



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

- [Ritonavir Mylan](#) (*ritonavir*)  generic of Norvir
Treatment of HIV infection

New medicines authorised

- [Symtuza](#) (*darunavir / cobicistat / emtricitabine / tenofovir alafenamide*)
Treatment of HIV infection
- [Vosevi](#) (*sofosbuvir / velpatasvir / voxilaprevi*)
Treatment of chronic hepatitis C

New information on authorised medicines




- [Stribild](#) (*elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil*) - new 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

- [Imatinib Teva B.V.](#) (*imatinib*)  generic of Glivec
Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)
- [Ontruzant](#) (*trastuzumab*)  biosimilar of Herceptin
Treatment of breast cancer and gastric (stomach) cancer
- [Tookad](#) (*padeliporfin*)
Treatment of adenocarcinoma of the prostate
- [Zejula](#) (*niraparib*) 
Treatment of ovarian cancer



New medicines authorised

- [Tecentriq](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer

New information on authorised medicines

- [Tasigna](#) (*nilotinib*) - new indication 
Treatment of chronic myelogenous leukaemia (CML)

Withdrawal of applications for new medicines


- [Fulphila](#) (*pegfilgrastim*)  biosimilar of Neulasta
Intended to reduce the duration of neutropenia (low level of white blood cells) in cancer patients
- [Ogivri](#) (*trastuzumab*)  biosimilar of Herceptin
Intended for the treatment of breast cancer and gastric (stomach) cancer

Withdrawal of application for extension of indication


- [Opdivo](#) (*nivolumab*)
Intended for the treatment of liver cancer

Dermatology

Positive CHMP opinions on new medicines

- [Cyltezo](#) (*adalimumab*)  biosimilar of Humira
Treatment of various inflammatory conditions
- [Tremfya](#) (*guselkumab*)
Treatment of plaque psoriasis (scaly patches on skin)

Withdrawal of applications for new medicines


- [Tigecycline Accord](#) (*tigecycline*)  generic of Tygacil
Intended for the treatment of infections of the skin and soft tissue (the tissue below the skin)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances




Diabetes

New medicines authorised


- [Insulin lispro Sanofi](#) (*insulin lispro*)  biosimilar of Humalog
Used to control blood glucose (sugar) levels in adults and children with diabetes who need insulin

Gastro-intestinal system

Positive CHMP opinions on new medicines


- [Cyltezo](#) (*adalimumab*)  biosimilar of Humira
Treatment of various inflammatory conditions
- [Imatinib Teva B.V.](#) (*imatinib*)  generic of Glivec
Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)
- [Ontruzant](#) (*trastuzumab*)  biosimilar of Herceptin
Treatment of breast cancer and gastric (stomach) cancer

Withdrawal of applications for new medicines

- [Ogivri](#) (*trastuzumab*)  biosimilar of Herceptin
Intended for the treatment of breast cancer and gastric (stomach) cancer


Gynaecology & Obstetrics

Positive CHMP opinions on new medicines


- [Zejula](#) (*niraparib*) 
Treatment of ovarian cancer

Haematology

Positive CHMP opinions on new medicines

- [Imatinib Teva B.V.](#) (*imatinib*)  generic of Glivec
Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)

Withdrawal of applications for new medicines

- [Fulphila](#) (*pegfilgrastim*)  biosimilar of Neulasta
Intended to reduce the duration of neutropenia (low level of white blood cells) in cancer patients

Safety communication update


- Review of [Factor VIII medicines](#) - CHMP Opinion (no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of factor VIII medicines)
Used in patients with haemophilia A

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

HIV

Positive CHMP opinions on new medicines

- [Ritonavir Mylan](#) (*ritonavir*)  generic of Norvir
Treatment of HIV infection

New medicines authorised


- [Symtuza](#) (*darunavir / cobicistat / emtricitabine / tenofovir alafenamide*)
Treatment of HIV infection

New information on authorised medicines


- [Stribild](#) (*elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil*) - new indication
Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines


- [Cyltezo](#) (*adalimumab*)  biosimilar of Humira
Treatment of various inflammatory conditions
- [Tremfya](#) (*guselkumab*)
Treatment of plaque psoriasis (scaly patches on skin)

New information on authorised medicines

- [Firazyr](#) (*icatibant*) - new indication 
Treatment of hereditary angioedema (swelling beneath the skin)



Metabolic system

Positive CHMP opinions on new medicines

- [Miglustat Gen.Orph](#) (*miglustat*)  generic of Zavesca
Treatment of type 1 Gaucher disease


Musculoskeletal system

Negative CHMP opinions on extension of indication

- [Raxone](#) (*idebenone*)  
Intended for use in patients with Duchenne muscular dystrophy to slow their gradual loss of breathing ability

Nervous system

New medicines authorised

- [Lacosamide Accord](#) (*lacosamide*)  generic of Vimpat
Treatment of partial-onset seizures


Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Mavenclad](#) (*cladribine*)
Treatment of multiple sclerosis
- [Reagila](#) (*cariprazine*)
Treatment of schizophrenia

Ophthalmology

Positive CHMP opinions on new medicines

- [Cyltezo](#) (*adalimumab*)  biosimilar of Humira
Treatment of various inflammatory conditions

Respiratory system

Positive CHMP opinions on new medicines


- [Elebrato Ellipta](#) / [Trelegy Ellipta](#) (*fluticasone furoate / umeclidinium / vilanterol*)
Treatment of chronic obstructive pulmonary disease (COPD)

New medicines authorised

- [Tecentrig](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer

Rheumatology

Positive CHMP opinions on new medicines

- [Cyltezo](#) (*adalimumab*)  biosimilar of Humira
Treatment of various inflammatory conditions

New information on authorised medicines

- [Benlysta](#) (*belimumab*) - new pharmaceutical form
Treatment of systemic lupus erythematosus (SLE)

Urology

New medicines authorised

- [Tecentrig](#) (*atezolizumab*)
Treatment of urothelial carcinoma (cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer

Other medicines

Positive CHMP opinions on new medicines

- [Nyxoid](#) (*naloxone*)
Treatment of opioid overdose

Key to symbols used

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- [VeraSeal](#) (*human fibrinogen / human thrombin*)
Used as a sealant during surgery
- [Zubsolv](#) (*buprenorphine / naloxone*)
Treatment of opioid dependence

Safety communication update

- Review of [paracetamol-modified release](#) (*paracetamol*) - PRAC recommendation (modified- or prolonged -release paracetamol products should be removed from market)
Relieve pain and fever

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development](#)
Deadline for comments: 31 March 2018
- [Draft guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza \(AI\), bluetongue \(BT\) and foot-and-mouth disease \(FMD\) - Revision 1](#)
Deadline for comments: 31 March 2018

Adopted guidelines

- [Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure - Revision 2](#)
- [Guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome](#)
- [Guideline on core summary of product characteristics and package leaflet for \(⁶⁸Ge/⁶⁸Ga\) generator](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - August 2017](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - Applications for new human medicines: September 2017](#)
- [CAT - agendas, minutes and reports](#)
- [COMP - agendas, minutes and meetings reports](#)

Key to symbols used

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- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC recommendations on safety signals](#)
- PCWP and HCPWP joint meeting - [meeting documents](#) - September 2017
- PCWP and HCPWP joint meeting: info session on antimicrobial resistance - [meeting documents](#) - September 2017

Other publications

- [EMA's first public hearing: giving EU citizens a voice to help reduce the risk of valproate](#)
- [Update on EMA relocation preparedness](#)
- [Exploring opportunities for collaboration between regulators and healthcare payers](#)
- [Reporting side effects of medicines](#)
- [Raising awareness of the perils of antimicrobial resistance](#)
- [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance](#) - infographic
- [Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 11-14 September 2017](#) - adopted
- [Overview of comments received on 'Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products', Revision 1](#) - adopted
- [Overview of comments on 'Concept paper on the revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products''](#) - adopted
- [Overview of comments received on draft Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure, Revision 2](#)
- [Overview of comments received on 'Guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome'](#)

Events





- [2017 European Union Good Clinical Practice Inspectors Working Group workshop](#) - October 2017
- [2017 Forum on bioequivalence inspections](#) - October 2017
- [The new EudraVigilance system and the electronic reporting of individual case safety reports \(ICSRs\) in the ISO/ICH E2B\(R3\) format: hands-on training course](#) - October 2017
- [The new EudraVigilance system and electronic reporting of ICSRs in the ISO/ICH E2B\(R3\) format: hands-on training course, Paris](#) - October 2017
- [EMA / DIA signal management information day](#) - October 2017
- [The new EudraVigilance system and the electronic reporting of ICSRs in the ISO/ICH E2B\(R3\) format: hands-on training course, San Marino](#) - November 2017
- [EMA information day on measuring the impact of pharmacovigilance activities](#) - November 2017

Key to symbols used

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- [EMA / DIA statistics forum: The role of observational data in assessing the benefits and risks of medicines](#) - December 2017
- [The new EudraVigilance system and the electronic reporting of ICSRs in the ISO/ICH E2B\(R3\) format: hands-on training course](#) - December 2017
- [Workshop on the reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development](#) - May 2018

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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