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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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Xerava (*eravacycline*)
  Treatment of complicated infections in adults

New information on authorised medicines

- Viekirax (*ombitasvir / paritaprevir / ritonavir*) - change to existing contraindication
  Contraindicated in patients with moderate hepatic impairment

Withdrawal of authorised medicines

- Victrelis (*boceprevir*)
  Treatment of hepatitis C

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Braftovi (*encorafenib*) and Mektovi (*binimetinib*)
  Combination treatment of metastatic melanoma (skin cancer)
- Gefitinib Mylan (*gefitinib*) generic of Iressa
  Treatment of non-small cell lung cancer
- Imfinzi (*durvalumab*)
  Treatment of non-small cell lung cancer
- Lenalidomide Accord (*lenalidomide*) generic of Revlimid
  Treatment of multiple myeloma (cancer of the bone marrow)
- Pelgraz (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients
- Udenyca (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients
- Verzenios (*abemaciclib*)
  Treatment of metastatic breast cancer

New information on authorised medicines

- Blincyto (*blinatumomab*) - new indication
  Treatment of acute lymphoblastic leukaemia (blood cancer) in children older than 1 year of age
- Darzalex (*daratumumab*) - new indication
  Treatment of adult patients with newly diagnosed multiple myeloma (cancer of the bone marrow)
- Keytruda (*pembrolizumab*) - new indications
  Treatment of non-small cell lung cancer and head and neck squamous cell carcinoma
- Mekinist (*trametinib*) - new indication
  Treatment of melanoma (skin cancer)
- Tafinlar (*dabrafenib*) - new indication
  Treatment of melanoma (skin cancer)

Withdrawal of applications for new medicines

- Raligize (*axalimogene filolisbac*)
  Intended for treatment of cancer of the cervix (the neck of the womb)

Withdrawal of applications for extension of indication

- Opdivo (*nivolumab*)
  Intended for treatment of stomach cancer
- Sutent (*sunitinib*)
  Intended for prevention of kidney cancer returning after surgery

Negative CHMP opinions on extension of indication

- Blincyto (*blinatumomab*)
  Intended for patients with residual disease after treatment for acute lymphoblastic leukaemia (ALL)

- Opdivo (*nivolumab*) and Yervoy (*ipilimumab*)
  Intended for combination treatment of renal cell carcinoma (kidney cancer)

Safety communication update

- Review of Xofigo (*radium Ra223 dichloride*) - CHMP opinion (Medicine should only be used after two previous treatments or when other treatments cannot be taken)
  Treatment of prostate cancer

Cardiovascular system

New information on authorised medicines

- Xarelto (*rivaroxaban*) - new indication
  Prevention of problems caused by blood clots, such as heart attack

Safety communication update

- Review of Omega-3 acid ethyl esters-containing medicinal products - review started (review of use in patients who have had a heart attack)
  Prevention of heart disease or stroke after a heart attack
- Valsartan containing medicinal products - review started (review of all medicines that contain valsartan supplied by Zhejiang Huahai Pharmaceuticals)
  Treatment of high blood pressure, recent heart attack and heart failure

Dermatology

Positive CHMP opinions on new medicines

- Braftovi (*encorafenib*) and Mektovi (*binimetinib*)
  Combination treatment of metastatic melanoma (skin cancer)
- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders
- Ilumetri (*tildrakizumab*)
  Treatment of moderate to severe plaque psoriasis

New information on authorised medicines

- Mekinist (*trametinib*) - new indication
  Treatment of melanoma (skin cancer)
- Tafinlar (*dabrafenib*) - new indication
  Treatment of melanoma (skin cancer)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Withdrawal of applications for extension of indication

- Opdivo (*nivolumab*)
  Intended for treatment of stomach cancer

Gynaecology & Obstetrics

Withdrawal of applications for new medicines

- Raligize (*axalimogene filolisbac*)
  Intended for treatment of cancer of the cervix (the neck of the womb)

Haematology

Positive CHMP opinions on new medicines

- Deferiprone Lipomed (*deferiprone*) generic of Ferriprox
  Treatment of iron overload in patients with thalassaemia major
- Pelgraz (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients
- Udenyca (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients

New information on authorised medicines

- Abseamed (*epoetin alfa*) - new indication biosimilar of Eprex/Erypo
  Treatment of anaemia
- Binocrit (*epoetin alfa*) - new indication biosimilar of Eprex/Erypo
  Treatment of anaemia
- Blincyto (*blinatumomab*) - new indication
  Treatment of acute lymphoblastic leukaemia (blood cancer) in children older than 1 year of age
- Epoetin Alfa Hexal (*epoetin alfa*) - new indication biosimilar of Eprex/Erypo
  Treatment of anaemia in adults
- Xarelto (*rivaroxaban*) - new indication
  Prevention of problems caused by blood clots, such as heart attack

Negative CHMP opinions on new medicines

- Dexxience (*betrixaban maleate*)
  Intended for prevention of venous thromboembolism (blood clots in a vein)

Negative CHMP opinions on extension of indication

- Blincyto (*blinatumomab*)
  Intended for patients with residual disease after treatment for acute lymphoblastic leukaemia (ALL)

Immune system

Positive CHMP opinions on new medicines

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders
- Ilumetri (*tildrakizumab*)
  Treatment of moderate to severe plaque psoriasis

New information on authorised medicines

- Nucala (*mepolizumab*) - extension to existing indication
  Add-on treatment for severe asthma in adults, adolescents and children aged 6 years and older

Nephrology

Withdrawal of applications for extension of indication

- Sutent (*sunitinib*)
  Intended for prevention of the return of kidney cancer after surgery

Negative CHMP opinions on extension of indication

- Opdivo (*nivolumab*) and Yervoy (*ipilimumab*)
  Intended for combination treatment of renal cell carcinoma (kidney cancer)

Nervous system

Positive CHMP opinions on new medicines

- Kigabeq (*vigabatrin*) generic of Sabril
  Treatment of epilepsy in infants and children up to 7 years of age
- Onpattro (*patisiran*)
  Treatment of transthyretin amyloidosis (build-up of abnormal protein)
- Slenyto (*melatonin*)
  Treatment of insomnia in children and adolescents with autism spectrum disorder

Ophthalmology

Positive CHMP opinions on new medicines

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New medicines authorised

- Verkazia (*ciclosporin*)
  Treatment of vernal keratoconjunctivitis (chronic eye allergy)

Respiratory system

Positive CHMP opinions on new medicines

- Gefitinib Mylan (*gefitinib*) generic of Iressa
  Treatment of non-small cell lung cancer
- Imfinzi (*durvalumab*)
  Treatment of non-small cell lung cancer
- Symkevi (*tezacaftor/ivacaftor*)
  Treatment of cystic fibrosis

New information on authorised medicines

- Kalydeco (*ivacaftor*) - extension of indication
  Treatment of cystic fibrosis in combination with tezacaftor
- Keytruda (*pembrolizumab*) - new indications
  Treatment of non-small cell lung cancer and head and neck squamous cell carcinoma
- Nucala (*mepolizumab*) - extension to existing indication
  Add-on treatment for severe asthma in adults, adolescents and children aged 6 years and older

Rheumatology

Positive CHMP opinions on new medicines

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders
- Onpattro (*patisiran*)
  Treatment of transthyretin amyloidosis (build-up of abnormal protein)

Negative CHMP opinions on new medicines

- Eladynos (*abaloparatide*)
  Intended for treatment of osteoporosis (a disease that makes bones fragile)

Other medicines

New medicines authorised

- Dzuveo (*sufentanil*)
  Treatment of pain

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft pegylated liposomal doxorubicin hydrochloride concentrate for solution 2 mg/ml product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018
- Concept paper on the need to develop a reflection paper on development of medicinal products to prevent and treat acute kidney injury
  Deadline for comments: 31 March 2019
- Draft guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells
  Deadline for comments: 31 July 2019

Adopted guidelines

- Guideline on the development of new medicinal products for the treatment of Crohn's Disease
- Guideline on the development of new medicinal products for the treatment of ulcerative colitis
- Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins
- Guideline on similar medicinal products containing somatropin (Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues)
- Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)
- Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)
- Guideline on the quality, non-clinical and clinical aspects of gene therapy medicinal products

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- Autologous adipose cells
- Exosomes carrying recombinant mRNA encoding for the cystic fibrosis transmembrane conductance regulator protein and microRNA-17
- Human foetal neural stem cells for treatment of amyotrophic lateral sclerosis
- Human foetal neural stem cells for treatment of spinal cord injury

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - June 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: July 2018
- CAT - agendas, minutes and reports
- 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

Other publications

- EMA Annual activity report 2017
- EMA Annual Accounts: Financial year 2017
- EMA communication perception survey 2017
- EMA's Pharmacovigilance and Risk Assessment Committee (PRAC) elects new Chair
- Clinical data publication (Policy 0070) report Oct 2016-Oct 2017
- EU and Japan reinforce their collaboration on inspections of medicine manufacturers
- Involvement of patient representatives in scientific advice procedures at the European Medicines Agency
- EMA Supporting medicine developers
- Workshop on the reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development - May 2018 - agenda and presentations
- Scientific publication - The European Medicines Agency's approval of new medicines for type 2 diabetes

Events

- Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies) - November 2018

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease.

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.

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.

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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