



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency decision P/345/2010

of 20 December 2010

on a class waiver on condition(s) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.



European Medicines Agency decision

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on a class waiver on condition(s) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the decision of the European Medicines Agency P/1/2007 of 3 December 2007 on a class waiver on condition(s) and the subsequent decisions on a class waiver on condition(s): decision P/17/2008 of 21 April 2008, decision P/47/2008 of 14 July 2008, decision P/65/2009 of 13 April 2009, decision P/146/2009 of 26 October 2009, decision P/63/2010 of 26 April 2010,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 10 December 2010 in accordance with Article 12 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion of its own motion on the granting of a waiver on condition(s)
- (2) It is therefore appropriate to adopt a decision granting a waiver on condition(s).

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A waiver on condition(s), the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is applicable to all natural and legal persons intending to market a product falling within the scope of Article 1 of this Decision.

Done at London, 20 December 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/806338/2010

Opinion of the Paediatric Committee on a class waiver on condition(s)

Waived conditions

See Annex I

Basis for opinion

On 3 December 2007, the European Medicines Agency adopted a decision P/1/2007 on a class waiver on conditions. Subsequently, the following decisions on a class waiver on conditions were adopted: decision P/17/2008 of 21 April 2008, decision P/47/2008 of 14 July 2008, decision P/65/2009 of 13 April 2009, decision P/146/2009 of 26 October 2009, and decision P/63/2010 of 26 April 2010.

According to Article 12 of Regulation (EC) No 1901/2006, the Paediatric Committee may, of its own motion, adopt an opinion on granting of a class waiver.

Opinion

1. The Paediatric Committee, having considered the conditions listed in Annex I, recommends:
 - pursuant to Article 12 of Regulation (EC) No 1901/2006, to grant a waiver for medicinal products intended to treat primary myelofibrosis in all subsets of the paediatric population, on the grounds that the condition occurs only in adult populations, in accordance with Article 11(1)(b) of said Regulation.
 - pursuant to Article 12 of Regulation (EC) No 1901/2006, to grant a waiver for medicinal products intended to treat diabetic macular oedema in all subsets of the paediatric population, on the grounds that the condition occurs only in adult populations, in accordance with Article 11(1)(b) of said Regulation.
 - pursuant to Article 12 of Regulation (EC) No 1901/2006, to grant a waiver for medicinal products intended to treat mesothelioma in all subsets of the paediatric population, on the grounds that the condition occurs only in adult populations, in accordance with Article 11(1)(b) of said Regulation.
 - pursuant to Article 12 of Regulation (EC) No 1901/2006, to grant a waiver for medicinal products intended to treat actinic keratosis in all subsets of the paediatric population, on the grounds that the condition occurs only in adult populations, in accordance with Article 11(1)(b) of said Regulation.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.



2. The conditions waived and the waivers revoked are set out in the Annex I.
3. The grounds for the granting of a waiver for each of the waived conditions are set out in the Annex II.

This opinion is forwarded to the Executive Director of the European Medicines Agency.

London, 10 December 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

List of conditions waived and waivers revoked

List of conditions waived

- Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)
- Treatment of lung carcinoma (small cell and non-small cell carcinoma)
- Treatment of basal cell carcinoma
- Treatment of breast carcinoma
- Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
- Treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
- Treatment of endometrial carcinoma
- Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)
- Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
- Treatment of hairy cell leukaemia
- Treatment of multiple myeloma
- Treatment of Alzheimer's disease
- Treatment of vascular dementia and vascular cognitive disorder/impairment
- Treatment of organic amnesic syndrome (excluding amnesic syndrome caused by alcohol and other psychoactive substances)
- Treatment of amyotrophic lateral sclerosis
- Treatment of Parkinson's disease (non-juvenile)
- Treatment of age-related macular degeneration
- Treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause
- Treatment of Chronic Obstructive Pulmonary Disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after (bone-marrow) transplantation).
- Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
- Treatment of adenocarcinoma of the pancreas
- Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, pheochromocytoma)
- Treatment of gastric carcinoids
- Treatment of adenocarcinoma of the colon and rectum

- Treatment of ureter and bladder carcinoma
- Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)
- Treatment of vaginal and vulvar carcinoma (excluding rhabdomyosarcoma and soft tissue sarcoma)
- Treatment of melanoma (from 0 to less than 12 years)
- Treatment of gastric adenocarcinoma
- Treatment of chronic lymphocytic leukaemia
- Treatment of cervix and corpus uteri carcinoma
- Treatment of follicular lymphoma
- Treatment of primary and secondary osteoarthritis
- Treatment of coronary atherosclerosis
- Treatment of peripheral atherosclerosis
- Treatment of Huntington Chorea
- Treatment of benign prostatic hyperplasia
- Treatment of erectile dysfunction
- Treatment of primary gout (excluding Lesch-Nyhan syndrome and other secondary forms of gout)
- Treatment of primary myelofibrosis
- Treatment of diabetic macular oedema
- Treatment of mesothelioma
- Treatment of actinic keratosis

List of waivers revoked

- Treatment of melanoma in all subsets of the paediatric population

Revoked on 14 July 2008

Therefore, in accordance with Article 14(3) of Regulation (EC) No 1901/2006, as amended, the requirements set out in Articles 7 and 8 shall not apply to this condition for the subsets of the paediatric population from 12 years to less than 18 years until 15 July 2011.

- Treatment of menopausal and other peri-menopausal disorders in all subsets of the paediatric population

Revoked on 13 April 2009

Therefore, in accordance with Article 14(3) of Regulation (EC) No 1901/2006, as amended, the requirements set out in Articles 7 and 8 shall not apply to 'treatment of menopausal and other peri-menopausal disorders' for all subsets of the paediatric population until 15 April 2012.

Annex II

Grounds for the granting of a waiver

Scope

Whereas the conditions listed below occur only in adult populations or also in some paediatric subsets, the Paediatric Committee (PDCO) recommends that for a medicinal product intended to treat these conditions, the production of the data in all or some subsets of the paediatric population in compliance with an agreed paediatric investigation plan shall be waived.

This list of waivers refers to symptomatic conditions only, as opposed to indications or diseases. In addition, the class waiver refers to the treatment of these conditions but not to the prevention or diagnosis of these conditions.

A medicinal product also developed for another condition not listed in Annex I will not be waived from the requirements of the Regulation (EC) No 1901/2006.

The conditions listed in Annex I should not prevent an applicant from considering the development of a medicinal product in different or related conditions/indications for use in the paediatric population.

The PDCO may adopt further opinions recommending the granting of waivers in other conditions.

In addition the PDCO may adopt an opinion advocating the review of granted waivers as per Article 14(2) of Regulation (EC) No 1901/2006.

Voluntary submission of a paediatric investigation plan for a waived condition is still possible.

Grounds

The references provided were identified through systematic search and may not be exhaustive or necessarily available for the EU population.

The PDCO acknowledges that there may be anecdotal cases of occurrence of waived conditions in the paediatric population.

- **Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)**

Carcinomas in the oral cavity, the pharynx, the larynx or the nasal cavity usually occurs after the age of 45 and the average age of diagnosis is around the age of 60 years (1). The incidence reported in children aged 10-14 and 15-19 years in the US is 0.3 and 0.4 per 100,000 respectively (2).

Nasopharyngeal carcinoma of the undifferentiated histological type III, also known as "lymphoepithelioma", occurs in the paediatric population and therefore is not included in the waiver.

- **Treatment of lung carcinoma (small cell and non-small cell)**

The mean age of diagnosis is above the age of 60, though rare cases occur in the 3rd decade of life. The incidence is less than 25 cases reported in children in the interval between 1997-2001 (2).

- **Treatment of basal cell carcinoma**

Basal cell carcinoma median age of diagnosis is around the age of 67, although 5-15 % of cases occur in patients aged 20-40 years. Basal cell carcinoma occasionally occurs in children with increased risk, e.g. following radiotherapy.

- **Treatment of breast carcinoma**

Age of diagnosis depends on the tumour type and can be as early as in the 3rd decade of life. The incidence is less than 25 cases reported in children in the interval between 1997-2001 (2).

- **Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)**

The median age of patients with ovarian carcinoma is 60 years (3). Ovarian carcinoma is usually diagnosed after the age of 40. The incidence reported in children aged 10-14 and 15-19 years in the US is 0.7 and 1.4 respectively per 100,000 (2). The waiver for ovarian carcinoma does not include rhabdomyosarcoma and germ cell tumours, for example, which are paediatric malignant diseases that may occur in the Fallopian tube, but are no carcinomas.

- **Treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)**

In an European case series (27), the mean age of patients at diagnosis was around 60 years, and no cases were reported in females aged fewer than 19 years in the literature. The waiver for Fallopian tube carcinoma does not include rhabdomyosarcoma and germ cell tumours, for example, which are paediatric malignant diseases that may occur in the Fallopian tube, but are no carcinomas.

- **Treatment of endometrial carcinoma**

Endometrial carcinoma is usually diagnosed after the age of 50 years. Rare cases are reported under the age of 35 years.

- **Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)**

Peritoneal carcinoma does not normally occur in children; one case reports for (primary) peritoneal carcinoma has been found (28). Also, secondary peritoneal carcinomas (e.g., metastases in the peritoneum of a carcinoma in a different location) normally do not occur in children. Peritoneal spread of non-carcinomatous malignancies, e.g., of blastomas and sarcomas, are not covered in the waiver.

- **Treatment of prostate carcinoma (excluding rhabdomyosarcoma)**

The incidence of prostate carcinoma increases with age and is rarely diagnosed before the age of 50 years (4,5). The incidence is less than 25 cases reported in children in the interval between 1997-2001 (2). The waiver for prostate carcinoma does not include rhabdomyosarcoma, for example, which is a paediatric malignant disease that may occur in the prostate, but is not a carcinoma.

- **Treatment of hairy cell leukaemia**

Hairy cell leukaemia is diagnosed on average around the age of 50.

- **Treatment of multiple myeloma**

Multiple myeloma median age of diagnosis is 71 years and only 1% of cases occur before the age of 40 (6). The incidence is less than 25 cases reported in children in the interval between 1997-2001 (2).

- **Treatment of Alzheimer's disease**

Alzheimer's disease rarely occurs before the age of 50 years and average age of onset is around the age of 65 (7). Familial Alzheimer's disease occurs earlier in life and has been reported to occur as early as the age of 30.

- **Treatment of vascular dementia and vascular cognitive disorder/impairment**

Vascular dementia is an age-related condition based on cardiovascular or cerebrovascular conditions and the average age of diagnosis is usually above the age of 60 years.

- **Treatment of organic amnesic syndrome (excluding amnesic syndrome caused by alcohol and other psychoactive substances)**

Organic amnesic syndrome does not normally occur in the paediatric population.

- **Treatment of amyotrophic lateral sclerosis**

Amyotrophic lateral sclerosis is an adult onset disease with the earliest age of onset in the 3rd decade of life. The average age of diagnosis is 55 years.

- **Treatment of Parkinson's disease (non-juvenile)**

Parkinson's disease is usually diagnosed after the age of 50, although rare cases occur before the age of 40 years.

- **Treatment of age-related macular degeneration**

The average age of onset is after the age of 50. The estimated prevalence for the European population 65 years and older is 3.3 % and increases with age (8).

- **Treatment of climacteric symptoms associated with decreased oestrogen levels as occurring at menopause**

Menopause starts 12 months after the last menstrual period, while perimenopause refers to the time before menopause when vasomotor symptoms and irregular menses often commence. Climacteric is the general term for the time from the period of this transition to the early postmenopausal phase.

Symptoms of menopause are considered to be secondary to the endocrine modifications that occur in perimenopause; these include fluctuation in ovarian steroid production, with an initially increased but subsequently permanently reduced estrogenic secretion. Typical climacteric symptoms include hot flashes or flushes, insomnia, weight gain and bloating, mood changes, irregular menses, mastodynia, and headache. These symptoms do not occur in paediatric age groups, except in very rare occasions of surgical or chemical castration when full ovarian activity was previously present, i.e. they do not occur in endocrine conditions associated with primary amenorrhoea.

The waiver does not cover conditions that may include reduced oestrogen levels as a risk factor, including (but not limited to) osteoporosis.

- **Treatment of Chronic Obstructive Pulmonary Disease (COPD)**

The condition should only be considered in an individual over the age of 40 with characteristic symptoms, according to the Global Initiative for Chronic Obstructive Lung Disease (9).

Granting a waiver for the condition COPD will not prevent consideration of paediatric development of medicinal products that might benefit paediatric patients with chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after bone-marrow transplantation, etc.

- **Treatment of adenocarcinoma of the pancreas**

Adenocarcinoma of the pancreas does not normally occur in the paediatric population and is usually diagnosed after the age of 45. The incidence reported in children below 20 years is 0.1 per 100,000 (10).

- **Treatment of gastric carcinoids**

Gastric carcinoids do not normally occur in the paediatric population. Gastric carcinoids usually occur after the age 30 years and the average age of diagnosis is around the age of 60 years (10, 11, 12, 13)

- **Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, pheochromocytoma)**

Gastroenteropancreatic neuroendocrine tumours normally do not occur in the paediatric population. The waiver does not include neuroendocrine tumours in any other than a gastroenteropancreatic location, such as neuroblastoma, neuroganglioblastoma or pheochromocytoma, which occur in the paediatric population.

- **Treatment of adenocarcinoma of the colon and rectum**

SEED cancer statistics.

- **Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)**

The condition does not normally occur in the paediatric population.

- **Treatment of ureter and bladder carcinoma**

Malignant bladder neoplasms of urothelial origin in children. are rare. Most cases in adults are reported over the age of 40 years. Cases of bladder cancer in children under the age of 18 years that have been reported include exposure to cyclophosphamide and post treatment of neuropathic bladder by augmentation cystoplasty (10, 14-23). The waiver for bladder carcinoma does not include rhabdomyosarcoma, for example, which is paediatric malignant diseases that well may occur in the bladder, but is not a carcinoma.

- **Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)**

The condition does not normally occur in the paediatric population.

- **Treatment of vaginal and vulvar carcinoma (excluding rhabdomyosarcoma and soft tissue sarcoma)**

The condition does not normally occur in the paediatric population.

- **Treatment of melanoma**

Melanoma does not normally occur in the paediatric population from 0 to less than 12 years. The incidence reported in the US population for the age groups of 1-5 years, 5-9 years and 10-14 years is 0.10, 0.16 and 0.37 per 100,000 respectively (26). The incidence of melanoma in adolescents, however, is reported at 1.72/100,000 (15 – 19 years)(26) which enables this population to be included in clinical trials.

- **Treatment of gastric adenocarcinoma**

Gastric adenocarcinomas do not normally occur in the paediatric population. The incidence reported in children aged 0-14 years in Europe in 2002 was 0.002 per 100,000 (24).

- **Treatment of chronic lymphocytic leukaemia**

Chronic lymphocytic leukaemia does not normally occur in the paediatric population and is usually diagnosed above the age of 60 years.

- **Treatment of cervix and corpus uteri carcinoma**

Cervix and corpus uteri cancer do not normally occur in the paediatric population.

- **Treatment of follicular lymphoma**

The condition does not normally occur in the paediatric population.

- **Treatment of primary and secondary osteoarthritis**

The condition does not normally occur in the paediatric population (29).

- **Treatment of coronary atherosclerosis**

The condition does not normally occur in the paediatric population.

- **Treatment of peripheral atherosclerosis**

The condition does not normally occur in the paediatric population.

- **Treatment of Huntington Chorea**

The condition does not normally occur in the paediatric population.

- **Treatment of benign prostatic hyperplasia**

Benign prostatic hyperplasia does not normally occur in the paediatric population. It is usually diagnosed in males above the age of 50 years, rare cases occur already in the 3rd decade of life (25).

- **Treatment of erectile dysfunction**

The condition does not normally occur in the paediatric population.

- **Treatment of primary gout (excluding Lesch-Nyhan syndrome and other secondary forms of gout)**

The condition does not normally occur in the paediatric population.

- **Treatment of primary myelofibrosis**

The condition does not normally occur in the paediatric population. Primary myelofibrosis (synonyms: Agnogenic Myeloid Metaplasia/ Idiopathic myelofibrosis) affects mostly middle-aged and elderly patients. The median age at diagnosis is 60 years (30). In children, myelofibrosis should be differentiated from metastatic neoplasms, connective tissue disease, and metabolic and bone diseases.

- **Treatment of diabetic macular oedema**

The condition does not normally occur in the paediatric population.

- **Treatment of mesothelioma**

The condition does not normally occur in the paediatric population. In children, mesothelioma has been reported in very few case reports (31, 32, 33, 34, 35 and 36).

- **Treatment of actinic keratosis**

The condition does not normally occur in the paediatric population. Actinic keratosis usually occurs in fair-skinned individuals over 45 years of age (37). The prevalence in individuals below 40 years of age is very low.

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