



HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

- [Biktarvy](#) (*bictegravir / emtricitabine / tenofovir alafenamide*)
Treatment of HIV infection

New medicines authorised

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

Public Hearing


- [Quinolone and fluoroquinolone containing medicines](#) (*nalidixic acid, piperidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin*) - hearing to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems
Treatment of bacterial infections

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

Cancer

Positive CHMP opinions on new medicines

- [Carmustine Obvius](#) (*carmustine*)  generic of Carmubris
Treatment of brain tumours, non-Hodgkin's lymphoma and Hodgkin's disease

New information on authorised medicines

- [Perjeta](#) (*pertuzumab*) - extension to existing indication
Treatment of breast cancer
- [Sprycel](#) (*dasatinib*) - extension to existing indication
Treatment of Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) and Ph+ acute lymphoblastic leukaemia (ALL)
- [Tagrisso](#) (*osimertinib*) - extension to existing indication
Treatment of non-small cell lung cancer (NSCLC)
- [Yervoy](#) (*ipilimumab*) - change in indication
Treatment of melanoma (skin cancer)

Safety communication update

- Review of [methotrexate containing medicinal products](#) (*methotrexate*) - review started (risk of dosing errors)
Treatment of various cancers and inflammatory conditions

Dermatology

New information on authorised medicines

- [Cimzia](#) (*certolizumab pegol*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)
- [Yervoy](#) (*ipilimumab*) - change in indication
Treatment of melanoma (skin cancer)

Diabetes

New medicines authorised

- [Steglatro](#) (*ertugliflozin*)
Treatment of type 2 diabetes
- [Steglujan](#) (*ertugliflozin / sitagliptin*)
Treatment of type 2 diabetes
- [Segluromet](#) (*ertugliflozin / metformin hydrochloride*)
Treatment of type 2 diabetes

New information on authorised medicines

- [Xultophy](#) (*insulin degludec / liraglutide*) - change in indication
Treatment of type 2 diabetes mellitus

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Withdrawal of applications for extension of indication

- [Otern](#) (*saxagliptin / dapagliflozin*)
Treatment of type 2 diabetes

Haematology

Positive CHMP opinions on new medicines

- [Carmustine Obvius](#) (*carmustine*)  generic of Carmubris
Treatment of brain tumours, non-Hodgkin's lymphoma and Hodgkin's disease

New information on authorised medicines

- [Sprycel](#) (*dasatinib*) - extension to existing indication
Treatment of Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) and Ph+ acute lymphoblastic leukaemia (ALL)

HIV

Positive CHMP opinions on new medicines

- [Biktarvy](#) (*bictegravir / emtricitabine / tenofovir alafenamide*)
Treatment of HIV infection

Immune system

New information on authorised medicines



- [Cimzia](#) (*certolizumab pegol*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)
- [Xeljanz](#) (*tofacitinib*) - new indication
Treatment of psoriatic arthritis

Safety communication update



- Review of [methotrexate containing medicinal products](#) (*methotrexate*) - review started (risk of dosing errors)
Treatment of various cancers and inflammatory conditions

Metabolic disorders


New medicines authorised

- [Lamzede](#) (*velmanase alfa*)  
Treatment of alpha-mannosidosis (rare inherited enzyme disorder)
- [Lokelma](#) (*sodium zirconium cyclosilicate*)
Treatment of hyperkalaemia (high levels of potassium in the blood)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Withdrawal of applications for new medicines

- [Prohippur](#) (sodium benzoate) 
Intended for the treatment of non-ketotic hyperglycaemia and urea cycle disorders

Musculoskeletal system

Public Hearing

- [Quinolone and fluoroquinolone containing medicines](#) (nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin) - hearing to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems
Treatment of bacterial infections

Nervous system

Negative CHMP opinions on new medicines

- [Alsitek](#) (masitinib) 
Treatment of amyotrophic lateral sclerosis (ALS)

Public Hearing

- [Quinolone and fluoroquinolone containing medicines](#) (nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin) - hearing to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems
Treatment of bacterial infections

Respiratory system

New medicines authorised

- [Riarify](#) (beclometasone / formoterol / glycopyrronium bromide)
Treatment of chronic obstructive pulmonary disease (COPD)

New information on authorised medicines

- [Tagrisso](#) (osimertinib) - extension to existing indication
Treatment of non-small cell lung cancer (NSCLC)

Rheumatology

New information on authorised medicines

- [Prolia](#) (denosumab) - new indication
Treatment of osteoporosis (bone loss)
- [Xeljanz](#) (tofacitinib) - new indication
Treatment of psoriatic arthritis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety communication update


- Review of [methotrexate containing medicinal products](#) (*methotrexate*) - review started (risk of dosing errors)
Treatment of various cancers and inflammatory conditions

Other medicines

Positive CHMP opinions on new medicines

- [Dzuvéo](#) (*sufentanil*)
Treatment of pain

New medicines authorised

- [Alofisel](#) (*darvadstrocel*) 
Treatment of anal fistulas in patients with Crohn's disease (inflammatory condition of the gut)

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Public consultation concerning the European Union template for good manufacturing practice \(GMP\) non-compliance statement](#)
Deadline for comments: 15/05/2018
- [Manufacture of the finished dosage form](#)
Deadline for comments: 22/10/2018
- [Draft guideline on clinical evaluation of vaccines - Revision 1](#)
Deadline for comments: 30/10/2018
- [Draft addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements - First version](#)
Deadline for comments: 30/10/2018

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - March 2018](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: April 2018](#)

Key to symbols used

-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [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](#)
- [Work plan for PCWP and HCPWP 2018-2019](#)

Other publications

- Extraordinary Management Board meeting: [6 February 2018 - Minutes](#) / [28 February 2018 - Minutes](#)
- 99th Management Board meeting: [15 March 2018 - Minutes](#)
- [Civil society representatives wanted for EMA's Management Board and Pharmacovigilance Committee](#)
- [European Immunization Week 2018: Statement of Guido Rasi, Executive Director, EMA](#)
- [Update of EU recommendations for 2018/2019 seasonal flu vaccine composition](#)
- [Updated rules for clinical development of vaccines](#)
- [EMA and the Netherlands agree on Seat Agreement](#)
- [EMA tracking tool: relocation to Amsterdam - Main milestones](#) (updated)
- [Redistribution of UK's portfolio of centrally authorised products](#)
- Public hearing: [13 June 2018](#)
- Patients, consumers, healthcare professionals - [key figures 2017](#) (updated)
- [Eye injuries in people and dogs when using Osumnia ear gel for dogs](#)
- [Ten years promoting high-quality scientific research in paediatric medicines](#)
- [Ethical use of animals in medicine testing](#)
- [2016 and 2017 annual report on independence](#)
- [Criteria for classification of critical medicinal products](#) (updated)
- [Increasing oversight of API manufacturing through international collaboration](#)
- Multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation - March 2018 - [meeting documents](#)

Events

- [HMA/ EMA Joint Big Data Task Force meeting: identifying solutions for big data challenges](#) - May 2018
- [2018 Annual workshop of the European Network of Paediatric Research at the European Medicines Agency \(Enpr-EMA\)](#) - June 2018
- [Paediatric strategy forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients](#) - September 2018

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

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.

Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

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

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If you have a question relating to the content of this Newsletter, please send it via www.ema.europa.eu/contact

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