Reports of Cases

JUDGMENT OF THE GENERAL COURT (Tenth Chamber)

23 September 2020 *

(Medicinal products for human use – Orphan medicinal products – Application for marketing authorisation for the medicinal product Trecondi-treosulfan – Decision to remove a medicinal product from the Register of Orphan Medicinal Products – Article 3(1)(b) of Regulation (EC) No 141/2000 – Concept of 'satisfactory method' – Article 5(12)(b) of Regulation No 141/2000 – Error of law)

In Case T-549/19,

Medac Gesellschaft für klinische Spezialpräparate mbH, established in Wedel (Germany), represented by: P. von Czettritz, lawyer,

applicant,

v

European Commission, represented by B.-R. Killmann and A. Sipos, acting as Agents,

defendant,

ACTION under Article 263 TFEU seeking the partial annulment of Commission Implementing Decision C(2019) 4858 final of 20 June 2019 granting marketing authorisation for the medicinal product for human use Trecondi-treosulfan,

THE GENERAL COURT (Tenth Chamber),

composed of A. Kornezov (Rapporteur), President, J. Passer and G. Hesse, Judges,

Registrar: E. Coulon,

gives the following

Judgment [1]

Background to the dispute

1 By decision of the Commission of the European Communities of 23 February 2004, a potential treosulfan-based medicinal product, sponsored by the applicant, Medac Gesellschaft für klinische Spezialpräparate mbH, was designated as an orphan medicinal product and entered into the European Union Register of Orphan Medicinal Products in accordance with Regulation (EC) No 141/2000 of the

* Language of the case: German.

1 Only the paragraphs of the present judgment which the Court considers it appropriate to publish are reproduced here.

European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1) ('the 2004 designation decision') for the following therapeutic indication: 'conditioning treatment prior to haematopoietic progenitor cell transplantation'.

2 On 13 October 2017, the applicant submitted to the European Medicines Agency (EMA) and, more specifically, to the Committee for Orphan Medicinal Products provided for in Article 4 of Regulation No 141/2000 ('the COMP'), a report on the maintenance of the designation of treosulfan as an orphan medicinal product at the time when the market authorisation (MA) was granted.

…

4 On 8 November 2018, in the context of the procedure initiated by the applicant's report of 13 October 2017 on the maintenance of the designation of treosulfan as an orphan medicinal product at the time when the MA was granted, the COMP forwarded to the applicant a provisional opinion on the maintenance of that designation ('the provisional opinion of 8 November 2018'). In that opinion, the COMP found that the prevalence criterion set out in Article 3(1)(a) of Regulation No 141/2000 was satisfied, that is to say, that that medicinal product was intended for the treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the European Union at the time when the application is made. As regards the existence of a significant benefit within the meaning of Article 3(1)(b) of Regulation No 141/2000, that committee found that the applicant had to establish the existence of such a benefit in comparison with the medicinal products busulfan (Busilvex) and thiotepa (Tepadina) as well as with melphalan- and cyclophosphamide-based medicinal products authorised at national level.

…

7 On 19 December 2018, the COMP adopted an opinion on the maintenance of the designation of Trecondi-treosulfan as an orphan medicinal product at the time when the MA was granted, in which it concluded that the applicant had established that Trecondi-treosulfan would be of significant benefit in comparison with busulfan (Busilvex) and thiotepa (Tepadina) but not in comparison with melphalan- and cyclophosphamide-based medicinal products.

8 On 19 March 2019, the applicant requested that the COMP re-examine its opinion of 19 December 2018 in accordance with Article 5(7) of Regulation No 141/2000. To that end, it submitted new analyses comparing Trecondi-treosulfan with melphalan- and cyclophosphamide-based treatments.

9 On 8 May 2019, the COMP adopted its final opinion on the maintenance of the designation of Trecondi-treosulfan as an orphan medicinal product at the time when the MA was granted ('the COMP's final opinion'), in which it confirmed the conclusions reached in its opinion of 19 December 2018. In particular, it found that the analyses submitted by the applicant in its request for re-examination of 19 March 2019 were not sufficiently reliable and, consequently, maintained its position that, in its view, the applicant had not established that Trecondi-treosulfan provided a significant benefit in comparison with melphalan- and cyclophosphamide-based medicinal products. Therefore, according to the COMP's final opinion, the conditions of Article 3(1)(b) of Regulation No 141/2000 were not fulfilled at the time when the MA was granted, which is why the Committee recommended to the Commission not to maintain the designation of Trecondi-treosulfan as an orphan medicinal product at the time when the MA was granted.

10 On 20 June 2019, the Commission adopted Decision C(2019) 4858 final granting an MA, under Regulation No 726/2004, for Trecondi-treosulfan, a medicinal product for human use ('the contested decision'). Article 1 of that decision states that 'the [MA] provided for in Article 3 of Regulation … No 726/2004 is granted for the medicinal product "Trecondi-treosulfan", the characteristics of which are summarised in Annex I to [that] decision' and that that medicinal product 'is registered in the … Union register of medicinal products under number EU/1/18/1351'.

11 However, on the basis of the COMP's final opinion, the Commission decided that Trecondi-treosulfan no longer met the criteria for designation established in Article 3 of Regulation No 141/2000 and that, therefore, it could not be designated as an orphan medicinal product (recital 4 of the contested decision). Consequently, Article 5 of the contested decision states that 'the medicinal product "Trecondi-treosulfan" is not to be classified as an orphan medicinal product' and that 'the [European Union] Register of Orphan Medicinal Products should be updated accordingly'.

Procedure and forms of order sought

12 By application lodged at the Court Registry on 8 August 2019, the applicant brought the present action.

13 On the same day, the applicant submitted an application for interim measures, which was rejected by order of 26 September 2019, *Medac Gesellschaft für klinische Spezialpräparate* v *Commission* (T-549/19 R, not published, EU:T:2019:695), confirmed by order of 26 February 2020, *Medac Gesellschaft für klinische Spezialpräparate* v *Commission* (C-832/19 P(R), not published, EU:C:2020:112).

14 On 18 October 2019, the Commission lodged its defence.

15 On 23 April 2020, the Court requested the parties, in the context of the measures of organisation of procedure provided for in Article 89 of its Rules of Procedure, to answer a number of questions ('the first MOP').

16 On 12 May 2020, the applicant informed the Court that it no longer wished to be heard at a hearing and requested the Court to allow it to submit written observations.

17 On 8 June 2020, the parties lodged their replies to the questions asked in the first MOP ('the replies to the first MOP').

18 On 18 June 2020, the Court requested the parties, in the context of the measures of organisation of procedure provided for in Article 89 of the Rules of Procedure, to submit their observations, including observations on the replies to the first MOP. The applicant complied with that request on 2 July 2020 and the Commission on 15 July 2020.

19 The applicant claims that the Court should:

– annul Article 5 of the contested decision;

– order the Commission to pay the costs.

20 The Commission contends that the Court should:

– dismiss the action as unfounded;

– order the applicant to pay the costs.

21 In the absence of a corresponding request made by the parties within three weeks after service of notification of the close of the written part of the procedure, the Court, on 17 July 2020, considering that it had sufficient information available to it from the material in the file, decided, pursuant to Article 106(3) of the Rules of Procedure, to give its ruling without an oral part of the procedure.

22 By document lodged at the Court Registry on 18 August 2020, the applicant submitted further evidence in support of the third and fifth pleas under Article 85 of the Rules of Procedure and, in the alternative, a new plea in law under Article 84 of the Rules of Procedure. It also requested the reopening of the oral part of the procedure under Article 113(2) of the Rules of Procedure. The Court decided not to reopen that part of the procedure, as none of the conditions provided for in Article 113(2) of the Rules of Procedure was met in the present case. In particular, the applicant's further evidence and new arguments were not, the Court found, of such a nature as to have a decisive bearing on the decision of the Court for the reasons set out below.

Law

23 In support of its action, the applicant relies on five pleas in law, alleging, first, a manifest error of law in the interpretation of the concept of 'satisfactory method' for the purposes of Article 3(1)(b) of Regulation No 141/2000; second, a misuse of powers and failure to comply with the Commission notice of 18 November 2016 on the application of Articles 3, 5 and 7 of Regulation No 141/2000 (OJ 2016 C 424, p. 3; 'the 2016 Commission notice'); third, breach of the principles of equal treatment and of the protection of legitimate expectations in so far as the Commission relied on a broader definition of the orphan condition covered by the medicinal product Trecondi-treosulfan than that initially adopted; fourth, a manifest misuse of powers resulting from the refusal to accept and the rejection of the comparison data that the applicant had supplied; and, fifth, a misuse of powers on account of a breach of the principle of equal treatment because of the rejection of the indirect comparison data.

…

The first and second pleas in law

…

Substance

49. Article 3(1)(b) of Regulation No 141/2000 provides for alternative criteria for the designation of a medicinal product as an orphan medicinal product, namely that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the European Union (first alternative), or, if such a method exists, that the medicinal product in question will be of significant benefit, compared with existing satisfactory methods, to those affected by that condition (second alternative).

50 The concept of 'condition' to which Article 3(1)(b) of Regulation No 141/2000 refers is that defined by Article 3(1)(a) of that regulation, that is to say, a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the European Union at the time when the application is made.

51 In the present case, as has been noted in paragraph 9 above, the COMP found that the applicant had established that Trecondi-treosulfan would be of significant benefit in comparison with busulfan (Busilvex) and thiotepa (Tepadina) but not in comparison with melphalan- and cyclophosphamide-based medicinal products. In that context, the applicant takes the view, in essence, that melphalan- and cyclophosphamide-based medicinal products are not, regard being had to their respective Summaries of Product Characteristics (SmPCs), 'satisfactory methods' for the treatment of the orphan condition covered by Trecondi-treosulfan and that, consequently, the COMP erred in rejecting the designation criterion laid down in the first alternative of Article 3(1)(b) of Regulation No 141/2000.

52 In that regard, it must be stated that, in order for a medicinal product to be classified as a 'satisfactory method' within the meaning of Article 3(1)(b) of Regulation No 141/2000, it must be 'authorised' in the European Union or in a Member State of the European Union for the same orphan 'condition' as that covered by the medicinal product for which an MA as an orphan medicinal product is sought.

53 According to Article 2(3), second subparagraph, heading (a), of Regulation No 847/2000, '[satisfactory methods] may include authorised medicinal products, medical devices or other methods of diagnosis, prevention or treatment which are used in the [European Union]', that method must, in addition, cover 'the condition in question' or 'that condition'.

54 For the purposes of determining the scope of authorisation of a medicinal product in the European Union, it must be recalled, first of all, that, under the first subparagraph of Article 6(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), 'no medicinal product may be placed on the market of a Member State unless an [MA] has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation [No 726/2004]'. The second subparagraph of Article 6(1) of that directive provides, in the case where a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, as follows:

'Any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial [MA]. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).'

55 Next, with a view to the grant of an MA at national level, an application must be made to the competent authority of the Member State concerned. That application must include an SmPC, pursuant to Article 8(3)(j) of Directive 2001/83. According to Article 11 of that directive, the SmPC must contain a set of information on the medicinal product in question in the order specified by that provision, such as therapeutic indications (point 4.1), posology and method of administration for adults and, where necessary, for children (point 4.2) and the 'date of revision of the text' of the SmPC (point 10). In accordance with Article 21(1) of Directive 2001/83, when the MA is issued, the holder is to be informed, by the competent authorities of the Member State concerned, of the SmPC as approved by it.

56 Finally, after an MA has been granted, Article 23(3) of Directive 2001/83 requires the MA holder to ensure that the product information is kept up to date with, in particular, the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation No 726/2004.

57 Thus, the scope of the authorisation of the existing medicinal product is defined in the decision granting the MA, of which the SmPC of the medicinal product in question forms part, as it might be updated at the time of the MA application for an orphan medicinal product.

58 It follows, first, that the off-label use of a medicinal product cannot be regarded, in the light of the foregoing, as being 'authorised' and that, consequently, a medicinal product used off-label cannot constitute a 'satisfactory method … that has been authorised in the [European Union]' within the meaning of Article 3(1)(b) of Regulation No 141/2000.

59 That finding is corroborated by the 2016 Commission notice, point B.4 of which, entitled 'Satisfactory method authorised in the Union', provides in its third and fourth subparagraphs as follows:

'Medicinal products taken into consideration should be authorised for the treatment of the disease as such or, at the very least, address exactly the same set of symptoms.

Any reference to an authorised medicinal product must be limited to the terms of the [MA]. Therefore, a product that is administered or applied outside the approved summary of product characteristics ("off-label" use) cannot be considered a satisfactory method for the purposes of Article 3(1)(b).'

60 That finding, moreover, is not disputed by the parties. In particular, the Commission accepts, in its defence, that an off-label use cannot be regarded as a satisfactory method.

61 Second, in order to determine whether the existing method referred to covers the same 'condition' as that covered by the orphan medicinal product which forms the subject of the application, account must be taken of all the essential elements surrounding authorised use of the existing method, and in particular its therapeutic indication and its target population, as defined in its SmPC.

62 In that regard, it must be stated that a medicinal product's SmPC cannot but be interpreted strictly. Before granting an MA, including in the context of the variation or extension of an existing MA, the competent authority must ensure, on the basis of the documents and particulars provided by the sponsor, that potential risks are outweighed by the therapeutic efficacy of the medicinal product (see recital 7 and Article 26 of Directive 2001/83). Likewise, according to recital 14 of Regulation No 726/2004, 'the quality, safety and efficacy criteria in Directives 2001/83/EC and 2001/82/EC … should [make it] possible to assess the risk-benefit balance of all medicinal products when they are placed on the market, at the time of the renewal of the authorisation and at any other time the competent authority deems appropriate'.

63 To that end, as has been pointed out in paragraph 54 above, the second subparagraph of Article 6(1) of Directive 2001/83 provides that any variations and extensions to an existing MA are also to be granted an authorisation in accordance with the first subparagraph of that provision or be included in the initial MA, while Article 23(3) of Directive 2001/83 requires the holder of a medicinal product that has already been authorised to keep the information on that medicinal product up to date with current scientific knowledge.

64 It follows that any variation to the SmPC, far from being a formality, must be further assessed in relation to the benefit/risk balance and the quality, safety and efficacy of the medicinal product for a proposed new indication must be subject, as appropriate, to clinical tests.

65 Therefore, the MA for a medicinal product does not extend to the diagnosis, prevention or treatment of conditions or categories of patients not mentioned in its SmPC.

66 Third, it must be stated that, where the medicinal product which is the subject of an application for an MA as an orphan medicinal product is intended for the diagnosis, prevention or treatment of conditions or categories of patients for which, at least in part, the reference medicinal products are not authorised, according to their respective SmPCs, those latter medicinal products cannot be regarded as being 'satisfactory methods' for those conditions or for those categories of patients.

67 Regard being had to the fact that some conditions occur so infrequently that the pharmaceutical industry would be unwilling to develop medicinal products to diagnose, prevent or treat them under normal market conditions (recital 1 of Regulation No 141/2000) and that the purpose of Regulation No 141/2000, set out in Article 1 thereof, is precisely to provide incentives for the research, development and placing on the market of medicinal products intended to treat such conditions, the

exclusion of a potential medicinal product from the benefits provided for by Regulation No 141/2000 on the ground that 'satisfactory methods' exist only for a portion of the rare conditions covered by it is contrary to the intended purpose.

68 In addition, it must be emphasised that Article 7(3) of Regulation No 141/2000 allows, specifically when an MA is granted for an orphan medicinal product, account to be taken of cases of partial overlap with MAs for other medicinal products, where it provides that 'the [MA] granted for an orphan medicinal product shall cover only those therapeutic indications which fulfil the criteria set out in Article 3' and that 'this is without prejudice to the possibility of applying for a separate [MA] for other indications outside the scope of this Regulation'. Thus, in so far as certain therapeutic indications for a medicinal product fulfil the criteria for designation set out in Article 3 of Regulation No 141/2000, that medicinal product is, in principle, eligible to be designated as an orphan medicinal product for those indications, whereas, as regards the indications in respect of which it does not fulfil the criteria set out in Article 3 of that regulation, a separate MA may be granted, outside the scope of Regulation No 141/2000.

69 It is in the light of the foregoing that it is thus appropriate to examine whether, in the present case, the treatment of the orphan condition and the categories of patients targeted by Trecondi-treosulfan are also covered by melphalan- and cyclophosphamide-based medicinal products, according to their respective SmPCs.

70 In that regard, it should be noted that, according to point 4.1 of the SmPC of Trecondi-treosulfan, annexed to the contested decision, 'treosulfan is indicated in combination with fludarabine as part of conditioning treatment prior to an allogeneic [HSC] transplantation in adult patients suffering from malignant and non-malignant pathological conditions and in paediatric patients over the age of one month, suffering from malignant pathological conditions'.

71 According to the explanations provided by the applicant in paragraph 6 to 9 of the application, which are not disputed by the Commission, the term 'HSC transplantation' designates the transfer of blood stem cells from a donor to a recipient which is carried out in the case of malignant haematological diseases concerning the patient's haemopoietic system and in the case of certain non-malignant conditions. As regards blood stem cell collection from the donor, there are three types, namely collection of blood stem cells from bone marrow, from peripheral stem cells or from umbilical cord blood. The term 'conditioning treatment' then designates the treatment prior to blood stem cell transplantation. The purpose of conditioning prior to a blood stem cell transplantation is, first, the induction of an immunosuppression in the patient in order to ensure the regenerative phase of blood formation following an allogeneic transplantation and to prevent primary transplantation failure, second, the anti-leukaemic effectiveness, in order to eliminate as many malignant cells as possible, and, third, the induction of a myelosuppression (bone marrow suppression) in order to 'make space' for the donor's stem cells before being transplanted. In addition, a distinction must be drawn between an autologous HSC transplantation, in which the donor and the recipient are the same person, and an allogeneic stem cell transplantation, in which the recipient receives cells from another healthy person.

72 Following that clarification, it must be stated that the SmPCs of the medicinal products which are being compared show clear differences, some of which are not disputed by the parties.

73 In the first place, as regards the pathological conditions treated respectively by Trecondi-treosulfan and by the melphalan-based medicinal products, it must be observed, first, that, according to the wording of point 4.1 of the SmPC of Trecondi-treosulfan, that medicinal product is authorised for conditioning treatment prior to an HSC transplantation without restriction as regards the pathological conditions which that treatment seeks to remedy. By contrast, according to the SmPC of the melphalan-based medicinal product authorised in Germany, placed in the file by the applicant, this covers treatment 'irrespective of whether or not' an HSC transplantation is carried out in patients who suffer only from certain pathological conditions which are listed exhaustively in the SmPC.

Similarly, the SmPC of that medicinal product, as authorised in France, contains an exhaustive list of pathological conditions and makes it clear that, beyond a certain dose, 'an autologous blood stem cell transplantation is necessary'.

74 It follows that, whereas melphalan-based medicinal products are authorised only for the treatment of patients who suffer from pathological conditions which are listed exhaustively in the SmPCs, Trecondi-treosulfan is authorised not only for patients suffering from those pathological conditions, for example, multiple myeloma or neuroblastoma in children, but also for patients who suffer from other pathological conditions not covered by the SmPC of melphalan-based medicinal products. That finding is not disputed by the Commission. In its reply to the first MOP, the Commission confirmed that the MA for Trecondi-treosulfan covered the treatment not only of the pathological conditions referred to in the SmPCs of melphalan- and cyclophosphamide-based medicinal products but also of pathological conditions which were not indicated there, such as myelodysplastic syndrome, a condition which is also included among those which are the subject of a clinical study under reference MC-FludT.14/L on which the applicant based its MA application.

75 Second, the Commission also does not dispute that the medicinal products in question differ as regards their target populations. Thus, as the applicant claims, Trecondi-treosulfan is indicated, according to its SmPC, for treatment prior to an allogeneic HSC transplantation in paediatric patients older than one month who suffer from malignant pathological conditions. By contrast, the SmPCs of melphalan-based medicinal products are indicated in children for only one pathological condition, namely neuroblastoma.

76 In that regard, it must be emphasised that the EU legislature attaches particular importance to the availability of medicinal products for paediatric use in the European Union. To that end, it adopted 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 No 726/2004 (OJ 2006 L 378, p. 1) which seeks, as is clear from recital 4 thereof, first, to facilitate the development and accessibility of medicinal products for use in the paediatric population, second, to ensure that medicinal products used to treat the paediatric population are subject to research of high quality, in accordance with ethical rules, and are appropriately authorised for use in the paediatric population, and, third, to improve the information available on the use of medicinal products in the various paediatric populations. In order to achieve those aims, Regulation No 1901/2006 provides a mechanism for compelling pharmaceutical companies to envisage as a matter of course the possibility of the paediatric use of the medicinal products that they develop (judgment of 14 December 2011, *Nycomed Danmark* v *EMA*, T-52/09, EU:T:2011:738, paragraph 43). It follows that the information concerning the paediatric populations contained in the SmPCs of the medicinal products which are being compared is of particular importance, including in the analysis of whether a 'satisfactory method' exists within the meaning of Article 3(1)(b) of Regulation No 141/2000.

77 In the second place, as regards the comparison between Trecondi-treosulfan and cyclophosphamide-based medicinal products, first, it must be noted that, according to the SmPCs for the latter medicinal products, as authorised in Germany, which have been placed in the file by the applicant, they are indicated, other than for chemotherapy treatment of certain conditions, for 'conditioning prior to bone marrow transplantation' in the case of certain pathological conditions that are exhaustively listed (severe aplastic anaemia; acute myeloid leukaemia and acute lymphoblastic leukaemia; chronic myelogenous leukaemia), in contrast, therefore, to the SmPC of Trecondi-treosulfan which covers conditioning treatment prior to an HSC transplantation for all types of malignant and non-malignant pathological conditions in adults. Thus, by way of example, the SmPCs of the cyclophosphamide-based medicinal products do not cover myelodysplastic syndrome or non-malignant pathological conditions in adults, whereas Trecondi-treosulfan does. The Commission does not dispute those differences.

78 Second, the Commission also does not dispute that the medicinal products in question differ as regards their target populations. Whereas the SmPCs of cyclophosphamide-based medicinal products refer only to the treatment of rhabdomyosarcoma in children, the SmPC of Trecondi-treosulfan covers all malignant pathological conditions in children above the age of one month.

79 It is clear from paragraphs 69 to 78 above that the SmPC of Trecondi-treosulfan covers pathological conditions and populations which are not covered by the SmPCs of melphalan- and cyclophosphamide-based medicinal products.

80 It follows that, for those pathological conditions and populations, melphalan- and cyclophosphamide-based medicinal products cannot be regarded as satisfactory methods within the meaning of the first alternative of Article 3(1)(b) of Regulation No 141/2000.

81 It is true, as the Commission notes, that there is a partial overlap between the conditions and the populations covered by the medicinal products which are being compared. However, the fact remains that Trecondi-treosulfan is indicated for conditioning treatment prior to an allogeneic HSC transplantation in the case of certain pathological conditions and certain categories of patients, for the treatment of which melphalan- and cyclophosphamide-based medicinal products are not indicated. In respect of those pathological conditions and patients, those medicinal products are not authorised, with the result that they cannot be regarded as being 'satisfactory methods', in accordance with the reasoning set out in paragraphs 69 to 78 above.

…

90 In the light of all of the foregoing, the first and second pleas in the action must be upheld and, without it being necessary to examine the fourth and fifth pleas in the action, as well as the admissibility or the merits of a possible new alternative plea raised by the applicant in its request of 18 August 2020, including the new offers of evidence presented on that date (see paragraph 22 above), Article 5 of the contested decision must be annulled.

…

On those grounds,

THE GENERAL COURT (Tenth Chamber)

hereby:

1. **Annuls Article 5 of European Commission Implementing Decision C(2019) 4858 (final) of 20 June 2019 granting marketing authorisation for the medicinal product for human use 'Trecondi-treosulfan';**

2. **Orders the Commission to pay the costs, including those relating to the interim proceedings.**

Kornezov Passer Hesse

Delivered in open court in Luxembourg on 23 September 2020.

[Signatures]