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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

Safety update

- Safety of COVID-19 vaccines
- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 8 September 2021
- COVID-19 vaccine safety update for Spikevax (previously COVID-19 Vaccine Moderna): 8 September 2021
- COVID-19 vaccine safety update for Comirnaty: 8 September 2021

Key to symbols used

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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Artesunate Amivas (*artesunate*)
  Treatment of severe malaria

New information on authorised medicines

- Noxafil (*posaconazole*) - change of indication
  Treatment of fungal infections
- Zepatier (*elbasvir / grazoprevir*) - extension of indication
  Treatment of chronic hepatitis C

Cancer

Positive CHMP opinions on new medicines

- Brukinsa (*zanubrutinib*) O
  Treatment of Waldenström's macroglobulinaemia (a type of blood cancer)
- Gavreto (*pralsetinib*)
  Treatment of patients with non-small cell lung cancer
- Qinlock (*ripretinib*)
  Treatment of advanced gastrointestinal stromal tumour (a cancer of the gut)

New information on authorised medicines

- Firmagon (*degarelix*) - extension of indication
  Treatment of prostatic cancer
- Keytruda (*pembrolizumab*) - new indication
  Treatment of locally recurrent unresectable or metastatic triple negative breast cancer
- Opdivo (*nivolumab*) - new indication
  Treatment of different types of cancers

Withdrawal of applications for new medicines

- Oportuzumab monatox DLRC Pharma Services (*oportuzumab monatox*)
  Intended for treatment and prevention of recurrence cancer of the bladder

Cardiovascular system

Positive CHMP opinions on new medicines

- Rivaroxaban Mylan (*rivaroxaban*) generic of Xarelto
  Treatment and prevention of blood clots

Withdrawal of authorised medicines

- Telmisartan Teva (*telmisartan*) generic of Micardis
  Treatment of hypertension (high blood pressure)

Diabetes

New information on authorised medicines

- Segluromet (*ertugliflozin / metformin hydrochloride*) - extension of indication
  Treatment of diabetes mellitus type 2
- Steglatro (*ertugliflozin*)- extension of indication
  Treatment of diabetes mellitus type 2

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Hukyndra/Libmyris (adalimumab)
  Treatment of certain inflammatory and autoimmune disorders
- Jyseleca (*filgotinib*)
  Treatment of rheumatoid arthritis and ulcerative colitis (an inflammatory disorder of the intestines)
- Qinlock (*ripretinib*)
  Treatment of advanced gastrointestinal stromal tumour (a cancer of the gut)

Withdrawal of authorised medicines

- Livmarli (*maralixibat*)
  Treatment of progressive familial intrahepatic cholestasis type 2 (inherited liver disorder)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Brukinsa (*zanubrutinib*)
  Treatment of Waldenström's macroglobulinaemia (a type of blood cancer)

Immune system

Positive CHMP opinions on new medicines

- Hukyndra/Libmyris (adalimumab)
  Treatment of certain inflammatory and autoimmune disorders
- Jyseleca (*filgotinib*)
  Treatment of rheumatoid arthritis and ulcerative colitis (an inflammatory disorder of the intestines)

New medicines authorised

- Icatibant Accord (*icatibant*) generic of Firazyr
  Treatment of hereditary angioedema (swelling beneath the skin)

New information on authorised medicines

- Nucala (*mepolizumab*) - extension of indication
  Treatment of asthma; eosinophilic granulomatosis with polyangiitis (a rare autoimmune disorder); hypereosinophilic syndrome (HES) (a rare blood disorder); and chronic rhinosinusitis with nasal polyps (inflammation and growths in the nose or the sinuses)

Supply shortages

- RoActemra (*tocilizumab*)
  Treatment of arthritis or giant cell arteritis

Direct Healthcare Professional Communication (DHPC)

RoActemra (tocilizumab): Temporary supply shortage for 162 mg solution for subcutaneous injection and RoActemra 20 mg/mL concentrate for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patient

Musculoskeletal system

Positive CHMP opinions on new medicines

- Sugammadex Mylan (*sugammadex*) generic of Bridion
  Reversal of the effects of muscle relaxants used during operations

Nervous system

Positive CHMP opinions on new medicines

- Vumerity (*diroximel fumarate*)
  Treatment of patients with relapsing remitting multiple sclerosis

New information on authorised medicines

- Paliperidone Janssen-Cilag International (*paliperidone*) - change of indication
  Treatment of schizophrenia

Respiratory system

New information on authorised medicines

- Adempas (*riociguat*) O - new contraindication
  Treatment of pulmonary hypertension

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Hukyndra/Libmyris (adalimumab)
  Treatment of certain inflammatory and autoimmune disorders
- Jyseleca (*filgotinib*)
  Treatment of rheumatoid arthritis and ulcerative colitis

Withdrawal of applications for new medicines

- Teriparatide Cinnagen (*teriparatide*)
  Intended for treatment of osteoporosis

Negative CHMP opinions on new medicines

- Raylumis (*tanezumab*)
  Intended to treat moderate to severe chronic pain of the hip or knee in adults with osteoarthritis

Supply shortages

- RoActemra (*tocilizumab*)
  Treatment of arthritis or giant cell arteritis

Direct Healthcare Professional Communication (DHPC)

RoActemra (tocilizumab): Temporary supply shortage for 162 mg solution for subcutaneous injection and RoActemra 20 mg/mL concentrate for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patient

Urology (urinary tract conditions)

New information on authorised medicines

- Firmagon (*degarelix*) - extension of indication
  Treatment of prostatic cancer

Withdrawal of authorised medicines

- Sildenafil FGK (*sildenafil*)
  Treatment of adult men with erectile dysfunction

Other medicines

Direct Healthcare Professional Communication (DHPC)

- CHAMPIX (varenicline) - lots to be recalled due to presence of impurity N-nitroso-varenicline above the acceptable intake limit

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Acenocoumarol, tablet, 1 mg and 4 mg product-specific bioequivalence guidance - First version

- Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance - First version
- 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
- Palbociclib hard capsule 75 mg, 100 mg and 125 mg and film-coated tablet 75 mg, 100 mg and 125 mg productspecific bioequivalence guidance - Revision 1

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - August 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - Applications for new human medicines: September 2021
- 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: September 2021
- PRAC recommendations on safety signals
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - virtual meeting - 2 March to 3 March 2022
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - virtual meeting - 1 June to 2 June 2022
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - virtual meeting - 15 November 2022
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - virtual meeting - 15 November 2022

COVID-19 publications

- ECDC and EMA highlight considerations for additional and booster doses of COVID-19 vaccines
- Increase in manufacturing capacity for COVID-19 vaccine from BioNTech/Pfizer
- EMA evaluating data on booster dose of COVID-19 vaccine Spikevax

Other publications

- Minutes of the 112th meeting of the Management Board: 17 June 2021
- DARWIN EU Advisory Board: Membership

- New legal basis and authorisation procedure values available in the Article 57 database
- Summary report - Technical workshop on real-world metadata for regulatory purposes
- Highlight report from the sixth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines
- EMA implements new measures to minimise animal testing during medicines development
- Transatlantic Taskforce continues international fight against antimicrobial resistance
- Clinical Trial Information System (CTIS) - Member state user personas
- Clinical Trial Information System (CTIS) - Sponsor user personas
- European Medicines Agency's Privacy Statement for the clinical data publication website
- Call for expressions of interest for civil society representatives to participate in work of Committee for Advanced Therapies
- Call for expressions of interest for civil society representatives to participate in work of EMA
- Pilot programme: European Medicines Agency-Food and Drug Administration parallel scientific advice for hybrid/complex generic products - General principles

Events

- EMA regular press briefing on COVID-19 - virtual meeting - 23 September 2021
- EMA regular press briefing on COVID-19 - Virtual meeting - 09 September 2021
- DARWIN EU Advisory Board meeting - virtual meeting - 28 June 2021
- Clinical Trials Information System (CTIS) - virtual information day - 26 October 2021
- Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the Clinical Trials Information System (CTIS) - virtual meeting - 29 November 2021
- Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities: Industry webinar - virtual meeting - 21 October 2021

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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http://www.ema.europa.eu

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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

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