Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

14 March 2018*

(Reference for a preliminary ruling — Directive 2001/83/EC — Medicinal products for human use — Articles 28 and 29 — Decentralised procedure for marketing authorisation for a medicinal product — Article 10 — Generic medicinal product — Data exclusivity period for the reference medicinal product — Power of the competent authorities of the Member States concerned to determine the point in time from which the exclusivity period starts to run — Jurisdiction of the courts of the Member States concerned to review the determination of the point in time from which the exclusivity period starts to run — Effective judicial protection — Charter of Fundamental Rights of the European Union — Article 47)

In Case C-557/16

REQUEST for a preliminary ruling under Article 267 TFEU from the Korkein hallinto-oikeus (Supreme Administrative Court, Finland), made by decision of 31 October 2016, received at the Court on 4 November 2016, in the proceedings

Astellas Pharma GmbH

joined parties:

Helm AG,

Lääkealan turvallisuus- ja kehittämiskeskus (Fimea),

THE COURT (Second Chamber),

composed of M. Ilešič, President of the Chamber, A. Rosas, C. Toader, A. Prechal and E. Jarašiūnas (Rapporteur), Judges,

Advocate General: M. Bobek,

Registrar: L. Carrasco Marco, Administrator,

having regard to the written procedure and further to the hearing on 20 September 2017,

after considering the observations submitted on behalf of

– Astellas Pharma GmbH, by B. Sträter, Rechtsanwalt, and by M.I. Manley, Solicitor, and M. Segercrantz, asianajaja,

– Helm AG, by P. von Czettritz, Rechtsanwalt, and K. Nyblin, asianajaja,

* Language of the case: Finnish.

– the Finnish Government, by J. Heliskoski, acting as Agent,

– the Belgian Government, by L. Van den Broeck and J. Van Holm, acting as Agents,

– the German Government, by T. Henze and J. Möller, acting as Agents,

– Ireland, by M. Browne, L. Williams, E. Creedon and A. Joyce, acting as Agents, and by S. Kingston, Barrister,

– the Spanish Government, by S. Jiménez García, acting as Agent,

– the United Kingdom Government, by D. Robertson, J. Kraehling and G. Brown, acting as Agents, and by G. Peretz, Barrister,

– the Kingdom of Norway, by K.B. Moen, E. Sawkins Eikeland and I.S. Jansen, acting as Agents,

– the European Commission, by A. Sipos and M. Huttunen, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 7 December 2017,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 28 and 29 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67, and corrigenda OJ 2009 L 87, p. 174, and OJ 2011 L 276, p. 63), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1) ('Directive 2001/83'), and of Article 10 of that directive, read in conjunction with Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter').

2 The request has been made in proceedings brought by Astellas Pharma GmbH with regard to the decision of the Lääkealan turvallisuus- ja kehittämiskeskus (the Finnish Medicines Agency) ('Fimea') authorising the marketing of a generic medicinal product called 'Alkybend', produced by Helm AG.

Legal context

3 Recital 14 of Directive 2001/83 states that the directive represents an important step towards achievement of the objective of the free movement of medicinal products.

4 Under Article 6(1) of that directive:

'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 [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)], read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use [and amending Regulation (EEC) No 1768/92, Directives 2001/20/EC and 2001/83 and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1)] and Regulation

(EC) No 1394/2007 [of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83 and Regulation (EC) No 726/2004 (OJ 2007 L 324, p. 121)].

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

5 Article 8(3)(i) of Directive 2001/83 provides that the application for marketing authorisation is to be accompanied by the results of pharmaceutical (physico-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials.

6 Article 10 of that directive provides:

'1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant 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.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

…

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) "reference medicinal product" shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. …

…

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

…'

7 Article 19(1) of Directive 2001/83 provides that, in order to examine the application submitted in accordance with Articles 8, 10, 10a, 10b and 10c, the competent authority of a Member State must verify whether the particulars submitted in support of the application comply with those articles and examine whether the conditions for issuing an authorisation to place medicinal products on the market are complied with.

8 According to Article 26(2) of that directive, marketing authorisation is to be refused if any particulars or documents submitted in support of the application do not comply with Articles 8, 10, 10a, 10b and 10c.

9 Article 28 of Directive 2001/83, relating to the mutual recognition procedure and the decentralised procedure, provides:

‘1. With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as “reference Member State” and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3.

2. Where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report on the medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be sent to the concerned Member States and to the applicant.

3. In cases where the medicinal product has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The reference Member State shall prepare these draft documents within 120 days after receipt of a valid application and shall send them to the concerned Member States and to the applicant.

4. Within 90 days of receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

5. Each Member State in which an application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement.’

10 Under Article 29(1) of Directive 2001/83:

'If, within the period laid down in Article 28(4), a Member State cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on the grounds of serious potential risk to public health, it shall give a detailed exposition of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be forthwith referred to the coordination group.'

The dispute in the main proceedings and the questions referred for a preliminary ruling

11 On 19 July 2005, the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products and Medical Devices, Germany) ('the German Federal Institute') granted to Astellas Pharma, in accordance with national law, a marketing authorisation ('MA') for the medicinal product known as 'Ribomustin', the active substance of which is bendamustine, for two indications, non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

12 After completion of a decentralised procedure, as provided for in Article 28 of Directive 2001/83, for which the Federal Republic of Germany was the reference Member State, the French Republic was the first Member State to grant, on 15 July 2010, a MA to Astellas Pharma for a medicinal product known as 'Levact', the active substance of which is also bendamustine, with indications for NHL, MM and chronic lymphocytic leukaemia (CLL).

13 On 7 November 2012, Helm applied for a MA for a medicinal product called 'Alkybend' by way of a decentralised procedure, in which the reference Member State was the Kingdom of Denmark and the Member States concerned were the Kingdom of Norway and the Republic of Finland. In its application, Helm stated that Alkybend was a generic medicinal product the active substance of which was bendamustine hydrochloride and the reference medicinal product was Levact, but that Ribomustin, however, ought to be regarded as the reference medicinal product with respect to the determination of the data exclusivity period.

14 Following that procedure, which concluded on 17 January 2014, Fimea granted Helm the MA for Alkybend on 28 March 2014, in accordance with the conclusions of the assessment report drawn up by the Danish competent authority. According to that report, the MA granted for Levact was to be regarded as part of the authorisation granted to Ribomustin in 2005 and the latter medicinal product constituted, for the purpose of assessing the data exclusivity period, the reference medicinal product.

15 Astellas Pharma brought an action challenging that decision before the Helsingin hallinto-oikeus (Administrative Court, Helsinki, Finland), which dismissed that action, taking the view that that company had obtained the first MA on 19 July 2005 and that, given that the duration of the protection period for Levact was six years as a consequence of the application of the transitional provisions, Fimea was fully entitled to grant a MA to Helm in respect of Alkybend on 28 March 2014.

16 Taking the view that the data exclusivity period started, not on 19 July 2005, but on 15 July 2010, the date of the first MA granted for Levact, Astellas Pharma brought the matter before the referring court, the Korkein hallinto-oikeus (Supreme Administrative Court, Finland), requesting it to set aside the decision of the court of first instance and to annul Fimea's decision.

17 Astellas Pharma submits, inter alia, in support of that appeal, that the decision of the German Federal Institute of 19 July 2005 was not in accordance with Directive 2001/83 and that it never came into force in respect of one of the indications requested for Ribomustin and refused by that institute. Astellas Pharma argues, furthermore, that the grant of the MA for Levact required extensive additional tests also for the indications that the German Federal Institute had authorised for Ribomustin.

18 The referring court notes, first, that Astellas Pharma was not a party to the decentralised procedure for a MA in respect of Alkybend and that it was therefore also not a party to the proceedings before Fimea, with the result that it was unable to ensure the protection of its data during the decentralised procedure. That court states, in this regard, that it has already held that the holder of the MA for the reference medicinal product has the right to bring an action challenging a decision regarding the MA issued for the generic medicinal product by claiming that that MA would adversely affect the data exclusivity of the reference medicinal product, in particular owing to an incorrect determination of the starting point for that protection. According to the referring court, that solution is consistent with the judgment of 23 October 2014, *Olainfarm*, (C-104/13, EU:C:2014:2316).

19 Secondly, the referring court notes that it follows from Article 29(1) of Directive 2001/83 and from the judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565) that a Member State receiving an application for mutual recognition cannot call into question, other than on the ground of a risk to public health, assessments carried out by the authorities of the reference Member State under the evaluation procedure for the medicinal product. Similarly, in its view, the possibilities for a Member State involved in a decentralised procedure to oppose a MA are limited to the case in which the reference medicinal product is regarded as presenting a risk to public health.

20 If, taking the above into account, and following the unanimous acceptance of the conclusions of the assessment report compiled in the decentralised procedure, Fimea does not have competence independently to assess the point in time from which the data evaluation period starts to run, the referring court asks how effective judicial protection of the rights of Astellas Pharma in Finland can be ensured. If it is held that a court of a Member State concerned by that procedure may decide on a dispute concerning the data exclusivity of the reference medicinal product, it also asks whether that court is able to assess, in that context, whether the initial MA granted to the holder of the MA for that medicinal product in another Member State is compatible with Directive 2001/83.

21 In those circumstances, the Korkein hallinto-oikeus (Supreme Administrative Court), decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Are Articles 28(5) and 29(1) of Directive 2001/83 … to be interpreted as meaning that the competent authorities of the concerned Member State in the decentralised procedure for [MAs] 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 [MA] 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 [MA] 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?’

Consideration of the questions referred

The first question

22 By its first question, the referring court asks, in essence, whether Article 28 and Article 29(1) of Directive 2001/83 must be interpreted as meaning that, in a decentralised procedure for MAs in respect of a generic product, the competent authority of a Member State concerned by that procedure may itself determine the time from which the data exclusivity period for the reference medicinal product starts to run when it adopts, under Article 28(5) of that directive, its decision on the placing on the market of the generic medicinal product in that Member State.

23 In that regard, it should be recalled that the decentralised procedure, provided for in Article 28 of Directive 2001/83, consists of several stages. First of all, paragraph 1 of that article provides that the applicant, with a view to the granting of a MA for a medicinal product in more than one Member State, submits an application based on an identical dossier in those Member States, which contains the information and documents required by that directive and the list of the Member States concerned and requests one of them to act as reference Member State and to prepare an assessment report on the medicinal product, a draft summary of product characteristics and a draft of the labelling and package leaflet. Next, in accordance with paragraphs 3 and 4 of that article, the reference Member State prepares those draft documents within 120 days of receipt of a valid application and sends them to the Member States concerned and to the applicant. Within 90 days of receipt of those documents, the Member States concerned approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. That Member State records the agreement of all parties, closes the procedure and informs the applicant accordingly. Lastly, under Article 28(5), each Member State in which an application has been submitted then adopts a decision in conformity with the assessment report, the summary of product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement.

24 Furthermore, Article 29 of Directive 2001/83 provides for a procedure for the settlement of disputes in cases where a Member State cannot, within the period of 90 days laid down in Article 28(4) of that directive, approve the assessment report, the summary of product characteristics and the labelling and package leaflet on grounds of serious potential risk to public health.

25 It is clear from those provisions that, as the Advocate General noted, in essence, in point 70 of his Opinion, the Member States concerned participate in the procedure which concludes with the acknowledgement, by the reference Member State, of the general agreement of the Member States in which the MA application was submitted and that, that acknowledgement being made, the competent authorities of those Member States are required to adopt a MA decision in conformity with the assessment report for the medicinal product in question.

26 Therefore, once that general agreement is acknowledged, the competent authorities of those Member States may not, when making their decision on the placing on the market of that medicinal product in their territory, call into question the outcome of that procedure. Apart from being contrary to the wording of Article 28(5) of Directive 2001/83, such an interpretation would deprive the decentralised procedure of all meaning and would, inter alia, compromise the attainment of the objective of free movement of medicinal products set out in recital 14 of that directive (see, by analogy, judgment of 16 October 2008, *Synthon*, C-452/06, EU:C:2008:565, paragraph 32).

27 With regard to the question whether the procedure which concludes with the acknowledgement of general agreement, in which all the Member States in which a MA application was submitted participate, includes verification of the expiry of the data exclusivity period for the reference medicinal product, it should be noted, first, that Article 28(1) of Directive 2001/83 requires the applicant to

provide all those Member States, in support of its request, with a file containing the information and documents referred to in, inter alia, Article 10 of that directive. The first subparagraph of Article 10(1) exempts the applicant from the requirement to provide the results of pre-clinical tests and 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 of that directive, for not less than eight years in a Member State or in the European Union. Thus, the data relating to the reference medicinal product are protected for the benefit of the holder of the MA for that medicinal product during that period and are, therefore, not available as a basis for a MA for a generic medicinal product.

28 Secondly, it is clear from Article 19(1) of Directive 2001/83 that, in order to examine an application under Article 10 of that directive, the competent authority of a Member State must verify whether the file submitted complies with that article and examine whether the conditions for issuing the MA are fulfilled. According to Article 26(2) of that directive, the MA must be refused if the information and documents submitted in support of the application do not comply with Article 10.

29 It follows that the expiry of the data exclusivity period for the reference medicinal product is a precondition for the granting of a MA for a generic medicinal product and that, in the decentralised procedure for MAs, compliance with that condition must be verified by all the Member States participating in that procedure. It is, therefore, for those States, after the application has been submitted, and in any event before acknowledgement of the agreement, to oppose that application if that precondition is not satisfied.

30 Therefore, having regard to the scheme of Directive 2001/83, in the specific case of disagreement between the Member States involved in the decentralised procedure for MAs for a generic medicinal product concerning compliance with that precondition, a Member State must be able not to approve the assessment report for that medicinal product if it considers that that condition is not satisfied. Therefore, it must be held that a Member State may refuse to approve the assessment report for the generic medicinal product in the event of disagreement on compliance with the precondition relating to the expiry of the data exclusivity period for the reference medicinal product.

31 Consequently, the procedure which concludes with the acknowledgement of general agreement, in which all the Member States in which a MA application was submitted participate, involves verifying the expiry of the data exclusivity period for the reference medicinal product, so that the competent authorities of those Member States may not, after acknowledgement of that agreement, repeat such verification.

32 In the light of those considerations, the answer to the first question is that Article 28 and Article 29(1) of Directive 2001/83 must be interpreted as meaning that, in a decentralised MA procedure for a generic medicinal product, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run when adopting, under Article 28(5) of that directive, its decision on the placing on the market of that generic medicinal product in that Member State.

The second question

33 By its second question, the referring court asks, in essence, whether Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, must be interpreted as meaning that a court of a Member State concerned by the decentralised procedure for MAs, hearing an action brought by the holder of the MA for the reference medicinal product against the MA decision for a generic medicinal product in that Member State taken by that State's competent authority, has jurisdiction to

review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run and to ascertain whether the initial MA for the reference medicinal product, granted in another Member State, was granted in accordance with that directive.

34 In that regard, the Court has previously held, in paragraph 37 of the judgment of 23 October 2014, *Olainfarm*, (C-104/13, EU:C:2014:2316), that Article 10 of Directive 2001/83 lays down the conditions under which the holder of a MA for a medicinal product is required to accept that the manufacturer of another medicinal product is entitled, in order to obtain a MA for that medicinal product, to refer to the results of pre-clinical tests and clinical trials contained in the dossier relating to the application for the MA of the former product, rather than perform those tests or trials himself, and that it is apparent that that article confers a concomitant right on the holder of the MA for the former medicinal product to demand that the rights attaching to him by virtue of those conditions are observed.

35 Thus, the Court held, in paragraph 38 of the judgement of 23 October 2014, *Olainfarm* (C-104/13, EU:C:2014:2316), that, without prejudice to the law relating to the protection of industrial and commercial property, the holder of a MA for a medicinal product has the right to demand, pursuant to Article 10(1) of Directive 2001/83, that that medicinal product is not to be used as a reference product for the purpose of authorising the placing on the market of a medicinal product of another manufacturer until a period of eight years has elapsed from the date on which that MA was granted, or to demand that a medicinal product authorised to be placed on the market on the basis of Article 10 is not to be marketed until a period of 10 years, which may, where appropriate, be extended to 11, has elapsed from the date on which that MA was granted.

36 Consequently, the Court held, in paragraphs 39 and 40 of the judgment of 23 October 2014, *Olainfarm*, (C-104/13, EU:C:2014:2316), that the holder of a MA for a medicinal product used as a reference product in an application for a MA under Article 10 of Directive 2001/83 is, by virtue of that provision, read in conjunction with Article 47 of the Charter, entitled to effective judicial protection in so far as concerns respect for his rights and therefore has the right to a judicial remedy against the decision of the competent authority which granted the MA for a generic product, on condition that that holder is seeking judicial protection of a right conferred on him by that Article 10.

37 It follows that the holder of the MA for the reference medicinal product has the right to a judicial remedy against the decision of the competent authority which granted the MA for the generic medicinal product for the purpose of ensuring data exclusivity in respect of the reference medicinal product under Article 10 of Directive 2001/83 and that holder must, for that purpose, be able to challenge the determination of the point in time from which the data exclusivity period starts to run in that action.

38 In the system for the decentralised procedure, provided for in Article 28 of Directive 2001/83, as referred to in paragraph 23 above, each of the Member States in which an application has been submitted adopts, pursuant to Article 28(5) of that directive, a MA decision for the generic medicinal product at the end of the procedure which concludes with the acknowledgement of the general agreement of those Member States. That directive does not provide for the adoption, during that procedure in which the holder of the MA for the reference medicinal product does not take part, of other measures against which the holder of the MA can bring an action or court proceedings enabling it to assert its rights before the adoption, by the competent authority of one of those Member States, of a MA decision.

39 It follows that effective judicial protection of the rights held by the holder of a MA for the reference medicinal product as regards the data exclusivity of that medicinal product can be ensured only if that holder can rely on those rights before a court of the Member State in which the competent authority

adopted a MA decision for the generic medicinal product and if it can, inter alia, plead before that court an error relating to the determination of the point in time from which the exclusivity period, affected by that decision, starts to run.

40 However, that requirement of effective judicial protection does not mean that the holder of the MA for the reference medicinal product may call into question before that court the compatibility with Directive 2001/83 of MA decisions for that medicinal product taken in other Member States. That holder of the MA has a right to a judicial remedy which it can exercise, or which it could have exercised within the time limits set, against those decisions before the courts having jurisdiction to review the legality of the decisions adopted by the competent national authorities in each Member State.

41 In the light of the foregoing considerations, the answer to the second question is that Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, must be interpreted as meaning that a court of a Member State involved in a decentralised procedure for MAs, hearing an action brought by the holder of the MA for the reference medicinal product against the MA decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial MA for the reference medicinal product granted in another Member State was granted in accordance with that directive.

Costs

42 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

1. **Article 28 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, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, must be interpreted as meaning that, in a decentralised marketing-authorisation procedure for a generic medicinal product, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run when adopting, under Article 28(5) of that directive, its decision on the placing on the market of that generic medicinal product in that Member State.**

2. **Article 10 of Directive 2001/83, as amended by Directive 2012/26, read in conjunction with Article 47 of the Charter of Fundamental Rights of the European Union, must be interpreted as meaning that a court of a Member State involved in a decentralised procedure for marketing authorisations, hearing an action brought by the holder of the marketing authorisation for the reference medicinal product against the marketing-authorisation decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial marketing authorisation for the reference medicinal product granted in another Member State was granted in accordance with that directive.**

[Signatures]