112 Issue 112
July 2018

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

Antivirals/anti-infectives 1
Cancer 2
Dermatology 2
Diabetes 2
Gynaecology & Obstetrics 3
Haematology 3
HIV 3
Immune system 4
Metabolic disorders 4
Musculoskeletal system 4
Nephrology 4
Nervous system 4
Respiratory system 5
Rheumatology 5
Urology 5
Other medicines 5
Medicines under additional monitoring 5
Guidelines 6
Other scientific recommendations 6
Scientific committee and working party activities 7
Other publications 7
Explanation of terms used 9

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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Biktarvy (*bictegravir / emtricitabine / tenofovir alafenamide*)
  Treatment of HIV infection

Public hearing

- Quinolone and fluoroquinolone containing medicines (*nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin*) - public hearing focusing on long-lasting effects mainly affecting musculoskeletal and nervous systems
  Treatment of bacterial infections

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Kymriah (*tisagenlecleucel*)
  Treatment of acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL) (blood cancers)
- Nerlynx (*neratinib*)
  Adjuvant treatment of breast cancer
- Vyxeos (*daunorubicin / cytarabine*)
  Treatment of acute myeloid leukaemia (AML) (blood cancer)
- Yescarta (*axicabtagene ciloleucel*)
  Treatment of diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL) (blood cancers)

New medicines authorised

- Pemetrexed Krka (*pemetrexed*) generic of Alimta
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- Lenvima (*lenvatinib*) - new indication and change to existing indication
  Treatment of thyroid and liver cancers
- Opdivo (*nivolumab*) - new indication
  Treatment of melanoma (skin cancer)

Withdrawal of applications for new medicines

- Graspa (*asparaginase*)
  Intended for the treatment of acute lymphoblastic leukaemia (ALL) (blood cancer)

Dermatology

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of melanoma (skin cancer)

Diabetes

New medicines authorised

- Amglidia (*glibenclamide*)
  Treatment of neonatal diabetes

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Ulipristal Acetate Gedeon Richter (*ulipristal acetate*)
  Treatment of uterine fibroids

Haematology

Positive CHMP opinions on new medicines

- Cablivi (*caplacizumab*) O
  Treatment of acquired thrombotic thrombocytopenic purpura (a clotting disorder)
- Kymriah (*tisagenlecleucel*) O
  Treatment of acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL) (blood cancers)
- Veyvondi (*vonicog alfa*) O
  Treatment of von Willebrand disease (inherited bleeding disorder)
- Vyxeos (*daunorubicin / cytarabine*) O
  Treatment of acute myeloid leukaemia (AML) (blood cancer)
- Yescarta (*axicabtagene ciloleucel*) O
  Treatment of diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL) (blood cancers)

New information on authorised medicines

- RoActemra (*tocilizumab*) - new indication
  Treatment of cytokine release syndrome (CRS) (an inflammatory disorder)

Withdrawal of applications for new medicines

- Graspa (*asparaginase*) O
  Intended for the treatment of acute lymphoblastic leukaemia (ALL) (blood cancer)

Safety communication update

- Review of hydroxyethyl starch (HES) containing medicinal products - revised CMDh Position (HES to remain on the market provided that a combination of additional measures to protect patients is implemented)
  Used for hypovolaemia (low blood volume) caused by acute (sudden) blood loss

HIV

New medicines authorised

- Biktarvy (*bictegravir / emtricitabine / tenofovir alafenamide*)
  Treatment of HIV infection

Immune system

New information on authorised medicines

- RoActemra (*tocilizumab*) - new indication
  Treatment of cytokine release syndrome (CRS) (an inflammatory disorder)

Metabolic disorders

Positive CHMP opinions on new medicines

- Duzallo (*allopurinol / lesinurad*)
  Treatment of gout (inflammation in the joints)
- Mepsevii (*vestronidase alfa*)
  Treatment of mucopolysaccharidosis type VII (lysosomal storage disease)

Musculoskeletal system

Public hearing

- Quinolone and fluoroquinolone containing medicines (*nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin*) - public hearing focusing on long-lasting effects mainly affecting musculoskeletal and nervous systems
  Treatment of bacterial infections

Nephrology

New information on authorised medicines

- Jinarc (*tolvaptan*) - extension to existing indication
  Treatment of polycystic kidney disease

Nervous system

New information on authorised medicines

- Inovelon (*rufinamide*) - extension to existing indication (to include children between 1 and 4 years of age)
  Adjunctive treatment of Lennox-Gastaut syndrome (type of epilepsy)

Public hearing

- Quinolone and fluoroquinolone containing medicines (*nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin*) - public hearing focusing on long-lasting effects mainly affecting musculoskeletal and nervous systems
  Treatment of bacterial infections

Respiratory system

New medicines authorised

- Pemetrexed Krka (*pemetrexed*) generic of Alimta
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- Rapamune (*sirolimus*) - new indication
  Treatment of sporadic lymphangioleiomyomatosis (rare lung disease)

Safety communication update

- Review of bacterial lysate medicines - review started (effectiveness in reducing the number and severity of respiratory infections)
  Treatment or prevention of respiratory tract infections and chronic (long-term) respiratory conditions

Rheumatology

Positive CHMP opinions on new medicines

- Duzallo (*allopurinol / lesinurad*)
  Treatment of gout (inflammation in the joints)

Urology

New information on authorised medicines

- Jinarc (*tolvaptan*) - extension to existing indication
  Treatment of polycystic kidney disease

Other medicines

New information on authorised medicines

- Dexdor (*dexmedetomidine*) - new indication
  For sedation in surgical procedures

Safety communication update

- Review of Septanest and associated names (*articaine (hydrochloride)/ adrenaline (tartrate*) - review started to harmonise the way the medicine is used in the different EU countries
  Prevention of pain and discomfort in the mouth during dental procedures

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft qualification opinion on Cellular therapy module of the European Society for Blood & Marrow Transplantation (EBMT) Registry
  Deadline for comments: 21 August 2018
- Concept paper on preparation of a revised guideline on the evaluation of medicinal products indicated for treatment of bacterial infections
  Deadline for comments: 13 September 2018
- Draft lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018
- Draft aliskiren film-coated tablet 150mg and 300mg product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018
- Draft gefitinib film-coated tablet 250 mg product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018
- Draft octreotide acetate depot powder and solvent for suspension for injection 10 mg, 20 mg or 30 mg product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018
- Draft apixaban film-coated tablet 2.5 and 5mg product-specific bioequivalence guidance
  Deadline for comments: 30 September 2018

Adopted guidelines

- Pegylated liposomal doxorubicin hydrochloride product-specific bioequivalence guidance
- Ibuprofen 200 - 800 mg oral use, immediate release formulations product-specific bioequivalence guidance
- Paliperidone product-specific bioequivalence guidance
- Prasugrel product-specific bioequivalence guidance
- Dimethyl fumarate gastro-resistant capsules 120 mg and 240 mg product-specific bioequivalence guidance
- Dabigatran etexilate, hard capsules, 75 mg, 110 mg and 4 150 mg product-specific bioequivalence guidance

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- Expanded autologous auricular chondrocytes
- Autologous enriched CD31+ cell fraction from peripheral blood
- Allogeneic pancreatic islets encapsulated by elastin-like recombinamers

- *Ex vivo* fused autologous human bone marrow-derived mesenchymal stem cell with allogenic human myoblast
- Allogeneic human neural stem cells derived from foetal central nervous system
- Allogenic mesenchymal stem cells isolated from umbilical cord
- Autologous bone marrow-derived human mesenchymal stem cells
- Autologous bone marrow-derived mesenchymal stem cells

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 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
- PCWP and HCPWP joint meeting: 17-18 April 2018 - meeting documents

Other publications

- Highlights of 100th Management Board meeting: June 2018 - meeting documents
- Reinforced EU/US collaboration on medicines
- EMA tracking tool: relocation to Amsterdam - Main milestones (updated)
- Public hearing on quinolones and fluoroquinolones: 23 speakers from 11 EU countries to share experience - summary report
- Stakeholder engagement report 2017 - report and annexes
- Annual training day for patients and healthcare professionals - infographic
- Modernising the orphan designation process
- Interested in joining the Committee for Advanced Therapies (CAT) to represent patients' associations or clinicians?
- Report from the CAT expert meeting on scientific and regulatory considerations for adeno-associated viral vector (AAV)-based gene therapy
- Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria

- Criteria to be fulfilled by patient, consumer and healthcare professional organisations involved in European Medicines Agency (EMA) activities
- RD-ACTION / EMA / DG SANTE workshop: how European Reference Networks can add value to clinical research - May 2018 - meeting documents
- 2018 Annual workshop of the European Network of Paediatric Research at the EMA (Enpr-EMA) - June 2018 - meeting documents
- European network of paediatric research at the EMA (Enpr-EMA) Coordinating Group and networks meeting - June 2018 - meeting documents

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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