

HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union 

IN THIS ISSUE

Antivirals/anti-infectives	1
Cancer	2
Dermatology	2
Diabetes	2
Haematology	2
HIV	3
Immune system	3
Metabolic disorders	3
Nervous system	3
Respiratory system	3
Rheumatology	3
Other medicines	4
Medicines under additional monitoring	4
Guidelines	4
Other scientific recommendations	5
Scientific committee and working party activities	6
Other publications	6
Events	7
Explanation of terms used	8

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

- [Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva](#) (efavirenz / emtricitabine / tenofovir disoproxil)  generic of Atripla
Treatment of HIV infection
- [Entecavir Mylan](#) (entecavir)  generic of Baraclude
Treatment of hepatitis B

New information on authorised medicines


- [Cubicin](#) (daptomycin) - extension to existing indication
Treatment of bacterial infections: complicated skin and soft-tissue infections, right-sided infective endocarditis (infection of the lining or the valves of the right side of the heart) and bacteraemia (infection of the blood)
- [Pegasys](#) (peginterferon alfa-2a) - extension to existing indication
Treatment of chronic hepatitis B and C

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Cancer

New medicines authorised


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

New information on authorised medicines

- [Alecensa](#) (*alectinib*) - extension to existing indication 
Treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer
- [Faslodex](#) (*fulvestrant*) - new indication
Treatment of breast cancer
- [Zytiga](#) (*abiraterone acetate*) - extension to existing indication
Treatment of prostate cancer

Dermatology

New medicines authorised

- [Bavencio](#) (*avelumab*) 
Treatment of Merkel cell carcinoma (skin cancer)
- [Dupixent](#) (*dupilumab*)
Treatment of atopic dermatitis (inflammation of the skin)

New information on authorised medicines

- [Cubicin](#) (*daptomycin*) - extension to existing indication
Treatment of bacterial infections: complicated skin and soft-tissue infections, right-sided infective endocarditis (infection of the lining or the valves of the right side of the heart) and bacteraemia (infection of the blood)

Diabetes

New information on authorised medicines

- [Bydureon](#) (*exenatide*) - change in indication
Treatment of diabetes mellitus

Haematology

Safety communication update


- Review of [hydroxyethyl starch \(HES\) containing medicinal products](#) - review started (studies show low adherence to restrictions aimed at reducing risks of kidney injury and death)
Used for the management of hypovolaemia (low blood volume) caused by acute (sudden) blood loss

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances


HIV

New medicines authorised

- [Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva](#) (efavirenz / emtricitabine / tenofovir disoproxil) 
generic of Atripla
Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines


- [Tacforius](#) (tacrolimus) 
generic of Advagraf
Used for prevention and treatment of transplant rejection

New medicines authorised

- [Dupixent](#) (dupilumab)
Treatment of atopic dermatitis (inflammation of the skin)

Metabolic disorders

New medicines authorised

- [Nitisinone MDK \(previously Nitisinone MendeliKABS\)](#) (nitisinone) 
generic of Orfadin
Treatment of tyrosinaemia type 1 (HT-1)


Nervous system

Safety communication update

- Review of [Zinbryta](#) (daclizumab) - PRAC recommendation (to be used only in a restricted patient group, with strict liver monitoring)
Treatment of multiple sclerosis


Respiratory system

New information on authorised medicines

- [Alecensa](#) (alectinib) - extension to existing indication 
Treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer

Rheumatology

New medicines authorised

- [Febuxostat Mylan](#) (febuxostat) 
generic of Adenuric
Treatment of hyperuricaemia (high levels of uric acid in the blood)

Key to symbols used

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Other medicines

New medicines authorised

- [Cuprior](#) (*trientine*)
Treatment of Wilson's disease (rare autosomal recessive inherited disorder)

Safety communication update

- Review of [flupirtine-containing medicinal products](#) (*flupirtine*) - review started (medicines are being used outside current restrictions and cases of liver damage have been reported)
Used as an analgesic (for pain relief)

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Reflection paper on the use of extrapolation in the development of medicines for paediatrics](#)
Deadline for comments: 14 January 2018
- [Draft guideline on clinical investigation of recombinant and 4 human plasma-derived factor VIII products](#)
Deadline for comments: 31 January 2018
- [Draft guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products](#)
Deadline for comments: 31 January 2018
- [Concept paper on the need for a paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous](#)
Deadline for comments: 31 January 2018
- [Draft guideline on the clinical evaluation of medicinal products indicated for the prophylaxis or treatment of respiratory syncytial virus \(RSV\) disease](#)
Deadline for comments: 30 April 2018

Adopted guidelines

- [Requirements for quality documentation concerning biological investigational medicinal products in clinical trials](#)
- ['Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials'](#) - overview of comments
- [Clinical investigation of medicinal products for the treatment of ankylosing spondylitis](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Annex I - Definitions \(Rev.4\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Annex V - Abbreviations \(Rev.1\)](#)

Key to symbols used

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- [Guideline on good pharmacovigilance practices \(GVP\): Module VIII – Post-authorisation safety studies \(Rev.3\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Module IX – Signal management \(Rev.1\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Module IX – Signal management \(Rev.1\)](#) - comments received from public consultation
- [Guideline on good pharmacovigilance practices \(GVP\): Module IX Addendum I – Methodological aspects of signal detection from spontaneous reports of suspected adverse reactions](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Module IX Addendum I – Methodological aspects of signal detection from spontaneous reports of suspected adverse reactions](#) - comments received from public consultation
- [Guideline on good pharmacovigilance practices \(GVP\): Module XV – Safety communication \(Rev.1\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Module XV – Safety communication \(Rev.1\)](#) - comments received from public consultation
- [Guideline on good pharmacovigilance practices \(GVP\): Annex II – Templates: Direct Healthcare Professional Communication \(DHPC\) \(Rev.1\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication \(CP DHPC\)](#)
- [Guideline on good pharmacovigilance practices \(GVP\): Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication \(CP DHPC\)](#) - comments received from public consultation
- [ICH guideline E18 on genomic sampling and management of genomic data - First version](#)
- [ICH E11\(R1\) step 5 guideline on clinical investigation of medicinal products in the pediatric population](#)
- [ICH Q11 Development and manufacture of drug substances \(chemical entities and biotechnological/biological entities\)](#)

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- [Viable chondrocytes cultured within a 3D hydrogel](#)
- [Messenger RNAs \(mRNAs\) encoding immunostimulatory proteins caTLR4, CD40L and CD70 and tumour associated antigens \(TAA\) tyrosinase, gp100, MAGE A3, MAGE C2 and PRAME](#)
- [Nuclease resistant, synthetic double-stranded small interfering RNA \(siRNA\)](#)
- [Allogeneic human glial-restricted precursors](#)
- [Allogeneic human glial-restricted precursors](#)
- [Autologous adipose tissue-derived mesenchymal stem cells](#)
- [Human autologous keratinocytes](#)
- [Stromal vascular fraction cells](#)
- [Human umbilical cord blood-derived mesenchymal stem cells](#)
- [Human autologous chondrocytes](#)

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Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - October 2017](#)
- [Medicinal products for human use: monthly figures - September 2017](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: November 2017](#)
- [CHMP - applications for new human medicines: October 2017](#)
- [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

- [EMA Management Board: highlights of October 2017 meeting](#)
- [EMA work programme 2017](#) - updated
- [EMA takes yet another step in public engagement with its first public hearing](#)
- [EMA's procedural handling of safety review was complete and independent](#)
- [EMA's Business Continuity Plan for Brexit published](#)
- [EMA publishes comments on Member States' hosting bids](#)
- [EMA process for engaging in external regulatory sciences and process improvement research activities for public and animal health](#)
- [General Court finds no fault in 2011 appointment procedure of EMA Executive Director](#)
- [New action plan to foster development of advanced therapies](#)
- [Enabling science that works for patients](#) – leaflet
- [Engaging with patients](#) - video
- [Better labelling of excipients for safe use of medicines](#)
- [Unparalleled access to clinical data - one year on](#)
- [Data privacy in the age of big data](#)
- [Countdown to launch of new EudraVigilance System](#)
- [EU scientific opinion: how to assess progress on reduction of antimicrobial resistance and antimicrobial consumption](#)
- [How to develop vaccines and medicines that prevent and treat respiratory syncytial virus \(RSV\) infection](#)

Key to symbols used





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- Cystic fibrosis workshop - Registries initiative - June 2017 - [meeting documents](#)
- Multiple sclerosis workshop - Registries initiative - July 2017 - [meeting documents](#)
- EMA - Payer Community meeting - September 2017 - [meeting documents](#)

Events

- [EMA Information Day on Measuring the Impact of Pharmacovigilance Activities](#) - November 2017
- [Data anonymisation workshop](#) - November 2017
- [A common data model in Europe? – Why? Which? How?](#) - December 2017

Key to symbols used

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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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<http://www.ema.europa.eu>

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