# ATTORNEY GENERAL – CIVIL AFFAIRS

To the Court of Justice of the European Union

Oslo, 16 February 2017

## WRITTEN OBSERVATIONS

## BY

## THE KINGDOM OF NORWAY

represented by Mr Ketil Bøe Moen, Advocate at the Attorney General of Civil Affairs, Ms Elisabeth Sawkins Eikeland, Assistant Advocate at the Attorney General of Civil Affairs, and Ms Ingunn S. Jansen, Senior Adviser at the Ministry of Foreign Affairs, acting as agents, submitted pursuant to the third paragraph of Article 23 of the Protocol on the Statute of the Court of Justice of the European Union, in

**Case C-557/16, Astellas Pharma**

in which Korkein hallinto-oikeus, the Supreme Administrative Court of Finland, has requested a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning on the European Union (TFEU) on the interpretation of Directive 2001/83/EC.

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## 1 INTRODUCTION

(1) The referring court has by a request lodged with the Court of Justice ('the Court') on 4 November 2016 asked for a preliminary ruling on the interpretation of Directive 2001/83/EC on the Community code relating to medicinal products for human use. The two questions concern the competence of national administrative authorities and national courts, respectively, to assess at which time the period of data exclusivity for a reference medicinal product under the so-called decentralised procedure under that directive starts to run.

(2) The questions read:

1. *Are Articles 28(5) and 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 to be 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?*

(3) The referring court has provided a fairly thorough explanation of the case before it, and the Government of Norway ('the Government') will therefore not repeat the factual or procedural background. Some supplementary remarks are nevertheless appropriate, and these are set out in section 2 below.

(4) The Government submits that the competent authorities of the concerned Member States under the decentralised procedure under Directive 2001/83 are not themselves competent to determine the time from which the data protection period begins to run. The first question should hence be answered in the positive, as substantiated in section 3 below.

(5) The Government will also comment upon some aspects of the second question. The Government submits, in short, that it is compatible with EU law and with inter alia the principle of legal protection that national courts in the concerned Member States do not, in a case like the present one, have a wider competence than the competent national authorities in assessing when the exclusivity period begins. These submissions are set out in section 4.

(6) Finally, the Government respectfully submits its suggested answers to the questions in section 5.

## 2 LEGAL AND FACTUAL BACKGROUND

(7) The dispute before the national court and the factual and legal background is set out in the request for a preliminary ruling, particularly in paragraphs 1-10. The Government will here provide some supplementary comments and information.

(8) It is recalled at the outset that the case before the referring court concerns a marketing authorisation for a generic medicinal product. Such an application cannot be submitted before the protection period for the original product (the reference product) is ended.

(9) An application for marketing authorisation for a generic medicinal product will regularly be sent to several EU/EEA States. Under the so-called decentralised procedure in Directive 2001/83, applicable in the present case, it must be differentiated between the 'reference state' and 'concerned states'. As set out in section 3 below, the 'reference state' has a particular responsibility in assessing whether the conditions under the directive for issuing a marketing authorisation for the generic medicinal product are complied with. Other states in which an authorisation has been applied for – the 'concerned states' – have a different and clearly less extensive role under the procedure. In addition to the reference state and concerned state, there may be a third state involved, albeit more indirectly, namely the state having issued the first marketing authorisation for the original product.

(10) In the case before the referring court, Denmark is the reference state under the decentralised procedure for a marketing authorisation to Helm AG ('Helm') for the generic product Alkybend, whereas Finland and Norway are concerned states.[1]

(11) The competent authorities in Denmark decided on 17 January 2014 that Ribomustin was to be treated as the relevant reference product for the purpose of calculating the end of the data exclusivity period, for which a marketing authorisation was issued to Astellas Pharma GmbH ('Astellas Pharma') in Germany on 19 July 2005. This was therefore also the starting point for the exclusivity period for the reference product, expiring in 2011 for those states – like Finland – having an exclusivity period of six years for marketing authorisations issued before 1 November 2005.[2]

(12) It should be added that it appears from the reference that Ribomustin has the same active substance as the product Levact, for which Astellas Pharma was issued a marketing authorisation in France on 15 July 2010.[3] Ribomustin and Levact are regarded as being included within the same Global Marketing Authorisation.

(13) The Finnish competent authorities issued a marketing authorisation for Alkybend on 28 Mars 2014, based on the decision by Denmark as the reference state. A similar decision was issued by the competent Norwegian authorities on 14 February 2014. Similar

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[1] Reference, para. 3
[2] Reference, para. 5
[3] Reference, paras. 1-2

decisions have also been taken in other states for other generics to Ribomustin, for instance in the United Kingdom and in Germany.

(14) There have been several legal proceedings relevant to the present case, some of which are still pending. Common to the proceedings seems to be that Astellas Pharma submits that the German decision of 19 July 2005 was incompatible with Directive 2001/83 and that this should be assessed and appreciated by national competent authorities or – at least – by national courts. This is, to the Government's knowledge, dismissed by all national court decisions. The Government finds it appropriate to provide a brief overview of some of these proceedings.

(15) First, in relation to the marketing authorisation issued to Astellas Pharma for the product Ribomustin in 2005, it appears that an appeal was made in Germany by Astellas Pharma on a rejection in relation to a specific therapeutic indication. The appeal gave suspensive effect to the decision to reject the specific indication. Astellas Pharma could therefore market Ribomustin also for the indication that was not approved as long as the case was pending. The appeal was settled by an agreement with the German authorities following Levacts marketing authorisation in 2010.[4] Astellas Pharma has more recently requested that the marketing authorisation for the generic medicinal product Alkybend was suspended. This was rejected by the Administrative Court in Cologne on 11 March 2016,[5] a decision which was upheld by the High Administrative Court in Nordrhein-Westfalen on 2 August 2016.[6]

(16) There are, however, also separate proceedings now initiated by Astellas Pharma before a German court on the validity of the decision of 19 July 2005 under Directive 2001/83. Such a validity assessment was, as far as the Government is aware of, not made under the recent court proceedings on the suspensive effect of the marketing authorisation for the generic product. The Government is not aware of the expected time frame for a ruling under this pending court procedure in Germany.

(17) Second, there have been court proceedings in Denmark, as the reference state for the generic medicinal product Alkybend. The City Court of Copenhagen dismissed by a judgment of 26 December 2015 Astellas Pharma's appeal against the decision of the

[4] Reference, para. 13
[5] Reference, para. 40
[6] The judgment in **Annex 1** to the observations.

competent authorities in Denmark of 17 January 2014. The judgment was upheld by the Eastern High Court in a judgment of 1 September 2016. The Eastern High Court found that the competent authorities in the reference Member State was obliged – in accordance with the principles of mutual recognition – to comply with the opinion of the German authorities when it came to the validity under Directive 2001/83 of the German decision of 19 July 2005, unless there were grounds to consider BfArM's statements clearly unfounded.[7]

(18) Third, there are pending court proceedings in several other countries, including in Finland and Norway as concerned states under the decentralised procedure. As set out in the Reference, the Administrative Court of Helsinki dismissed the appeal from Astellas Pharma. The same conclusion was drawn in Norway. By a judgment of 22 May 2015 Oslo District Court upheld the competent authority's decision to base the exclusivity period on the German decision of 19 July 2005.[8] The District Court found, inter alia, that the Norwegian competent authority did not as a concerned state under the decentralised procedure have the right or duty to independently evaluate the validity of the German decision of 19 July 2005 as it could not deviate from the assessment report from the competent Danish authority as the reference state.

(19) The ruling from Oslo District Court has been appealed by Astellas Pharma. The proceedings before Borgarting Court of Appeal are however stayed in accordance with Astellas Pharma's request, pending a ruling from a German court as set out above on the validity of the initial marketing authorization of Ribomustin of 19 July 2005.

## 3 OBSERVATIONS TO THE FIRST QUESTION

(20) The first question concerns whether the competent authorities of a concerned Member State in the decentralised procedure for marketing authorisations for generic medicinal products in accordance with Article 28(3) of Directive 2001/83, are competent when issuing a national marketing authorisation to independently evaluate and determine the time from which the period of data exclusivity for the reference medical product begins to run.

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[7] The judgment in **Annex 2** to the observations.
[8] The judgment in **Annex 3** to the observations.

(21) Specifically, the referring court asks about the interpretation of Article 28(5) and Article 29(1).

(22) The Government submits that it follows directly from the wording of those provisions, and in particular from Article 28(5), that the authorities in the concerned Member States (including Finland) must, in a situation like the one before the referring court, adopt a decision in accordance with the *approved assessment report* issued by the reference state (in this case Denmark). There is therefore no room for individual assessments by the authorities in each of the concerned States of when the exclusivity period begins. In particular, it cannot be for the authorities in the different concerned States to rule on the validity of the authorisation for the original product in Germany in 2005, on which the reference state has relied.

(23) The Government holds that Article 28 provides a clear division of competence and obligations in the marketing authorisation procedure between the reference Member State and the concerned Member States involved in the decentralised procedure.

(24) The first paragraph of that provision provides that the applicant for marketing authorisation in more than one Member State 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, and include a list of all States concerned as well as a suggestion for a reference Member State. The reference Member State shall prepare a draft assessment report that must be forwarded to all concerned states as well as to the applicant, cf. Article 28(3). All concerned states must approve the assessment report within 90 days, cf. Article 28(4). It then follows from paragraph 5 of Article 28 that all concerned States *"shall adopt a decision in conformity with the approved assessment report"*.

(25) The Government is of the opinion that the competence of the competent authority in the concerned Member State in the decentralised procedure is hence restricted to first, validating the formal requirements of the application as stated in Article 28(1) and secondly, approving the assessment rapport under Article 28(4).

(26) Under the initial validation check, it follows from Article 19 that the competent authority in the Member State must verify whether the particulars submitted in support of the

application comply with the said Articles 8, 10, 10a, 10b and 10c and whether the conditions for issuing an authorisation to place medicinal products on the market are complied with. Hence, the competent authorities in the Member States must verify that the data exclusivity period formally is expired. The directive does not, in regard of the validation check, regulate the intensity of the examination required in relation to the data exclusivity period. The Government is of the opinion, however, that the division of competence provided for in Article 28 of the directive, must imply that it is under the competence of the reference state to examine the application in detail. The concerned state shall simply check the length of the period of data exclusivity to be applied for the given reference medical product in that Member State, and that the applicable period is expired.

(27) The Government submits that it follows from the wording, as well as the intention and objective of Article 28 of the directive, that the discretion for the concerned States not to approve the assessment of the reference state is limited. The reason not to approve the report from the reference state is set out in article 29(1), namely *"on grounds of potential serious risk to public health"*. Should a concerned state disagree with the assessment report on such a ground during the validation period, it must hence initiate the procedure laid down in Article 29 of the directive. Conversely, the concerned states cannot refuse to accept the assessment report on other grounds.

(28) The Court has confirmed this understanding of the directive in *Synthon*, holding inter alia:[9]

> *... it is clear from the wording of Article 28(4) of Directive 2001/83 that the existence of a risk to public health, within the meaning of Article 29(1) of that directive, constitutes the only ground that a Member State is entitled to rely on to object to the recognition of a marketing authorisation granted by another Member State. In addition, Article 29 provides that a Member State wishing to rely on such a ground is required to comply with a specifically prescribed procedure for provision of information, concerted action, and arbitration.*
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> *It follows that, as Synthon, the Polish Government and the Commission of the European Communities point out, a Member State to which an application for*

[9] Judgment in *Synthon*, C-452/06, EU:C:2008:565, para. 28

*mutual recognition is made pursuant to Article 28 of Directive 2001/83 cannot call into question, on grounds other than those relating to the risk to public health, the assessments carried out by the reference Member State's authorities in the context of the procedure for evaluating the medicinal product, such as those concerning essential similarity within the meaning of Article 10(1) of the directive.*

(29) It is hence clear, as also emphasised by the referring court, that the other Member States cannot call into question the assessment made by the reference Member State on grounds other than those relating to the risk to public health. Moreover, Article 29 on public health must be relied upon during the validation period and under the conditions set up in Article 29.

(30) *Synthon* concerned the mutual recognition procedure under the directive, whereas the present case concerns the decentralised procedure. These procedures are essentially similar, regulated by the second and third paragraph of Article 28, respectively. Indeed, the provisions relied upon in *Synthon* – Articles 28(4) and 29(1) – apply to both procedures. The ruling in *Synthon* should therefore be equally relevant for the concerned Member States competence under the decentralised procedure.

(31) Consequently, it follows from the provisions of the directive themselves and from the judgment in *Synthon* that a concerned Member State cannot call into question the assessments carried out by the reference Member State's authorities in the context of the procedure for evaluating the medicinal product, unless it invokes the exception set out in Article 29(1) of the directive during the evaluation process, based on the existence of a potential serious risk to public health.

(32) This also follows from Article 126 of Directive 2001/83, which states that *"[an] authorization to market a medical product shall not be refused, suspended or revoked except on the ground set out in this Directive".*

(33) *Synthon*, as set out above, is confirmed in the subsequent judgment in Case C-145/11 *European Commission v France*.[10] The judgment concerns Directive 2001/82/EC on veterinary medicinal products and provides further clarification as regards the validation

[10] Judgment in *European Commission v France*, C-145/11, EU:C:2012:490

phase. As the wording of the Articles in the veterinary Directive and human Directive 2001/83 regulating the procedures for marketing authorisations are similar, in addition to the shared objective of the directives, the judgement is equally relevant to the present case.

(34) It follows from the judgment that the general purpose of the validation check done by the concerned Member State is to verify that the applicant complies with formal requirements. It is instead for the reference Member State to evaluate the application in detail. The concerned Member States are under an obligation to apply the assessment report issued by the reference state, and can only make objections in relation to potential serious health risks.[11]

(35) This interpretation is clearly supported by the objective of Directive 2001/83 and of Article 28 in particular. Article 28 is an important tool towards harmonising the marketing authorisation procedures and will thereby be facilitating the free movement of medicinal products based on the principle of mutual recognition.[12] Importantly, the procedure eliminates repeated assessments and varying evaluations that could otherwise have been made by national competent authorities of different states.

(36) Consequently, the Government is of the opinion that an obligation for the concerned competent authority to individually assess the time period for the data exclusivity is not consistent with the purpose and legal framework implemented by Directive 2001/83, Articles 28, 29 and 126 in particular.

(37) It is added that the underlying submission by Astellas Pharma seems to be that the marketing authorisation for the original medicinal product in Germany in 2005 was incompatible with Directive 2001/83. The validity of that decision is not among the issues that are to be assessed by the concerned states under Article 28. It also seems questionable whether the relevant authorities or courts in the reference state can rule on this matter themselves or whether it rather is for the authorities having made this decision – in this case Germany – to make this assessment. This is, for instance, what is

[11] Ibid, para. 34
[12] See also the preamble of Directive 2001/83, recitals 12 and 14

held by the District Court of Copenhagen and The Eastern High Court with reference to the principle of mutual recognition.[13]

(38) In the light of the arguments above, the Government submits that Articles 28(5) and 29(1) of Directive 2001/83 are to be interpreted as meaning that the competent authorities of the concerned Member States 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. In particular, with reference to the main argument from Astellas Pharma, it cannot be for the authorities in the different concerned States to rule on the validity of the authorisation for the original product in Germany in 2005, on which the reference state has relied.

## 4 OBSERVATIONS TO THE SECOND QUESTION

(39) The second question concerns the competence of the national *courts* in the concerned member states if the competent *authorities* in those states are not competent to determine the time from which the data exclusivity of the reference medicinal product starts to run. The three sub-questions under this second question will be examined together below. The referring court asks, in essence, (i) whether the national court is subject to the same limitation of competence as the national authorities, (ii) whether that is compatible with the effective legal protection of the holder of the marketing authorisation of the reference medicinal product, and (iii) whether this would also apply to the question whether the original marketing authorisation was issued in accordance with Directive 2001/83.

(40) The Government submits that it is compatible with EU law that national courts in the concerned states, in a situation like the present one, are subject to the same limitation of competence as the national authorities when it comes to assessing when the exclusivity period starts to run. This includes submissions relating to the validity of the original marketing authorisation under Directive 2001/83.

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[13] See paragraph 17 above

(41) It is common ground that EU law rests on the principle of national procedural autonomy. It is for the courts of the Member States to safeguard the rights of individuals derived from EU law under the procedural and judicial systems of each state.[14] If a concerned Member State has limited the competence of its courts as set out in the question from the referring court, that would therefore as a starting point be compatible with EU law.

(42) Indeed, under the circumstances of the present case, another conclusion would be unwarranted and incompatible with the structure and objective of Directive 2001/83. As set out under the assessment of question 1 above, the directive provides for a division of competence between the reference state for the authorisation of the generic medicinal product, and the concerned states. In addition, the state issuing the first marketing authorisation may play an important role, albeit more indirectly in the decentralised procedure. This division of competence is essential for the facilitating of the internal market of medicinal products.

(43) If the competent *authorities* in each of the concerned States were to determine the time frame of the exclusivity period, including submissions on the validity of the original marketing authorisation, the procedures established under Directive 2001/83 would be *"[deprived of all meaning and seriously compromise the attainment of the objectives of Directive 2001/83"*.[15] Exactly the same would be the case if the *courts* of each of the concerned States would rule independently on these matters.

(44) The principle of national procedural autonomy is not absolute. It is subject to the principles of equivalence and effectiveness and the right to *"an effective remedy before a tribunal"*.[16] This right to an effective remedy cannot imply, however, that national courts in the concerned States have to rule on the time from which the data exclusivity period for the reference medicinal product begins to run in relation to a decentralised procedure for marketing authorisations under the directive.

(45) Indeed, the Court has ruled out that the legal framework established by the EU Treaties was not intended to create new remedies in the national courts to ensure the observance of EU law other than those already laid down by national law. It would be

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[14] Judgment in *Inuit Tapiriit Kanatami and Others v Parliament and Council,* C-583/11 P, EU:C:2013:625, para 102

[15] Judgment in *Synthon*, C-452/06, EU:C:2008:565, para. 32

[16] Judgment in *Olainfarm*, C-104/13, EU:C:2014:2316, para. 35

otherwise only if it were apparent from the overall scheme of the national legal system in question that no legal remedy existed which made it possible to ensure, even indirectly, respect for an individual's rights under EU law.[17]

(46) The Government submits that the competence of the national courts should be seen in light of the competence of the respective States under Directive 2001/83. The courts of the concerned States should rule on those matters that it is for the authorities of the concerned States to decide, the courts of the reference state should rule on matters that is within the competence of the reference state to decide, etc.

(47) Consequently, there would always be at least one state in which the holder of the original marketing authorisation could try its case before a court, providing it of "an effective remedy" as required by *Olainfarm*.

(48) *Olainfarm* confirms that the right for judicial protection of the holder of the marketing authorisations must be viewed in light of the rights conferred on the holder in the directive. Accordingly, it is the Governments opinion that this right must also be viewed in light of the clear division of competence of the authorities in the respective states, as set out above.

(49) *Olainfarm* is differentiated from the present case before the Court. In *Olainfarm*, all relevant authorisations were issued in one State.[18] It was therefore necessary that the holder of the original marketing authorisation was given the possibility to try its rights under Directive 2001/83 before a court in that specific State. In the present case, on the other hand, the first marketing authorisation was issued in Germany, the reference state for the generic authorisation was Denmark, and concerned states were Finland and Norway. It should hence be assessed, on the basis of the rights conferred upon Astellas Pharma under the directive, and the submissions raised in relation to the directive, under which of these states' jurisdictions an effective remedy should be secured.

(50) None of the submissions of Astellas Pharma seem to relate to matters that fall within the concerned States' competence under Directive 2001/83. However, they relate to the

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[17] To this effect, see e.g. judgment in *UNIBET*, C-432/05, EU:C:2007:163, paras. 40-41
[18] *Olainfarm*, C-104/13, EU:C:2014:2316, paras. 11-14

competences of the reference state (Denmark) and/or to the competence of the state issuing the original marketing authorisation (Germany).

(51) In the present dispute – where the decisive question seems to be whether the German decision of 19 July 2005 to issue a marketing authorisation for Ribomustin complied with Directive 2001/83 – it is the Government's view that the validity of this decision should be challenged before German courts. This provides the holder of the original marketing authorisation of an adequate, effective legal protection before a court. Indeed, it is the courts in Germany that are best placed to rule on this matter.

(52) It is recalled from above that the holder of that marketing authorisation, Astellas Pharma, in 2005 had the chance to challenge the decision of 19 July 2005 before a German court, but came to a settlement with the authority and withdrew the appeal. Moreover, Astellas Pharma has, as mentioned above, currently challenged the marketing authorisation in Germany for the generic medicinal product, Alkybend, for which Ribomustin is the reference product. Hence, Astellas Pharma has access to a judicial review of the validity of the contested decision of 19 July 2005 to issue a marketing authorisation for Ribomustin in Germany. That court case would provide Astellas Pharma with another possibility of effective legal protection before a court in the state best placed to rule on the matter.

(53) It is also recalled that Astellas Pharma brought proceedings in Denmark as the reference state for issuing the marketing authorisation for the generic medicinal product. The reference state has particular tasks in determining whether a marketing authorisation shall be issued through the decentralised procedure. The reference state shall prepare the draft assessment report, the draft summary of product characteristics and the draft of the labelling and package leaflet, and finally record the agreement of all parties, close the procedure and inform the applicant accordingly, cf. Article 28 (3) and (4) of the directive.

(54) The courts of the reference state must in the Government's opinion ensure an adequate judicial remedy in relation to the competences of this State. However, when it comes to the validity of an original marketing authorisation issued in another State, it seems appropriate that this is to be assessed by the courts in that latter state only, based on the principle of mutual recognition on which Article 28 of Directive 2001/83 rests.

(55) It is noted, finally, that a wider competence for the courts in the concerned state would not only be contrary to the scope and system of Directive 2001/83. It would have implied the creation of a new type of remedy in national courts by giving them a wider competence to challenge the administrative decision than the one of the relevant administrative body that has made the contested decision. A suggestion to such an effect should not be followed, as demonstrated above.

## 5 SUGGESTED ANSWERS TO THE QUESTIONS

(56) In the light of the foregoing considerations, the Government respectfully submits that the questions should be answered in the following way:

1. *Articles 28(5) and 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 is to be 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. *The court of a concerned Member State may be subject to the same limitations of competence as the national authorities of that Member State when dealing with an appeal by the holder of the marketing authorisation for the reference medicinal product. The claim for effective legal protection does not 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.*

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Oslo, 16 February 2017

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