extension of indication

- [Sutent](#) (*sunitinib*)
Intended to prevent a reoccurrence of kidney cancer


Dermatology

Safety communication update

- Review of [retinoid-containing medicinal products](#) (*acitretin, adapalene, alitretinoin, bexarotene, isotretinoin, tretinoin, tazarotene*) - PRAC recommendation (updating measures for pregnancy prevention during retinoid use)
Used to treat acne, eczema, psoriasis and other skin conditions, and certain types of cancer

Diabetes

Positive CHMP opinions on new medicines

- [Amglicia](#) (*glibenclamide*) 
Treatment of neonatal diabetes

Key to symbols used

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New medicines authorised

- [Ozempic](#) (*semaglutide*)
Treatment of type 2 diabetes

Gynaecology & Obstetrics

New medicines authorised

- [Intrarosa](#) (*prasterone*)
Treatment of vulvar and vaginal atrophy in postmenopausal women

Safety communication update

- Review of [Esmya](#) (*ulipristal acetate*) - PRAC recommendation (regular liver monitoring for women taking Esmya for uterine fibroids, while review is ongoing)
Treatment of uterine fibroids

Haematology

New medicines authorised


- [Adynovi](#) (*rurioctocog alfa pegol*)
Treatment and prevention of bleeding in patients with haemophilia A

New information on authorised medicines


- [Feraccru](#) (*ferric maltol*) - extension to existing indication
Treatment of iron deficiency

HIV

New medicines authorised


- [Darunavir Krka](#) (*darunavir*)  generic of Prezista
Treatment of HIV infection

New information on authorised medicines

- [Efavirenz/Emtricitabine/Tenofovir disoproxil Krka](#) (*efavirenz / emtricitabine / tenofovir disoproxil*)  generic of Atripla
Treatment of HIV infection
- [Isentress](#) (*raltegravir*) - extension to existing indication
Treatment of HIV infection

Immune system

New medicines authorised

- [Anagrelide Mylan](#) (*anagrelide*)  generic of Xagrid
Reduction of platelets in thrombocythaemia (blood clotting disorder)

Key to symbols used

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New information on authorised medicines

- [Kineret](#) (*anakinra*) - new indication
Treatment of Still's disease (inflammation of joints)

Musculoskeletal system

New information on authorised medicines

- [Kineret](#) (*anakinra*) - new indication
Treatment of Still's disease (inflammation of joints)

Nervous system

Safety communication update

- Review of [Valproate and related substances](#) (*sodium valproate, valproate magnesium, valproate semisodium, valproic acid, valpromide*) - PRAC recommendation (new measures to avoid valproate exposure in pregnancy)
Treatment of epilepsy, bipolar disorder and migraine

Respiratory system

Positive CHMP opinions on new medicines

- [Riarify](#) / [Trydonis](#) (*beclometasone dipropionate anhydrous / formoterol fumarate dihydrate / glycopyrronium*)
Treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

New information on authorised medicines

- [Kineret](#) (*anakinra*) - new indication
Treatment of Still's disease (inflammation of joints)

Other medicines

Safety communication update

- Review of [flupirtine-containing medicinal products](#) (*flupirtine*) - PRAC recommendation (withdrawal of marketing authorisation)
Treatment of pain

Medicines under additional monitoring

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

Key to symbols used

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Other information

Guidelines

Guidelines open for consultation

- [Qualification opinion - The European Cystic Fibrosis Society Patient Registry \(ECFSPR\)](#)
Deadline for comments: 09 April 2018
- [Draft guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products](#)
Deadline for comments: 30 April 2018
- [Questions and answers on the Haemagglutination Inhibition \(HI\) test for qualification of influenza vaccine \(inactivated\) seed preparations](#)
Deadline for comments: 31 July 2018
- [Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population](#)
Deadline for comments: 31 July 2018
- [Quality aspects included in the product information for vaccines for human use](#)
Deadline for comments: 31 July 2018
- [Questions and answers on bovine spongiform encephalopathies \(BSE\) and vaccines](#)
Deadline for comments: 31 July 2018
- [Draft guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus - Revision 2](#)
Deadline for comments: 15 August 2018

Adopted guidelines

- [Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease - Revision 2](#)
- [Reflection paper on physical frailty: instruments for baseline characterisation of older populations in clinical trials](#)
- [Paracetamol oral use, immediate release formulations product-specific bioequivalence guidance](#)
- [Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance](#)
- [Tadalafil product-specific bioequivalence guidance](#)
- [Dolutegravir, film-coated tablet, 10mg, 25mg, 50mg, product-specific bioequivalence guidance](#)
- [Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance](#)
- [Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to Mycobacterium Tuberculosis](#)
- [Influenza vaccines - quality module](#)
- [Strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products](#)

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Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- [Human burn eschar and debrided adipose tissue cells \(suspension\)](#)
- [Human burn eschar and debrided adipose tissue cells \(sheet\)](#)
- [Human burn eschar and debrided adipose tissue cells \(on acellular dermal matrix\)](#)
- [Human burn eschar and debrided adipose tissue cells \(on acellular amniotic matrix\)](#)
- [Haematopoietic stem cells genetically modified to express a zinc finger nuclease which disrupts the enhancer of BCL11A expression](#)
- [Cultured human retinal pigment epithelial cells genetically modified to express human factor IX protein](#)
- [CD1c \(BDCA-1\)+ myeloid dendritic cells](#)
- [Autologous bone-marrow derived CD34+ cells](#)
- [Autologous adipose-derived stem cells seeded on a collagen matrix scaffold](#)
- [Human autologous stromal vascular fraction \(SVF\) cells and human autologous adipose-derived mesenchymal stem cells \(ADSC\) cells](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - January 2018](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: February 2018](#)
- [CAT - agendas, minutes and reports](#)
- [Committee for Advanced Therapies \(CAT\) - Work Plan 2018](#)
- [COMP - agendas, minutes and meetings reports](#)
- [Committee for Orphan Medicinal Products \(COMP\) work plan 2018](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PDCO work plan 2018](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC recommendations on safety signals](#)
- [Work plan for the Modelling and Simulation Working Group for 2018](#)
- [Work plan for the Good Manufacturing Practice / Good Distribution Practice Inspectors Working Group 2018](#)
- [Work plan for Biostatistics Working Party \(BSWP\) 2018](#)
- [EudraVigilance Expert Working Group \(EV-EWG\) work programme 2018](#)

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Other publications

- [Management Board initiates building approval process for EMA premises in Amsterdam](#)
- Management Board meeting: 13-14 December 2017 - [minutes](#)
- [General Court confirms EMA approach to transparency](#)
- [Revised guideline on clinical studies for Alzheimer's disease medicines](#)
- [Strengthened guidance on follow-up and risk management for ATMP developers](#)
- [Towards more ethical use of animals in medicine testing](#)
- [Evaluation of advanced therapy medicines](#)
- Medicine evaluation figures - [Annual medicines highlights](#)
- Orphan medicines figures 2000-2017 - [presentation](#) - updated
- [Letter of support for intermediate age related macular degeneration \(AMD\) biomarker and novel clinical endpoint development](#)
- Twelfth industry stakeholder platform on the operation of pharmacovigilance in the European Union - 24 November 2017 - [report](#)
- Workshop on site and histology - Independent indications in oncology - 14-15 December 2017 - [documents](#)

Events

- Second international awareness session for international regulators, academia and non-governmental organisations: 8-9 March 2018 - [agenda](#)
- EudraVigilance and signal management information day - 16 March 2018 - [agenda](#)
- EMA/EC multi-stakeholder workshop to further improve the implementation of paediatric regulation - 20 March 2018 - [agenda](#)

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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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