158 Issue 158
May 2022

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union

IN THIS ISSUE

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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

You can find details on how to cancel / unsubscribe to an RSS feed on the RSS reader tool that you are using, for example Unsubscribe from an RSS Feed for users of Microsoft Outlook.

For further information on the processing of your personal data, please find EMA's Privacy statement regarding the sending of electronic newsletters click here.

Information on medicines

Antivirals/anti-infectives

Withdrawal of opinion on medicine for use outside EU

- Umbipro (*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 C
  Treatment of follicular lymphoma (blood cancer)
- Tabrecta (*capmatinib*)
  Treatment of advanced non-small cell lung cancer

Key to symbols used

O Orphan medicine | Generic medicine | Biosimilar medicine | C Conditional approval | E Exceptional circumstances

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*) O
  Treatment of uveal melanoma (a cancer of the eye)

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Treatment of breast cancer
- Retsevmo (*selpercatinib*) C - extension of indication
  Treatment of non-small cell lung cancer
- Tecentriq (*atezolizumzb*) - new indication
  Treatment of non-small cell lung cancer
- Yescarta (*axicabtagene ciloleucel*) O - 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*) O
  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 guideline Q14 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 guidance - 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 guideline 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 trials
- 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 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.

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

In particular, you may be interested in these links:

About us

Patients and carers

Healthcare professionals

European public assessment reports

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

European Medicines Agency

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Website www.ema.europa.eu **Telephone** +31 (0)88 871 6000

An agency of the European Union