Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

13 July 2023 *

(Appeal – Medicinal products for human use – Regulation (EC) No 726/2004 – Decision by the European Medicines Agency (EMA) not to renew a scientific advisory group – Action for annulment brought by the applicant for a marketing authorisation – Admissibility – Interest in bringing proceedings – Vested and current interest which may arise from another legal action – Conditions)

In Case C-136/22 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 25 February 2022,

Debrégeas et associés Pharma SAS (D & A Pharma), established in Paris (France), represented initially by E. Gouesse, D. Krzisch and N. Viguié, avocats, and subsequently by E. Gouesse and N. Viguié, avocats,

appellant,

the other party to the proceedings being:

European Medicines Agency (EMA), represented by C. Bortoluzzi, S. Drosos, H. Kerr and S. Marino, acting as Agents,

defendant at first instance,

THE COURT (Fourth Chamber),

composed of C. Lycourgos (Rapporteur), President of the Chamber, L.S. Rossi, J.-C. Bonichot, S. Rodin and O. Spineanu-Matei, Judges,

Advocate General: L. Medina,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: French.

Judgment

1 By its appeal, Debrégeas et associés Pharma SAS (D & A Pharma) requests the Court of Justice to set aside the order of the General Court of the European Union of 22 December 2021, *D & A Pharma* v *EMA* (T-381/21, 'the order under appeal', EU:T:2021:960), by which the General Court dismissed as being inadmissible its action for annulment of the decision of the European Medicines Agency (EMA) not to renew the scientific advisory group on psychiatry of the Committee for Medicinal Products for Human Use ('the decision at issue').

Legal context

2 Article 5 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 (OJ 2019 L 4, p. 24) ('Regulation No 726/2004'), provides:

'1. A Committee for Medicinal Products for Human Use is hereby established. The Committee shall be part of the [EMA].

2. Without prejudice to Article 56 or to other tasks which Union law may confer on it, the Committee for Medicinal Products for Human Use shall be responsible for drawing up the opinion of the [EMA] on any matter concerning the admissibility of the files submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place a medicinal product for human use on the market in accordance with the provisions of this Title, and pharmacovigilance. …

…'

3 Article 9 of that regulation provides:

'1. The [EMA] shall forthwith inform the applicant [for a marketing authorisation] if the opinion of the Committee for Medicinal Products for Human Use is that:

(a) the application does not satisfy the criteria for authorisation set out in this Regulation;

…

2. Within 15 days after receipt of the opinion referred to in paragraph 1, the applicant may give written notice to the [EMA] that he wishes to request a re-examination of the opinion. In that case, the applicant shall forward to the [EMA] the detailed grounds for the request within 60 days after receipt of the opinion.

Within 60 days following receipt of the grounds for the request, the said Committee shall re-examine its opinion … The reasons for the conclusion reached shall be annexed to the final opinion.

3. Within 15 days after its adoption, the [EMA] shall send the final opinion of the said committee to the [European] Commission, to the Member States and to the applicant. …

…’

4 Article 10(2) of that regulation states:

‘The Commission shall, by means of implementing acts, take a final decision within 15 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. …’

5 Article 56 of that regulation provides:

‘1. The [EMA] shall comprise

(a) the Committee for Medicinal Products for Human Use, which shall be responsible for preparing the opinion of the [EMA] on any question relating to the evaluation of medicinal products for human use;

…

2. The committees referred to in points (a), (aa), (c), (d), (da) and (e) of paragraph 1 of this Article may each establish standing and temporary working parties. The committee referred to in point (a) of paragraph 1 of this Article may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which it may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 5.

…’

Background to the dispute

6 The background to the dispute was set out by the General Court in paragraphs 1 to 12 of the order under appeal and may, for the purposes of the present proceedings, be summarised as set out below.

7 The appellant submitted an application for a, conditional, marketing authorisation (‘MA’) for the medicinal product Hopveus – sodium oxybate (‘Hopveus’) to the EMA. That medicinal product is intended to treat alcohol dependence.

8 On 17 October 2019, the Committee for Medicinal Products for Human Use (‘the CHMP’) issued an unfavourable opinion on that application.

9 On 29 October 2019, the appellant requested a re-examination of that opinion pursuant to Article 9(2) of Regulation No 726/2004.

10 For the purposes of that re-examination, the CHMP convened an ad hoc expert group, the composition of which was, however, disputed by the appellant.

11 By email of 24 February 2020, the CHMP informed the appellant of its decision to convene a second ad hoc expert group.

12 In response to the appellant’s questions concerning the convening of an ad hoc expert group rather than the Scientific Advisory Group on psychiatry (‘the Psychiatry SAG’), which was one of the scientific advisory groups (‘SAGs’) established by the CHMP in accordance with Article 56(2)

of Regulation No 726/2004, the EMA stated, by an email dated 6 March 2020, that, where the issues being re-examined relate to a therapeutic area for which no SAG has been established, an ad hoc expert group is organised and that, in the instant case, the CHMP took the view that an ad hoc group was the most appropriate expert body.

13 The EMA nevertheless added that the members of the Psychiatry SAG would be contacted in order to participate, if possible, in the meeting which the ad hoc expert group would be devoting to Hopveus. That meeting was scheduled for 6 April 2020.

14 The appellant continued to dispute the lawfulness of convening an ad hoc group instead of the Psychiatry SAG.

15 On 6 April 2020, it presented Hopveus to the ad hoc expert group.

16 Following a further unfavourable opinion by the CHMP, based on the evaluation carried out by that expert group, the Commission, by an implementing decision adopted on 6 July 2020, rejected the application for an MA in relation to Hopveus ('the implementing decision').

17 The appellant brought before the General Court an action for annulment of the implementing decision, which was registered under number T-556/20. In support of that action, the appellant submitted in particular that that decision was vitiated by a procedural defect in that the CHMP had failed to consult the Psychiatry SAG.

18 On 5 May 2021, the EMA published on its website, with a view to the renewal of SAG mandates, a document entitled 'Public call for expressions of interest for experts to become members of the [EMA]'s [SAG]', in which there was no reference to the Psychiatry SAG, as well as a press release entitled 'Becoming a member of one of [the EMA's] [SAGs]'.

19 Having become aware of that public call and that press release, the appellant requested the EMA to explain why there was no reference to the Psychiatry SAG in those documents. The EMA replied, by an email dated 4 June 2021, as follows:

'Please note that in accordance with Article 56(2) of Regulation [No 726/2004], the CHMP may establish [SAGs] in connection with the evaluation of specific types of medicinal products or treatments. By that token, the CHMP has the discretion to not renew the mandate of an existing [SAG].

Further to the above, it is confirmed that the mandate of [the Psychiatry SAG] will not be renewed. Similarly, the mandate of [the SAG] on diabetes/endocrinology will also not be renewed. For this reason, the … call for expressions of interest … does not include a reference to either of these two [SAGs].'

The action before the General Court and the order under appeal

20 By application lodged at the Registry of the General Court on 5 July 2021, the appellant brought an action seeking annulment of the decision at issue. It based that action, inter alia, on an infringement of the principles of equal treatment and of impartiality.

21 By separate document, the EMA raised a plea of inadmissibility in respect of the action.

22 By the order under appeal, the General Court dismissed the action as being inadmissible, on the ground that the appellant had no interest in bringing proceedings against the decision at issue.

23 In paragraph 26 of that order, the General Court stated that the appellant submitted that it had a vested and current interest in bringing proceedings in so far as the possible annulment of the implementing decision in Case T-556/20, since the CHMP's failure to consult the Psychiatry SAG would have the effect of placing it in the legal situation it was in prior to the adoption of that decision, that is to say, at the stage of the request for re-examination. The disbanding of the Psychiatry SAG by the decision at issue is capable of calling into question the effects of such an annulment, since it would deprive it of the benefit of the SAG being convened.

24 The General Court rejected that argument, holding, in paragraphs 27 and 28 of that order, that the interest in bringing proceedings was future and hypothetical, since it was based on the possible annulment of the implementing decision.

25 In paragraphs 29 to 31 of that order, the General Court added that the benefit relied on by the appellant was based on the premiss that the General Court might issue a direction to the EMA, in the instant case requiring the Psychiatry SAG to be convened in the event that the implementing decision had to be annulled. However, the General Court does not have jurisdiction to issue directions when conducting a review of lawfulness based on Article 263 TFEU.

26 In paragraph 34 of the order under appeal, the General Court stated that the appellant also submitted that, even if its action in Case T-556/20 were dismissed, it would have an interest in the examination and re-examination procedures involving consultation of the Psychiatry SAG should a new MA application procedure in respect of Hopveus be initiated.

27 The General Court rejected that argument, stating, in paragraphs 35 and 36 of that order that the appellant could rely on such an interest in a future legal situation only if the adverse effect was already certain. In the present case, it was not certain that the appellant would submit a new MA application in respect of Hopveus.

28 Since the appellant had also relied on the risk that the unlawfulness alleged by it might recur, the General Court noted, in paragraphs 37 and 38 of that order, that such a factor was also not capable of conferring an interest in bringing proceedings in relation to the decision at issue, as the case-law relied on by the appellant had been developed in cases where the appellant initially had an interest in bringing proceedings, but where the question arose as to whether that interest had ceased to exist in the course of the proceedings. That case-law is therefore not relevant in the present case.

Forms of order sought by the parties

29 By its appeal, the appellant claims that the Court should:

– set aside the order under appeal;

– refer the case back to the General Court or, should the Court of Justice decide that the state of the proceedings so permits, annul the decision at issue; and

– order the EMA to pay the costs.

30 The EMA contends that the Court should:

– dismiss the appeal;

– order the appellant to pay the costs; and

– in the alternative, should the order under appeal have to be set aside, refer the case back to the General Court and reserve the costs.

The appeal

31 The appellant puts forward two grounds of appeal in support of its appeal. By those grounds of appeal, it criticises paragraphs 27 to 38 of the order under appeal.

The first ground of appeal

Arguments of the parties

32 The appellant submits that the General Court erred in law, coupled with a manifest error of assessment, in finding that annulment of the decision at issue would confer no definite benefit on it.

33 According to the appellant, the annulment of that decision will have a positive effect on its legal situation by providing it with the procedural guarantee that, should the implementing decision be set aside, the Psychiatry SAG could be consulted. Such a guarantee must, in its view, be classified as a benefit within the meaning of the case-law on an interest in bringing proceedings.

34 In that regard, the appellant refers, in particular, to points 28, 39 to 41, 76 and 88 of the Opinion of Advocate General Mengozzi in *Mory and Others* v *Commission* (C-33/14 P, EU:C:2015:409), in which he stated that the interest in bringing proceedings need not necessarily be characterised in terms of an economic advantage, but may also arise from a requirement for judicial protection where there is a link between the case in question and another legal action.

35 The Court followed that approach proposed by Advocate General Mengozzi when it held, in paragraph 76 of the judgment of 17 September 2015, *Mory and Others* v *Commission* (C-33/14 P, EU:C:2015:609), that, where there is a link between the case at issue and another legal action, the existence of an interest in bringing proceedings in the case at issue does not depend on the likelihood of that other set of proceedings being well founded.

36 In the present case, the action against the decision at issue was linked with the action against the implementing decision, since that was based on the CHMP's failure to consult the Psychiatry SAG. In the context of the re-examination of an MA application, the CHMP must, according to the appellant, consult a SAG in order to ensure the independence of the experts and the consistency of the CHMP's opinions. In its view, applicants for MAs are entitled to that procedural guarantee.

37 If the decision at issue could not be challenged before the courts, the fact that the Psychiatry SAG has ceased to exist would deprive the appellant of that guarantee and would force it to bring the matter before the General Court once more in a forthcoming procedure before the EMA in order to challenge the failure to convene that SAG.

38 Furthermore, since the existence of the Psychiatry SAG is a procedural guarantee for all applicants for MAs in the field of psychiatric illnesses, the disbanding of that SAG has, according to the appellant, altered not only its own legal situation but also that of all other applicants for an MA in that field. The absence of a SAG in the field of psychiatry is likely to lead to inconsistencies and unequal treatment of applicants for MAs.

39 In addition, the alleged unlawfulness is likely to recur. As the Psychiatry SAG has been disbanded, the CHMP could, as from now, in re-examination procedures concerning medicinal products intended for psychiatric use, systematically convene ad hoc expert groups, which, according to the appellant, is unlawful.

40 Moreover, contrary to the finding by the General Court, the present action does not amount to requesting the General Court to issue a direction to the EMA. The sole purpose of that action is to ensure, by means of setting aside the decision at issue, that any annulment of the implementing decision can have practical effect.

41 In its reply, the appellant added that the fact that, after the present appeal was lodged, the General Court dismissed, by the judgment of 2 March 2022, *D & A Pharma* v *Commission and EMA* (T-556/20, EU:T:2022:111), the action against the implementing decision in no way invalidates the existence of an interest in bringing proceedings against the decision at issue. In that judgment, the General Court left open the question whether, as the appellant claims in the present action, there is a legal obligation to establish a SAG in the field of psychiatry. In so far as the General Court found in that judgment that the CHMP was not, in the instant case, required to consult the Psychiatry SAG, the appellant points out that an appeal is pending before the Court of Justice (Case C-291/22 P).

42 According to the EMA, the first ground of appeal is unfounded.

Findings of the Court

43 According to settled case-law, any action for annulment brought under Article 263 TFEU by a natural or legal person must be based on an interest on the part of the applicant in bringing proceedings. The existence of such an interest presupposes that annulment of the contested measure must be capable of procuring an advantage for that person (judgment of 21 January 2021, *Germany* v *Esso Raffinage*, C-471/18 P, EU:C:2021:48, paragraphs 101 and 103 and the case-law cited).

44 That interest, which is an essential and fundamental prerequisite for the action, must be vested and current. Since it may not concern a future and hypothetical situation, it must exist at the stage of lodging the action, failing which the action will be inadmissible, and continue until the final decision, failing which there will be no need to adjudicate (see, to that effect, judgment of 27 March 2019, *Canadian Solar Emea and Others* v *Council*, C-237/17 P, EU:C:2019:259, paragraphs 75 and 76 and the case-law cited).

45 The question whether, in the light of the facts and evidence assessed by the General Court, the annulment sought of the contested measure is capable of conferring a benefit on the appellant is a question of law which comes within the scope of the Court of Justice's review in the context of an appeal (see, to that effect, judgment of 7 November 2018, *BPC Lux 2 and Others* v *Commission*, C-544/17 P, EU:C:2018:880, paragraph 31 and the case-law cited).

46 In the present case, it is apparent from paragraph 26 of the order under appeal, which is not disputed in the present appeal, and from the arguments put forward in support of the first ground of appeal that the appellant submits, for the purposes of establishing its interest in bringing proceedings against the decision at issue, that the implementing decision by which its MA application for Hopveus was rejected without the Psychiatry SAG first having been consulted is the subject of an action before the EU Courts and could be set aside, which would entail a re-examination of that application, in the context of which the appellant risks being deprived of the benefit of consulting the Psychiatry SAG, which had in the meantime been disbanded by the decision at issue. Annulment of the latter decision would therefore be capable of conferring a benefit on it, namely the guarantee that the re-examination of that application would entail consulting the SAG.

47 As is apparent, moreover, from paragraph 34 of the order under appeal, the content of which is confirmed by the arguments supporting the first ground of appeal, the appellant also relies on the possibility that it might, in the future, submit a new MA application in respect of Hopveus.

48 As regards the second of the two factors thereby relied on, it is sufficient to observe that the appellant cannot rely, for the purposes of establishing an interest in bringing proceedings, on the mere possibility that it might in the future submit an application for an MA in respect of a pharmaceutical product intended for psychiatric use, an application in relation to which, according to the appellant, the Psychiatry SAG ought to be consulted. It is clear that a vested and current interest cannot arise from such a future and hypothetical situation.

49 As regards the first factor relied on by the appellant, relating to the fact that an application for an MA relating to Hopveus, a product in respect of which evaluation, in its view, requires consultation by the Psychiatry SAG, led to an implementing decision which is the subject of a dispute which has not yet been definitively settled, it is necessary to examine the relevance of the case-law on which the appellant relies, concerning the interest in bringing proceedings which may arise from a link between the case at issue and another legal action.

50 In accordance with that case-law, an interest in bringing proceedings may arise from any action before the national courts in the context of which the possible annulment of the contested act before the EU Courts is capable of benefiting the applicant (judgments of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 81, and of 7 November 2018, *BPC Lux 2 and Others* v *Commission*, C-544/17 P, EU:C:2018:880, paragraph 44).

51 For the purposes of determining whether such an interest in bringing proceedings exists, there is no need to assess the likelihood that the other legal action is well founded (see, to that effect, judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 76).

52 The interest in bringing proceedings arising from another legal action also does not presuppose that the action before the EU Courts and the action before the national court have the same subject matter. By contrast, the annulment sought of the decision at issue must be capable of having an effect on that other action (judgment of 7 November 2018, *BPC Lux 2 and Others* v *Commission*, C-544/17 P, EU:C:2018:880, paragraphs 51, 52 and 55).

53 Those principles relating to the interest in bringing proceedings which may arise from a link between the action in question and another action may be applied to cases in which that other action is pending, not before a national court, but before the EU Courts.

54 However, in the present case, contrary to the appellant's assertions, the annulment, in the context of the present action, of the decision at issue is not capable of having an effect on the action brought against the implementing decision, which the General Court dismissed by the judgment of 2 March 2022, *D & A Pharma* v *Commission and EMA* (T-556/20, EU:T:2022:111), currently under appeal (Case C-291/22 P).

55 In that other action, the appellant sought to have the implementing decision, which was adopted in 2020, set aside on the ground that the Psychiatry SAG, which at that time was one of the SAGs established within the EMA, had not been consulted. For the purposes of examining whether that SAG ought to have been consulted, it is irrelevant to establish whether the EMA was entitled, without infringing EU law, to decide in 2021 not to renew that SAG by means of the decision at issue. Consequently, the annulment of the latter decision would not be capable of having an effect on the dispute concerning the lawfulness of the implementing decision.

56 In so far as the appellant submits that an interest in bringing proceedings against the decision at issue must nevertheless be established in order to preserve the practical effect of its action against the implementing decision, the fact remains that that argument is based on the premiss that, in the event that the implementing decision is annulled on the ground that it ought to have been taken after consulting the Psychiatry SAG, as the appellant submitted in the action which it brought against that decision, the EMA would be in a position to comply with the obligations following from such an annulment only if the Psychiatry SAG had already been re-established as a result of the decision at issue having been set aside.

57 However, that premiss is incorrect. In that regard, suffice it to state that the obligation which would follow from any judgment setting aside the implementing decision would be to re-examine the application for an MA in respect of Hopveus. For the purposes of that re-examination, the CHMP, in its capacity as the relevant EMA committee, is, in any event, in a position – the decision not to renew the Psychiatry SAG not preventing it from doing so – to re-establish that SAG and to consult it in relation to Hopveus.

58 Furthermore, if the opposite were the case, were the CHMP, after the annulment of the implementing decision, to decide not to re-establish the Psychiatry SAG and, accordingly, to re-examine the MA application in respect of Hopveus assisted by an ad hoc committee, the appellant would not, for that reason, be deprived of effective judicial protection. If its application for an MA were once more rejected, it would be open to the appellant, to bring an action against the new implementing decision, on the basis of the ground of appeal raised in the present case, that the examination of an application for an MA for a product such as Hopveus always requires a Psychiatry SAG to be consulted.

59 It follows that bringing the action which led to the order under appeal was in no way necessary in order to preserve the existence of conditions enabling the EMA to comply with the obligations which would follow from a judgment which was favourable to the appellant in the case concerning the lawfulness of the implementing decision.

60 It follows from the foregoing that the General Court was fully entitled to declare inadmissible the action brought by the appellant against the decision at issue for lack of interest in bringing proceedings.

61 In those circumstances, it was not necessary, as the General Court was also correct in observing, to examine whether the infringement of EU law alleged by the appellant is likely to recur, since that aspect may, as the General Court held in paragraphs 37 and 38 of the order under appeal, be relevant only in cases where the appellant initially had an interest in bringing proceedings and where the question arises as to whether that interest has ceased to exist in the course of the proceedings.

62 Consequently, the first ground of appeal is unfounded and must be rejected.

The second ground of appeal

Arguments of the parties

63 By its second ground of appeal, the appellant claims that the General Court erred in law in holding that the interest on which it relies is not current and certain, but only future and hypothetical.

64 It observes that the interest relating to a future legal situation may be current and certain where it is established that the adverse effect is already certain. On account of the link, which has been discussed in the context of the first ground of appeal, between the action against the decision at issue and the action against the implementing decision, the appellant argues that it is certain that setting aside the decision at issue would confer a benefit on it in the context of the action brought against the implementing decision, namely a procedural guarantee.

65 The EMA contends that the second ground of appeal is inextricably linked with the first ground of appeal and that it is, like the first ground of appeal, unfounded.

Findings of the Court

66 As is apparent from the findings made in the examination of the first ground of appeal, the action against the decision at issue has no link with the action against the implementing decision which is capable of establishing, so far as concerns the appellant, a vested and current interest in the present case.

67 Therefore, the second ground of appeal is, like the first ground of appeal, unfounded and must be rejected.

68 It follows that the appeal must be dismissed in its entirety.

Costs

69 In accordance with Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to the costs. Article 138(1) of the Rules of Procedure, which is applicable to appeal proceedings by virtue of Article 184(1) of those rules, provides that the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

70 Since the EMA has applied for costs and the appellant has been unsuccessful, the appellant must be ordered to bear its own costs and to pay those incurred by the EMA in the appeal.

On those grounds, the Court (Fourth Chamber) hereby:

1. **Dismisses the appeal;**

2. **Orders Debrégeas et associés Pharma SAS (D & A Pharma) to bear its own costs and to pay those of the European Medicines Agency (EMA) relating to the appeal.**

[Signatures]