Class waivers

The need for a paediatric development may be waived for classes of medicinal products that are likely unsafe or ineffective in children, that lack benefit for paediatric patients or are for diseases and conditions that only affect the adult population. This page lists the class waivers granted by the European Medicines Agency (EMA).

The requirement to submit a paediatric investigation plan (PIP) shall be waived for specific medicinal products or classes of medicinal products that:

- are likely to be ineffective or unsafe in part or all of the paediatric population;
- are intended for conditions that occur only in adult populations;
- do not represent a significant therapeutic benefit over existing treatments for paediatric patients.

In accordance with the Paediatric Regulation (Regulation (EC) No 1901/2006), the Paediatric Committee (PDCO) has adopted a **review of the class waiver list on 23 July 2015**. The review included all previously granted class waivers, most of which referred to specific diseases. In its review, the PDCO took into account recent paediatric data concerning these diseases and medicines used for treating them. The PDCO assessed, for all class waivers, the available information on the disease area, the characteristics of the medicines and any available evidence on their possible use in children. It has revoked eight class waivers, updated 15 class waivers and confirmed nine class waivers in the current class waiver list.

- The consolidated EMA decision on the revised list of class waivers adopted on 23 July 2015

This decision contains an opinion with the updated list of waived conditions, and includes a summary report on the scientific discussion for the revision of the class waivers. It **supersedes** all previous class waiver decisions. Regulatory submissions will be **subject to the revised list of class waivers from July 2018 onwards**.

For regulatory submission **until July 2018**, the list of of waived conditions included in the PDCO decision adopted on 8 September 2010 may be consulted:

- The consolidated EMA decision on the list of class waivers adopted on 20 December 2010

All classes of medicinal products intended to treat these conditions are exempt from the requirement for a PIP until July 2018.

For more information and guidance, see

- question 10 on the PIP guidance questions and answers page - What shall I submit in case my product is developed for a condition listed in the European Medicines Agency decision on class waiver?
- Questions and answers on the EMA/PDCO review of the list of granted class waivers

Short table of the EMA class waivers (this list may be used for regulatory submissions until July 2018*):

Class of medicinal products	Condition	Decision date
	Treatment of adenocarcinoma of the colon and rectum	21/04/2008
	Treatment of adenocarcinoma of the pancreas	21/04/2008
	Treatment of age-related macular degeneration	03/12/2007
	Treatment of Alzheimer's disease	03/12/2007

Related documents

- European Medicines Agency decision CW-0001-2015 of 23 July 2015 on class waivers in accordance with Regulation EC No 1901-2006 of the European Parliament and of the Council (23/07/2015)
- EMA/PDCO Summary Report on the review of the list of granted Class Waivers (23/07/2015)
- Questions and answers EMA/PDCO review of the list of granted Class Waivers (23/07/2015)

Related content

- Stimulating the development of medicines for children (23/7/2015)

Contact point

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	Treatment of amyotrophic lateral sclerosis	03/12/2007
	Treatment of basal cell carcinoma	03/12/2007
	Treatment of benign prostatic hyperplasia	21/04/2008
	Treatment of breast carcinoma	03/12/2007
	Treatment of cervix and corpus uteri carcinoma	21/04/2008
	Treatment of chronic lymphocytic leukaemia	21/04/2008
	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).	03/12/2007
	Treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause	03/04/2009
	Treatment of coronary atherosclerosis	21/04/2008
	Treatment of endometrial carcinoma	03/12/2007
	Treatment of erectile dysfunction	21/04/2008
	Treatment of fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	26/10/2009
	Treatment of follicular lymphoma	21/04/2008
	Treatment of gastric adenocarcinoma	21/04/2008
	Treatment of gastric carcinoids	21/04/2008
	Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)	26/10/2009
	Treatment of hairy cell leukaemia	03/12/2007
	Treatment of Huntington chorea	21/04/2008
	Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)	21/04/2008
	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	21/04/2008
	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	03/12/2007
	Treatment of melanoma (from 0 to less than 12 years old)	03/12/2007
	Treatment of primary myelofibrosis	20/12/2010

	Treatment of diabetic macular oedema	20/12/2010
	Treatment of mesothelioma	20/12/2010
	Treatment of actinic keratosis	20/12/2010
	Treatment of melanoma (from 12 to less than 18 years old) (Revoked 14/07/2008*) ** The requirements of art. 7 and art. 8 of Regulation (EC) No 1901/2006 shall not apply to 12 to less than 18 years old children, until 14 July 2011. Please check the EMA decision for the grounds.*	03/12/2007
	Treatment of menopausal and other perimenopausal disorders (Revoked 13/04/2009**) *** The requirements of art. 7 and art. 8 of Regulation (EC) No 1901/2006 shall not apply to "treatment of menopausal and other perimenopausal disorders" to all subsets of the paediatric population until 15 April 2012. Please check the EMA decision* for the grounds.	03/12/2007
	Treatment of multiple myeloma	03/12/2007
	Treatment of organic amnesic syndrome (excluding amnesic syndrome caused by alcohol and other psychoactive substances)	03/12/2007
	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)	26/10/2009
	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	03/12/2007
	Treatment of Parkinson's disease (non-juvenile)	03/12/2007
	Treatment of peripheral atherosclerosis	21/04/2008
	Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)	26/10/2009
	Treatment of primary gout (excluding Lesch-Nyhan syndrome and other secondary forms of gout)	21/04/2008
	Treatment of primary osteoarthrosis (excluding secondary osteoarthrosis)	21/04/2008
	Treatment of primary and secondary osteoarthrosis	26/04/2010
	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)	03/12/2007
	Treatment of ureter and bladder carcinoma	26/10/2009
	Treatment of vaginal and vulvar carcinoma (excluding rhabdomyosarcoma and soft tissue sarcoma)	26/10/2009
	Treatment of vascular dementia and vascular cognitive disorder/impairment	03/12/2007
Peroxisome proliferator-activated		

receptor (PPAR)-gamma modulators, including dual and multiple PPAR modulators (e.g., thiazolidinediones, glitazars, triple modulators)	Treatment of type II diabetes mellitus	08/09/2008

*An updated table with the revised EMA class waivers following the PDCO's decision on 23 July 2015 will be provided shortly.

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