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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.

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Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Dovato (*dolutegravir / lamivudine*)
  Treatment of HIV

Cancer

Positive CHMP opinions on new medicines

- Arsenic trioxide Accord (*arsenic trioxide*) generic of Trisenox
  Treatment of acute promyelocytic leukaemia (blood cancer)
- Bortezomib Fresenius Kabi (*bortezomib*) generic of Velcade
  Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- Ivozall (*clofarabine*) generic of Evoltra
  Treatment of acute lymphoblastic leukaemia (blood cancer)

Key to symbols used

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

- Xospata (*gilteritinib*)
  Treatment of acute myeloid leukaemia (AML) with a FLT3 mutation (blood cancer)

New information on authorised medicines

- Bavencio (*avelumab*) O C - new indication
  Treatment of metastatic Merkel cell carcinoma (skin cancer)
- Docetaxel Zentiva (*docetaxel*) - extension to an existing indication
  Treatment of metastatic hormone-sensitive prostate cancer
- Taxotere (*docetaxel*) - extension to an existing indication
  Treatment of metastatic hormone-sensitive prostate cancer

Safety update

- Review of Picato (*ingenol mebutate*) - review started (data on skin cancer to be evaluated)
  Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)

Dermatology

New information on authorised medicines

- Bavencio (*avelumab*) O C - new indication
  Treatment of metastatic Merkel cell carcinoma (skin cancer)

Safety update

- Review of Picato (*ingenol mebutate*) - review started (data on skin cancer to be evaluated)
  Treatment of actinic keratosis (skin condition caused by too much sunlight exposure)

Diabetes

Positive CHMP opinions on new medicines

- Qtrilmet (*metformin hydrochloride / saxagliptin / dapagliflozin*)
  Treatment of diabetes mellitus

New information on authorised medicines

- Trulicity (*dulaglutide*) - change to the existing indication
  Treatment of diabetes mellitus

Gastro-intestinal system

Safety update

- Review of ranitidine medicines - review started (tests showed that some products contained an impurity called N-nitrosodimethylamine (NDMA))
  Used to treat and prevent conditions caused by excess acid in the stomach such as heartburn and stomach ulcers

Haematology

Positive CHMP opinions on new medicines

- Arsenic trioxide Accord (*arsenic trioxide*) generic of Trisenox
  Treatment of acute promyelocytic leukaemia (blood cancer)
- Bortezomib Fresenius Kabi (*bortezomib*) generic of Velcade
  Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)
- Ivozall (*clofarabine*) generic of Evoltra
  Treatment of acute lymphoblastic leukaemia (blood cancer)

HIV

New medicines authorised

- Dovato (*dolutegravir / lamivudine*)
  Treatment of HIV

Immune system

New information on authorised medicines

- Dupixent (*dupilumab*) - new indication
  Treatment of chronic rhinosinusitis with nasal polyposis (inflammation in the nose and sinuses)
- Remsima (*infliximab*) biosimilar of Remicade - new route of administration, strength and pharmaceutical form
  Treatment of rheumatoid arthritis

Nervous system

New medicines authorised

- Inbrija (*levodopa*)
  Treatment of Parkinson's disease
- Lacosamide UCB (*lacosamide*)
  Treatment of epilepsy

Ophthalmology

Positive CHMP opinions on new medicines

- Rhokiinsa (*netarsudil*)
  Treatment of glaucoma or ocular hypertension (increased pressure in the eye)

New information on authorised medicines

- Lucentis (*ranibizumab*) - extension to the existing indication
  Treatment of proliferative diabetic retinopathy (diabetes complication that affects eyes)

Respiratory system

New medicines authorised

- Temybric Ellipta (*fluticasone furoate / umeclidinium / vilanterol*)
  Treatment of chronic obstructive pulmonary disease (condition causing difficulty in breathing)

Rheumatology

New information on authorised medicines

- Benlysta (*belimumab*) - extension to the existing indication
  Treatment of autoantibody- positive systemic lupus erythematosus (SLE) (condition causing inflammation and organ damage)
- Remsima (*infliximab*) biosimilar of Remicade - new route of administration, strength and pharmaceutical form
  Treatment of rheumatoid arthritis

Other medicines

Positive CHMP opinions on new medicines

- Senstend (*lidocaine / prilocaine*)
  Treatment of premature ejaculation

Other information

- Review of presence of nitrosamines in human medicines - outcome of Art 5 (3)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - August 2019
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: August 2019
- COMP - agendas, minutes and meetings reports

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC statistics: September 2019
- PRAC recommendations on safety signals
- PCWP meeting: 24 September 2019 - Agenda
- HCPWP meeting: 24 September 2019 - Agenda
- PCWP and HCPWP joint meeting: 25 September 2019 - Agenda

Other publications

- Preparedness of medicines' clinical trials in paediatrics: Recommendations by the Enpr-EMA working group on trial preparedness
- Working parties for healthcare professionals and for patients and consumers elect new co-chairs
- EMA advises companies on steps to take to avoid nitrosamines in human medicines

Events

- Workshop on the use of registries for tumour histology-independent cancer therapies - 29 November 2019 - Agenda

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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