



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

- [Xofluza](#) (*baloxavir marboxil*)
Treatment and prophylaxis of influenza


New medicines authorised

- [Arikayce liposomal](#) (*amikacin*)
Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC)
- [Obiltoxaximab SFL](#) (*obiltoxaximab*)
Treatment of inhalational anthrax
- [Supemtek](#) (*quadrivalent influenza vaccine (recombinant, prepared in cell culture)*)
Vaccine to prevent influenza

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

Withdrawal of authorised medicines


- [Ribavirin Mylan](#) (INN) 
Treatment of chronic hepatitis C

Safety update


- Direct healthcare professional communication: [Tecfidera \(dimethyl fumarate\): Updated recommendations in the light of cases of progressive multifocal leukoencephalopathy \(PML\) in the setting of mild lymphopenia](#)

Cancer



Positive CHMP opinions on new medicines

- [Onbevzi](#) (*bevacizumab*) biosimilar of Avastin 
Treatment of cancer of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer
- [Phesgo](#) (*pertuzumab/trastuzumab*)
Treatment of breast cancer

Positive CHMP opinions on new medicines-following re-examination

- [Elzonris](#) (*tagraxofusp*) 
Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a type of acute myeloid leukaemia (blood cancer)

New medicines authorised

- [Calquence](#) (*acalabrutinib*) 
Treatment of chronic lymphocytic leukaemia (blood cancer)
- [Nyvepria](#) (*pegfilgrastim*) biosimilar of Neulasta 
Treatment of neutropenia (low level of white blood cells) in cancer patients
- [Phelinun](#) (*melphalan*)
Treatment of blood and bone marrow cancers and preparing patients for blood stem cell transplants

New information on authorised medicines

- [Kyprolis](#) (*carfilzomib*) - extension of indication
Treatment of adult patients with multiple myeloma (blood cancer)


Withdrawal of applications for new medicines

- [Tibsovo](#) (*ivosidenib*)
Treatment of acute myeloid leukaemia, a cancer of white blood cells

Safety update

- Review of [Ifosfamide](#) - under evaluation (Art. 31)
Treatment of different types of cancers, including various solid tumours and blood cancers such as lymphomas (cancer of white blood cells)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Cardiovascular system

New information on authorised medicines

- [Pradaxa](#) (*dabigatran etexilate*) - new indication / extension of indication / new contraindication
Treatment and prevention of blood clots
- [Xarelto](#) (*rivaroxaban*) - new indication and extension of indication
Treatment and prevention of blood clots

Safety update

- Review of [angiotensin-II-receptor antagonists \(sartans\) containing a tetrazole group](#) - CHMP Opinion (EMA aligns recommendations for sartans with those for other medicines)
Treatment of hypertension (high blood pressure)
- Direct healthcare professional communication: [Angiotensin-II-receptor antagonists \(sartans\) containing a tetrazole group](#)


Gynaecology & Obstetrics (pregnancy and female reproductive)

Safety update




- Review of [Ulipristal acetate 5mg medicinal products](#) - CHMP Opinion (Art.31) EMA recommends restricting use
Treatment of uterine fibroids

Haematology (blood conditions)

Positive CHMP opinions on new medicines-following re-examination

- [Elzonris](#) (*tagraxofusp*) 
Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a type of acute myeloid leukaemia (blood cancer)

New medicines authorised

- [Adakveo](#) (*crizanlizumab*)
Prevention of recurrent vaso-occlusive crises in patients with sickle cell disease
- [Calquence](#) (*acalabrutinib*) 
Treatment of chronic lymphocytic leukaemia (blood cancer)
- [Nyvepria](#) (*pegfilgrastim*) biosimilar of Neulasta 
Treatment of neutropenia (low level of white blood cells) in cancer patients
- [Phelinun](#) (*melfalan*)
Treatment of blood and bone marrow cancers and preparing patients for blood stem cell transplants
- [Rivaroxaban Accord](#) (*rivaroxaban*) 
Treatment and prevention of blood clots

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Kyprolis](#) (*carfilzomib*) - extension of indication
Treatment of adult patients with multiple myeloma

Withdrawal of applications for new medicines

- [Roctavian](#) (*Valoctocogene roxaparvovec*)
Intended for the treatment of severe haemophilia A
- [Tibsovo](#) (*ivosidenib*)
Treatment of acute myeloid leukaemia, a cancer of white blood cells

Safety update

- Direct healthcare professional communication: [Ondexxya \(andexanet alfa\): Avoid use of andexanet prior to heparinization](#)

HIV

New information on authorised medicines

- [Tivicay](#) (dolutegravir) - new indication
Treatment of Human Immunodeficiency Virus (HIV-1)

Immune system

Negative CHMP opinions on new medicines

- [Gamifant](#) (*emapalumab*) - re-examination
Intended for the treatment of primary haemophagocytic lymphohistiocytosis (a genetic disease characterised by an overactive immune system)

Musculoskeletal system

Withdrawal of applications for new medicines

- [Puldysa](#) (*idebenone*)
Treatment of Duchenne muscular dystrophy

Nervous system

New information on authorised medicines

- [Xyrem](#) (*sodium oxybate*) - extension of indication
Treatment of narcolepsy

Safety update

- Direct healthcare professional communication: [Gilenya \(fingolimod\): Updated recommendations to minimise the risk of drug-induced liver injury \(DILI\)](#)
- Direct healthcare professional communication: [Tecfidera \(dimethyl fumarate\): Updated recommendations in the light of cases of progressive multifocal leukoencephalopathy \(PML\) in the setting of mild lymphopenia](#)

Key to symbols used

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Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- [Roclanda](#) (*latanoprost / netarsudil*)
Reduction of pressure in the eye in patients with glaucoma or ocular hypertension

Respiratory system

New information on authorised medicines

- [Trimbow](#) (*beclomethasone / formoterol / glycopyrronium bromide*) - new indication
Maintenance treatment of asthma

Vaccines

New medicines authorised

- [MenQuadfi](#) (*meningococcal group A, C, W-135 and Y conjugate vaccine*)
Prevention against invasive meningococcal disease (infection that cause meningitis or blood poisoning)

Other medicines

New medicines authorised

- [Oxlumo](#) (*Ilumasiran*)
Treatment of primary hyperoxaluria type 1 (rare disorder that affects kidneys)

Medicines under additional monitoring

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

Other information

Guidelines

Adopted guidelines

- [Palbociclib hard capsule 75 mg, 100 mg and 125 mg and film-coated tablet 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance - Revision 1](#)
- [Abiraterone tablets 250 mg and 500 mg product-specific bioequivalence guidance - Revision 1](#)

Key to symbols used

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Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - October 2020](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: November 2020](#)
- [COMP - agendas, minutes and meetings reports](#)
- [Call for expressions of interest for Committee for Orphan Medicinal Products \(COMP\) members positions representing patient organisations](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [Call for independent scientific experts to join EMA's Pharmacovigilance Risk Assessment Committee \(PRAC\) - deadline extended](#)
- [PRAC statistics: November/December 2020](#)
- [PRAC recommendations on safety signals](#)

COVID-19

- [EMA starts rolling review of mRNA COVID-19 vaccine by Moderna Biotech Spain, S.L.](#)
- [EMA publishes safety monitoring plan and guidance on risk management planning for COVID-19 vaccines](#)
- [International regulators and WHO join forces to address COVID-19 challenges](#)
- [Pharmacovigilance plan of the EU Regulatory Network for COVID-19 vaccines](#)
- [Consideration on core requirements for RMPs of COVID-19 vaccines](#)
- [Global regulators urge continuation of COVID-19 vaccine trials for longer-term safety and efficacy follow-up](#)
- [Update on remdesivir - EMA will evaluate new data from Solidarity trial](#)
- [HMA/EMA statement on approval of vaccines](#)
- [EMA considerations on COVID-19 vaccine approval](#)

Other publications

- [Message from EMA's outgoing Executive Director, Guido Rasi](#)
- [Emer Cooke takes office as head of EMA](#)
- [Letter from the chairs of EMA's Management Board to Guido Rasi at the end of his term as EMA's Executive Director](#)

Key to symbols used


-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Nitrosamines: EMA aligns recommendations for sartans with those for other medicines](#)
- [Call for independent scientific experts to join EMA's Pharmacovigilance Risk Assessment Committee \(PRAC\)](#)
- [Regulatory information – 1.7% and 1.6% increase of pharmacovigilance fees from 1 November 2020](#)
- [Report - Workshop on benefit-risk of medicines used during pregnancy and breastfeeding](#)
- [EMA marks European Antibiotic Awareness Day](#)
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Events

- [Multi-stakeholder webinar to support implementation of Article 117 of the MDR 2017/745 on drug-device combinations](#) - Virtual event - 27 November 2020
- [EMA roundtable with stakeholders on the 15-year anniversary of the SME Regulation](#) - Virtual meeting - 27 November 2020
- [Fifth industry stakeholder platform on research and development support](#) - Virtual meeting - 16 November 2020
- [EMA organises public meeting on COVID-19 vaccines](#) - Virtual meeting - 11 December 2020

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. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.
- 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 to generate complete data on the medicine.
- 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. These medicines are subject to specific post-authorisation obligations and monitoring.

Medicines assessed under Article 58

Article 58 of Regulation (EC) No 726/2004 allows the [CHMP](#) to give opinions, in co-operation with the World Health Organization, on [medicinal products](#) that are intended exclusively for markets outside of the European Union.

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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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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