Reports of Cases

OPINION OF ADVOCATE GENERAL
MEDINA
delivered on 7 September 2023 [1]

Case C-291/22 P

Debregeas et associés Pharma (D & A Pharma)
v
European Commission,

European Medicines Agency (EMA)

(Appeal – Medicinal products for human use – Application for marketing authorisation – Procedure before the European Medicines Agency (EMA) – Committee for Medicinal Products for Human Use (CHMP) – Consultation of a Scientific Advisory Group (SAG) or an ad hoc expert group – Regulation (EC) No 726/2004 – Articles 56 and 62 – Guidelines on the re-examination procedure – Independence of the experts – Article 41 of the Charter of Fundamental Rights of the European Union – Right to good administration – Requirement of objective impartiality – Criteria for verifying the absence of conflicts of interest – Consultancy activities for another pharmaceutical company)

I. Introduction

1. This Opinion concerns an appeal brought by the pharmaceutical company D & A Pharma, the appellant in the present case, seeking to have the judgment of 2 March 2022, *D & A Pharma* v *Commission and EMA* (T-556/20, 'the judgment under appeal', EU:T:2022:111) set aside.

2. By that judgment, the General Court dismissed the appellant's action for the annulment of the Commission's Implementing Decision of 6 July 2020 refusing marketing authorisation for Hopveus – sodium oxybate, a medicinal product for human use, under Regulation (EC) No 726/2004 [2] ('the contested decision').

3. In particular, the General Court found that the contested decision had not been made following an irregular procedure before the European Medicines Agency (EMA), in particular as regards the choice of the group of experts responsible for re-examining the application for marketing authorisation submitted by the appellant. In addition, the General Court found that the procedure had not been vitiated by any legitimate doubt as to the impartiality of the experts involved in that re-examination.

[1] Original language: French.

[2] Regulation 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).

4. The present appeal gives the Court of Justice the opportunity to clarify the discretion available to the Committee for Medicinal Products for Human Use (CHMP) of the EMA to convene scientific advisory groups ('SAGs') or, alternatively, ad hoc groups of experts during the procedure for re-examining an application for marketing authorisation ('MA'). This case also allows the Court of Justice to rule on the conditions of objective impartiality applicable to the members of groups involved in the re-examination of MA applications, particularly when they carry out consultancy activities for other pharmaceutical companies. [3]

II. The facts giving rise to the dispute and the main proceedings

A. Background to the dispute

5. The background to the dispute was set out by the General Court in paragraphs 2 to 12 of the judgment under appeal and can, for the purposes of this Opinion, be summarised as follows.

6. On 26 June 2018, the appellant filed a conditional MA application with the EMA for the medicinal product Hopveus – sodium oxybate ('the medicinal product Hopveus') under Regulation (EC) No 507/2006, [4] as part of a centralised procedure.

7. The medicinal product Hopveus, which contains sodium oxybate as its active substance, is intended to combat dependence on alcohol, a condition which, according to the background described by the General Court, is generally defined as a psychiatric disorder with adverse physical, mental and psychological effects, with serious social consequences and a likelihood of chronic relapse.

8. On 17 October 2019, the CHMP issued an initial unfavourable opinion on the application referred to above, on the grounds that the efficacy of the medicinal product Hopveus had not been sufficiently demonstrated.

9. On 29 October 2019, following the negative opinion issued by the CHMP, the appellant requested a re-examination, in accordance with Article 9(2) of Regulation No 726/2004.

10. In order to respond to the comments made by the CHMP, the appellant proposed the following revised therapeutic indications: first, continued abstinence in alcohol-dependent patients under close medical supervision, as well as psychosocial support and ongoing social rehabilitation and, second, treatment of alcohol withdrawal syndrome, without complications or with perception disorders.

11. The appellant also formally requested that the CHMP consult with the scientific advisory group dedicated to psychiatry ('the SAG on Psychiatry'). For the purposes of the re-examination, however, the CHMP convened an ad hoc group of experts in place of the SAG on Psychiatry.

12. Following a new unfavourable opinion from the CHMP dated 30 April 2020, the appellant's MA application was refused under the contested decision on the grounds, *inter alia*, that the medicinal product Hopveus had not been shown to be effective.

[3] On this subject, see the recent judgment of 22 June 2023, *Germany and Estonia* v *Pharma Mar and Commission* (C-6/21 P and C-16/21 P, EU:C:2023:502).

[4] Commission Regulation of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6).

B. Procedure before the General Court and the judgment under appeal

13. The appellant brought an action against the European Commission and the EMA, seeking the annulment of the contested decision.

14. It put forward six pleas in law in support of its action. The first three pleas alleged defects in the procedure before the EMA, while the fourth to sixth pleas alleged an error of law, manifest errors of assessment and breaches of the principle of equal treatment.

15. In the judgment under appeal, the General Court held those pleas to be unfounded and therefore dismissed the action in its entirety.

16. In paragraphs 21 and 22 of the judgment under appeal, the General Court found that the contested decision emanated from the Commission and that the action was therefore inadmissible in so far as it was directed against the EMA. Although the General Court therefore dealt with the grounds of the action only in so far as it was directed against the Commission, it nevertheless examined the lawfulness of the procedure before the EMA, in so far as the Commission relied on the opinion provided by the CHMP, which is an integral part of the EMA.

17. As regards the first plea in law, alleging a procedural defect in that the CHMP convened an ad hoc expert group and not the SAG on Psychiatry, the General Court stated, first, in paragraph 49 of the judgment under appeal, that, in accordance with the case-law of the Court of Justice, the EMA, in adopting the guidelines on the procedure for the re-examination of CHMP opinions,[5] had imposed a limit on the exercise of its discretion.

18. The General Court then found, in paragraphs 50 and 51 of the judgment under appeal, that it follows from point 6.1 of the Guidelines on the Re-examination Procedure, read in conjunction with Article 11 of the CHMP Rules of Procedure[6] and Article 56(2) and Article 62(1), final sentence, of Regulation No 726/2004, that the CHMP must consult a SAG where, in the context of a re-examination procedure, the MA applicant expresses a wish to that effect; that does not mean, however, that the applicant has the right to choose the type of expert group. That choice would depend on whether or not a SAG is available in the field concerned and whether that SAG can provide the most relevant scientific contribution.

19. The General Court added, in paragraph 58 of the judgment under appeal, that the appellant still failed, in any event, to prove how consultation of the SAG on Psychiatry, possibly supplemented by other experts, rather than the convening of an ad hoc group of experts, which included members of that SAG, could have led to the re-examination procedure producing a different outcome.

20. As regards the second plea of the action, alleging a lack of impartiality on the part of two members (A and B) of the ad hoc group of experts, the General Court, in paragraphs 88 to 92 of the judgment under appeal, referred to the case-law of the Court of Justice concerning the right to good administration, enshrined in Article 41 of the Charter of Fundamental Rights of the European Union, which includes the requirement of impartiality.

[5] Procedural Advice on the Re-examination of CHMP Opinions ('Guidelines on the Re-examination Procedure'), available at: www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-re-examination-chmp-opinions_en.pdf.

[6] Committee for Medicinal Products for Human Use – Rules of Procedure ('CHMP Rules of Procedure'), available at: www.EMA.europa.EU/documents/other/chmp-rules-procedure_en.pdf.

21. In paragraphs 93 to 96 of the judgment under appeal, the General Court recalled the wording of Article 63(2) of Regulation No 726/2004 and noted that, in accordance with that provision, the EMA adopted the policy of 6 October 2016,[7] which specifies, as regards the evaluation of pharmaceutical products, the scope of the requirement of impartiality by aiming to strike a fair balance between preventing conflicts of interest and making the best expertise available. Furthermore, in paragraph 97 of that judgment, the General Court noted that the appellant did not claim that the two experts in question had shown personal bias or prejudice. The second plea therefore had to be regarded, in the view of the General Court, as seeking to establish a failure to meet the requirement of objective impartiality, as a result of conflicts of interest. However, in paragraphs 99 to 123 of the judgment under appeal, the General Court rejected the allegations of a conflict of interests against A and B in accordance with the EMA's policy.

22. Finally, since the appellant also argued that the policy of 6 October 2016 was insufficient to guarantee the impartiality of the experts involved in the re-examination procedure, the General Court stated, in paragraphs 124 to 136 of the judgment under appeal that, irrespective of that issue, the activities of A and B were not capable of giving rise to a legitimate doubt as to their impartiality. In that regard, the General Court added that the conclusions of the ad hoc expert group convened for the re-examination of the medicinal product Hopveus were adopted in a collegiate manner by 10 members and that, in accordance with case-law, collegiality constitutes a guarantee of impartiality. This is all the more the case where, as in the present case, the experts whose impartiality has been called into question did not exercise management or coordination functions enabling them to have a dominant influence on the conduct or outcome of the procedure.

III. Forms of order sought

23. By its appeal, the appellant claims that the Court of Justice should:

– set aside the judgment under appeal;

– give final judgment on the action brought before the General Court, by annulling the contested decision; and

– order the Commission and the EMA to pay the costs.

24. The Commission and the EMA contend that the Court of Justice should:

– dismiss the appeal; and

– order the appellant to pay the costs.

[7] European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts ('the policy of 6 October 2016'), available at: www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-declarations-interests-scientific-committees_en.pdf. A new version of the EMA policy, which is not applicable *ratione temporis* to the present case, was adopted on 15 December 2022 and entered into force on 1 January 2023.

IV. Legal analysis

25. In support of its appeal, the appellant relies on two grounds of appeal challenging the General Court's assessment of the regularity of the re-examination procedure conducted by the EMA in the adoption of the contested decision. The first ground of appeal alleges that the General Court erred in law in finding that the decision not to convene the SAG on Psychiatry was not unlawful; the second alleges that the General Court erred in law in its examination of the requirement of objective impartiality in respect of experts A and B.

26. As a preliminary point, it should be borne in mind, as set out in paragraphs 25 to 30 of the judgment under appeal, that the primary task of the EMA, established by Regulation No 726/2004, is the protection and promotion of public and animal health through the evaluation and supervision of medicinal products for human and veterinary use. According to Article 57(1) of that regulation, the EMA is to provide the Member States and the institutions of the European Union with the 'best possible scientific advice' on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it. In particular, it is responsible for coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products that are subject to MA procedures in the European Union.

27. As regards MA applications for medicinal products for human use in the European Union, filed under the centralised procedure provided for by Regulation No 726/2004, that procedure involves the submission by the pharmaceutical company concerned of an application which is subject to examination and an opinion by the EMA and the adoption of a MA decision by the Commission.

28. As regards the EMA's opinion, it follows from Article 5(2) of Regulation No 726/2004, read in the light of recital 23 of that regulation, that 'exclusive responsibility' for its preparation is vested in the CHMP, established by Article 121 of Directive 2001/83/EC. [8]

29. Under Article 56(2) of Regulation No 726/2004, the CHMP may establish standing and temporary working parties and also 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 on MA applications. [9] According to that provision, where the CHMP establishes those groups, it is to provide for their consultation in its rules of procedure, in accordance with Article 61(8) of Regulation No 726/2004.

30. The CHMP's initial opinion on the MA application may be subject to a re-examination if the applicant so requests pursuant to Article 9(2) of Regulation No 726/2004. The Guidelines on the Re-examination Procedure, cited in point 17 above, describe the manner in which that procedure is to be conducted and provide guidance for the re-examination of the various types of CHMP opinions, including with regard to the consultation of standing SAGs or, alternatively, ad hoc expert groups, [10] formed for a single occasion. In addition, the EMA has issued a document

[8] Directive 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).

[9] See also recital 25 of Regulation No 726/2004.

[10] See point 1 of the Guidelines on the Re-examination Procedure.

setting out the mandate, objectives and rules of procedure applicable to those groups.[11] At the time the MA application for the medicinal product Hopveus was re-examined, there were 8 standing SAGs, each composed of 12 members, in particular in the fields of cardiovascular products, anti-infection products, diabetes/endocrinology, viral diseases, neurology, oncology, psychiatry and vaccines.

31. The final opinion of the CHMP, together with a report describing its assessment of the medicinal product and stating the reasons for its conclusions, is to be sent to the Commission, the Member States and the applicant, in accordance with Article 9(3) of Regulation No 726/2004.

32. In accordance with Article 10 of Regulation No 726/2004, the Commission, assisted by the CHMP, is to prepare a draft decision within 15 days of receiving the opinion from the CHMP. The draft decision is to be forwarded to the Member States and the applicant. The Commission must then take a final decision in accordance with the procedure referred to in Article 87(3) of the regulation, which may differ from the abovementioned opinion. In such cases, it is to attach an annex setting out in detail the reasons for the differences.

33. It is in the light of the foregoing observations that the two grounds of appeal relied on by the appellant are to be examined.

A. The first ground of appeal, alleging that the General Court erred in law in finding that the decision not to convene the SAG on Psychiatry was not unlawful

34. By its first ground of appeal, the appellant argues that the General Court erred in law in finding that the CHMP's decision not to convene the SAG on Psychiatry was in compliance with the provisions applicable to the re-examination procedure and that no infringement of essential procedural requirements could therefore be imputed to the EMA during that procedure.

35. That first ground of appeal is divided into two parts, alleging, first, an error of law in that the General Court found that the decision to consult an ad hoc group of experts, instead of the SAG on Psychiatry, was not vitiated by any irregularity and, second, an error of law in that the General Court held that the appellant was in any event required to demonstrate that such irregularity could have influenced the content of the contested decision.

1. The first part, alleging that the General Court erred in law in finding that the consultation of an ad hoc group of experts, instead of the SAG on Psychiatry, was not vitiated by any irregularity

36. In the first part, the appellant argues that the General Court erred in finding that the decision to consult an ad hoc group of experts rather than the SAG on Psychiatry during the re-examination procedure for the medicinal product Hopveus was not vitiated by any irregularity. In essence, it claims that, by reaching such a conclusion, the General Court infringed Article 62(1) of Regulation No 726/2004, Article 11 of the CHMP Rules of Procedure and point 6.1 of the Guidelines on the Re-examination Procedure.

[11] Mandate, objectives and rules of procedure for the scientific advisory groups (SAGs) and ad-hoc experts groups, available at: www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-scientific-advisory-groups-sags-ad-hoc-experts-groups_en.pdf ('the Rules of Procedure relating to SAGs'). Those rules were adopted under Article 56(2) of Regulation No 726/2004, read in conjunction with Article 61(8) of that regulation.

37. First, according to the appellant, the General Court's error arises from the finding that the CHMP has discretion to determine which group of experts to consult at the re-examination stage, even if a standing SAG exists in the therapeutic area concerned by the medicinal product under re-examination. In that regard, the appellant states that, in accordance with point 6.1 of the Guidelines, if a request to consult the SAG comes from the applicant, the CHMP will 'systematically' consult the SAG requested.

38. Next, the appellant submits that, even assuming that the CHMP has discretion to consult a SAG of its choosing, the General Court erred in finding that consultation of the SAG on Psychiatry was not relevant in the present case in the light of the specific characteristics of the medicinal product under re-examination and the nature of the questions asked by the CHMP.

39. Lastly, the appellant complains that the General Court failed to have regard to its argument that standing SAGs and ad hoc expert groups do not offer equivalent procedural guarantees to MA applicants.

40. The Commission and the EMA dispute those arguments.

41. First of all, the Commission and the EMA maintain that the ad hoc group of experts was convened for the purposes of the re-examination of the medicinal product Hopveus in accordance with the rules applicable to that procedure. In that regard, they state that renowned experts were selected and that the members of the SAG on Psychiatry were also invited to take part. Similarly, they assert that the rules applicable to the re-examination procedure do not give MA applicants the right to impose on the CHMP the SAG of their choosing, which is consistent with the objective of those rules, namely the protection of public health.

42. Next, as regards point 6.1 of the Guidelines on the Re-examination Procedure, which should be read in conjunction with the final sentence of Article 62(1) of Regulation No 726/2004, the Commission and the EMA note that there can be no systematic consultation of a SAG where no such group has been established in the therapeutic area concerned. Furthermore, although alcohol dependence can be characterised as a psychiatric disorder, it is a pathology that crosses medical disciplines, which justified, in their view, the consultation of an ad hoc group of experts, supplemented by the invitation sent to members of the SAG on Psychiatry.

43. Finally, the Commission and the EMA state that Hopveus, the medicinal product at issue in the present case, is intended to combat a disorder which requires specialist input from experts in the field of addictology, rather than psychiatry, in so far as the active substance of that medicinal product itself creates dependency.

44. As a preliminary point, it should be recalled that, as is apparent from paragraphs 45 to 48 of the judgment under appeal, pursuant to 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, to which it may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30 of that regulation.

45. As set out in the final sentence of the fourth subparagraph of Article 62(1) of Regulation No 726/2004, 'the applicant may request that the [CHMP] consult a [SAG] in connection with the re-examination'.

46. Article 11(2) of the CHMP Rules of Procedure states in that regard that 'the applicant may request that the Committee consult a [SAG] (if and when established) in connection with the re-examination' and that 'in this case, the Committee shall request the advice of additional available expertise'.

47. Point 6.1 of the Guidelines on the Re-examination Procedure states as follows:

'The decision on consultation of the SAG for a re-examination procedure will amongst others depend on the CHMP or the […] request for consultation of the SAG by CHMP [made by the applicant].

In case the applicant […] requests [the consultation of] a SAG, the applicant […] will preferably inform the CHMP of this request as early as possible. Such request should be duly motivated […]. In case of a request for consultation of the SAG coming from the applicant, the CHMP will systematically consult the SAG.

In a therapeutic area where no SAG is established, the advice of additional available expertise will be requested in the form of consultation of an ad hoc expert group meeting.

During the CHMP meeting following receipt of the applicant/MAHs written notice to the Agency or detailed grounds for requesting a re-examination of the opinion, the CHMP decides on the consultation of the SAG and its composition (with regard to experts other than the SAG core group), and the CHMP adopts a List of Questions to the SAG.

If the LOQ to the SAG has not yet been adopted during a CHMP meeting, it will be adopted by written procedure.

[…]'

48. In paragraph 50 of the judgment under appeal, the General Court established that, in accordance with the wording of the aforementioned provisions, the CHMP is obliged to consult a SAG where the MA applicant so requests in the context of a re-examination procedure. The General Court added, however, that it is not apparent from those provisions that they confer on the applicant the right to choose which type of group – a standing SAG or an ad hoc expert group – the CHMP should consult when the applicant makes that request.

49. In my view, such an interpretation of the rules applicable to the re-examination procedure should be endorsed.

50. As the General Court notes in paragraph 51 of the judgment under appeal, the choice of a standing SAG depends, first, based on a joint reading of Article 11(2) of the CHMP Rules of Procedure and point 6.1 of the Guidelines on the Re-examination Procedure, on the availability of that SAG in the field concerned. Second, as stated in point 26 of the present Opinion, Article 57(1) of Regulation No 726/2004 requires the EMA to give the Member States and the institutions of the European Union the best possible scientific advice on any question concerning the evaluation of the quality, safety and efficacy of medicinal products for human use which is referred to it. [12]

[12] See also recital 19 of Regulation No 726/2004.

51. In that context, even though point 6.1 of the Guidelines on the Re-examination Procedure states that the CHMP must 'systematically' consult the requested SAG in the event of a request for such consultation, as the appellant submits, it should be recognised that the CHMP has discretion for the purpose of determining whether the requested SAG can provide the most relevant scientific contribution in relation to the therapeutic area concerned by the medicinal product which is the subject of the re-examination procedure.

52. From the outset, that interpretation is supported, from a textual point of view, by the first sentence of point 6.1 of the Guidelines on the Re-examination Procedure, which emphasises, by using the words 'amongst others', that the decision whether to consult a standing SAG in connection with a re-examination procedure does not depend solely on whether such consultation is requested by the applicant.

53. Furthermore, point 6.1 of the Guidelines requires that the request to consult the standing SAG be duly motivated by the applicant for re-examination. That obligation to provide reasons would be meaningless if it could not be subject to subsequent assessment by the CHMP, in particular as to the relevance of the SAG requested in relation to the therapeutic area concerned by the medicinal product under re-examination.

54. Lastly, it is also clear, in the light of the principle of the hierarchy of norms, that the CHMP Rules of Procedure and the Guidelines on the Re-examination Procedure adopted by the EMA cannot under any circumstances influence the obligations imposed on that agency by virtue of a higher regulatory norm, such as Article 57(1) of Regulation No 726/2004. That would be the case if the possibility of requesting the consultation of a standing SAG recognised by Article 11(2) of the CHMP Rules of Procedure, and the term 'systematically' stemming from point 6.1 of the Guidelines on the Re-examination Procedure, had to be interpreted as being intended to prevent the CHMP from adapting the request made by a MA applicant for a desired standing SAG to the therapeutic field most relevant to the medicinal product under re-examination.

55. It follows that, contrary to the applicant's claim, the CHMP must be regarded as having discretion for the purpose of deciding to consult either a standing SAG or an ad hoc expert group, even where the applicant seeking a re-examination of the initial CHMP opinion makes a specific request to that effect. The General Court does not appear to me to have erred in that regard.

56. However, although I can agree with the premises established in the judgment under appeal, in particular as regards the discretion as to the choice of the group responsible for re-examining a MA application, the inferences drawn by the General Court in the context of the present case seem to me to be erroneous.

57. As is apparent from paragraph 49 of the judgment under appeal, it should first be borne in mind that any institution or agency concerned, in this case the EMA, may impose a limit on the exercise of its discretion by adopting guidelines. In those cases, such an institution or agency cannot depart from those guidelines without being found, where appropriate, to be in breach of general principles of law, such as the principles of equal treatment, legal certainty or the protection of legitimate expectations. [13]

[13] See, by analogy, judgment of 8 March 2016, *Greece* v *Commission* (C-431/14 P, EU:C:2016:145, paragraph 69 and the case-law cited).

58. In the judgment under appeal, the General Court states, in paragraph 53, that 'even if the fight against alcohol dependence falls in principle within the field of psychiatry, a field for which the SAG on [P]sychiatry [was] competent, the questions formulated by the CHMP for the purposes of the re-examination procedure were of a specialised nature, covering inter alia the fields of general medicine, psychiatry and gastroenterology, as well as addiction'.

59. It follows from that paragraph that, according to the General Court's finding – and as also acknowledged by the Commission and the EMA in their pleadings – psychiatry was the field normally relevant to the evaluation of a medicinal product such as Hopveus,[14] even if other fields also merited consideration for the purpose of granting a MA for that medicinal product. This finding is consistent with the General Court's statement in paragraph 2 of the judgment under appeal, as part of the background to the dispute, which describes alcohol dependence as an illness generally defined as a 'psychiatric disorder' with adverse physical, mental and psychological effects.

60. In that regard, it should be noted that, in accordance with Article 11(2) of the CHMP Rules of Procedure, referred to above, when an applicant requests consultation of an established standing SAG, it is also possible to request the opinion of additional available experts.

61. In this respect, Section IV of the Rules of Procedure relating to SAGs provides that a standing SAG comprises both a core group – which ensures continuity and consistency within the group – and, if necessary, additional experts who may be called upon to participate in a given meeting or series of meetings on a specific issue about which they have relevant professional education, training and experience. According to that same section, those experts are supposed to provide additional expertise in specific domains on a case-by-case basis.

62. Section VII, point 4, of the Rules of Procedure relating to SAGs, under the heading 'Participation of additional experts in SAG meetings', specifies that proposals for additional experts should be made on the basis of their expertise in the therapeutic area or field to be covered by the particular SAG during its meeting, according to the CHMP list of questions for the SAG.

63. Reading the foregoing rules leads me to conclude that, where the field normally relevant to the evaluation of the re-examination of a medicinal product falls within the subject matter of one of the standing SAGs set up by the EMA, it is the standing SAG set up for that field which must be consulted, even though it is possible to propose additional members specialising in other fields, in particular where that proves necessary in order to provide the most relevant scientific contribution for the medicinal product under re-examination.

64. In the present case, it seems to me that the involvement of the SAG on Psychiatry, supplemented by experts in additional fields in accordance with Section IV of the Rules of Procedure relating to SAGs, was more in line with the statement made by the General Court in paragraph 53 of the judgment under appeal, in so far as the fight against alcohol dependence, which normally falls within the field of psychiatry, warranted an examination by the standing SAG established in that field, without prejudice to the fact that other questions, concerning in

[14] See also, as the appellant points out, 'International Classification of Diseases', established by the World Health Organisation, which includes alcohol dependence among 'Mental, behavioural or neurodevelopmental disorders', available at: https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f1580466198.

particular general medicine, gastroenterology and addiction, might also require additional experts to be invited in order to ensure a thorough evaluation of the medicinal product in question. [15]

65. Such a finding respects the conclusion that, even though the provisions applicable to the procedure at issue do not confer on a MA applicant the right to choose which type of SAG should be consulted, the CHMP's discretion, which is justified by the obligation to provide the most appropriate scientific contribution in accordance with Article 57 of Regulation No 724/2006, cannot go so far as to frustrate the expectations created on the part of the those requesting the re-examination. Otherwise, as the appellant rightly claims, the Guidelines on the Re-examination Procedure would be meaningless and the choice of the group of experts responsible for re-examining a MA would risk becoming discretionary.

66. That conclusion cannot be invalidated, first, by the statement made by the General Court in paragraph 55 of the judgment under appeal that all the members of the SAG on Psychiatry were 'invited to participate' in the meeting of the ad hoc group of experts and that three of them did in fact participate. In that regard, it is sufficient to note that such a formation or composition of the group of experts responsible for the re-examination does not correspond to that required in the present case, in accordance with my analysis, by the provisions applicable to that procedure.

67. Second, I do not take the view that the argument put forward by the EMA and the Commission that alcoholism falls within the field of addictology rather than psychiatry, which would justify an ad hoc group of experts being convened, merits acceptance. In that regard, it should be noted that such a conclusion is not apparent from paragraph 53 of the judgment under appeal, with the result that, without a finding that the General Court has distorted the facts, which is not pleaded by the parties to the procedure before the Court of Justice, such a conclusion cannot form the basis of the legal conclusions in the present case.

68. Third, I am likewise not persuaded by the argument put forward by the EMA and the Commission that the list of questions drawn up by the CHMP justified the choice of an ad hoc group of experts rather than the SAG on Psychiatry. In this respect, it should be noted that, as already explained, point 6.1 of the Guidelines on the Re-examination Procedure states that 'during the CHMP meeting following receipt of the applicant[…]'s written notice to the Agency […], the CHMP decides on the consultation of the SAG and its composition […], and the CHMP adopts a List of Questions to the SAG'. It follows that the decision on the choice of the group responsible for the re-examination of a MA application precedes the establishment of the list of questions to be examined by that group, which is also consistent with the fact that, according to that same paragraph of the Guidelines on the Re-examination Procedure, if the list of questions to the SAG was not adopted at the CHMP meeting, it is adopted at a later date – and, therefore, after the SAG has been chosen – in accordance with a written procedure.

69. In the light of the foregoing, I would therefore propose that the Court of Justice should find that the General Court erred in law in finding, in paragraph 56 of the judgment under appeal, that the decision to consult an ad hoc group of experts possibly supplemented by other experts, instead of the SAG on Psychiatry, was in accordance with the rules applicable to the procedure for the re-examination of MA applications and that that decision was therefore not vitiated by any

[15] It should be pointed out that, even if the discretion enjoyed by the CHMP for the purpose of determining whether the SAG requested by an applicant can provide the most relevant scientific contribution could be subject to review by the EU judicature (see, by analogy, judgment of 8 July 2010, *Afton Chemical*, C-343/09, EU:C:2010:419, paragraph 34), that question does not arise in the present case, since the appellant does not challenge the finding made in paragraph 53 of the judgment under appeal, but criticises the legal consequences drawn by the General Court from that finding in the light of the rules applicable to the re-examination procedure.

irregularity. There is no need to examine whether or not, as the appellant argues for the sake of completeness, the standing SAGs and the ad hoc expert groups offer equivalent procedural guarantees to MA applicants.

70. The first part of the first ground of appeal should, in my view, be upheld.

2. The second part, alleging an error of law in that the General Court found that the appellant was in any event required to show that the irregularity on the part of the CHMP could have influenced the outcome of the contested decision

71. In the second part, the appellant claims that the General Court erred in law in finding that, even accepting the procedural irregularity on the part of the CHMP in the re-examination of its initial opinion, the appellant had not been able to establish that consultation of the SAG on Psychiatry, instead of an ad hoc group of experts, might have led to a different outcome at the end of the procedure.

72. First, the appellant claims that the CHMP was required to consult the SAG on Psychiatry for the medicinal product Hopveus in the same way as it had consulted that SAG for the medicinal product Selincro. The appellant adds that, if the CHMP had consulted the SAG on Psychiatry, as it did during the evaluation of the medicinal product Selincro, the outcome of the contested decision might have been different. The appellant also complains that the General Court found that the medicinal products Selincro and Hopveus were not comparable for those purposes.

73. Second, the appellant claims that, even if it was correct to determine that Hopveus and Selincro were non-comparable medicinal products, the General Court nevertheless erred in law by failing to recognise the procedural defects concerning the organisation and expertise of the ad hoc group of experts responsible for the re-examination of the medicinal product Hopveus.

74. The Commission and the EMA reject those arguments.

75. According to the Commission and the EMA, the appellant's claim alleging an erroneous legal characterisation of the impact on the CHMP's opinion of the decision to convene an ad hoc group of experts rather than the SAG on Psychiatry should not succeed. In particular, the Commission and the EMA state that three members of the SAG on Psychiatry participated in the meeting of the ad hoc expert group and that they unanimously agreed with the answers provided by that group to the CHMP's questions. It is contended that in those circumstances, it cannot be accepted that the content of the contested decision would have been different if the SAG on Psychiatry had been consulted.

76. As a preliminary point, it should be recalled that, in paragraph 59 of the judgment under appeal, the General Court established that, in accordance with settled case-law, a procedural irregularity entails the annulment of the decision taken at the end of the administrative procedure at issue only if, in the absence of that irregularity, that procedure could have led to a different outcome. On that basis, the General Court found, in paragraph 65 of that judgment, that, even if the CHMP had wrongly convened the ad hoc group of experts instead of consulting the SAG on Psychiatry, such consultation would not have led to a different outcome in the light of the arguments put forward by the appellant. In particular, the General Court found that consultation of the SAG on Psychiatry for the medicinal product Hopveus was not justified by

the mere fact that that same standing SAG had been consulted for the medicinal product Selincro, since those two medicinal products were not comparable for the purposes of the re-examination procedure.

77. The Court of Justice has repeatedly held, including in the judgment of 18 June 2020, *Commission* v *RQ* (C-831/18 P, EU:C:2020:481), cited by the General Court, that an infringement of the rights of the defence, in particular the right to be heard, results in the annulment of the decision taken at the end of the administrative procedure at issue only if, had it not been for such an irregularity, the outcome of the procedure might have been different. In this regard, the Court has also stated that an appellant who alleges an infringement of his or her rights of defence cannot be required to show that the decision of the EU institution concerned would have been different in content but simply that such a possibility cannot be totally ruled out. [16] Furthermore, this question must be assessed in the light of the specific factual and legal circumstances of the case. [17]

78. In the present case, however, it must be noted that the appellant's criticism of the procedure for the re-examination of the medicinal product Hopveus did not allege infringement of its rights of defence or, more specifically, its right to be heard. On the contrary, the appellant claimed, in essence, in its action for annulment before the General Court, that it was the essential procedural requirements – in particular concerning the choice and composition of the group responsible for re-examining the initial opinion on its MA application – that the CHMP had infringed, by deciding unlawfully, in its view, to consult an ad hoc group of experts rather than the SAG on Psychiatry.

79. In that regard, I would like to point out that, as Advocate General Fennelly explained and illustrated in his Opinion in the *Commission* v *ICI* cases, [18] procedural requirements which are intrinsically linked to the formation and expression of the intention of the adopting authority are essential, and their observance is in the general interest. Those requirements, which go beyond the subjective rights or interests of a party in an administrative procedure, constitute objective standards of legality of EU law, with the result that *any* breach entails an annulment of the subsequent act, regardless of whether or not the outcome of the procedure might have been any different had they been respected. [19] This is true, in particular, of procedural rules which the institutions or agencies of the European Union have adopted for themselves or have had imposed on them. [20]

80. I note that the above reasoning is reflected in the case-law of the Court of Justice, which has consistently held that failure to comply with the procedural rules relating to the adoption of an act adversely affecting an individual constitutes an infringement of essential procedural requirements. In cases such as these, the Court of Justice has held that if the EU judicature finds, on examining the act at issue, that it was not regularly adopted, it must draw the necessary conclusions from the infringement of an essential procedural requirement and, consequently, annul the act vitiated by that defect. [21]

16 See, inter alia, judgment of 1 October 2009, *Foshan Shunde Yongjian Housewares & Hardware* v *Council* (C-141/08 P, EU:C:2009:598, paragraph 94 and the case-law cited).

17 See, to that effect, judgment of 10 September 2013, *G. and R.* (C-383/13 PPU, EU:C:2013:533, paragraph 40 and the case-law cited).

18 Opinion of Advocate General Fennelly in *Commission* v *ICI* (C-286/95 P and C-287/95 P, EU:C:1999:578, points 22 to 26).

19 Opinion of Advocate General Fennelly in *Commission* v *ICI* (C-286/95 P and C-287/95 P, EU:C:1999:578, point 28). See also Opinion of Advocate General Sharpston in *Spain* v *Commission* (C-114/17 P, EU:C:2018:309, point 95).

20 Opinion of Advocate General Fennelly in *Commission* v *ICI* (C-286/95 P and C-287/95 P, EU:C:1999:578, point 28).

21 Judgment of 20 September 2017, *Tilly-Sabco* v *Commission* (C-183/16 P, EU:C:2017:704, paragraph 115 and the case-law cited).

81. It follows that, where the conduct of the EU institution or agency concerned constitutes an infringement of essential procedural requirements, as established by the applicable rules, the appellant cannot be required to show that a different outcome would have been possible if the rules had been followed.

82. In the present case, even supposing that the approach adopted by the General Court could be endorsed, it should, in my view, be considered that, given that the formation of the group of experts consulted during the re-examination procedure would have differed if the SAG on Psychiatry had been convened, both as regards the number and identity of its members,[22] the outcome of that re-examination *could* have been different, without the need to examine, as the General Court did in the judgment under appeal, whether or not the medicinal products Hopveus or Selincro were comparable. Imposing on the appellant a more demanding demonstration requirement as to the potentially different outcome of the re-examination procedure would be liable to distort the case-law cited in point 80 above, which only requires proof of the mere probability of a different outcome.

83. In any event, I consider that, by extending case-law relating, in particular, to the rights of the parties involved in an administrative procedure, such as the rights of the defence, to an irregularity concerning the formation of a group of experts responsible for the scientific evaluation carried out during the procedure for the re-examination of MA applications, the General Court failed to examine the irregularity relied on by the appellant as an infringement of essential procedural requirements.

84. In that regard, it should be borne in mind that the lack of consultation or irregular consultation of a body or committee – such as, in the present case, the SAG on Psychiatry – has generally been regarded by the Court of Justice as constituting an infringement of an essential procedural requirement,[23] in so far as it is capable of vitiating the content of the act concerned and, at the same time, depriving it of the possibility of ensuring its legality.[24] That is all the more the case where, as in the present case and as I have set out in points 29 to 32 above, the consultation of a group of experts – either on the basis of a standing or ad hoc formation – has an impact on the scientific opinion supporting the CHMP's assessment at the end of the re-examination procedure and, ultimately, the decision to grant or refuse a MA application.

85. It follows that the irregularity alleged by the appellant in its action for annulment, relating to the irregular consultation of the ad hoc group of experts, should result, assuming it were well founded, in the annulment of the contested decision without any further demonstration on the appellant's part. Again, in this context, the reasoning concerning the comparison of the respective re-examination procedures applied to the medicinal products Hopveus and Selincro also becomes superfluous.

86. In the light of the foregoing, I would therefore propose that the Court of Justice find that the complaint made by the appellant in the present part of the first ground of appeal is well founded and hold that the General Court erred in law, in paragraph 58 of the judgment under appeal, in finding that, even assuming that the CHMP had wrongly decided to consult the ad hoc expert

[22] In that regard, it is sufficient to note, in the light of paragraph 130 of the judgment under appeal, that the ad hoc group of experts convened to evaluate the re-examination of the medicinal product Hopveus was formed of ten members – only three of which were from the SAG on Psychiatry – whereas, at the time it was established, that standing SAG was formed of 12 members.

[23] See, in that regard, judgment of 20 September 2017, *Tilly Sabco* v *Commission* (C-183/16 P, EU:C:2017:704, paragraph 115), and Opinion of Advocate General Fennelly in *Commission* v *ICI* (C-286/95 P and C-287/95 P, EU:C:1999:578, paragraph 24).

[24] See Gnes, M., 'Administrative Procedure and Judicial Review in the European Union', *Judicial Review of Administration in Europe*, Oxford University Press, 2021, p. 49.

group instead of the SAG on Psychiatry in the re-examination of its initial opinion, the appellant still failed to establish how such an irregularity could have led to the re-examination procedure having a different outcome in the present case.

87. The second part of the first ground of appeal should, in my view, be upheld, as should the first ground of appeal in its entirety.

B. The second ground of appeal, alleging that the General Court erred in law in its assessment of the requirement of objective impartiality in respect of experts A and B

88. By its second ground of appeal, the appellant criticises the General Court for finding that the conduct of the re-examination procedure, through the ad hoc group of experts, was not vitiated by a lack of objective impartiality, in particular as regards experts A and B.

89. First of all, the appellant claims that the General Court applied an incorrect legal criterion – specifically, that of subjective impartiality – when examining its second ground for annulment, alleging breach of the principle of objective impartiality. Next, the appellant argues that the General Court incorrectly assessed whether the activities of experts A and B complied with the principle of objective impartiality. Finally, the appellant submits that the General Court erred in law in so far as it failed to find that the policy of 6 October 2016 was insufficient for the purpose of guaranteeing the objective impartiality of the experts involved in the procedure for the re-examination of a medicinal product.

90. The Commission and the EMA dispute those arguments.

91. According to the Commission and the EMA, the EMA struck a very careful balance between the need for impartiality and the need for a high level of expertise. They state that Annex I to the policy of 6 October 2016 sets out that balancing operation. In addition, they claim that the General Court was right in noting that the conclusions of the ad hoc group of experts were adopted collectively by all of its members and that the principle of collegiate responsibility serves to guarantee objective impartiality. Finally, they state that the General Court was also right to find that none of the activities of A and B called into question by the appellant was capable of constituting a conflict of interest for the purposes of the policy of 6 October 2016.

92. Article 41 of the Charter of Fundamental Rights provides that every person has the right to have his or her affairs handled impartially by the European Union.

93. In accordance with settled case-law, that requirement of impartiality encompasses, on the one hand, subjective impartiality, in so far as no member of the institution concerned who is responsible for the matter may show bias or personal prejudice, and, on the other hand, objective impartiality, in so far as there must be sufficient guarantees to exclude any legitimate doubt as to bias on the part of the institution concerned. [25]

94. As regards the objective impartiality of the CHMP, it is established case-law of the Court of Justice that it may be jeopardised where one of its members could have a conflict of interest as the result of an overlap in function, irrespective of that member's actual conduct. [26] In so far as the CHMP may, in accordance with Article 56(2) of Regulation No 726/2004, delegate certain

[25] See judgment of 11 July 2013, *Ziegler* v *Commission* (C-439/11 P, EU:C:2013:513, paragraph 155 and the case-law cited).

[26] Judgment of 27 March 2019, *August Wolff and Remedia* v *Commission* (C-680/16 P, EU:C:2019:257, paragraph 30).

tasks relating to the preparation of scientific opinions on MA applications, such case-law must be understood as being applicable *mutatis mutandis* to the experts of the advisory groups established for those purposes.

95. Furthermore, as the General Court points out in paragraphs 93 to 96 of the judgment under appeal, the EMA adopted, pursuant to Article 63(2) of Regulation No 726/2004, the policy of 6 October 2016, a comprehensive document which applies without distinction to all medicinal products [27] and is applicable to committee members and experts of the SAGs and ad hoc groups. [28] The purpose of that policy is to strike a fair balance between preventing conflicts of interest and making the best expertise available for the evaluation and supervision of medicinal products in the European Union. [29]

96. To that end, restrictions on a person's participation in the work of the EMA are defined, in accordance with a broad discretion, [30] with regard to three factors: the nature of the declared interest, the time frame during which such an interest occurred and the type of activities in which the expert participates. [31] The last of those factors involves taking into account the group in which the individual is involved (scientific committee, such as the CHMP, working party or SAG) as well as his or her duties (in particular, chair or deputy chair, member or expert). These restrictions are set out in a table included in the annex to the policy of 6 October 2016.

97. In particular, this table provides that in the case of an expert who retains a 'current interest' by providing consultancy services for a pharmaceutical company on an individual medicinal product ('consultancy to company (individual medicinal product)'), [32] that expert may not be a member of the CHMP, but may, by contrast, be a member of a SAG or an ad hoc group of experts for the evaluation of pharmaceutical products. The only exception applicable in this respect concerns the evaluation of the product for which the expert is providing consultancy services ('No involvement with respect to procedures involving the relevant medicinal product […]').

98. In contrast, according to that table, an expert who retains a 'current interest' by providing general consultancy or strategic advisory services to one or more pharmaceutical companies ('consultancy to company (cross medicinal products/general)' or 'strategic advisory role for company (cross medicinal products/general)'), may not participate in any SAG or ad hoc expert group.

99. Lastly, it should be noted that, in accordance with the table annexed to the policy of 6 October 2016, where an expert retains a current interest as principal investigator in the clinical trial of a medicinal product, [33] he or she may form part of a SAG or an ad hoc group of experts for the purposes of a re-examination procedure, including with regard to the medicinal product concerned by his or her research tasks, although he or she may not participate in final deliberations or voting as regards that medicinal product.

[27] Judgment of 22 June 2023, *Germany and Estonia* v *Pharma Mar and Commission* (C-6/21 P and C-16/21 P, EU:C:2023:502, paragraph 46).

[28] See policy of 6 October 2016, section 2, under the heading 'Scope'.

[29] See policy of 6 October 2016, sub-section 4.1.

[30] Judgment of 22 June 2023, *Germany and Estonia* v *Pharma Mar and Commission* (C-6/21 P and C-16/21 P, EU:C:2023:502, paragraph 52).

[31] See policy of 6 October 2016, sub-section 4.2.1.2.

[32] For a definition of the term 'consultancy to a pharmaceutical company', see policy of 6 October 2016, section 3.2.1.1.

[33] For a definition of the term 'principal investigator', see policy of 6 October 2016, section 3.2.1.2.

100. In the present case, in respect of, in the first place, Expert A, the General Court found, in paragraph 117 of the judgment under appeal, as follows:

'It is apparent from [Expert] A's replies to the EMA's requests for clarification, dated 5 February and 2 April 2020, that the consultancy activities in question ended in January 2016 for Servier and in February 2015 for Sanofi Pasteur. In contrast, it appears that those consultancy activities were still in progress for the companies Janssen and Lundbeck at the time of the meeting of the ad hoc committee of experts on 6 April 2020. In that regard, as the appellant claims, the fact that [Expert] A indicated to the EMA in his email of 2 April 2020 that the date of his last consultancy activity for the latter two companies was March 2020 may not necessarily mean that those activities ended in March 2020 and that he had no current interest within the pharmaceutical industry at the time of that meeting.'

101. Contrary to what the Commission and the EMA maintained at the hearing, the General Court's finding in paragraph 117 of the judgment under appeal leads to the classification of Expert A, in accordance with the table annexed to the policy of 6 October 2016, as a provider of general consultancy services to one or more pharmaceutical companies ('consultancy to company (cross medicinal products/general)'), in particular to the companies Janssen and Lundbeck, and not as a provider of consultancy services for a pharmaceutical company on an individual medicinal product ('consultancy to company (individual medicinal product)').

102. Under the policy of 6 October 2016, such a finding should therefore have led the General Court to hold that, for as long as Expert A carried out those activities, he could not be a member of any group of experts responsible for re-examining a MA application.

103. However, it should be noted, first, that, in paragraph 118 of the judgment under appeal, the General Court found that the activity carried out by Expert A did not prevent him from being a member of the ad hoc group of experts set up for the purpose of re-examining the MA application for the medicinal product Hopveus, provided that the consultancy services provided by that expert to the pharmaceutical industry did not concern rival products.

104. Second, the General Court added, in paragraph 119 of the judgment under appeal, that, even if it was established that Expert A was engaged in consultancy activities for rival products of Hopveus, he was authorised to participate in the ad hoc group of experts responsible for the re-examination relating to the medicinal product Hopveus, provided that he had not been assigned a leading or coordinating role – chair, deputy chair, rapporteur or similar – in that group.

105. I note that the conclusions drawn by the General Court from the finding made in paragraph 117 of the judgment under appeal do not correspond to those set out in the policy of 6 October 2016, in particular for experts providing general consultancy services to one or more pharmaceutical companies. As indicated in point 98 of the present Opinion, that policy prohibits the participation of these experts in the re-examination procedure for pharmaceutical products before the EMA while their interest in the pharmaceutical industry is current, whether in a leading/coordinating role or as a simple member.

106. In those circumstances, it should be noted that the judgment under appeal does not follow the rules contained in the policy of 6 October 2016, and the General Court should have found that those rules prohibited the participation of Expert A in the re-examination procedure for the MA application relating to the medicinal product Hopveus.

107. Furthermore, the concept of 'rival product'[34] is, under the policy of 6 October 2016, only relevant in certain cases, which differ from the case identified by the General Court in the judgment under appeal. It follows that, in finding that, for the purpose of assessing the impartiality of Expert A, it was necessary to examine whether Selincro, which is manufactured and marketed by Lundbeck, was a rival product vis-à-vis the medicinal product Hopveus, the General Court added a criterion to its examination which was not relevant to the case at hand.

108. The appellant's claims as to the lack of objective impartiality on the part of Expert A should, consequently, be held to be well founded.

109. As regards, in the second place, Expert B, the General Court established, in paragraphs 103 to 112 of the judgment under appeal, first, that his activity as principal investigator for the product entitled 'AD 04' did not preclude his participation in the evaluation of the medicinal product Hopveus, in so far as those two products had different clinical objectives and targeted different groups of patients and were therefore not rival products. Second, the General Court found that the interests of Expert B about which the appellant complained were no longer current at the time of the meeting of the ad hoc group of experts and that, in any event, they related to products that did not compete with the medicinal product Hopveus.

110. It should be noted, in the light of the table annexed to the policy of 6 October 2016, that the General Court's assessment of Expert B's alleged conflict of interest is correct.

111. Indeed, in relation to the product 'AD 04', the activity of Expert B was not prohibited within the meaning of the policy of 6 October 2016, since, as indicated in point 99 of the present Opinion, that policy only prohibits a member of an ad hoc expert group from participating in the final deliberations and voting where the re-examination procedure relates to the same product as that for which that expert is acting as principal investigator, which is not the case here – without any need to examine whether the two medicinal products were rival products. As regards the remainder of the activities to which the appellant objected, it is sufficient to note that, in so far as they were no longer current at the time of the meeting of the ad hoc group of experts, they were likewise not capable of constituting a conflict of interest under the policy of 6 October 2016.

112. It follows that the complaints made by the appellant with regard to expert B are unfounded and should therefore not be upheld.

113. In the light of the foregoing, given that the appellant's claims as to the lack of objective impartiality on the part of Expert A should be upheld, it should be concluded that the General Court erred in law in finding that the conduct of the re-examination procedure, through the ad hoc group of experts, was not vitiated by a lack of impartiality. It is not necessary to examine, in that context, the appellant's argument raised for the sake of completeness as to whether the policy of 6 October 2016 was sufficient to ensure compliance with the principle of objective impartiality, as derived from Article 41 of the Charter.

114. The second ground of appeal should therefore, in my view, be upheld.

[34] For a definition of the term 'rival product', see policy of 6 October 2016, section 3.2.2.

C. Final remarks

115. In points 69 and 114 of this Opinion, I propose that the Court of Justice uphold the grounds of appeal relied on by the appellant, alleging, first, failure to consult the SAG on Psychiatry and, second, failure to observe the requirement of objective impartiality in relation to Expert A, who was a member of the ad hoc group of experts responsible for re-examining the MA application submitted by the appellant. The judgment under appeal should therefore be set aside, either on the basis of the two grounds of appeal, or alternatively on the basis of one of the two grounds of appeal.

116. Pursuant to the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the Court of Justice quashes the decision of the General Court it may itself give final judgment in the matter, where the state of the proceedings so permits. As can be seen from my analysis of the two grounds relied on by the appellant in support of its appeal, that is my position in the present case.

117. Finally, under Article 184(2) of the Rules of Procedure of the Court of Justice, the Court of Justice is to make a decision as to costs where the appeal is well founded and the Court itself gives final judgment in the case. Under Article 138(1) of the Rules of Procedure, which applies to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In the present case, as the appellant has sought an order that the Commission and the EMA pay the costs incurred before the General Court and before the Court of Justice, and as the Commission and the EMA are, in my view, unsuccessful, they should be ordered to pay the appellant's costs and to bear their own costs.

V. Conclusion

118. In the light of the foregoing, I propose that the Court of Justice:

– set aside the judgment of 2 March 2022, *D & A Pharma* v *Commission and EMA* (T-556/20, EU:T:2022:111);

– uphold the action for annulment brought by D & A Pharma at first instance against the Commission Implementing Decision of 6 July 2020 refusing the marketing authorisation application for the medicinal product for human use Hopveus – sodium oxybate pursuant to 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 and to annul that decision;

– order the European Commission and the European Medicines Agency to pay the costs.