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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

COVID-19 vaccines and treatments

New medicines authorised

- Nuvaxovid (*COVID-19 Vaccine (recombinant, adjuvanted)*) C
  Prevention of coronavirus disease 2019 (COVID-19)

New information on authorised medicines

- Comirnaty (*Tozinameran/COVID-19 mRNA Vaccine (nucleoside modified)*) C - extension of indication
  Prevention of coronavirus disease 2019 (COVID-19), booster extended to individuals from 12 years age
- Spikevax (previously COVID-19 Vaccine Moderna) (*COVID-19 mRNA Vaccine (nucleoside modified)*) C - extension of indication
  Prevention of coronavirus disease 2019 (COVID-19) extended to individuals 6 years of age and older

Key to symbols used

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

Safety update

- COVID-19 vaccines safety update

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- PreHevbri (*Hepatitis B vaccine (recombinant, adsorbed)*)
  Prevention of hepatitis B virus infection

Cancer

Positive CHMP opinions on new medicines

- Kimmtrak (*tebentafusp*)
  Treatment of uveal melanoma (a cancer of the eye)
- Orgovyx (*relugolix*)
  Treatment of prostate cancer
- Padcev (*enfortumab vedotin*)
  Treatment of urothelial cancer (cancer of the bladder and urinary tract)

New medicines authorised

- Rybrevant (*amivantamab*)
  Treatment of advanced non-small cell lung cancer

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of several types of cancers
- Verzenios (*abemaciclib*) - extension of indication
  Treatment of breast cancer
- Yervoy (ipilimumab) - new indication
  Treatment of several types of cancers

Cardiovascular system

New medicines authorised

- Rivaroxaban Mylan (*rivaroxaban*) generic of Xarelto
  Treatment that prevents blood clotting (anti-coagulant)

Direct Healthcare Professional Communication (DHPC)

- Xagrid (anagrelide hydrochloride): Risk of thrombosis (blood clots) including cerebral infarction upon abrupt treatment discontinuation

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

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

Diabetes

Positive CHMP opinions on new medicines

- Inpremzia (*insulin human* (*rDNA*))
  Treatment of diabetes mellitus
- Sitagliptin Accord (*sitagliptin*) generic of Januvia
  Treatment of diabetes mellitus
- Truvelog Mix 30 (*insulin aspart*)
  Treatment of diabetes mellitus

Haematology (blood conditions)

New medicines authorised

- Evrenzo (*roxadustat*)
  Treatment of the symptoms of anaemia (low red blood cell counts) caused by chronic kidney failure
- Rivaroxaban Mylan (*rivaroxaban*) generic of Xarelto
  Treatment that prevents blood clotting (anti-coagulant)

HIV

New information on authorised medicines

- Delstrigo (*doravirine / lamivudine / tenofovir disoproxil*) - extension of indication
  Treatment of HIV infection
- Pifeltro (*doravirine*) - extension of indication
  Treatment of HIV infection

Hormone system

New medicines authorised

- Lonapegsomatropin Ascendis Pharma (*lonapegsomatropin*)
  Treatment of growth hormone deficiency

Key to symbols used

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

Immune system

Safety update

- Review of Janus Kinase inhibitors (JAKi) - review started (Art.20)
  Treatment of several chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, ulcerative colitis and atopic dermatitis)

Metabolic disorders

Positive CHMP opinions on new medicines

- Amversio (*betaine anhydrous*) generic of Cystadane
  Treatment of homocystinuria, a rare genetic metabolic disorder

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

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

Safety update

- Review of Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome - review started (*art.31*)
  Treatment of kidney problems in patients with advanced liver disease, as well as bleeding from enlarged veins in the passage between the mouth and the stomach (the oesophagus) and certain forms of bleeding associated with surgery

Nervous system

Positive CHMP opinions on new medicines

- Dimethyl fumarate Polpharma (*dimethyl fumarate*) generic of Tecfidera
  Treatment of relapsing-remitting multiple sclerosis
- Dimethyl fumarate Neuraxpharm (*dimethyl fumarate*) generic of Tecfidera
  Treatment of relapsing-remitting multiple sclerosis
- Dimethyl fumarate Mylan (*dimethyl fumarate*) generic of Tecfidera
  Treatment of relapsing-remitting multiple sclerosis
- Quviviq (*daridorexant*)
  Treatment of insomnia
- Vydura (*rimegepant*)
  Treatment and prevention of migraine

Re-examination of initial application following Negative CHMP opinions on new medicines

- Aduhelm (*aducanumab*)
  Treatment of Alzheimer's disease

Direct Healthcare Professional Communication (DHPC)

- Mavenclad (cladribine) – risk of serious liver injury and new recommendations about liver function monitoring

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- Beovu (*brolucizumab*) - new indication
  Treatment of visual impairment in diabetic macular oedema (eye condition in people with diabetes)

Negative CHMP opinions on new medicines

- Ipique (*bevacizumab*)
  Intended for the treatment of neovascular (wet) age-related macular degeneration (a disease affecting the retina at the back of the eye)

Rheumatology (immune and inflammatory conditions)

Safety update

- Review of Janus Kinase inhibitors (JAKi) - review started (Art.20)
  Treatment of several chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, ulcerative colitis and atopic dermatitis)

Vaccines

Positive CHMP opinions on new medicines

- PreHevbri (*Hepatitis B vaccine (recombinant, adsorbed)*)
  Prevention of hepatitis B virus infection

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials, with particular emphasis on the handling of expiry dates

Scientific committee and working party activities

- Medicinal products for human use: monthly figures—December 2021
- Medicinal products for human use: monthly figures - January 2022
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 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 statistics: February 2022
- PRAC recommendations on safety signals
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 2 and 3 March 2022 - Agenda

COVID-19 publications

- EMA recommends authorisation of booster doses of Comirnaty from 12 years of age
- EMA evaluating data on booster dose of COVID-19 vaccine Comirnaty in adolescents

Other publications

- Human medicines: highlights of 2021
- Big Data Highlights - Issue 1
- Hydroxyethyl-starch solutions for infusion recommended for suspension from the market

- PRAC recommends suspending hydroxyethyl-starch solutions for infusion from the market
- Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU
- Public consultation on reflection paper on prophylactic use of antimicrobials in animals
- Highlight report from the seventh meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines
- European medicines regulatory network adopts EU common standard for electronic product information

Events

- DARWIN EU: multi-stakeholder information webinar - Virtual meeting - 24 February 2022
- System demo: digital application dataset integration (DADI) and Product Management Service (PMS) - Virtual meeting - 15 March 2022
- Repurposing of medicines pilot project webinar - Virtual meeting - 17 February 2022
- Introducing DADI: webinar on the digital application dataset integration (DADI) network project to replace electronic application forms - Virtual meeting - 18 January 2022
- Nitrosamine Implementation Oversight Group (NIOG) meeting - Virtual meeting - 7 March 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.

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