

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



- [Juluca](#) (*dolutegravir / rilpivirine*)
Treatment of HIV infection

New medicines authorised

- [Shingrix](#) (*herpes zoster vaccine (recombinant, adjuvanted)*)
Prevention of shingles and post-herpetic neuralgia (long lasting pain after shingles)



Cancer

Positive CHMP opinions on new medicines

- [Kanjinti](#) (*trastuzumab*)  biosimilar of Herceptin
Treatment of breast and gastric (stomach) cancer
- [Pemetrexed Krka](#) (*pemetrexed*)  generic of Alimta
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Rubraca](#) (*rucaparib*)  
Treatment of ovarian cancer

New information on authorised medicines


- [Cabometyx](#) (*cabozantinib*) - extension to existing indication
Treatment of renal cell carcinoma (kidney cancer)
- [Ivemend](#) (*fosaprepitant*) - extension to existing indication
Prevention of nausea and vomiting associated with chemotherapy

Safety communication update

- Review of [Xofigo](#) (*radium Ra223 dichloride*) - PRAC recommendation - temporary measures while review is ongoing (Xofigo should not be used with Zytiga and prednisone/prednisolone due to increased risk of death and fractures)
Treatment of prostate cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- [Prasugrel Mylan](#) (*prasugrel*)  generic of Efient
Prevention of problems caused by blood clots, such as heart attack

New information on authorised medicines

- [Repatha](#) (*evolocumab*) - new indication
Treatment of atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease)

Negative CHMP opinions on new medicines

- [Dexxience](#) (*betrixaban*)
Intended for the prevention of venous thromboembolism (formation of blood clots in veins)

Supply shortages


- [Arixtra](#) (*fondaparinux sodium*) - shortage resolved
Prevention and treatment of problems caused by blood clots, such as heart attack

Safety communication update

- Review of [omega-3 acid ethyl esters-containing medicinal products](#) (*Omega-3 fatty acid ethyl esters*) - review started (recent data indicate these medicines may not prevent recurrence of heart disease or stroke)
Preventing heart disease or stroke and reducing certain types of blood fats

Dermatology

Positive CHMP opinions on new medicines

- [Zessly](#) (*infliximab*)  biosimilar of Remicade
Treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis (inflammations of the gut), ankylosing spondylitis, psoriatic arthritis and psoriasis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety communication update

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



Diabetes

Communication on prevention of medication errors

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



Gastro-intestinal system

Positive CHMP opinions on new medicines

- [Kanjinti](#) (*trastuzumab*)  biosimilar of Herceptin
Treatment of breast and gastric (stomach) cancer
- [Zessly](#) (*infliximab*)  biosimilar of Remicade
Treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis (inflammations of the gut), ankylosing spondylitis, psoriatic arthritis and psoriasis

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- [Rubraca](#) (*rucaparib*)  
Treatment of ovarian cancer

Haematology

New medicines authorised

- [Hemlibra](#) (*emicizumab*)
Treatment and prevention of bleeding in patients with haemophilia A who have factor VIII inhibitors

Withdrawal of applications for extension of indication

- [Aranesp](#) (*darbepoetin alfa*)
Intended for the treatment of anaemia due to myelodysplastic syndromes

HIV

Positive CHMP opinions on new medicines

- [Juluca](#) (*dolutegravir / rilpivirine*)
Treatment of HIV infection

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances


Hormone system

New medicines authorised

- [Alkindi](#) (*hydrocortisone*)
Treatment of adrenal insufficiency (rare hormonal disorder)

Immune system

Positive CHMP opinions on new medicines

- [Zessly](#) (*infliximab*)  biosimilar of Remicade
Treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis (inflammations of the gut), ankylosing spondylitis, psoriatic arthritis and psoriasis

New medicines authorised

- [Fasenra](#) (*benralizumab*)
Treatment of eosinophilic asthma

Metabolic disorders

New medicines authorised

- [Crysvita](#) (*burosumab*)  
Treatment of X-linked hypophosphataemia (rare bone disorder)

Musculoskeletal system

New medicines authorised

- [Crysvita](#) (*burosumab*)  
Treatment of X-linked hypophosphataemia (rare bone disorder)

Nephrology

New information on authorised medicines

- [Cabometyx](#) (*cabozantinib*) - extension to existing indication
Treatment of renal cell carcinoma (kidney cancer)

Nervous system

Safety communication update

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


Key to symbols used

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- Review of [zinbryta](#) (*daclizumab*) - PRAC recommendation - temporary measures while review is ongoing (immediate suspension and recall of the medicine, following reports of serious inflammatory brain disorders worldwide, including encephalitis and meningoencephalitis)
Treatment of multiple sclerosis

Respiratory system

Positive CHMP opinions on new medicines


- [Pemetrexed Krka](#) (*pemetrexed*)  generic of Alimta
Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New medicines authorised

- [Fasenra](#) (*benralizumab*)
Treatment of eosinophilic asthma

Rheumatology

Positive CHMP opinions on new medicines

- [Zessly](#) (*infliximab*)  biosimilar of Remicade
Treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis (inflammations of the gut), ankylosing spondylitis, psoriatic arthritis and psoriasis

Negative CHMP opinions on new medicines

- [Eladynos](#) (*abaloparatide*)
Intended for the treatment of osteoporosis (a disease that makes bones fragile)

Other medicines

Supply shortages

- [Nulojix](#) (*belatacept*)
To prevent the body from rejecting a transplanted kidney

Safety communication update

- Review of [flupirtine-containing medicinal products](#) (*flupirtine*) CMDh Position (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

Adopted guidelines

- [Core SmPC and package leaflet for sodium iodide \(¹³¹I\) for therapeutic use](#)
- [Good pharmacogenomic practice](#)
- [Overview of comments received on 'Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues' \(Rev. 1\)](#)

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- [Allogeneic mesenchymal stem cells suspended in cell supernatant](#)
- [Autologous dendritic cells, pulsed with allogeneic tumour cell lysate](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - February 2018](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: March 2018](#)
- [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 - Work Plan 2018](#)
- [PRAC recommendations on safety signals](#)
- [Work plan for Good Clinical Practice Inspectors Working Group 2018](#)
- [Work plan for the HMPC Quality Drafting Group \(Q DG\) 2018](#) - updated
- [Work plan for the Working Party on European Union Monographs and List \(MLWP\) 2018](#) - updated
- [Mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs \(replacement, reduction and refinement\) in regulatory testing of medicinal products \(J3RsWG\)](#) - updated
- PCWP and HCPWP joint meeting: 17-18 April 2018 - [agenda](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Other publications

- EMA Management Board March 2018 meeting: [highlights](#) - [meeting documents](#)
- [Multiannual work programme 2018-2020](#)
- [New tracking tool for EMA's relocation to Amsterdam](#)
- [EU recommendations for 2018/2019 seasonal flu vaccine composition](#)
- [Four more EU Member States benefit from EU-US mutual recognition agreement for inspections](#)
- [EC guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'](#)
- [Launch of the new EudraVigilance system: questions and answers from stakeholders](#) - updated
- Second international awareness session for international regulators, academia and non-governmental organisations - March 2018 - [meeting documents](#)

Events

- [PCWP and HCPWP joint meeting](#) - April 2018
- [Haemophilia registries workshop](#) - June 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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