121 Issue 121
April 2019

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

Cancer

New medicines authorised

- Erleada (*apalutamide*)
  Treatment of prostate cancer

New information on authorised medicines

- Imnovid (previously Pomalidomide Celgene) (*pomalidomide*) O - extension of indication
  Treatment of multiple myeloma (in patients who have received at least one prior treatment regimen including lenalidomide)
- Mozobil (*plerixafor*) O - extension of indication
  Used to collect blood stem cells in patients with cancer
- Revlimid (*lenalidomide*) O - change of indication
  Treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma (conditions affecting blood cells and bone marrow)

Key to symbols used

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

Dermatology

Safety update

- Review of fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products - review started (to examine existing screening methods and their value in identifying patients at increased risk of severe side effects)
  Treatment of various skin conditions and fungal infections

Product update

- Review of basiron AC and associated names (*benzoyl peroxide*) - CHMP Opinion (change in formulation cannot be approved in all concerned Member States)
  Treatment of acne

Gastro-intestinal system

New medicines authorised

- Rizmoic (*naldemedine*)
  Treatment of opioid-induced constipation

Haematology

Positive CHMP opinions on new medicines

- Zynteglo (*autologous CD34+ cells encoding βA-T87Q-globin gene*) O
  Treatment of beta-thalassaemia (inherited blood condition)

New medicines authorised

- Lusutrombopag Shionogi (*lusutrombopag*)
  Treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease undergoing surgery

New information on authorised medicines

- Mozobil (*plerixafor*) O - extension of indication
  Used to collect blood stem cells in patients with cancer
- Revlimid (*lenalidomide*) O - change of indication
  Treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma (conditions affecting blood cells and bone marrow)

Immune system

Supply shortages

- Nulojix (*belatacept*)
  Used to prevent kidney transplant rejection

Safety update

- Xeljanz *(tofacitinib)* - Increased risk of blood clots with higher doses
  Treatment of rheumatoid and psoriatic arthritis

Metabolic disorders

New medicines authorised

- Febuxostat Krka (*febuxostat*) generic of Adenuric
  Treatment of hyperuricaemia (high blood levels of uric acid)

Rheumatology

Safety update

- Xeljanz *(tofacitinib)* - Increased risk of blood clots with higher doses
  Treatment of rheumatoid and psoriatic arthritis

Other medicines

New medicines authorised

- Lusutrombopag Shionogi (*lusutrombopag*)
  Treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease undergoing surgery

Product update

- Review of septanest and associated names (*lenalidomide*) - CHMP Opinion (summary of product characteristics should be harmonised)
  Local anaesthetic (to prevent pain and discomfort during medical procedures)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance
  Deadline for comments: 30 June 2019

Adopted guidelines

- Guideline on the investigation of subgroups in confirmatory clinical trials
- Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - February 2019
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 2019
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PDCO - work plan 2019
- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals
- PRAC - work plan 2019
- Mandate, objectives and rules of procedure for the joint CHMP/CVMP Quality Working Party

Other publications

- EMA Management Board meeting: 21 March 2019 - meeting documents
- Management Board re-elects Christa Wirthumer-Hoche as chair
- EMA now operating from Amsterdam
- Questions & answers: EU actions to prevent medicine shortages due to Brexit
- From laboratory to patient: the journey of a centrally authorised medicine
- EMA - About us - updated
- 20 years of sampling and testing programme for medicines authorised for the EU
- New EudraVigilance system improves reporting of side effects and detection of safety signals

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

In particular, you may be interested in these links:

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

European Medicines Agency

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