39 Issue 39
April 2012

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

# Information on medicines

## Cardiovascular system

### New marketing authorisations

- Sabervel (*irbesartan*)
  Treatment of hypertension

### Arbitration procedures

- Lipitor (*atorvastatin*)
  Treatment of high blood cholesterol levels and the prevention of a first cardiovascular event

## Diabetes

### Positive CHMP opinions on new medicines

- Forxiga (*dapagliflozin*)
  Treatment of type 2 diabetes

**Key to symbols used**

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

### New marketing authorisations

- Pioglitazone Teva and Pioglitazone Teva Pharma (*pioglitazone*)
  Treatment of type 2 diabetes
- Sepioglin (*pioglitazone*)
  Treatment of type 2 diabetes
- Paglitaz (*pioglitazone*)
  Treatment of type 2 diabetes
- Pioglitazone Accord (*pioglitazone*)
  Treatment of type 2 diabetes
- Pioglitazone Actavis Group and Pioglitazone Actavis (*pioglitazone*)
  Treatment of type 2 diabetes

### Withdrawal of marketing authorisation applications

- Pioglitazone ratio, Pioglitazone ratiopharm and Pioglitazone ratiopharm GmbH (*pioglitazone*)
  Intended for the treatment of type 2 diabetes
- Pioglitazone Teva Generics (*pioglitazone*)
  Intended for the treatment of type 2 diabetes

### New information on authorised medicines

- Lantus and Optisulin (*insulin glargine*) - change to indication
  Treatment of diabetes

# Haematology

### Positive CHMP opinions on new medicines

- Jakavi (*ruxolitinib*)
  Treatment of chronic idiopathic myelofibrosis
- Rienso (*ferumoxitol*)
  Treatment of iron deficiency anaemia

# Hormone diseases

### Arbitration procedures

- Norditropin (*somatropin*)
  Treatment of growth hormone deficiency

### Safety communication update

- Somatropin (*somatropin*)
  Treatment of growth hormone deficiency

# Nervous system

### Safety communication update

- Gilenya (*fingolimod*)
  Treatment of multiple sclerosis

# Respiratory system

### Arbitration procedures

- Flutiform and Iffeza (*fluticasone propionate / formoterol fumarate*)
  Treatment of asthma

### Safety communication update

- Suppositories containing terpenic derivatives
  Treatment of bronchial disorders

# Vaccines

### Withdrawal of marketing authorisation applications

- Fluad Paediatric (*influenza vaccine, surface antigen, inactivated, adjuvanted with MF59C.1*)
  Intended to be used to prevent influenza

### Other information

- Amended European Union recommendations for the seasonal influenza vaccine composition for the season 2012/2013

# Other medicines

### Withdrawal of marketing authorisations

- Livensa (*testosterone*)
  Intended for the treatment of hypoactive sexual desire disorder (HSDD)

### Negative CHMP opinions on new medicines

- Glybera (*alipogene tiparvovec*)
  Intended for the treatment of lipoprotein lipase deficiency

### Arbitration procedures

- Lipitor (*atorvastatin*)
  Treatment of high blood cholesterol levels and the prevention of a first cardiovascular event
- Yvidually (ethinylestradiol / drospirenone)
  Contraception
- Ethinylestradiol-Drospirenone 24+4 and Yaz 24+4 (ethinylestradiol / drospirenone)
  Contraception

### Safety communication update

- Nimesulide-containing medicines
  Treatment of acute pain and primary dysmenorrhoea (restricted indication)

# Other information

## Guidelines

**Guidelines open for consultation**

- Draft list of EU reference dates for periodic safety update reports in preparation for introduction of the new pharmacovigilance legislation
  Deadline for comments: 04 June 2012
- Draft reflection paper on clinical aspects related to tissue-engineered products
  Deadline for comments: 31 July 2012
- Reflection paper on classification of advanced-therapy medicinal products
  Deadline for comments: 31 July 2012

**Adopted guidelines**

- Reflection paper on ethical and good-clinical-practice aspects of clinical trials of medicinal products for human use conducted outside of the European Union (EU)/European Economic Area and submitted in marketing-authorisation applications to the EU regulatory authorities

## Scientific committee activities

- CHMP highlights from the April 2012 meeting
- Eric Abadie resigns as chair of the CHMP
- CAT monthly report from the April 2012 meeting
- COMP monthly report from the April 2012 meeting
- PDCO monthly report from the April 2012 meeting
- PhVWP monthly report from the December 2011 meeting
- PhVWP monthly report from the March 2012 meeting
- PhVWP monthly report from the April 2012 meeting
- EMA's Scientific Coordination Board starts reflection on best cooperation between scientific committees

## Other publications

- EMA workshop on Pharmacogenomics: from science to clinical care
  EMA, London, UK, 08-09 October 2012; registration open until 01 June 2012 (limited places)
- Presentations from the EMA workshop on medicines for older people
- European Presentations from the EMA-EFPIA modelling and simulation workshop
- Management Board meeting of 22-23 March 2012
- European Medicines Agency tightens conflicts-of-interests policies with immediate effect

- Good pharmacovigilance practices
- European regulators propose way forward for publication of full clinical trial data
- European Medicines Agency publishes new document on regulatory procedural advice on similar biological medicines
- Agnès Saint Raymond appointed to UN Commission on life-saving commodities for women and children

**Key to symbols used**

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

# 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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