90 **Issue 90**
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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.

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

## Cancer

### New medicines authorised

- Bortezomib Sun (*bortezomib*)
  Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)

## Cardiovascular system

### Positive CHMP opinions on new medicines

- Mysildecard (*sildenafil*)
  Treatment of pulmonary arterial hypertension

## Haematology

### New medicines authorised

- Bortezomib Sun (*bortezomib*)
  Treatment of multiple myeloma and mantle cell lymphoma (blood cancers)

**Key to symbols used**

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

# Other information

## Guidelines

**Guidelines open for consultation**

- Concept paper on revision of guidelines on the clinical investigation and core SmPC of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144533/2009 rev. 1) (EMA/CHMP/BPWP/1619/1999 rev. 2)
  Deadline for comments: 30 Sep. 2016
- Concept paper on the need for revision of the guideline on the clinical development of medicinal products for the treatment of cystic fibrosis (CHMP/EWP/9147/2008) - Revision 1
  Deadline for comments: 31 Oct. 2016
- Draft exenatide powder and solvent for prolonged-release suspension for injection, 2 mg, and powder and solvent for prolonged-release suspension for injection in pre-filled pen, 2 mg product-specific bioequivalence guidance
  Deadline for comments: 31 Oct. 2016
- Draft questions and answers on production of water for injections by non-distillation methods – reverse osmosis and biofilms and control strategies
  Deadline for comments: 04 Nov. 2016
- Draft guideline on the development of new medicinal products for the treatment of Ulcerative Colitis - Revision 1
  Deadline for comments: 31 Jan. 2017
- Draft addendum to the 'guideline on the evaluation of medicinal products indicated for treatment of bacterial infections' to address the clinical development of new agents to treat disease due to Mycobacterium tuberculosis - Revision 1
  Deadline for comments: 31 Jan. 2017
- Clinical investigation of medicinal products for the management of Crohn's disease
  Deadline for comments: 31 Jan. 2017

**Adopted guidelines**

- Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations II: Biological medicinal products
- Guideline on good pharmacovigilance practices (GVP) - Module VIII Addendum I – Requirements and recommendations for the submission of information on non-interventional post-authorisation safety studies (Rev. 2) (updated)
- Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev. 2) (updated)
- Guideline on development, production, characterisation and specification for monoclonal antibodies and related products - Revision 1
- Guideline on potency testing of cell based immunotherapy medicinal products for the treatment of cancer - Revision 1

- Guideline on production and quality control of animal immunoglobulins and immunosera for human use - Revision 1

# Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - medicinal products for human use: July 2016
- 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
- Annual report of the GCP Inspectors Working Group 2015

# Other publications

- EU collaboration strengthens safety monitoring of medicines
- Data integrity: key to public health protection
- Adaptive pathways: key learnings and next steps
- Transparency in drug regulation
- Better monitoring of biological medicines
- Development of medicines to treat tuberculosis
- New layout for EMA scientific guidelines
- HCPWP workshop with academia - meeting documents - June 2016
- Workshop on single-arm trials in oncology - meeting documents - June 2016
- Medical literature monitoring workshop - Sep. 2016
- IMI WEB-RADR workshop: mobile technologies and social media as new tools in pharmacovigilance - Oct. 2016
- Patient registries workshop - Oct. 2016
- Addressing challenges of innovative cancer immunotherapy medicines - Nov. 2016
- Identifying opportunities for 'Big data' in medicines development and regulation - Nov. 2016

# 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.

### Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

In particular, you may be interested in these links:

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