EMADOC-1700519818-2155553

European Medicines Agency decision

CW/0001/2025

of 2 June 2025

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

CW/0001/2025

of 2 June 2025

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 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the decision of the European Medicines Agency P/1/2007 on a class waiver on conditions and the subsequent decisions on a class waiver on conditions: 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 CW/0001/2015 of 23 July 2015,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 23 May 2025 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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.

Article 3

The decision CW/0001/2015 of the European Medicines Agency adopted on 23 July 2015 is hereby superseded and replaced by this decision.

EMADOC-1700519818-2008870
Amsterdam, 23 May 2025

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 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 CW/0001/2015 of 23 July 2015.

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 for the diagnosis of IgE-mediated allergy in all subsets of the paediatric population, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients in accordance with Article 11(1)(c) of said Regulation.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The conditions waived are set out in the Annex I.

3. The grounds for the granting of a waiver for the waived condition are set out in the Annex II.

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

Annex I

List of conditions waived

List of conditions waived

Conditions

1. the classes of androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products for treatment of breast malignant neoplasms, prostate malignant neoplasms and neuroendocrine malignant neoplasms;
2. the class of first-generation taxoid medicinal products for treatment of breast malignant neoplasms, gynaecological epithelial malignant neoplasms, prostate malignant neoplasms, intestinal malignant neoplasms, pancreatic malignant neoplasms, head and neck epithelial malignant neoplasms as well as lung malignant neoplasms;
3. the class of Ecteinascidin medicinal products for treatment of gynaecological epithelial malignant neoplasms;
4. the class of Her- / epidermal growth factor-receptor antibody medicinal products for treatment of breast malignant neoplasms, intestinal malignant neoplasms and head and neck epithelial malignant neoplasms;
5. the class of thymidylate synthase inhibitor medicinal products for the treatment of intestinal malignant neoplasms and lung malignant neoplasms;

on the ground that these classes of medicinal products are likely to be ineffective in all of the paediatric population in the concerned condition, in accordance with Article 11.1 (a) of said Regulation;

6. the class of Colchicum alkaloids (colchicine and its derivatives) medicinal products for the treatment of primary gout;
7. the class of androgen antagonist medicinal products for treatment of benign prostatic hyperplasia;
8. the class of pyrimidine- and pyrimidine analogue-containing medicinal products for treatment of breast malignant neoplasms, intestinal malignant neoplasms, lung malignant neoplasms, pancreatic malignant neoplasms, head and neck epithelial malignant neoplasms, skin malignant neoplasms and actinic keratosis;
9. the class of first- and second-generation platinum-containing medicinal products for treatment of urinary tract malignant neoplasms, head and neck epithelial malignant neoplasms and lung malignant neoplasms;
10. the class of alkylating-methylating medicinal products for treatment of skin malignant neoplasms;
11. the class of ribonucleotide reductase-beta-2 inhibitor medicinal products for treatment of myeloproliferative neoplasms;
12. the class of primarily alkylating medicinal products for treatment of myeloproliferative neoplasms and mature B, T and NK cell neoplasms;
13. the class of photosensitising medicinal products for treatment of head and neck epithelial malignant neoplasms;

14. the class of retinoic X receptor-activating medicinal products for treatment of mature B, T and NK cell neoplasms;

15. the class of immunomodulatory cytokine medicinal products for treatment of neuroendocrine malignant neoplasms, skin malignant neoplasms, myeloproliferative neoplasms and mature B, T and NK cell neoplasms;

16. all classes of medicinal products for diagnosis of IgE-mediated allergy;

on the ground that the classes of medicinal products do not represent a significant therapeutic benefit over existing treatments for paediatric patients in the concerned condition, in accordance with Article 11.1 (c) of said Regulation;

17. the class of peroxisome proliferator-activated receptor (PPAR)-gamma modulators, including dual and multiple PPAR modulator (e.g., thiazolidinediones, glitazars, triple modulators) medicinal products for treatment of type II diabetes mellitus;

on the ground that these classes of medicinal products are likely to be unsafe in all of the paediatric population in the concerned condition, in accordance with Article 11.1 (a) of said Regulation;

18. all classes of medicinal products for treatment of primary and secondary osteoarthrosis;

19. all classes of medicinal products for treatment of organic amnestic syndrome (excluding amnestic syndrome caused by alcohol and other psychoactive substances);

20. all classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema;

21. all classes of medicinal products for treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause;

22. all classes of medicinal products for treatment of Alzheimer’s disease;

23. all classes of medicinal products for treatment of erectile dysfunction;

24. all classes of medicinal products for 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);

25. all classes of medicinal products for treatment of vulvar intraepithelial neoplasia;

on the ground that the disease or condition for which the specific medicinal product is intended occurs only in adult populations, in accordance with Article 11.1 (b) of said Regulation.

Annex II

Grounds for the granting of a waiver

Grounds for the granting of a waiver

Scope

Clinical studies with medicinal products, intended to diagnose IgE-mediated allergy, are not expected to bring a significant therapeutic benefit to or to fulfil a therapeutic need of the paediatric population. This is because sensitivity and specificity of diagnostic allergens can be extrapolated from adults to children.

This will avoid unnecessary trials in the paediatric population.

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.

Medicinal products that are likely to be ineffective in the paediatric population

Class of medicinal product	**References**	**Group of conditions where the medicinal product is authorised for treatment**
Androgen receptor modulator, oestrogen receptor modulator, growth and sex hormone as well as their releasing or inhibiting factors, sex hormone-metabolism modulator medicinal products [1]	(Bourdeaut et al. 2009) (Janem et al. 2010) (Skapek et al. 2013) (Michalski et al. 2010)	• Breast malignant neoplasms • Prostate malignant neoplasms • Neuroendocrine malignant neoplasms

[1] Examples: Tamoxifen, Toremifene, Fulvestrant, Degarelix,Enzalutamide, Abiraterone, Somatostatin, Octreotide

First-generation taxoid medicinal products[2]	(Horton et al. 2008) (Norwegian Medicines Agency 2010) (Sanofi 2012) (Jacobs et al. 2010)	• Breast malignant neoplasms • Gynaecological epithelial malignant neoplasms • Prostate malignant neoplasms • Intestinal malignant neoplasms • Head and neck epithelial malignant neoplasms • Lung malignant neoplasms • Pancreatic malignant neoplasms
Her-/Epidermal growth factor-receptor antibody medicinal products[3]	(Trippett et al. 2009) (Ebb et al. 2012) (European Medicines Agency 2009)	• Breast malignant neoplasms • Intestinal malignant neoplasms • Head and neck epithelial malignant neoplasms
Ecteinascidin medicinal products	(Baruchel et al. 2012) (European Medicines Agency 2014)	• Gynaecological epithelial malignant neoplasms
Thymidylate synthase inhibitor medicinal product[4]	(Warwick et al. 2013) (Horton et al. 2005) (Malempati et al. 2007)	• Intestinal malignant neoplasms • Lung malignant neoplasms

[2] Examples: Paclitaxel, Docetaxel, Ixabepilone

[3] Examples: Trastuzumab, Pertuzumab

[4] Examples: Pemetrexed, Raltitrexed

Medicinal products that lack significant therapeutic benefit over existing treatments for paediatric population

Class of medicinal product	Reference(s)	Group of conditions where the medicinal product is used for the treatment of
Pyrimidine- and pyrimidine analogue-containing medicinal products[5]	(Kilburn et al. 2013) (Hoffmann-La Roche 2014) (Trobaugh-Lotrario & Katzenstein 2012) (Buehrlen et al. 2012)	• Breast malignant neoplasms • Intestinal malignant neoplasms • Head and neck epithelial malignant neoplasms • Lung malignant neoplasms • Pancreatic malignant neoplasms • Skin malignant neoplasms • Actinic keratosis
First- and second-generation platinum-containing medicinal products[6]	(Pizzo & Poplack 2011, p.301)	• Urinary tract malignant neoplasms • Intestinal malignant neoplasms • Head and neck epithelial malignant neoplasms • Lung malignant neoplasms
Immunomodulatory cytokine medicinal products[7]	(Buehrlen et al. 2012)	• Neuroendocrine malignant neoplasms • Skin malignant neoplasms • Myeloproliferative neoplasms • Mature B, T and NK cell neoplasms • Neuroblastoma
Photosensitising medicinal products	(Basset-Seguin et al. 2014)	• Head and neck epithelial malignant neoplasms
Colchicum alkaloids (colchicine and its derivatives)	(Medicines & Healthcare products Regulatory Agency (MHRA) 2012) (Kallinich et al. 2007)	• Primary gout • Auto-inflammatory syndromes

[5] Examples: 5-Fluorouracil, Capecitabine

[6] Examples: Cisplatin, carboplatin, oxaliplatin

[7] Examples: Interleukin 2, Interferon alpha

Alkylating-methylating medicinal products[8]	(Pizzo & Poplack 2011, pp.304, 649, 290)	• Skin malignant neoplasms • Brain tumours • Neuroblastoma • Sarcoma • Hodgkin lymphoma
Androgen antagonists[9]	(Speiser et al. 2010)	• Benign prostatic hyperplasia • Congenital adrenal hyperplasia • Hyperandrogenism
Ribonucleotide reductase beta-2 inhibitor medicinal products[10]	(Sharma et al. 2014, sec. O–079) (Pizzo & Poplack 2011, p 621)	• Myeloproliferative neoplasms • Leukaemia
Primarily alkylating medicinal products	(Pizzo & Poplack 2011, pp 290 and 299) (Michel et al. 2011)	• Myeloproliferative neoplasms • Mature B, T and NK cell neoplasms • Hodgkin lymphoma
Retinoic X receptor-activating medicinal products[11]	(Mehta et al. 2012)	• Mature B, T and NK cell neoplasms
Diagnosis of IgE-mediated allergy medicinal products	(Bousquet et al. 2012) (Ansotegui et al. 2020) (Heinzerling et al. 2013) (Riggioni et al. 2023)	• Diagnosis of IgE-mediated allergy

[8] Examples: Dacarbazine (DTIC), Temozolomide

[9] Example: Finasteride

[10] Example: Hydroxycarbamide (hydroxyurea)

[11] Examples: Bendamustine, Carmustine (BCNU); Temoporfin; Bexarotene

Previously granted, revoked and revised waivers

Condition in previous class condition waiver	**Groups of condition or condition referred to in revised class waiver**	**Class(es) of medicinal product referred to in revised class waiver**	**Scientific assessment conclusion**
Oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)	Head and neck epithelial malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Her- / epidermal growth factor-receptor antibody medicinal products	Likely ineffective
		Pyrimidine- and pyrimidine analogue-containing medicinal products	Do not represent significant therapeutic benefits
		Photosensitising medicinal products	Do not represent significant therapeutic benefits
		First- and second generation platinum-containing medicinal products	Do not represent significant therapeutic benefits
Lung carcinoma (small cell and non-small cell carcinoma)	Lung malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Thymidylate synthase inhibitor medicinal products	Likely ineffective
		First- and second-generation platinum-containing medicinal products	Do not represent significant therapeutic benefits
Basal cell carcinoma	Skin malignant neoplasm	Pyrimidine- and pyrimidine analogue-containing medicines	Do not represent significant therapeutic benefits
		Alkylating-methylating medicines	Do not represent significant therapeutic benefits
		Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits

Breast carcinoma	Breast malignant neoplasms	Androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products	Likely ineffective
		First-generation taxoid medicinal products	Likely ineffective
		Her- / epidermal growth factor-receptor antibody medicinal products	Likely ineffective
		Pyrimidine- and pyrimidine analogue-containing medicines	Do not represent significant therapeutic benefits
Ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Gynaecological epithelial malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Ecteinascidin medicinal products	Likely ineffective
Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Gynaecological epithelial malignant neoplasms	First-generation taxoid medicines	Likely ineffective
		Ecteinascidin medicinal products	Likely ineffective
Endometrial carcinoma	Gynaecological epithelial malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Ecteinascidin medicinal products	Likely ineffective
Peritoneal carcinoma (excluding blastomas and sarcomas)	Gynaecological epithelial malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Ecteinascidin medicinal products	Likely ineffective
Prostate carcinoma (excluding rhabdomyosarcoma)	Prostate malignant neoplasms	Androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-	Likely ineffective

		metabolism modulator medicinal products First-generation taxoid medicinal products	Likely ineffective
Hairy cell leukaemia	Mature B, T and NK cell neoplasms	Primarily alkylating medicinal products Retinoic X receptor-activating medicinal products Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Multiple myeloma	Mature B, T and NK cell neoplasms	Primarily alkylating medicinal products Retinoic X receptor-activating medicines Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Alzheimer's disease	Alzheimer’s disease		Confirmed
Vascular dementia and vascular cognitive disorder/impairment	Coronary atherosclerosis, peripheral atherosclerosis, vascular dementia and vascular cognitive disorder / impairment		Revocation
Organic amnesic syndrome (excluding amnesic syndrome caused by alcohol and other psychoactive substances)	Organic amnestic syndrome (excluding amnesic syndrome caused by alcohol and other psychoactive substances)		Confirmed
Amyotrophic lateral sclerosis	Amyotrophic lateral sclerosis		Revocation
Parkinson's disease (non-juvenile)	Parkinson disease (non-juvenile)		Revocation

Age-related macular degeneration	Age-related macular degeneration and diabetic macular oedema		Confirmed
Climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause	Climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause		Confirmed
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).	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)		Confirmed
Liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	Liver and intrahepatic bile duct carcinoma		Revocation
Adenocarcinoma of the pancreas	Pancreatic malignant neoplasms	First-generation taxoid medicinal products Pyrimidine- and pyrimidine analogue-containing medicines	Likely ineffective Do not represent significant therapeutic benefits
Gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)	Neuroendocrine malignant neoplasms	Androgen receptor modulators, of oestrogen receptor modulators, of growth and sex hormones as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulators Immunomodulatory cytokine medicinal products	Likely ineffective Do not represent significant therapeutic benefits

Gastric carcinoids	Neuroendocrine malignant neoplasms	Androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products	Likely ineffective
		Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits
Adenocarcinoma of the colon and rectum	Intestinal malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective
		Her- / epidermal growth factor-receptor antibody medicinal products	Likely ineffective
		Thymidylate synthase inhibitor medicinal products	Likely ineffective
		First- and second generation platinum-containing medicinal products	Do not represent significant therapeutic benefits
		Pyrimidine- and pyrimidine analogue-containing medicinal products	Do not represent significant therapeutic benefits
Ureter and bladder carcinoma	Ureter and bladder carcinoma	First- and second generation platinum-containing medicinal products	Do not represent significant therapeutic benefits
Kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)	Kidney and renal pelvis carcinoma		Revocation

Vaginal and vulvar carcinoma (excluding rhabdomyosarcoma and soft tissue sarcoma)	Gynaecological malignant neoplasms	First-generation taxoid medicinal products Ecteinascidin medicinal products	Likely ineffective Likely ineffective
Melanoma (from 0 to less than 12 years)	Skin malignant neoplasm	Pyrimidine- and pyrimidine analogue-containing medicinal products Alkylating-methylating medicinal products Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Gastric adenocarcinoma	Intestinal malignant neoplasms	First-generation taxoid medicinal products Her- / epidermal growth factor-receptor antibody medicinal products Thymidylate synthase inhibitor medicinal products First- and second generation platinum-containing Pyrimidine- and pyrimidine analogue-containing medicinal products	Likely ineffective Likely ineffective Likely ineffective Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Chronic lymphocytic leukaemia	Mature B, T and NK cell neoplasms	Primarily alkylating medicinal products Retinoic X receptor-activating medicinal products Do not represent significant therapeutic benefits	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Cervix and corpus uteri carcinoma	Gynaecological epithelial malignant neoplasms	First-generation taxoid medicinal products	Likely ineffective

		Ecteinascidin medicinal products	Likely ineffective
Follicular lymphoma	Mature B, T and NK cell neoplasms	Primarily alkylating medicinal products Retinoic X receptor-activating medicinal products Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Primary and secondary osteoarthrosis	Primary and secondary osteoarthrosis		Confirmed
Coronary atherosclerosis	Coronary atherosclerosis, peripheral atherosclerosis, vascular dementia and vascular cognitive disorder / impairment		Revocation
Peripheral atherosclerosis	Coronary atherosclerosis, peripheral atherosclerosis, vascular dementia and vascular cognitive disorder / impairment		Revocation
Huntington chorea	Huntington chorea		Revocation
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Androgen antagonist medicinal products	Do not represent significant therapeutic benefits
Erectile dysfunction	Erectile dysfunction		Confirmed
Primary gout (excluding Lesch-Nyhan syndrome and other secondary forms of gout)	Primary gout	Colchicum alkaloid (colchicine and its derivatives) medicinal products	Do not represent significant therapeutic benefits
Primary myelofibrosis	Myeloproliferative neoplasms	Ribonucleotide reductase beta-2 inhibitor medicinal products	Do not represent significant therapeutic benefits

		Primarily alkylating medicinal products Immunomodulatory cytokine medicinal products	Do not represent significant therapeutic benefits Do not represent significant therapeutic benefits
Diabetic macular oedema	Age-related macular degeneration and diabetic macular oedema		Confirmed
Mesothelioma	Lung malignant neoplasms	First-generation taxoid medicinal products Thymidylate synthase inhibitor medicinal products	Likely ineffective Likely ineffective
Actinic keratosis	Actinic keratosis	Pyrimidine- and pyrimidine analogue-containing medicines	Do not represent significant therapeutic benefits
Vulvar intraepithelial neoplasia	Vulvar intraepithelial neoplasia		Confirmed

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