

UMAN MEDICINES

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



IN THIS ISSUE	
Antivirals/anti-infectives	1
Cancer	1
Dermatology	2
Diabetes	2
Gynaecology & Obstetrics	3
Haematology	3
Hormone system	3
Immune system	3
Metabolic disorders	4
Nervous system	4
Ophthalmology	4
Respiratory system	4
Other medicines	4
Medicines under additional monitoring	4
Guidelines	5
Scientific committee and working party activities	5
Other information on Covid-	·19 6
Other publications	6
Events	6
Explanation of terms used	7

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

Withdrawal of opinion on medicine for use outside EU

<u>Umbipro</u> (chlorhexidine digluconate) Intended for the prevention of infection of the umbilical cord in newborn babies

Cancer

Positive CHMP opinions on new medicines

- Lunsumio (mosunetuzumab) O Treatment of follicular lymphoma (blood cancer)
- Tabrecta (capmatinib) Treatment of advanced non-small cell lung cancer

Key to symbols used



New medicines authorised

Breyanzi (lisocabtagene maraleucel)

Treatment of large B-cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B (blood cancers)

Kimmtrak (tebentafusp)

Treatment of uveal melanoma (a cancer of the eye)

New information on authorised medicines

Keytruda (pembrolizumab) - new indication Treatment of breast cancer

Retsevmo (selpercatinib) - extension of indication Treatment of non-small cell lung cancer

Tecentria (atezolizumzb) - new indication Treatment of non-small cell lung cancer

Yescarta (axicabtagene ciloleucel) - new indication Treatment of follicular lymphoma (blood cancer)

Safety update

Review of Rubraca (rucaparib camsylate) - review started (recommended not to start new patients on Rubraca)

Treatment of cancer of the ovary, fallopian tubes or peritoneum (abdominal cavity lining)

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

Filsuvez (birch bark extract) Treatment of epidermolysis bullosa (hereditary skin condition that causes blisters on the skin)

New medicines authorised

Kapruvia (difelikefalin)

Treatment of moderate-to-severe pruritus (itching) associated with chronic kidney disease

Diabetes

Positive CHMP opinions on new medicines

Actrapid (insulin human) / Insulatard (insulin human) - medicine for use outside EU Treatment of diabetes mellitus

New information on authorised medicines

Bydureon (exenatide) - change of indication Treatment of diabetes mellitus





Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines

Yselty (linzagolix choline) - revised opinion Treatment of symptoms of uterine fibroids

New information on authorised medicines

NovoSeven (eptacog alfa) - new indication Treatment of severe bleeding after childbirth

Haematology (blood conditions)

Positive CHMP opinions on new medicines

Lunsumio (mosunetuzumab) Treatment of follicular lymphoma (blood cancer)

New medicines authorised

- Breyanzi (lisocabtagene maraleucel) Treatment of large B-cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B (blood cancers)
- Stimufend (pegfilgrastim) ** Treatment of neutropenia (low levels of neutrophils, a type of white blood cell)

Hormone system

New information on authorised medicines

Elonva (corifollitropin alfa) - new indication Treatment of hypogonadotropic hypogonadism in males (reduced testosterone production)

Supply shortages

Natpar (parathyroid hormone) Treatment of hypoparathyroidism (under-active parathyroid glands)

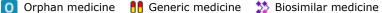
Immune system

Withdrawal of applications for new medicines

Neffy (adrenaline) Intended for the emergency treatment of allergic reactions, including anaphylaxis (severe allergic reaction)







Metabolic disorders

Withdrawal of applications for new medicines

Miplyffa (arimoclomol) Intended for the treatment of Niemann-Pick disease type C (a disease in which fats accumulate in cells)

Nervous system

New information on authorised medicines

Tecfidera (dimethyl fumarate) - extension of indication following re-examination Treatment of multiple sclerosis

Withdrawal of applications for new medicines

Aduhelm (aducanumab) Intended for the treatment of Alzheimer's disease

Ophthalmology (eye conditions)

New medicines authorised

Kimmtrak (tebentafusp) Treatment of uveal melanoma (a cancer of the eye)

Respiratory system

Positive CHMP opinions on new medicines

- Pirfenidone AET (pirfenidone) Treatment of idiopathic pulmonary fibrosis (a condition in which the lungs are scarred and damaged)
- Tabrecta (capmatinib) Treatment of advanced non-small cell lung cancer

Other medicines

Withdrawal of authorised medicines

Palonosetron Hospira (palonosetron hydrochloride) Prevention of nausea and vomiting associated with cancer chemotherapy

Medicines under additional monitoring

Updated list of medicines under additional monitoring



Other information

Guidelines

Guidelines open for consultation

- ICH quideline O14 on analytical procedure development Step 2b 31 July 2022
- ICH Q2(R2) Validation of analytical procedures 31 July 2022
- Draft paracetamol oral use immediate release formulations product-specific bioequivalence quidance -Revision 1 - 31 July 2022
- Draft ibuprofen oral use immediate release formulations 200 800 mg product-specific bioequivalence guidance - Revision 1 - 31 July 2022
- Draft ICH quideline E11A on pediatric extrapolation Step 2b Deadline for comments: 6 August 2022

Adopted guidelines

- Draft tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance - Revision 2
- Points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical
- ICH E8 General considerations for clinical studies

Scientific committee and working party activities

- Medicinal products for human use: monthly figures March 2022
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- CHMP applications for new human medicines: April 2022
- 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
- PCWP and HCPWP Working Parties joint meeting 2-3 March 2022-meeting summary

Other information on COVID-19

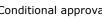
- ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines
- COVID-19 vaccines Safety update: 13 April 2022
- EMA regular press briefing on COVID-19 5 May 2022

Other publications

- European Immunization Week 2022: Statement by Executive Director Emer Cooke Why vaccines contribute to a "Long Life for All"
- Minutes of the 114th meeting of the Management Board: 15-16 December 2021
- Annual report on the use of the special contribution for orphan medicinal products 2021
- PRIME: Analysis of the first 5 years' experience
- EMA and the EUnetHTA 21 consortium set priorities for their collaboration
- EMA / eligible healthcare professional organisations policy officers' group (HCP POG) pilot: one-year review
- PRAC strategy on measuring the impact of pharmacovigilance activities

Events

- Multistakeholder workshop on EMA's extended mandate 1 April 2022 meeting documents
- Clinical Trials Information System (CTIS) bitesize talk: Requests for information 28 April 2022
- Sixth Nitrosamine Implementation Oversight Group (NIOG) meeting 26 April 2022
- Third Nitrosamine Implementation Oversight Group (NIOG) meeting with pharmaceutical industry 4 May 2022



Explanation of terms used

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.

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')

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)

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.

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 <u>CHMP</u> to give opinions, in co-operation with the World Health Organization, on <u>medicinal products</u> 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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