27 February 2026
EMA/OD/0000301910
EMADOC-1700519818-2965037
Committee for Orphan Medicinal Products

Orphan Maintenance Assessment Report

of an orphan medicinal product submitted for marketing authorisation application

Ojemda (tovorafenib)
Treatment of glioma
EU/3/21/2434

Sponsor: Ipsen Pharma

Note

Assessment report as adopted by the COMP with all information of a commercially confidential nature deleted.

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Table of contents

1. Product and administrative information

Product	
Designated active substance	6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide
Other name	--
International Non-Proprietary Name	Tovorafenib
Tradename	Ojemda
Orphan condition	Treatment of glioma
Sponsor's details:	Ipsen Pharma 70 Rue Balard 75015 Paris France
Orphan medicinal product designation procedural history	
Sponsor/applicant	Parexel International (Irl) Limited
COMP opinion	15 April 2021
EC decision	20 May 2021
EC registration number	EU/3/21/2434
Post-designation procedural history	
Transfer of sponsorship	Transfer from Parexel International (Irl) Limited to S-cubed Pharmaceutical Services ApS – EC decision of 26 June 2023
Transfer of sponsorship	Transfer from S-cubed Pharmaceutical Services ApS to Ipsen Pharma– EC decision of 19 September 2024
Marketing authorisation procedural history	
Rapporteur / Co-rapporteur	Alexandre Moreau / Martin Mengel
Applicant	Ipsen Pharma
Application submission	26 February 2025
Procedure start	27 March 2025
Procedure number	EMA/H/C/006140
Invented name	Ojemda
Approved therapeutic indication	Ojemda is indicated as monotherapy for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies. Further information on Ojemda can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/en/medicines/human/EPAR/ojemda
CHMP opinion	26 February 2026

COMP review of orphan medicinal product designation procedural history	
COMP rapporteurs	Frauke Naumann-Winter / Cécile Dop
Sponsor's report submission	9 October 2025
COMP discussion	17-19 February 2026
COMP opinion (adoption via written procedure)	27 February 2026

2. Grounds for the COMP opinion

The COMP opinion that was the basis for the initial orphan medicinal product in designation in 2021 was based on the following grounds:

Having examined the application, the COMP considered that the sponsor has established the following:

- the intention to treat the condition with the medicinal product containing 6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide was considered justified based on preliminary clinical data showing confirmed responses in a few paediatric low grade glioma patients;
- the condition is chronically debilitating due to symptoms caused the tumour compressing the surrounding brain tissue including headache, anorexia, nausea, vomiting, seizures, neurological deficits, personality and cognitive impairment. The condition is also life-threatening, with poor 5-year survival of less than 5% for glioblastoma multiforme patients;
- the condition was estimated to be affecting approximately 2.3 in 10,000 persons in the European Union, at the time the application was made.

Thus, the requirements under Article 3(1)(a) of Regulation (EC) No 141/2000 on orphan medicinal products are fulfilled.

In addition, although satisfactory methods of treatment of the condition exist in the European Union, the sponsor has provided sufficient justification for the assumption that the medicinal product containing 6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide will be of significant benefit to those affected by the condition. The sponsor has provided preliminary clinical data that demonstrate that patients with refractory low-grade glioma responded to treatment. The Committee considered that this constitutes a clinically relevant advantage.

Thus, the requirement under Article 3(1)(b) of Regulation (EC) No 141/2000 on orphan medicinal products is fulfilled.

The COMP concludes that the requirements laid down in Article (3)(1) (a) and (b) of Regulation (EC) No 141/2000 on orphan medicinal products are cumulatively fulfilled. The COMP therefore recommends the designation of this medicinal product, containing 6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide as an orphan medicinal product for the orphan condition: treatment of glioma.

3. Review of criteria for orphan designation at the time of marketing authorisation

Article 3(1)(a) of Regulation (EC) No 141/2000

Intention to diagnose, prevent or treat a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand people in the Community when the application is made

Condition

Glioma is a collective term used to describe neoplasms derived from glial cells, a specialised cell found in the central and peripheral nervous system that functions in neuronal homeostasis. Histologically, gliomas can resemble astrocytes, oligodendrocytes, or ependymal cells; thus, on the basis of their morphologic appearance they were historically classified as astrocytomas, oligodendrogliomas, or ependymomas, respectively (Giannini et al, 2001; van den Bent et al, 2010).

The fifth edition of WHO CNS classifies 'Gliomas', 'Glioneuronal Tumours', and 'Neuronal Tumours' into 6 different families: (1) 'Adult-type diffuse gliomas' (the majority of primary brain tumours in adults); (2) 'Paediatric-type diffuse low-grade gliomas' (expected to have good prognoses); (3) 'Paediatric-type diffuse high-grade gliomas' (expected to behave aggressively); (4) 'Circumscribed astrocytic gliomas' ("circumscribed" referring to their more solid growth pattern, as opposed to the inherently "diffuse" tumours in groups 1, 2, and 3); (5) 'Glioneuronal and neuronal tumours' (a diverse group of tumours, featuring neuronal differentiation); and (6) 'Ependymomas' (Louis et al., 2021).

The majority of gliomas are sporadic, but some familial cases have been reported (<5%, Lu et al, 2016). The aetiology of sporadic gliomas is largely unknown. Several occupations, environmental carcinogens, and diet (N nitroso compounds) however have been reported to be associated with an elevated glioma risk, but the only environmental factor unequivocally associated with an increased risk of brain tumours, including gliomas, is therapeutic X-irradiation (Bondy et al, 2008; Sadetzki et al, 2005; Preston et al, 2002).

Paediatric low-grade gliomas (pLGGs) are a heterogeneous group of neoplasms that primarily comprise tumours of glial histology, including astrocytic and/or oligodendroglial, as well as tumours of mixed neuronal-glial morphology. Paediatric LGG represent the most common brain tumours in childhood, accounting for approximately 35% during the first year of life and up to 50% in older children (Roka et al, 2024, Ostrom et al, 2022). Unlike LGGs in adults which primarily arise in the cerebral hemispheres and inevitably transform to higher-grade glioma, pLGGs occur throughout the CNS, exhibit chronic and relentless growth bec(Waanders et al, 2016).

The approved therapeutic indication "Ojemda is indicated as monotherapy for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies" falls within the scope of the designated orphan condition "Treatment of glioma".

Intention to diagnose, prevent or treat

The medical plausibility is pending confirmation by the positive benefit/risk assessment of the CHMP, see EPAR.

Chronically debilitating and/or life-threatening nature

Gliomas are the most common primary intracranial tumour, representing 81% of malignant brain tumours. Median survival times decreases with increasing grade of disease and vary substantially across disease types. Among these, glioblastoma has the poorest overall survival, with only 0.05% to 4.7% of patients surviving five years past diagnosis (Ostrom et al, 2014).

LGGs are the most frequent brain tumour in children. Although pLGGs are histologically benign tumours and exhibit a 10-year overall survival comprised between 85% to 96% (Krishnatry et al, 2016; Bandopadhayay et al, 2014; Bergthold et al, 2014), they can be associated with substantial adverse effects on health, including but not limited to significant morbidity and even life-threatening consequences as a result of their capacity to occupy space within the cranium and exert effects of local infiltration (McKinney et al, 2004). Many patients suffer profound tumour- and treatment-associated morbidity, including cognitive, physical, neurological, and endocrinological deficits, leading to disability, reduced quality of life, and poorer socioeconomic outcomes (Ris et al, 2019; Strother et al, 2002).

Most children present with a few months to year's history of subtle symptoms mainly related to the location of the tumour or to chronic hydrocephalus (posterior fossa, tectal location, or subependymal giant cell astrocytoma):

- Visual symptoms are very common for the optic pathway glioma group including nystagmus, esotropia, scotoma, visual field defect, or decreased visual acuity.
- Within the suprasellar location patients often present with endocrinopathies including growth hormone deficiency and diencephalic syndrome.
- Brainstem lesions may present with Parinaud syndrome (near light dissociation, retraction nystagmus, and limited up gaze), unexplained vomiting without headache, postural hypotension, dysphagia, hoarse voice, and/or obstructive or central apnoea.
- Seizures are common in temporal or parietal locations (Scheinemann et al, 2024).

The sponsor has not identified any significant changes in the seriousness of glioma since the orphan designation was granted in 2021.

The COMP acknowledged that the condition remains chronically debilitating due to symptoms caused by the tumour compressing the surrounding brain tissue including headache, anorexia, nausea, vomiting, seizures, neurological deficits, personality changes and cognitive decline. The condition is also life-threatening.

Number of people affected or at risk

At the time of the orphan designation in 2021, the COMP concluded that glioma affected approximately 2.3 in 10,000 persons in the European Union (EU). An updated epidemiological search was conducted for this Orphan Designation Maintenance Report, covering all available data from database inception through 30 January 2026, which served as the cut-off date for data inclusion. This search incorporated established epidemiological sources, including the Global Cancer Observatory (GLOBOCAN), the Institute for Health Metrics and Evaluation, and the European Cancer Information System (ECIS), as well as a targeted review of the published literature.

The assumptions applied in this assessment are based on the Central Brain Tumors Registry US statistical report (Price et al, 2025), which provide robust and well-characterised estimates of the proportion of gliomas within both malignant and non-malignant CNS tumours. This is essential because the epidemiological data available from major cancer registries and international sources—such as the

GLOBOCAN, the ECIS, and the Global Burden of Disease Study—report only malignant CNS tumours (ICD-10 codes C70–C72). However, the therapeutic indication for this Orphan Designation encompasses all glioma subtypes, including lower-grade forms. Therefore, the proportions described by Price et al. were used to extrapolate from malignant-only registry data to an estimate that reflects the full spectrum of gliomas relevant to the indication.

- GLOBOCAN estimates that, in 2022, the 5-year prevalence of malignant brain and CNS tumours in Europe (EU-27) was 181,754 cases. Applying the non-malignant-to-malignant ratio of 2.8 reported by Price et al. (2025), the estimated total number of CNS tumours is 508,958 cases, corresponding to a prevalence of 11.4 per 10,000 persons (based on a population of 445,181,229). Assuming, as per Price, that gliomas account for 20.8% of all brain/CNS tumours, the resulting estimated prevalence of glioma in the EU-27 is approximately 2.4 per 10,000 persons.
- ECIS estimates that, in 2020, the prevalence of malignant brain and neuroepithelial tumours in Europe (EU-27) was 227,061 cases. Applying the benign-to-malignant ratio of 2.8 reported by Price et al. (2025), the estimated total number of CNS tumours (non-malignant and malignant) is approximately 635,771 cases, corresponding to a prevalence of 14.2 per 10,000 persons (based on a population of 447,300,000). Assuming that gliomas represent 20.8% of all brain/CNS tumours, the resulting estimated prevalence of glioma in the EU-27 is approximately 2.96 per 10,000 persons.

A systematic literature search was conducted in PubMed, Embase, and Scopus to identify studies reporting the incidence and/or prevalence of glioma in European populations across all age groups. A total of 16 articles meeting eligibility criteria were identified. An overview of the key results across all reviewed studies is provided in Table.

Table 1. Incidence and Estimated Prevalence in Europe of the condition "treatment of glioma"

Reference	Source	Country	Data Collection Year	Incidence /100,000	Estimate Prevalence /10,000
Bauchet et al 2025	French Brain Tumor DataBase	France	2016-2024	6.6	3.21[a]
Skaga et al 2024	Cancer Registry of Norway	Norway	2002-2021	7.4	3.60[a]
Sharifian et al 2024	Nationwide registries	Norway	2004-2021	7.1	3.45[a]
Pinson et al 2023	Belgian cancer registry	Belgium	2017-2019	8.55	2.56[b]
Pierri et al 2022	South Sardinia	Italia	2016-2019	6.62	3.22[a]
Wanner et al 2020	Cancer Registry Zurich	Switzerland	2009-2012	8.22	3.99[a]
Defossez et al 2019	French Brain Tumour Database	France	2018	2.74	1.33[a]
Rasmussen et al 2017	DNOR	Denmark	2009-2014	7.3	3.55[a]
Fuentes-Raspall et al 2017	Girona Cancer Registry	Spain	1994-2013	7.45	4.36[a]
Gatta et al 2017	EUROCARE-5[c]	Europe	2000-2007	5.59	2.71[b]
Busco et al 2015	AIRTUM	Italia	2015	5.53	3.85[b]
Ho et al 2014	Danish Neuro-Oncology Registry (DNOR)	Denmark	2010	5.9	2.09[a]
Crocetti et al 2012	RARECARE	Europe	1995-2002	5.4	2.62[b]
Baldi et al 2011	Gironde Registry	France	2000-2007	7.86	3.82[a]
Gousias et al 2009	Northwest Greece	Greece	2005-2007	5.73	2.78[a]
Wöhrer et al 2009	Austrian Brain Tumour Registry	Austria	2005	6.89	3.35[a]

[a] In the absence of specific prevalence data for glioma in large populations, a crude approximation may be employed as a provisional measure. In the event that the mean duration of disease and the population of patients remain constant, the prevalence can be estimated by the incidence (I) and the mean duration of disease (D) using the following equation: Prevalence (P) can be approximated by the product of incidence (I) and mean duration of disease (D). In accordance with the findings of Crocetti et al. (2012), the estimated incidence rate for glioma was 5.35 per 100,000 person-years, while the prevalence rate was 26 per 100,000 individuals. On the basis of the survival data, a crude approximation of the mean duration of glioma may be calculated as follows: (26/100,000 persons / 5.35/100,000 person-years)=4.86 years.
[b] Complete prevalence provided by the authors.
[C] None of the literature based on EUROCARE-6 was in line with the systematic literature search presented above.

The sponsor concluded that considering the available evidence, and based on the most recent data, the prevalence of glioma is estimated to **2.2 per 10,000 individuals**, which represents a minor change compared to the initial prevalence in the ODD (2.3 in 10,000 individuals).

The COMP concluded that the figure of 2.95 from ECIS should be adopted and rounded it to approximately 3 in line with the most recently adopted figure.

Article 3(1)(b) of Regulation (EC) No 141/2000

Existence of no satisfactory methods of diagnosis prevention or treatment of the condition in question, or, if such methods exist, the medicinal product will be of significant benefit to those affected by the condition.

Existing methods

In pLGG, the goals of therapy have historically been to preserve function and to limit the need for aggressive, therapies (i.e. chemotherapy and radiation) by controlling growth of the tumour which may be associated with high morbidity. Paediatric LGGs are therefore treated through a combination of approaches tailored to each patient's needs:

- Surgery is often the first step, with complete resection being the most favourable predictor of patient outcome. For approximately 50% of patients, this single surgical approach is curative (Tihan et al, 2012). However, complete resection is not always feasible, especially for highly infiltrative or deep-seated tumours which have a high risk of functional impact if the tumour is completely removed.
- For patients whose disease recurs after surgery or for whom surgery was not an option, chemotherapy is commonly used in first line therapy, especially in younger children, to avoid the long-term effects of radiation therapy. There are no approved chemotherapy regimens for pLGG, but carboplatin and vincristine are a widely used combination (Ater et al, 2012; Gnekow et al, 2019), as well as single agent vinblastine (Lassaletta et al, 2016). Chemotherapies are associated with low response rates: the largest study of chemotherapy in the recurrent/refractory population was performed with single-agent vinblastine, which resulted in an ORR of 21% (one CR, 10 PR, out of 51 patients; Bouffet et al, 2012). Chemotherapies also have many associated toxicities, including risks for myelosuppression, peripheral neuropathy, allergic/anaphylactic reaction, constipation, sodium dysregulation, secondary malignancy, and renal and hepatic dysfunction. Chemotherapeutic agents also require intravenous (IV) infusion combined with the use of indwelling catheter (such as a portocath or a long line) (Gnekow et al, 2019).
- Targeted therapies, such as BRAF and mitogen-activated extracellular signal-regulated kinase (MEK) inhibitors, are increasingly used for tumours with specific genetic mutations. Recently, the combination of dabrafenib plus trametinib received US FDA approval (March 2023) and EU approval (November 2023) for the treatment of paediatric patients one year of age and older with LGG harbouring a BRAF V600E mutation who require systemic therapy (Finlee SmPC; Spexotras SmPC). This indication is restricted to tumours with a BRAF V600E mutation and does not cover other more frequent BRAF alterations.
- Importantly, for patients with relapsed or recurrent pLGG with BRAF fusions or without BRAF alterations, there are currently no approved agents and there is no established SoC. Chemotherapy may be attempted again, or a targeted therapy may be offered in clinical studies (Bouffet et al, 2012).
- Radiotherapy is typically reserved as a last resort, particularly for older paediatric patients (>seven years) in the salvage setting, as radiation has been associated with cognitive decline, endocrine deficiencies, secondary malignancies/malignant transformation, vascular damage, and growth abnormalities in survivors of paediatric brain tumours (de Blank et al, 2019).

The sponsor also presented a table with the medicinal products authorised for the treatment of glioma. The table has been revised to include all the medicinal products authorised for glioma and the

conclusion on whether they should be considered as satisfactory methods based on the authorised indications.

Table 2. Summary of authorised medicinal products in the EU for the treatment of gliomas

INN (tradename)	**Authorised Indication**	**Satisfactory method**
Carmustine (Carmustine Medac)	Carmustine alone or in combination with other antineoplastic agents and/or other therapeutic measures (radiotherapy, surgery) for the treatment of adult patients with brain tumours (glioblastoma, brain-stem gliomas, medulloblastoma, astrocytoma and ependymoma), brain metastases.	No: Carmustine's indication is limited to adult patients with brain tumours. Tovorafenib's proposed indication is for patients 6 months of age and older with paediatric low-grade glioma.
Carmustine wafers (Gliadel)	Treatment of adult patients with newly diagnosed high-grade malignant glioma as an adjunct to surgery and radiation. Adjunct to surgery for the treatment of adult patients with recurrent histologically proved glioblastoma multiforme and for whom surgical resection is indicated.	No: Carmustine's indication is limited to adult patients with high grade glioma and glioblastoma. Tovorafenib's proposed indication is for patients 6 months of age and older with paediatric low-grade glioma.
Lomustine (Medac)	As palliative or supplementary treatment, usually in combination with radiotherapy and/or surgery as part of multiple drug regimens in brain tumours (primary or metastatic)	No. Theuse of lomustine in paediatric LGG is limited to multidrug combination therapy in a third- or fourth line setting.
Temozolomide (Temodal)	Treatment of: adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as monotherapy treatment. Children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.	No: Temozolomide is indicated for patients from the age of three years with glioblastoma multiforme or anaplastic astrocytoma whereas tovorafenib's proposed indication is for patients 6 months of age and older with paediatric low-grade glioma harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies.
Procarbazine	- Treatment of adult patients with brain tumours - Treatment in combination with lomustine and vincristine in adult patients with anaplastic oligodendroglial tumours in addition to radiotherapy as part of primary therapy	No: Procarbazine's indication is limited to adult patients. Tovorafenib's proposed indication is for patients 6 months of age and older with paediatric low-grade glioma.

Vincristine	As a component of various chemotherapy regimens to treat a variety of cancers including that of the brain.	No: Vincristine is indicated as a component of various chemotherapy regimens to treat a variety of cancers including that of the brain which may comprise pLGGs (which overlaps with tovorafenib's proposed indication). However, vincristine cannot be considered as satisfactory method since it is recommended as standard of care for earlier lines of treatment such as first line combination treatment
Dabrafenib (Finlee) Trametinib (Spexotras)	LGG: Dabrafenib (Finlee) in combination with trametinib (Spexotras) is indicated for the treatment of paediatric patients aged one year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. HGG: Dabrafenib (Finlee) in combination with trametinib (Spexotras) is indicated for the treatment of paediatric patients aged one year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment.	No: The indication of dabrafenib/trametinib overlaps with tovorafenib for patients harbouring BRAF V600 mutation but does not cover patients with BRAF fusion or rearrangement. In addition, tovorafenib's proposed indication is for patients 6 months of age which is broader than the indication of dabrafenib/trametinib which covers paediatric patients aged one year and older
Vorasidenib (Voranigo)	Voranigo as monotherapy is indicated for the treatment of predominantly non-enhancing Grade 2 astrocytoma or oligodendroglioma with an IDH1 R132 or IDH2 R172 mutation in adult and adolescent patients aged 12 years and older and weighing at least 40 kg who only had surgical intervention and are not in immediate need of radiotherapy or chemotherapy.	No: Vorasidenib is indicated for adult-type diffuse gliomas with an IDH1-R132 mutation or IDH2-R172 mutation. Tovorafenib's proposed indication is for patients 6 months of age and older with pLGG harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation.

Abbreviations: BRAF=v-raf murine sarcoma viral oncogene homolog B; EU=European Union; HGG=high grade gliomas; INN= International Nonproprietary Names; LGG=low-grade gliomas; MAH=marketing authorization holder.

However, the COMP agreed that vincristine cannot be considered as satisfactory method since it is recommended as standard of care for earlier lines of treatment such as first line combination treatment (Roka 2024, Gnekow 2019). In addition, for lomustine, the indication is based on older, broad usage and it is not referenced in current treatment guidelines, hence it is difficult to consider a satisfactory therapeutic option. In addition, use of lomustine in paediatric LGG is limited to multidrug combination therapy in a third- or fourth line setting.

In conclusion no satisfactory method has been authorised for the entirety of the patient population targeted by tovorafenib for patients affected by the condition.

Significant benefit

Not applicable.

4. COMP position adopted on 27 February 2026

The COMP concluded that:

- the proposed therapeutic indication falls entirely within the scope of the orphan condition of the designated Orphan Medicinal Product.
- the prevalence of glioma (hereinafter referred to as "the condition") was estimated to remain below 5 in 10,000 and was concluded to be approximately 3 in 10,000 persons in the European Union, at the time of the review of the designation criteria;
- the condition is chronically debilitating due to symptoms caused by the tumour compressing the surrounding brain tissue including headache, anorexia, nausea, vomiting, seizures, neurological deficits, personality changes and cognitive decline. The condition is also life-threatening, with a limited median overall survival;
- at present, no satisfactory method has been authorised for the entirety of the patient population targeted by tovorafenib in the European Union for patients affected by the condition.

The COMP, having considered the information submitted by the sponsor and on the basis of Article 5(12)(b) of Regulation (EC) No 141/2000, is of the opinion that:

- the criteria for designation as set out in the first paragraph of Article 3(1)(a) are satisfied;
- the criteria for designation as set out in Article 3(1)(b) are satisfied.

The Committee for Orphan Medicinal Products has recommended that Ojemda, 6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide, tovorafenib for treatment of glioma (EU/3/21/2434) is not removed from the Community Register of Orphan Medicinal Products.