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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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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.

To receive an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Para-aminosalicylic acid Lucane (*para-aminosalicylic acid*) O
  Treatment of multi-drug resistant tuberculosis
- Deltyba (*delamanib*) O C
  Treatment of multi-drug resistant tuberculosis

New information on authorised medicines

- Vfend *(voriconazole)* - new indication
  Prophylaxis, prevention of invasive fungal infections

Cancer

Positive CHMP opinions on new medicines

- Gazyvaro *(obinutuzumab)* O
  Treatment of previously untreated chronic lymphocytic leukaemia

Key to symbols used

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

New information on authorised medicines

- Arzerra (*ofatumumab*) O - new indication
  Treatment of previously untreated chronic lymphocytic leukaemia (CLL)
- Halaven *(eribulin)* - change in indication
  Treatment of patients with locally advanced or metastatic breast cancer

Negative CHMP opinions on extension of indication

- Avastin (*bevacizumab*)
  Intended for the treatment of glioblastoma

Safety communication update

- Review of Iclusig (*ponatinib*) O - further review started (due to risk of blood clots or blockages in arteries or veins)
  Treatment of leukaemia

Cardiovascular system

Withdrawal of authorised medicines

- Clopidogrel Teva Generics B.V. (*clopidogrel*)
  Prevention of atherothrombotic events (problems caused by blood clots and hardening of the arteries)

Safety communication update

- Review of Iclusig (*ponatinib*) O - further review started (due to risk of blood clots or blockages in arteries or veins)
  Treatment of leukaemia
- Review of Corlentor/Procoralan (*ivabradine*) - review started (concerns over the increase of cardiovascular side effects)
  Treatment of angina and heart failure
- Review of renin-angiotensin-system (RAS)-acting agents - CHMP opinion (combined use restricted due to increased risk of side effects)
  Treatment of high blood pressure and congestive heart failure
- Review of hydroxyzine-containing medicines - review started (concerns over the side effects of these medicines on the heart)
  Various uses including relief of anxiety disorders, premedication before surgical procedures, relief of urticaria or various other conditions associated with pruritus (itching), and treatment of sleep disorders

Diabetes

New medicines authorised

- Vokanamet (*canagliflozin / metformin*)
  Treatment of type 2 diabetes mellitus

Gynaecology & Obstetrics

New medicines authorised

- Bemfola (*follitropin alfa*)
  Treatment of fertility disorders

Haematology

Positive CHMP opinions on new medicines

- Nuwiq (*simoctocog alfa*)
  Treatment and prevention of bleeding
- Gazyvaro (*obinutuzumab*) O
  Treatment of previously untreated chronic lymphocytic leukaemia

New information on authorised medicines

- Arzerra (*ofatumumab*) O - new indication
  Treatment of previously untreated chronic lymphocytic leukaemia (CLL)

Safety communication update

- Review of Iclusig (*ponatinib*) O - further review started (due to risk of blood clots or blockages in arteries or veins)
  Treatment of leukaemia

Hormone system

Safety communication update

- Review of renin-angiotensin-system (RAS)-acting agents - CHMP opinion (combined use restricted due to increased risk of side effects)
  Treatment of high blood pressure and congestive heart failure

Immune system

Positive CHMP opinions on new medicines

- Envarsus *(tacrolimus)*
  Prevention of transplant rejection

Supply shortages

- Enbrel *(etanercept)* - resolved
  Treatment of arthritis and psoriasis

Musculoskeletal system

Positive CHMP opinions on new medicines

- Translarna *(ataluren)* C O
  Treatment of Duchenne muscular dystrophy

Nervous system

Positive CHMP opinions on new medicines

- Plegridy *(peginterferon beta-1a)*
  Treatment of relapsing-remitting multiple sclerosis

New medicines authorised

- Pregabalin Pfizer (*pregabalin*)
  Treatment of epilepsy, neuropathic pain and generalised anxiety disorder

Arbitration procedures

- Seroquel / Seroquel XR and associated names *(quetiapine)*
  Treatment of schizophrenia

Ophthalmology

Positive CHMP opinions on new medicines

- Simbrinza (*brinzolamide / brimonidine tartrate*)
  Treatment of elevated intraocular pressure

Respiratory system

New medicines authorised

- DuoResp Spiromax / BiResp Spiromax (*budesonide / formoterol*)
  Treatment of asthma and chronic obstructive pulmonary disease
- Ulunar Breezhaler (*indacaterol / glycopyrronium bromide*)
  Treatment of chronic obstructive pulmonary disease
- Incruse (*umeclidinium bromide*)
  Treatment of chronic obstructive pulmonary disease

Rheumatology

Withdrawal of applications for extension of indication

- Protelos / Osseor (*strontium ranelate*)
  Intended for the treatment of osteoarthritis of the knee and hip

Other medicines

New medicines authorised

- Hemangiol (*propranolol*)
  Treatment of infantile haemangioma (strawberry mark)

Safety communication update

- Review of hydroxyzine-containing medicines - review started (concerns on the side effects of these medicines on the heart)
  Various uses including relief of anxiety disorders, premedication before surgical procedures, relief of urticaria or various other conditions associated with pruritus (itching), and treatment of sleep disorders

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft best practice guidance for pilot EMA / HTA parallel scientific advice procedures
  Deadline for comments: 14 July 2014
- Draft concept paper on viral safety of plasma-derived medicinal products with respect to hepatitis E virus
  Deadline for comments: 31 July 2014
- Draft concept paper on the need for revision of the guideline on the clinical investigation of plasma-derived fibrin sealant / haemostatic products and the related core summary of product characteristics
  Deadline for comments: 31 August 2014
- Draft guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis
  Deadline for comments: 15 November 2014

Adopted guidelines

- Questions and answers on the withdrawal of the guideline on pharmacokinetics and metabolic studies in the safety evaluation of new medicinal products in animals (3BS11A)
- Questions and answers: Positions on specific questions addressed to the pharmacokinetics working party
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use topic E 2 C (R2): Questions and answers - Step 5
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guideline Q3C (R5) on impurities: guideline for residual solvents - Step 5

- Quality risk management (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Q9)
- Note for guidance on pharmaceutical quality system (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Q10)

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 2014
- 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
- PRAC rules of procedure
- Work plan for the Safety Working Party 2014
- Work plan for the Pharmacovigilance Inspectors Working Group for 2014
- EMA PCWP/ HCPWP joint meeting - June 2014

Other publications

- EMA Management Board - minutes of the 83rd meeting
- EMA presents first report on implementation of pharmacovigilance legislation to the European Commission
- European Medicines Agency welcomes publication of the Clinical Trials Regulation
- European Medicines Agency response to European Ombudsman letter regarding proactive publication of and access to clinical trial data
- Public consultation regarding the request to the EMA from the European Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals
- EMA releases best practice guidance on parallel scientific advice with health-technology-assessment bodies
- EMA and European Chemicals Agency enhance cooperation
- Transatlantic Taskforce on Antimicrobial Resistance reports progress and outcomes of 17 recommendations
- EMA and US Food and Drug Administration release joint proposal to facilitate clinical investigation of new medicines for Gaucher disease in children
- Pharmacovigilance in the paediatric population workshop - meeting documents

- EudraVigilance training on electronic reporting of ICSRs in the EEA - May 2014 and June 2014
- Paediatric osteoporosis expert meeting - June 2014
- Workshop of the Enpr-EMA – June 2014
- EMA and German Society for Transfusion Medicine and Immunohaematology to co-organise workshop on advanced therapies - September 2014
- EMA workshop on the investigation of subgroups in confirmatory clinical trials - November 2014

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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