Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 7 December 2017 [1]

Case C-557/16

Astellas Pharma GmbH
joined parties:
Helm AG,
Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)

(Request for a preliminary ruling from the Korkein hallinto-oikeus (Supreme Administrative Court, Finland))

(Reference for a preliminary ruling — Medicinal products for human use — Marketing authorisation issued for a generic of a reference medicinal product — Decentralised procedure — Powers of the competent authority of the concerned Member State — Judicial review — Determination of the data exclusivity period)

I. Introduction

1. In 2014, Helm AG obtained a Finnish marketing authorisation for a generic copy of medicinal products previously developed by Astellas Pharma GmbH.That authorisation was granted pursuant to the decentralised procedure regulated by Directive 2001/83/EC. [2] In that procedure, Finland was one of the *concerned* Member States. Denmark acted as the *reference* Member State.

2. Astellas Pharma GmbH disagreed with the calculation of the data exclusivity period carried out in the assessment of Helm AG's application. It challenged the marketing authorisation issued by the competent Finnish authority before the Finnish courts.

3. The ensuing legal question referred to this Court is one of competence of the national bodies to review such an assessment: may a regulator of a concerned Member State, such as the competent Finnish authority, and/or the courts of the same concerned Member State, review a previous determination of the data exclusivity period made within the decentralised procedure?

II. Facts, national proceedings and questions referred

4. On 19 July 2005, pursuant to the applicable national law, [3] the competent authority of the Federal Republic of Germany granted Astellas Pharma GmbH ('Astellas Pharma') a marketing authorisation for the medicinal product Ribomustin. The active substance of that product was bendamustine ('the 2005 Ribomustin MA').

1 Original language: English.

2 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).

3 Gesetz über den Verkehr mit Arzneimitteln (German Law on medicinal products) of 24 August 1976 (BGBl. I, p. 2445).

5. On 15 July 2010, Astellas Pharma obtained a marketing authorisation for another medicinal product called Levact. The active substance of that product is also bendamustine, but it has different therapeutic indications ('the 2010 Levact MA'). The 2010 Levact MA was granted by the competent French authority, under the decentralised procedure provided for in Article 28(3) of Directive 2001/83.

6. On 7 November 2012, Helm AG ('Helm') applied for a marketing authorisation for the medicinal product Alkybend. That application was also made under the decentralised procedure. Helm requested that Denmark be the reference Member State, with Finland and Norway as the concerned Member States. The application stated that Alkybend is a generic medicinal product within the meaning of Article 10(1) of Directive 2001/83.[4] Its stated reference medicinal product is Levact.

7. On 17 January 2014, the competent Danish authority issued an assessment report. That report stated that all the States participating in the decentralised procedure used Levact as the reference medicinal product. To calculate the data exclusivity period however, Ribomustin was the reference medicinal product. This was because it was considered that the 2010 Levact MA was included within the global marketing authorisation[5] of Ribomustin. The assessment report further stated that the data exclusivity period had expired in those States which, at the relevant time, opted for a six-year data protection period.[6]

8. On 28 March 2014, the competent authority, Lääkealan turvallisuus- ja kehittämiskeskus (the Finnish Medicines Agency) ('FIMEA') issued a national marketing authorisation for Alkybend ('the 2014 Alkybend MA').

9. Astellas Pharma brought an action against that decision before the Helsingin hallinto-oikeus (Administrative Court, Helsinki, Finland). That court rejected the action. It held, inter alia, that Astellas Pharma was granted the first marketing authorisation for the reference medicinal product (Ribomustin) on 19 July 2005. The data exclusivity period, starting from that date and applicable also to Levact, was six years. FIMEA could therefore issue the 2014 Alkybend MA.

10. Astellas Pharma appealed before the Korkein hallinto-oikeus (Supreme Administrative Court, Finland), the referring court. It asked that court to set aside the first-instance decision as well as the 2014 Alkybend MA.

11. Astellas Pharma's view is that the applicable data exclusivity period should have been calculated from the 2010 Levact MA. The 2005 Ribomustin MA was not relevant because it had not been granted in accordance with Directive 2001/83. That marketing authorisation did not become final as there was disagreement between the competent German authority and Astellas Pharma over some of the therapeutic indications initially applied for. The issuance of the marketing authorisation for Levact required extensive additional research. The applicable data exclusivity period should have been examined independently of the data exclusivity period that applied to Ribomustin.

12. FIMEA asked the referring court to dismiss the appeal. The data exclusivity period was calculated from the 2005 Ribomustin MA. For Finland, the applicable six-year data exclusivity period had expired at the time the 2012 Alkybend application had been made. The shape, dosage and method of administration or administration route of Alkybend pertained to a pre-existing marketing authorisation.

4 Article 10(1) of Directive 2001/83 states that 'by way of derogation …the applicant [for a marketing authorisation] shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community'.

5 Within the meaning of Article 6(1) second subparagraph of Directive 2001/83.

6 During the period concerned by the present case, the Member States could apply a data exclusivity period of six or more years.

13. Helm also asked the referring court to dismiss the appeal. It stated that the 2005 Ribomustin MA complied with Directive 2001/83. It further stated that the 2005 Ribomustin MA could not be challenged in Finland. In its view, the Member States concerned in the decentralised procedure can oppose a national marketing authorisation solely on the ground of risk to public health. Therefore, FIMEA lacked competence to review the 2005 Ribomustin MA.

14. In those circumstances, Korkein hallinto-oikeus (Supreme Administrative Court) stayed the proceedings and referred the following questions to the Court:

'(1) Are Articles 28(5) and 29(1) of Directive 2001/83/EC …to be as interpreted as meaning that, the competent authorities of the concerned Member State in the decentralised procedure for marketing authorisations for generic medicinal products in accordance with Article 28(3) of that directive, are not themselves competent when issuing a national marketing authorisation to determine the time from which the data exclusivity period for the reference medicinal product begins to run?

(2) If the answer to the first question is that, when issuing a national marketing authorisation, the competent authorities of a Member State are not competent to determine the time from which the period of data exclusivity of the reference medicinal product starts to run:

— is the court of that Member State when dealing with an appeal by the holder of the marketing authorisation for the reference medicinal product required to determine the time from which the period of data exclusivity starts to run, or is it subject to the same limit as the national authorities of that Member State?

— in those circumstances, how is the national court to give effect to the right of the holder of the marketing authorisation of the reference medicinal product under Article 47 of the Charter of Fundamental Rights of the European Union and Article 10 of Directive 2001/83 to effective legal protection with regard to data exclusivity?

— does the claim for effective legal protection require the national court to examine whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/83?'

15. Written submissions were made by Astellas Pharma, Helm, the Belgian and German Governments, Ireland, the Finnish, United Kingdom, and Norwegian Governments, as well as by the European Commission.

16. Astellas Pharma, Helm, the Spanish Government, Ireland, the Finnish, United Kingdom, and Norwegian Governments, and the Commission presented oral argument at the hearing that took place on 20 September 2017.

III. Assessment

17. It appears from the facts presented in the order for reference that the application for marketing authorisation for Alkybend was made under the abridged procedure. That procedure is applicable, inter alia, to marketing authorisations for generic medicinal products. In simple terms, the abridged procedure, governed by Article 10(1) of Directive 2001/83, means that the applicant can refer to the results of toxicological and pharmacological tests or the results of clinical trials existing for the reference medicinal product. If the applicant can demonstrate that the medicinal product concerned

by the marketing authorisation application is a generic of the reference medicinal product,[7] the applicant does not have to produce those data *ex novo*.

18. The abridged procedure can be used, in essence, upon the expiration of the data exclusivity period related to the reference medicinal product. By providing for a data exclusivity period, Article 10 of Directive 2001/83 protects the rights of the holder of the initial marketing authorisation granted for the relevant reference medicinal product, the data of which are relied on by the applicant that wishes to manufacture or market the generic copy.[8]

19. The data exclusivity period is currently eight years.[9] However, as follows from the order for reference, under the previous legal regime, Finland opted for a data exclusivity period of six years.[10]

20. This additional explanation provides for a better understanding of the background to the dispute in the main proceedings. It ought to be stressed, however, that the case referred before this Court concerns general, systemic questions relating to procedures and the competences of the actors involved in those procedures. The referring court asks about the possibility and potential scope of *administrative* and *judicial* review of the determination of the data exclusivity period in one of the *concerned* Member States.

21. Although the rather complex factual elements of the present case were discussed by the parties at the hearing in quite some detail, those questions are not for this Court to solve. This Opinion therefore takes no position on which of the medicinal products concerned in the main proceedings should have been used as the reference medicinal product or when the applicable data exclusivity period started running and when it expired.

22. This Opinion is structured as follows: first I will make some introductory remarks about the evolution and the exact nature of the authorisation procedure that is relevant in this case (A). I will then deal with the scope and limits of *administrative* review available in the concerned Member State acting within the decentralised procedure (B). Next, I shall turn to the admissibility and scope of *judicial* review in the concerned Member State (C).

7 Which is or has been authorised for not less than eight years in a Member State or in the European Union. See above footnote 4.

8 See judgment of 23 October 2014, *Olainfarm* (C-104/13, EU:C:2014:2316, paragraph 37).

9 In principle and subject to a transitional regime: reference is often made to the '8 + 2 formula', which comprises eight years of data protection (during which the applicant for a generic product cannot cross-refer to the respective data) and two years of marketing protection during which the generics cannot yet be placed on the market.

10 That, according to the order for reference, already expired with respect to Ribomustin when Helm applied for the marketing authorisation for Alkybend. For the applicable data exclusivity period, see the transitional provision provided for in Article 2 of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 on the Community code relating to medicinal products for human use (OJ 2004 L 136, p. 4), read in conjunction with Article 3 of that directive. It follows that the data exclusivity period introduced by Directive 2004/27 did not apply to reference medicinal products for which an application for authorisation had been submitted before 30 October 2005.

A. The evolution of the authorisation procedures under Directive 2001/83

23. Directive 2001/83[11] regulates (one part of) the process of granting marketing authorisation of medicinal products for human use within the European Union. Under Article 6(1), first subparagraph 'no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004'.[12]

24. There are therefore two types of procedure for obtaining a marketing authorisation within the European Union: 'vertical' (centralised EU-wide procedures, with the EU institutions as the decision-takers); or 'horizontal' (mutual recognition and decentralised procedures, with the Member States' authorities as the decision-takers).

25. Although based on a series of successive or parallel national decisions, the horizontal procedures make the application process easier. The applicant does not need to submit the relevant information on the medicinal product at issue in each Member State separately.

26. Only the horizontal type of marketing authorisation procedure, and more specifically the *decentralised* one, is relevant for the present case. The horizontal type of procedure provided for in Directive 2001/83 has evolved considerably over time. The key change came with Directive 2004/27. I will therefore refer to the 'pre-2004' and 'post-2004' versions of Directive 2001/83 so as to distinguish between the two different regimes.

27. I will first outline the pre-2004 authorisation regime (1), before turning to the decentralised procedure and, more generally, to the current (to the extent that it is relevant for the present case) post-2004 authorisation regime (2). I will conclude by making some remarks on the co-decision rationale that, in my view, characterises the current regime (3).

1. The pre-2004 marketing authorisation regime and mutual recognition

28. Before 2004, where the applicant for a marketing authorisation wished to market a medicinal product (whether generic or not) in more than one Member State, Directive 2001/83 provided for the mutual recognition procedure. That procedure could be used by an applicant that had already been granted a marketing authorisation in one of the Member States. The Member State that had issued the first marketing authorisation was designated, for the purpose of the mutual recognition procedure, as the 'reference Member State'. The mutual recognition procedure made it possible for the holder of a pre-existing marketing authorisation to have the latter recognised in another/other Member State(s). These States were referred to as the 'Member States concerned'.

29. More specifically, pursuant to Article 28 of the pre-2004 version of Directive 2001/83, before submitting the application for mutual recognition, such a holder (and applicant) had to inform the reference Member State that the application for mutual recognition was to be made.

11 That directive codified the pre-existing authorisation regime put into place by Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ, English Special Edition, Series I, Volume 1965-1966, p. 20); and its subsequent amendments.

12 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). This centralised procedure is compulsory for medicinal products listed in the Annex to the Regulation.

30. The holder had to make it possible for the reference Member State to verify whether the dossier related to the initial marketing authorisation and the dossier related to the mutual recognition procedure were identical. A request also had to be made that the reference Member State prepare an assessment report [13] in respect of the medicinal product at issue, or, if necessary, to update any such existing report. Within 90 days, the report had to be sent to the Member States concerned, to which the holder simultaneously submitted its applications. [14]

31. Within a subsequent period of 90 days, the Member States concerned had to recognise the (initial) marketing authorisation granted by the reference Member State, 'save in the exceptional case', where, pursuant to Article 29, the Member States concerned deemed that the medicinal product at issue presented 'a risk to public health'. In such a case, the 'objecting' Member States had the obligation to inform the applicant, the reference Member State and any other Member State concerned. All the Member States concerned had to 'use their best endeavours to reach agreement' in this respect. The failure to reach such an agreement led to the matter being referred to the Agency. [15]

32. With regard to this pre-2004 mutual recognition procedure, the Court held in *Synthon* that the Member States had the obligation to give effect to the pre-existing marketing authorisation. The invocation of a risk to public health was the only ground on which a Member State could rely to object to such recognition. If such an objection were not raised, the initial marketing authorisation had to be recognised. The Member States concerned were prevented from questioning the assessment conducted by the reference Member State. [16]

33. The factual circumstances of the *Synthon* case illustrate how, once a holder has already obtained a marketing authorisation and triggered the mutual recognition procedure, the pre-existing marketing authorisation has to be recognised by the Member States concerned. In that particular case, the applicant sought to obtain mutual recognition in the United Kingdom in respect of a pre-existing marketing authorisation that it had obtained in Denmark.

34. Thus, the key element of the pre-2004 procedure was the existence of a marketing authorisation, which had *already been granted* in one Member State, and which, as the Court stated, had to be recognised by the competent authorities in other Member States. That 'clear and precise' obligation [17] could be called into question only if the public health objection was raised within the prescribed procedure, which did not happen in that case.

13 In simple terms, the assessment report is the key document of the mutual recognition procedure as well as the decentralised procedure (the features of which are explained below in this Opinion). It explains why a marketing authorisation and each of the proposed indications have been or can be approved or rejected by the reference Member State. It further explains the terms of the summary of product characteristics, package leaflet and labelling. It details the benefit-risk assessment for the medicinal product. In particular, it scientifically evaluates the quality, safety and efficacy of a medicinal product. It has been emphasised that the assessment reports 'should be sufficiently detailed to allow for secondary assessment by other Member States' experts. As such these reports are central to the efficient operation of the mutual recognition procedure and the decentralised procedure'. See Best Practice Guide on the Assessment Report for mutual recognition and decentralised procedures, Coordination Group for Mutual Recognition and Decentralised Procedures — Human, January 2017, p. 3. See also Commission document 'Notice to Applicants. Procedures for marketing authorisation. Chapter 2: Mutual Recognition', February 2007, pp. 24 to 25.

14 As provided by Article 28(2) of the pre-2004 version of Directive 2001/83, the holder shall identify any additions or amendments. In the latter case, he shall certify that the summary of the product characteristics proposed by him in accordance with Article 11 is identical to that accepted by the reference Member State in accordance with Article 21. Moreover, he shall certify that all the dossiers filed as part of the procedure are identical.

15 The European Agency for the Evaluation of Medicinal Products ('the Agency') established previously by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use (OJ 1993 L 214, p. 1), now, the European Medicines Agency. The Agency evaluates applications for marketing authorisations submitted through the centralised procedure provided for by Regulation No 726/2004. It also resolves issues such as the safety of medicinal products arising during the mutual recognition procedure or the decentralised procedures.

16 Judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565, paragraphs 25, 28 and 29).

17 Judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565, paragraph 45).

2. The post-2004 authorisation regime: a new decentralised procedure

35. Within that framework, Directive 2004/27 first modified the pre-2004 mutual recognition procedure and, second and more importantly, added the *decentralised* procedure. Thus, under the post-2004 version of Directive 2001/83, there are now two horizontal procedures allowing the applicant to obtain marketing authorisations in more than one Member State.

36. This case concerns the decentralised procedure (that was introduced post-2004), which is to be used to obtain *simultaneously* more than one national marketing authorisation for a medicinal product that has *never been granted one before*. That fundamentally distinguishes this new decentralised procedure from the mutual recognition one. The latter procedure is maintained under post-2004 regime, but its use continues to be conditional on the prior issuance of a marketing authorisation. [18]

37. The *decentralised* procedure is provided for in Article 28(3) et seq. of the post-2004 version of Directive 2001/83. Its structure is as follows: the applicant chooses one of the Member States, in which he seeks to obtain a marketing authorisation, to act as the reference Member State. [19] Within 120 days, the reference Member State prepares a draft of the assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet (these documents together are referred to, in this Opinion, as 'product-related documents'). The reference Member State sends those documents to the applicant and to the concerned Member States. [20]

38. Further to Article 28(4), within 90 days of receipt of the product-related documents, the concerned Member States shall approve them and shall inform the reference Member State accordingly. The reference Member State records the agreement, closes the procedure, and informs the applicant.

39. Under Article 28(5) of the post-2004 version of Directive 2001/83, each Member State in which an application under the decentralised procedure has been submitted shall adopt, within 30 days, a decision in conformity with the approved product-related documents. It is then in fact through such parallel national decisions that the actual marketing authorisation for marketing the medicinal product on the territory of each individual Member State is granted.

40. If, however, one of the concerned Member States cannot approve the product-related documents on the grounds of 'potential serious risk to public health', the specific procedure under Article 29 of the Directive 2001/83is triggered. In the first step, if an agreement cannot be reached among the concerned Member States, the matter is referred to a coordination group. In the second step, if even that fails, the matter is referred to the Agency. [21]

41. Pending the outcome of that referral procedure, the Member States that have approved the product-related documents, at the request of the applicant, may authorise the medicinal product, [22] but again only with regard to their own territory.

18 Article 28(2) of the post-2004 version of Directive 2001/83 ('Where the medicinal product has already received a marketing authorisation at the time of application […]').

19 See Article 28(1), first subparagraph, of the post-2004 version of Directive 2001/83.

20 Article 28(3) of the post-2004 version of Directive 2001/83.

21 Article 29(4) and (5) of the post-2004 version of Directive 2001/83.

22 Article 29(6) of the post-2004 version of Directive 2001/83. In that event, the authorisation granted shall be without prejudice to the outcome of the pending procedure concerning the objection raised by another concerned Member State.

42. Thus, for a concrete decentralised procedure to be finalised, there must first be *an agreement* on the product-related documents by the competent authorities involved. Only then, in the second step, will those authorities that agreed each have the obligation to adopt their own *national* marketing authorisation. These decisions are issued in parallel, in no particular order, within the 30-day limit set in Article 28(5) of Directive 2001/83.

43. In sum, the genuine operation of the decentralised procedure, despite it forming part of a regime heralded as an 'important step towards achievement of the objective of the free movement of medicinal products',[23] arguably remains somewhat distant from a unified procedural framework for the internal market in medicinal products. In contrast to the potential obligation to satisfy all conditions and evidentiary requirements in the concerned Member States, the decentralised procedure certainly contains elements of welcome simplification. However, the procedure as it stands can hardly be described as any form of automatic and categorical mutual recognition: the adoption of the final national decision is made conditional upon the completion of an intermediary step, namely the approval of the product-related documents.

44. I further note that Directive 2004/27 extended this two-step mechanism to the mutual recognition procedure to improve the 'opportunities for cooperation between Member States'.[24] The specifics of the mutual recognition procedure are described in Article 28(2) of the post-2004 version of Directive 2001/83. In other words, the post-2004 mutual recognition and decentralised procedures are framed by the same basic rules that apply from the moment when the reference Member State sends the respective product-related documents to the concerned Member States.[25]

3. Mutual recognition or co-decision?

45. The essence of the present case is the determination of the scope of administrative and judicial review of a finding made within a decentralised procedure.

46. As was explained in the previous section, since its inception in 2004, that procedure has been of a distinctly hybrid nature. Some of the parties in this case argued that the conclusions reached by the Court in the judgment in *Synthon* in respect of the *pre-2004 mutual recognition* procedure should also be applied to the *decentralised* procedure.

47. The general importance of mutual recognition in the European Union can hardly be overstated. Thus, once a decision has been duly *adopted* by one Member State, the others must recognise it, save in exceptional circumstances.

48. However, such reasoning and logic can technically be applied only once *there is a decision* issued by one Member State which others shall recognise.

49. The purpose of this rather long and detailed introduction is to show that compared to the pre-2004 recognition procedure, the decentralised procedure is simply of a different kind and nature. In a decentralised procedure, all of the Member States *participate* in the elaboration of their decision *at the same time*. To put it metaphorically, cooking with friends is not the same as sharing meals that have already been prepared.

23 Recital 14 of the Directive 2001/83. See also recitals 4 and 5 of the same Directive, as well as the judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565, paragraphs 25 and 32).

24 According to recital 11 of Directive 2004/27.

25 To be specific, the procedural steps pursuant to paragraphs 4 and 5 of Article 28 of the post-2004 version of Directive 2001/83 are the same. The public health-related exception applies to both procedures as well.

50. Thus, the approach to the present case simply needs to be nuanced in view of the changed nature of the procedure in question. The current Articles 28 and 29 of Directive 2001/83 are different from those applicable at the time of the facts relevant for the Court's judgment in *Synthon*. That case was assessed in the light of the pre-2004 version of Directive 2001/83.

51. The evolution from the pre-2004 to post-2004 versions of Directive 2001/83 was marked by the insertion of an intermediary step that brought all the concerned Member States into the pre-authorisation approval procedure. Whether, in the light of the stated aim of the 2004 amendments,[26] that was in fact a step forward in terms of harmonisation of the authorisation rules and procedures reached previously may be left for legal scholars to assess. What is nonetheless clear for the purpose of the present case is that the rules of the game have changed.

52. It ought to be added that this two-step system consisting in collective approval, followed by national marketing authorisations being issued in parallel, applies under the post-2004 version of Directive 2001/83, not only to the decentralised procedure, but to the mutual recognition procedure as well. Although the latter procedure is not at issue in the present case, I note that the pre-2004 mutual recognition logic seems to have shifted to what looks like a 'co-decision' mechanism that chronologically precedes, and is clearly separate from, the issuance of individual marketing authorisations.

53. In the light of the foregoing, I am of the view that, for the purpose of the present case which concerns a *decentralised* procedure, the approach taken by the Court in *Synthon* remains applicable by analogy only once the agreement among the authorities of the concerned Member States (and the reference Member State) concerning the product-related documents has been reached. However, until such an agreement, the obligation to issue a decision is simply not triggered. Even less so is there a *decision* to be recognised that could trigger the principle of mutual recognition.[27] The obligation to adopt a decision, or rather the parallel national decisions, is triggered only subsequently, once the above-mentioned agreement has been reached.

54. However, it ought also to be stressed that once the agreement concerning the product-related documents has been reached, the competent authorities of the concerned Member States cannot unilaterally start revisiting and re-assessing those very same documents. Once they agree, they are bound. They have an explicit and precise obligation to adopt their own national marketing authorisations within the 30-day time-limit.

B. Question 1: Powers of competent administrative authorities in the decentralised procedure

55. By the first preliminary question, the referring court asks in essence whether the competent authority of one of the concerned Member States can assess, *unilaterally*, the finding concerning the expiration of the data exclusivity period agreed upon previously within the decentralised procedure.

56. As already suggested above, once all the Member States have reached an agreement, they cannot start subsequently and unilaterally revisiting it. All parties to the agreement are bound by the terms of that agreement. Similarly to what the Court noted in *Commission* v *France*,[28] it is from this moment (approval of the product-related documents) that the authorities of the concerned Member States cannot refuse to follow, or depart from the result of that process.

26 Above, footnote 24.

27 Save again for the scenario under Article 29(6) in the post-2004 version of Directive 2001/83.

28 Judgment of 19 July 2012, *Commission* v *France* (C-145/11, not published, EU:C:2012:490). That case concerned an analogous provision of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1).

57. That *Synthon*-based logic still holds true. But it answers only half of the question posed by the national court. The second part of the question is effectively about the duties and the role of the national authorities of the concerned Member States *before* the agreement has been reached.

58. In order to suggest a reply to the second part of that question, which is also relevant for the issue of admissibility and scope of potential judicial review, I will first examine the exact nature of competence that the concerned Member States enjoy in the decentralised procedure (1). I will then turn to the notion of 'potential serious risk to public health': pursuant to Article 29 of Directive 2001/83, that is the only possible objection that a competent authority may raise in this context (2).

1. The competence of the concerned Member States in the decentralised procedure

59. The submissions made by the parties in the present proceedings advanced several approaches to the assessment of the scope of the competence of the competent authorities involved in a decentralised procedure. With some degree of simplification, two overall approaches can be identified.

60. Under the first approach, the 'mutual recognition' logic appears also to extend to the pre-approval stage. The authorities of the concerned Member States are seen as mere 'rubber stamping' authorities that are not supposed to genuinely intervene in the assessment made during the pre-approval stage. They have the obligation to approve the documents sent to them by the reference Member State. This is, in essence, the position of Helm, the German and Spanish Governments, Ireland, and the Finnish and Norwegian Governments.

61. Under the second approach, the authorities of the concerned Member States act as participants in the approval process. They do more than mere rubber stamping. They are supposed to cooperate. As they are entitled to add substantive input on the content of the assessment report, they become jointly responsible for the output. In this manner, the approval process is seen as a cooperative dialogue, rather than a mechanical copy-paste exercise of what would otherwise be prepared by the reference Member State. This is essentially the position adopted by the Commission. In this sense, the Commission notes that the determination of the data protection period makes up part of the general agreement that the competent authorities involved in the decentralised procedure approve. Once that agreement has been reached, these authorities cannot depart from it. Conversely, Astellas Pharma considers that there is an obligation for the competent authorities of the concerned Member States to review the data protection period when deciding upon the national marketing authorisation. Similarly, the Belgian and the United Kingdom Governments consider that these authorities have the power to make such an assessment.

62. In my view, the text, context and the logic of the relevant provisions of the post-2004 version of Directive 2001/83 would indicate that what the legislature had in mind for the approval process before a joint decision is reached was the latter approach.

63. First, if the powers of the competent authorities of the concerned Member States were limited to mechanical approval without any intervention on the substance, it would make little sense to give them also the power to block the whole agreement twice (have the matter referred first to coordination group and, on failing to reach an agreement there, to the Agency). Why establish rather complex procedures in Article 29(4) and Article 32 of Directive 2001/83, whose purpose is to overcome disagreement among the competent authorities, if those authorities were not supposed to voice their concerns, if they feel that it is appropriate?

64. Second, each of the Member States is supposed to adopt a separate marketing authorisation at the end of the whole process. If the role of the authorities of the concerned Member States were circumscribed to mechanical copying, it would be more logical to simply provide for the obligation to recognise the initial marketing authorisation (as regards the mutual recognition procedure) or the

product-related documents as established by the reference Member State.[29]

65. Third, the adoption of the respective national marketing authorisations, each of them with its own territorial validity, has to be done within the time limit prescribed in Article 28(5) of Directive 2001/83. I note that, in this respect all the competent authorities involved are put on an equal footing, including the reference Member State, as shown by the fact that Directive 2001/83 does not provide for the adoption of those national marketing authorisations to occur in a pre-established chronological order. Thus, it may even occur that the marketing authorisation in the concerned Member State(s) is issued *before* the marketing authorisation in the reference Member State.

66. Fourth, it is certainly true that the reference Member State plays a distinct role in the entire process, as some of the parties to these proceedings submitted. It prepares the draft product-related documents. The guidelines of the Coordination Group for Mutual Recognition and Decentralised Procedures — Human further suggest that the concerned Member States should rely on the assessment of the reference Member State which channels the dialogue between them and the applicant.[30]

67. However, once again, that does not mean that the concerned Member States have no role to play. They are still under the obligation to communicate any serious risks to public health and 'points for consideration'.[31] As a result, the authorities of the concerned Member States are considered to be places of the secondary assessment of the evaluation made by the reference Member State.[32]

68. Fifth, consider the fact that an authority of a concerned Member State contributes to, and can take an autonomous position within, the approval process. That further transpires through the possibility, given in Article 29(6) of Directive 2001/83, for certain concerned Member States to issue a national marketing authorisation, namely, those who approved the product-related documents, in the event that another concerned Member State had raised a health-related objection, and that objection was still subject to the applicable procedure.

69. Thus, by the 2004 amendments, the EU legislature has put into place a horizontal dialogue between the respective authorities. National authorities were given a possibility to intervene as long as the approval process is open, that is, until the product-related documents are approved.[33]

29 As a matter of practice, it appears that the applicant engages in an informal process of 'validation' of the application with all the concerned Member States (including the reference Member State) in order to confirm that the application to be submitted does not contain any flaws that would make it unfit for the procedure. 'The validation is split between [the reference Member State] (full validation check) and CMS [the concerned Member States] (limited list). Both CMS and [the reference Member State] will start validating in parallel using the respective checklists. …CMS should inform both the applicant and the [reference Member State] via email about any validation issues by using the CMS checklist.' See document 'Procedural advice: Automatic validation of MR/Repeat-use/DC Procedures', Coordination Group for Mutual Recognition and Decentralised Procedures — Human, October 2016, Doc. Ref.: CMDh/040/2001/Rev.5, p. 1.

30 Best Practice Guide for decentralised and mutual recognition procedures, Coordination Group for Mutual Recognition and Decentralised Procedures — Human, April 2013, Doc. Ref.: CMDh/068/1996/Rev.1, see p. 2, especially points 10 and 11.

31 *Ibidem*, p. 2, point 10.

32 'The reports should be sufficiently detailed to allow for secondary assessment by other Member States' experts.' See Best Practice Guide on the Assessment Report for mutual recognition and decentralised procedures, Coordination Group for Mutual Recognition and Decentralised Procedures — Human, January 2017, *Doc. Ref.: CMDh/073/2003*, Rev5, p. 3.

33 It might be added that the contemplated cooperative nature of the process also transpires from the legislative history of the 2004 amendment, namely from the description made in this respect by the Commission in the Proposal COM(2001) 404 final (proposal eventually leading to Directive 2004/27) where it was stated that 'The mutual recognition procedure has been criticised because of difficulties encountered in practice. Under the present system, the Member States must recognise an initial authorisation granted by the reference Member State. *It is always more difficult to go back on a scientific decision than to take an initial decision jointly as part of a scientific cooperation procedure*. … There would be cooperation between Member States before the decision is taken on the basis of the evaluation conducted by one of them' (emphasis added).

70. To sum up: the system provided for in Article 28 of Directive 2001/83 is a system based on 'co-decision' logic. In that system, all of the participating authorities have to reach an agreement on the three types of documents referred to in that provision. It is only once that agreement has been reached (as an intermediary, preparatory, and internal act) that the competent authorities will proceed to the issuance of the individual national marketing authorisations. While each of the competent authorities has to act in conformity with the approved product-related documents, their successive steps in their respective national systems are largely independent of each other.

2. What is a 'potential serious risk to public health'

71. Having clarified the nature of the procedure under Article 28 of Directive 2001/83, I now turn to the issue of objection(s) that may be raised in the pre-agreement stage. Can the competent authorities in the concerned Member States actually voice any concerns relating to potentially incorrect calculation of the data protection period by the authority of the reference Member State?

72. Article 29(1) of Directive 2001/83 provides for only one type of potential objection that may be raised by the concerned Member State(s) in that process: 'potential serious risk to public health'.

73. I readily acknowledge that a potential objection formulated in this way does not seem, at first sight, to be overly broad. In a way, the formulation of that exception appears to remain firmly rooted in the pre-2004 mutual recognition vocabulary.[34] However, as with a number of other elements of Directive 2001/83 in its pre-2004 and post-2004 versions, the outer shell does not entirely correspond with the inner content.

74. Although the language of that exception still remains in the pre-2004 realm of 'mutual recognition', the 2006 Commission Guideline issued under Article 29(2) of Directive 2001/83 giving flesh to that notion is considerably more generous in scope.[35] By analogy to what I stated elsewhere, Commission guidelines are certainly not legally binding.[36] But the Commission guideline in question provides useful clarification as to the possible scope of the notion at issue.

75. Considering the scope of what might fall under 'a potential serious risk to public health', the 2006 Guideline is very far from being restrictive. I note that that guideline includes a comprehensive list of possible aspects that may be examined in order to detect whether a given medicinal product represents 'a potential serious risk to public health'. Apart from issues such as efficacy, safety, quality, and overall risk-benefit assessment, with all of those (already rather broad indeterminate notions) being an addition and merely illustrative, I note that 'product information' that is 'misleading or incorrect for either the prescribers or the patients', is also among the examined issues.

76. Can the issue of the data exclusivity period fall under such a broadly conceived notion of public health?

77. The initial intuitive reply to that question is likely to be 'no'. The expiry of data protection of a third party might be an issue of the correct application of the law, appropriate incentives for stimulating innovation, or the right to property. But it is not really an issue of public health for the purpose of the registration of a new generic medicinal product.

34 Similarly to the pre-2004 situation. See Article 29 of the pre-2004 version of Directive 2001/83 and judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565, point 29).

35 Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (OJ 2006 C 133, p. 5).

36 See my Opinion in Joined Cases *Novartis Europharm* v *Commission*, (C-629/15 P and C-630/15 P, EU:C:2016:1003, point 41) in which I referred to the same position expressed by Advocate General Wahl in *Olainfarm* (C-104/13, EU:C:2014:342, point 39 and the case-law cited).

78. There is, however, a deeper layer to the assessment of 'a potential serious risk to public health'. Since what is being requested is the authorisation of a generic product, that process relies on the extant data of the reference product. Now if the data protection period has not yet lapsed, then there is no data to be relied on. If the relevant data cannot yet be consulted, it is logically impossible to conduct any scientific assessment of the generic medicinal product at issue.

79. I therefore agree in substance with arguments advanced by the Governments of Belgium and the United Kingdom in their submissions. The impossibility of referring to the data of a reference medicinal product logically hampers, in my view, the evaluation of a public health risk of the generic product. In this manner, the agreement as to the expiration of the data exclusivity period is, in a way, a preliminary, but indispensable, part of the approval process.

80. In the light of the abovementioned, I consider, in response to the first preliminary question posed, that Article 28(5) and Article 29(1) of Directive 2001/83 should be interpreted as meaning that the competent authority of the concerned Member State, acting in the decentralised procedure for marketing authorisation for a generic medicinal product, is not competent, when issuing the national marketing authorisation pursuant to Article 28(5) of Directive 2001/83, to determine unilaterally the time from which the data exclusivity period for the reference medicinal product begins to run. However, that authority takes part in that assessment at an earlier stage in the decentralised procedure pursuant to Article 28(3) and (4) of Directive 2001/83. The participation of the competent authority of the concerned Member State in the approval process thus makes that authority co-responsible for the documents approved in that procedure.

C. Question 2: Admissibility and scope of judicial review in the concerned Member State

81. The competent authorities of the concerned Member State cannot unilaterally decide on matters covered by the approved documents, such as the data exclusivity period. These issues are determined collectively, through the 'co-decision mechanism' under Article 28 of Directive 2001/83. In that 'co-decision mechanism', the authorities of the concerned Member States co-approve, and become co-responsible for, the resulting product-related documents, which are subsequently to be incorporated in parallel national marketing authorisations.

82. Given that the suggested reply to the first preliminary question partially departs from (or rather goes beyond) the exact wording of the question posed by the national court, it is necessary to respond to the second preliminary question. The second question posed by the national court enquires about the admissibility and the scope of the judicial review of the content of product-related documents, such as the determination of the data exclusivity period.

83. As far as the answer to the second question is concerned, the submissions made in these proceedings also differ considerably. One line of reasoning advocates that the judicial review should be *centralised* before the courts of the reference Member State. This is essentially the position advocated by Helm, the German and Spanish Governments, Ireland, and the Finnish and Norwegian Governments. There is a further nuance within this line of reasoning based on the distinction of whether such a review should be carried out with regard to: (i) the assessment report approved by all the participating national authorities, or (ii) the national marketing authorisation decision adopted by the reference Member State. Under both scenarios, but more strongly perhaps in the latter, the next issue that concerns both would be how to trigger cross-border legal effects of such a review. If there were, following the judicial review in the reference Member State, a modification of the national marketing decision adopted in that Member State, why and how should its outcome be taken into account in any of the other concerned Member States? In the context of this particular case, what potential effect could a review of a Danish marketing authorisation concerning Alkybend have on the marketing authorisation adopted in 2014 by FIMEA?

84. This line of reasoning appears to be based on the premise [37] that within the decentralised procedure, the reference Member State plays a pivotal and conclusive role in the scientific assessment of the application. Therefore, any alleged errors in the approved documents should be attributable to and challengeable only in that Member State. If successful, the result of that challenge would (or even should) then be replicated by all other concerned Member States in their national marketing authorisations. In the present case, that would mean that judicial review would be admissible only in Denmark, and its potential results ought to be taken into account in all the other concerned Member States.

85. The other line of reasoning accepts that judicial review may be possible in the concerned Member States. They might be different in the scope of that review, but it is accepted that as each of the Member States adopts their individual national administrative decisions, there should also be, as a matter of principle, the possibility to review those decisions in each of the Member States that adopted them. That position has, in essence, been advocated by Astellas Pharma, the United Kingdom Government, as well as by the Commission

86. I must admit that for a number of principled as well as practical reasons, I agree with the latter line of reasoning: I see no other option than to suggest that in a *decentralised* procedure, where each of the national authorities adopts a formally independent administrative decision valid exclusively on their national territory, *decentralised* judicial review must be available with regard to each of the individual national administrative decisions. Logically, the nature of the review must follow the nature of the administrative decision.

1. A decentralised *administrative procedure with* centralised *judicial review?*

87. There are two substantial problems with the propositions falling under the first approach set out in point 83 of this Opinion. The first is the absence of any written legal basis whatsoever for any of those propositions. Second, even if one were ready to sail away from such problems, *quod non*, there are a number of practical problems which such, indeed novel, type of judicial review could pose.

88. I turn first to the suggestion relating to the possibility to challenge the assessment report (or other product-related documents), presumably in the reference Member State, as the Spanish and Finnish Governments advocate.

89. In that respect I note that the approval process consists of communication (more or less formalised) among the respective administrative authorities of the concerned Member States and the reference Member State. The holder of the initial marketing authorisation may not even be aware of the fact that a decentralised procedure has been initiated and that the 'co-decision mechanism' has been triggered. If the holder is aware, it is unlikely to be a party to the procedure under national law. [38]

90. Even if the holder becomes aware of that fact (because, on a practical level, that holder is likely to foresee the moment of expiration of the different data exclusivity periods of its medicinal products), difficulties are likely to arise generally in a number of legal systems of the Member States as to his standing. It would of course be a matter of the procedural law of the given reference Member State

37 Discussed above at point 66 of this Opinion.

38 Under Article 28(4) of Directive 2001/83, only the applicant for marketing authorisation is informed, by the reference Member State's authority, about the agreement reached within the procedure.

whether the holder is allowed to challenge the assessment report or not. In a number of Member States, it is quite likely that that report may be classified as a preparatory act and thus not amenable to judicial review. It is the final, formalised marketing authorisation in the reference Member State that is likely to be seen as a challengeable act under national law. [39]

91. Last but not least, the rules on standing are likely to differ from one Member State to another. Therefore, construing the system of judicial review in a decentralised procedure on the exclusive jurisdiction of the reference Member State, which could, hypothetically, be exercised with regard to a document such as the assessment report, would be bound to generate loopholes.

92. By contrast, these issues should not, in principle, arise in the context of the judicial review directed against the (final) *national marketing authorisation* decision adopted by the *reference* Member State. In that case, however, then a series of other serious issues arise, relating to the territorial nature of each of the marketing authorisations and the necessary correlating territorial nature of judicial review carried out in those Member States.

93. As a starting point, it is unclear to me what it is that the holder of the initial marketing authorisation is supposed to challenge in the scenario such as the one in the main proceedings. Astellas Pharma wishes to challenge the FIMEA's decision. One is bound to ask why that action should be launched in Denmark. Even if one were to consider the suggestion that Danish courts could (indirectly or even directly?) assess the legality of a decision adopted by a Finnish regulator, it is difficult to perceive how the (clearly extraterritorial) effects of such a decision would then be 'transposed' in Finland. What exactly would be the effects of a judgment issued by a Danish court in Finland? Would it, on a rather expansionist interpretation of the duty of sincere cooperation amongst the Member States, automatically trigger annulment of the Finnish marketing authorisation? By whom? Or would FIMEA have the obligation to initiate *ex officio* proceedings to annul and/or review its own decision?

94. Problematic though they might be, such considerations would be limited to cases in which a potential illegality were present in both or all parallel decisions adopted by the respective national authorities. But what would be the correct way to proceed if one wanted to challenge the parts of the FIMEA's decision which are *purely national*? Examples include procedural flaws, or substantive determination not being covered by the approved product-related documents, for instance, the length of the data exclusivity period, which in the pre-2004 or post-2004 transitional regime could differ from one Member State to another. Would the applicant in such cases be obliged to go before Danish courts in order to challenge the potential irregularities that concern only the Finnish marketing authorisation? Would that make Danish courts competent to rule on matters of Finnish law?

95. Since this is hardly a defendable proposition, a certain 'intermediary' option was discussed in the submissions of some parties and at the hearing. That option would essentially be splitting the judicial review into two parts: (i) the part of the decision that is materially covered by the scope of the product-related documents approved within the decentralised procedure; and (ii) the purely national part. The review of the first part ought to be 'centralised', that is, carried out before the courts of the reference Member State. The review of the second part would be 'decentralised', that is, be a matter for each of the concerned Member States.

39 For similar issues in the field of public procurement, see my Opinion in *Marina del Mediterráneo and Others* (C-391/15, EU:C:2016:651).

96. True, such a suggestion would alleviate some of the issues previously identified, at least on the level of principle. However, apart from the persisting problem of the lack of legal basis for any of these propositions, I have considerable reservations about the practical possibility of drawing clear and foreseeable lines between purely national and other elements. What about elements which have some basis in the original agreement, but have been further developed? What about elements of discretion? And above all, how is the initial marketing authorisation holder supposed to unravel all of those elements, in order to decide where to sue?

97. It is not without reason that the rules on jurisdiction, whether in allocating competence vertically (between the European Union and the Member States) or horizontally (amongst the Member States) tend to be based primarily on the formal element of the authorship of an act (who issued the act that is being challenged) rather than on attempting to unravel the individual substantive elements thereof.

98. Finally, all of those problematic issues were based on the assumption that all the individual actors would agree, acknowledge each other's authority, and cooperate and comply in good faith. But what if they did not? Imagine that in the reference Member State, the marketing authorisation issued in that state is reviewable and the court comes to the conclusion that the administrative authority in question misapplied the law. However, upon reading that decision, the administrative authorities of the concerned Member States do not agree with that assessment.

99. In any one functional legal order, it is at this moment that formal authority prevails over substantive reasons. A final judicial decision must be followed by the administrative authority operating within the same legal order irrespective of the substantive disagreement of the latter. In a nutshell, the basic and insurmountable obstacle to the answer to the second question posed by the national court in the way proposed by the first line of reasoning is the simple absence of any such ultimate formal authority[40] on the horizontal level.[41]

2. Decentralised *procedure implies* decentralised *review*

100. All this leads me to a simple conclusion: a *decentralised* administrative procedure is to be followed by a *decentralised* judicial review. Certainly, there is no doubt that the basis of the ultimate national marketing authorisation is a common one, captured in the approved product-related documents that all the participating Member States' authorities are bound to put into national decisions. However, there is also no doubt that the ultimate acts that generate legal effects within the territory of each Member State involved are, and remain, the respective national marketing authorisations.

101. For all the reasons outlined in the previous section, not only concerning respect for the first paragraph of Article 47 of the Charter of Fundamental Rights, but rather as a matter of basic logic of the system, I fail to see any option other than to affirm the possibility of parallel and full judicial review of the respective marketing authorisation(s) issued in any of the Member States as the result of the decentralised procedure, namely in reference Member States and each of the concerned Member States.

40 I am ready to accept the (in some circles certainly disdainful) label of a 'traditional' or even 'positivist' lawyer, who believes that for a correctly operating legal system, formal authority and hierarchy matter. Intriguing as they may be at the level of abstract propositions in legal theory, I am not sure that an answer seeking to implement the tenets of (whatever stream of) European legal pluralism would be very helpful for the national court in this case (not to speak of providing any concrete and useful guidance for the work of national administrative authorities in their assessment of authorisation applications).

41 For the sake of completeness, it might be added that the answer proposed by some parties in this case is that, if there were any dispute about the calculation of the data exclusivity period and the validity of the marketing authorisation issued for the reference medicinal product in the individual case between two or more Member States, that question ought to be compulsorily submitted to the Court of Justice under Article 267 TFEU. That does not provide any structural answer. The function of the preliminary ruling mechanism instituted by the Treaty is to provide uniform interpretation of EU law and the assessment of validity of acts of the EU institutions, not to solve individual cases before national courts, and even less to provide arbitration in essentially factual disputes between Member States in individual cases.

102. From the point of view of the overall structure of the procedure, however, there is nothing revolutionary in such a proposition if one considers the prior participation of all the concerned Member States in the decentralised procedure. Each of the competent authorities of the Member States participates in the procedure. Each of them has to approve the product-related documents. If they disagree, each of them is entitled to block the process and call in the conciliation procedure first, or even then have the matter referred to the Agency. Each of them has the obligation to issue a separate national decision that transforms what has been agreed upon previously into a nationally relevant administrative act.

103. Within such a context, it seems only reasonable and fair to me that each of those authorities may be asked to defend the outcome of their joint deliberation before their respective national courts. Going back to the cooking metaphor: the Member States' authorities cannot be said to be obliged to serve a meal that was forced on them. They were in the kitchen when it was being prepared and could have had their say in what was being cooked. They are therefore co-responsible for its quality.

104. I acknowledge that the solution that I recommend may result in particularism. The courts of each of the concerned Member States will be able to adopt their own view on questions such as the correct determination of the data exclusivity period. There can be conflicting judgments.

105. However, there are two replies to this objection, apart from the basic fact of absence of better alternatives. First, that it is simply the necessary consequence of having a decentralised system under Article 28 of Directive 2001/83. It is the consequence of a system composed of separate national marketing authorisations. The fact that all of them relate to underlying collectively prepared and approved product-related documents does not do away with the polycentric nature of the ultimate phase of the whole authorisation process.

106. If, as a number of interveners in this case have suggested, there is the imperative need for establishing a fully operational and unified internal market for medicinal products, to which decentralised judicial review, thus understood, would be an obstacle, it would perhaps be ideal to voice those needs to the European legislature and initiate the adoption of an appropriate legislative regime reflecting those needs. I find it, however, unacceptable to first embrace a legislative framework which is quite decentralised,[42] and then to use the argument of the need for a uniform regime to effectively deprive individual applicants of legal protection within that legislatively particularised regime. Simply put, market integration is not a good reason for creating black holes in judicial protection.

107. Second, I note that the Member States have the obligation to inform each other based on the specific rules of Directive 2001/83[43] and also within the general obligation of sincere cooperation as defined in Article 4(3) TEU. Thus, should any of the competent authorities of a concerned Member State discover an issue possibly affecting the correctness of a marketing authorisation granted by other concerned Member States including the reference Member State, that competent authority should inform its counterparts accordingly. That may lead to reconsideration of existing national marketing authorisations through, for example, an *ex officio* review mechanism pursuant to the applicable national law.

108. Lastly, a specific sub-question has been raised by the referring court concerning the competence of the national court of the concerned Member State to review the legality of the original marketing authorisation granted in another Member State, including compatibility with Directive 2001/83.

42 See the evolution underlining the 2004 amendment above in points 51 and 69.

43 See Article 122 of Directive 2001/83.

109. In conformity with the territorial limits to which the decentralised procedure is subject, and the overall logic of the answer given to the referring court's second question, I am of the view that legality must be assessed in the Member State issuing the initial marketing authorisation.

110. In the light of foregoing, I suggest that the response to the second question posed by the referring court is that the courts of the concerned Member State are competent, when deciding upon an appeal brought by the holder of the marketing authorisation for the reference medicinal product, to review a determination made by the competent authority of the same concerned Member State regarding the time from which the period of data exclusivity starts to run. That national court, however, cannot review the legality of the original marketing authorisation granted in another Member State, as that legality, including under Directive 2001/83, must be assessed in the Member State that issued that initial marketing authorisation.

IV. Conclusion

111. In the light of the foregoing, I suggest that the Court respond to the question posed by the Korkein hallinto-oikeus (Supreme Administrative Court, Finland) as follows:

(1) Article 28(5) and Article 29(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use should be interpreted as meaning that the competent authority of the concerned Member State, acting in the decentralised procedure for marketing authorisation for a generic medicinal product, is not competent, when issuing the national marketing authorisation pursuant to Article 28(5) of Directive 2001/83, to determine unilaterally the time from which the data exclusivity period for the reference medicinal product begins to run. However, that authority takes part in that assessment at an earlier stage in the decentralised procedure pursuant to Article 28(3) and (4) of Directive 2001/83. The participation of the competent authority of the concerned Member State in the approval process thus makes that authority co-responsible for the documents approved in that procedure.

(2) The courts of the concerned Member State are competent, when deciding upon an appeal brought by the holder of the marketing authorisation for the reference medicinal product, to review a determination made by the competent authority of the same concerned Member State regarding the time from which the period of data exclusivity starts to run. That national court, however, cannot review the legality of the original marketing authorisation granted in another Member State, as that legality, including under Directive 2001/83, must be assessed in the Member State that issued that initial marketing authorisation.