

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


- [Daptomycin Hospira](#) (*daptomycin*) 
Treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- [Jylamvo](#) (*methotrexate*)
Treatment of rheumatological disorders, psoriasis and acute lymphoblastic leukaemia (blood cancer)


New information on authorised medicines

- [Revlimid](#) (*lenalidomide*)  - change in indication
Treatment of multiple myeloma (cancer of the bone marrow)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Withdrawal of applications for new medicines


- [Zioxtenzo](#) (*pegfilgrastim*) 
Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients

Withdrawal of applications for an extension of indication

- [Xgeva](#) (*denosumab*)
Intended for the treatment of hypercalcemia (high levels of calcium in the blood caused by cancer)

Cardiovascular system

Positive CHMP opinions on new medicines




- [Daptomycin Hospira](#) (*daptomycin*) 
Treatment of bacterial infections

New medicines authorised

- [Granpidam](#) (*sildenafil*) 
Treatment of patients with pulmonary arterial hypertension

Dermatology

Positive CHMP opinions on new medicines

- [Amgevita](#) (*adalimumab*) 
Treatment of inflammatory conditions
- [Daptomycin Hospira](#) (*daptomycin*) 
Treatment of bacterial infections
- [Solymbic](#) (*adalimumab*) 
Treatment of inflammatory conditions

Safety communication update

- Review of [medicines containing dienogest and ethinylestradiol](#) - CHMP Opinion (use should be limited to women who choose oral contraception)
Oral contraceptives used for the treatment of moderate acne in women


Diabetes

New information on authorised medicines

- [Synjardy](#) (*empagliflozin / metformin*) - change in indication
Treatment of diabetes


Gastro-intestinal system

Positive CHMP opinions on new medicines

- [Amgevita](#) (*adalimumab*) 
Treatment of inflammatory conditions

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances


- [Solymbic](#) (*adalimumab*)  Treatment of inflammatory conditions

Haematology


Positive CHMP opinions on new medicines

- [Jylamvo](#) (*methotrexate*) Treatment of rheumatological disorders, psoriasis and acute lymphoblastic leukaemia (blood cancer)

New information on authorised medicines

- [Revlimid](#) (*lenalidomide*)  - change in indication
Treatment of multiple myeloma (cancer of the bone marrow)

Withdrawal of applications for new medicines


- [Zioxtenzo](#) (*pegfilgrastim*)  Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients

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- [Xgeva](#) (*denosumab*) Intended for the treatment of hypercalcemia (high levels of calcium in the blood caused by cancer)

HIV

New medicines authorised

- [Atazanavir Mylan](#) (*atazanavir*)  Treatment of HIV-1 infection



Hormone system

Safety communication update

- Review of [medicines containing dienogest and ethinylestradiol](#) - CHMP Opinion (use should be limited to women who choose oral contraception)
Oral contraceptives used for the treatment of moderate acne in women

Immune system

Positive CHMP opinions on new medicines

- [Amgevita](#) (*adalimumab*)  Treatment of inflammatory conditions
- [Jylamvo](#) (*methotrexate*) Treatment of rheumatological disorders, psoriasis and acute lymphoblastic leukaemia (blood cancer)
- [Solymbic](#) (*adalimumab*)  Treatment of inflammatory conditions
- [Xeljanz](#) (*tofacitinib*) Treatment of rheumatoid arthritis

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Withdrawal of authorised medicines

- [Budesonide/Formoterol Teva](#) (*budesonide / formoterol*)
Treatment of asthma and chronic obstructive pulmonary disease (COPD)



Metabolic system

Positive CHMP opinions on new medicines

- [Yargesa](#) (*miglustat*) 
Treatment of Gaucher disease

Ophthalmology

Positive CHMP opinions on new medicines

- [Amgevita](#) (*adalimumab*) 
Treatment of inflammatory conditions
- [Solymbic](#) (*adalimumab*) 
Treatment of inflammatory conditions

Respiratory system

Positive CHMP opinions on new medicines



- [Rolufta](#) (*umeclidinium*)
Treatment of chronic obstructive pulmonary disease (COPD)

Withdrawal of authorised medicines

- [Budesonide/Formoterol Teva](#) (*budesonide / formoterol*)
Treatment of asthma and chronic obstructive pulmonary disease (COPD)

Rheumatology

Positive CHMP opinions on new medicines

- [Amgevita](#) (*adalimumab*) 
Treatment of inflammatory conditions
- [Jylamvo](#) (*methotrexate*)
Treatment of rheumatological disorders, psoriasis and acute lymphoblastic leukaemia (blood cancer)
- [Solymbic](#) (*adalimumab*) 
Treatment of inflammatory conditions
- [Xeljanz](#) (*tofacitinib*)
Treatment of rheumatoid arthritis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Other medicines

Positive CHMP opinions on new medicines

- [Tadalafil Lilly](#) (*tadalafil*)
Treatment of erectile dysfunction and benign prostatic hyperplasia (enlarged prostate gland)

Medicines under additional monitoring

- [Updated list of medicinal products under additional monitoring](#)

Other information

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - December 2016](#)
- [CHMP - agendas, minutes and highlights](#)
- [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](#)
- [Mandate, objectives and rules of procedure of the Scientific Advice Working Party \(SAWP\)](#) - updated

Other publications

- [Human medicines: highlights of 2016](#)
- [Conditional marketing authorisations give patients access to important new medicines earlier](#)
- [EnprEMA newsletter: December 2016](#)
- [Involvement of patient representatives in scientific advisory groups at the EMA](#) - updated
- [Involvement of patient representatives in scientific advice procedures at the EMA](#) - updated
- PCWP and HCPWP joint meeting - Sept 2016 - [meeting documents](#)
- Workshop on identifying opportunities for 'big data' in medicines development and regulatory science - Nov 2016 - [meeting documents](#)

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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