Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

8 October 2020*

(Reference for a preliminary ruling – Articles 34 and 36 TFEU – Free movement of goods – Quantitative restrictions – Measures having equivalent effect – Refusal to approve an amendment to the particulars and documents relating to a medicinal product which is the subject of a parallel import licence – Protection of the health and life of humans – Directive 2001/83/EC)

In Case C-602/19,

REQUEST for a preliminary ruling under Article 267 TFEU from the Verwaltungsgericht Köln (Administrative Court, Cologne, Germany), made by decision of 9 July 2019, received at the Court on 9 August 2019, in the proceedings

kohlpharma GmbH

v

Bundesrepublik Deutschland,

THE COURT (Fourth Chamber),

composed of M. Vilaras (Rapporteur), President of the Chamber, N. Piçarra, D. Šváby, S. Rodin and K. Jürimäe, Judges,

Advocate General: G. Pitruzzella,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– kohlpharma GmbH, by W. Rehmann, Rechtsanwalt,

– the Bundesrepublik Deutschland, by K. Hechinger, acting as Agent,

– Ireland, by G. Hodge, M. Browne, J. Quaney and A. Joyce, acting as Agents,

– the Polish Government, by B. Majczyna, acting as Agent,

– the European Commission, by E. Manhaeve, M. Noll-Ehlers and A. Sipos, acting as Agents,

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

* Language of the case: German.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 34 and 36 TFEU.

2 The request has been made in proceedings between kohlpharma GmbH and the Bundesrepublik Deutschland (Federal Republic of Germany) concerning the refusal of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal and Medical Products, 'Federal Institute for Medicinal Products') to approve an amendment to the particulars and documents relating to a medicinal product which is the subject of a parallel import licence.

Legal context

European Union law

3 Under Article 1(28d) 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'), 'pharmacovigilance system' is defined as 'a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance'.

4 Article 6(1) of that directive provides:

'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, Directive 2001/20/EC, Directive 2001/83/EC 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/EC and Regulation (EC) No 726/2004 (OJ 2007 L 324, p. 121)].

…'

5 Article 8(3) of that directive sets out the particulars and documents which must accompany the marketing authorisation application submitted to the competent authority of the Member State concerned, which include the results of pharmaceutical (physico-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials.

6 Article 26 of that directive provides:

‘1. The marketing authorisation shall be refused if, after verification of the particulars and documents listed in Articles 8, 10, 10a, 10b and 10c, it is clear that:

(a) the risk-benefit balance is not considered to be favourable; or

(b) its therapeutic efficacy is insufficiently substantiated by the applicant; or

(c) its qualitative and quantitative composition is not as declared.

2. Authorisation shall likewise be refused if any particulars or documents submitted in support of the application do not comply with Articles 8, 10, 10a, 10b and 10c.

3. The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and the data submitted.’

7 Title IX, entitled ‘Pharmacovigilance’, of Directive 2001/83 includes Article 101 of that directive, which provides:

‘1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in [European] Union pharmacovigilance activities.

The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards patients or public health. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.

2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. …’

8 Under Article 104 of that directive:

‘1. The marketing authorisation holder shall operate a pharmacovigilance system for the fulfilment of his pharmacovigilance tasks equivalent to the relevant Member State’s pharmacovigilance system provided for under Article 101(1).

2. The marketing authorisation holder shall by means of the pharmacovigilance system referred to in paragraph 1 evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.

…

3. As part of the pharmacovigilance system, the marketing authorisation holder shall:

(a) have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance;

(b) maintain and make available on request a pharmacovigilance system master file;

(c) operate a risk management system for each medicinal product;

(d) monitor the outcome of risk minimisation measures which are contained in the risk management plan or which are laid down as conditions of the marketing authorisation pursuant to Articles 21a, 22 or 22a;

(e) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.

…'

German law

9 The Gesetz über den Verkehr mit Arzneimitteln (Law relating to trade in medicinal products) of 24 August 1976 (BGBl. 1976 I, p. 2445), in the version published on 12 December 2005 (BGBl. 2005 I, p. 3394), as amended by the Law of 6 May 2019 (BGBl. 2019 I, p. 646) ('the AMG') provides, in Paragraph 29(1), that the holder of the marketing authorisation for a medicinal product must forthwith inform the Federal Institute for Medicinal Products of any amendments to the particulars and documents concerning the medicinal product in question.

10 Paragraph 29(2a) of the AMG states that such an amendment, including, in particular, a change of the pharmaceutical form or an amendment to the particulars concerning the dosage of the medicinal product in question may be made only following approval by the higher federal authority.

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

11 kohlpharma placed on the German market, in the context of a parallel import, the medicinal product Impromen 5 mg, in tablet form, which requires a doctor's prescription. That medicinal product, which contains the active ingredient Bromperidol and is prescribed to treat certain forms of psychosis requiring neuroleptic medication, was granted a marketing authorisation by the competent authority of the Italian Republic and was placed on the market of that Member State.

12 On 17 September 1990, kohlpharma obtained from the competent authority of the Federal Republic of Germany a parallel import licence for that medicinal product, imported from Italy. That authorisation was granted subject to it being adjusted to future amendments to the marketing authorisation of reference in Germany, which concerned the medicinal product Consilium 5 mg (Impromen 5 mg), also in tablet form, containing the same active ingredient and used for the same treatment as the medicinal product Impromen 5 mg.

13 The holder of that marketing authorisation of reference was also authorised to market and subsequently marketed Consilium 5 mg (Impromen 5 mg) in drop form and used a combined information leaflet for the drops and the tablets.

14 That marketing authorisation of reference expired on 30 June 2010 and the medicinal product Consilium 5 mg (Impromen 5 mg) in tablet form is no longer available on the German market; only the medicinal product in drop form remains on the market. According to the referring court, the Italian Republic is the only Member State which still authorises the marketing of that pharmaceutical preparation in its two forms.

15 On 30 November 2015, kohlpharma notified the Federal Institute for Medicinal Products, pursuant to Paragraph 29 of the AMG, of certain amendments to the information leaflet and the technical characteristics relating to the dosage of the medicinal product that it imports into Germany, taking by analogy the dosage indications for the drops authorised in that Member State. More specifically, the

dosage recommendation for the pharmaceutical preparation in drop form, Impromen Tropfen 2 mg/ml, which is covered by a marketing authorisation issued by the competent authorities of the Federal Republic of Germany, was reproduced and included in the information leaflet of the medicinal product in tablet form imported by kohlpharma into Germany. That leaflet states that, where a precise dosage has been prescribed that does not correspond to the dosage of the tablets, Impromen is available also in drop form.

16 By letter of 25 February 2016, the Federal Institute for Medicinal Products informed kohlpharma of its decision refusing to approve the amendments that kohlpharma had notified to it, given that the parallel import licence had been granted only subject to an adjustment to the marketing authorisation of reference and that such an adjustment had not been possible for years. In its view, amending the information leaflet on the basis of the pharmaceutical preparation in drop form was impossible from a regulatory point of view, in particular since treatment in the form of drops by means of Impromen Tropfen 2 mg/ml could be administered in 0.5 ml or 1 mg, whereas in tablet form, treatment could be administered in 5 mg only. Therefore, the individual dosage could not be adjusted in the same manner with the tablets.

17 kohlpharma filed an opposition against that decision, claiming that the amendments that it had notified referred to a medicinal product containing the same active ingredient and merely transposed the indications in respect of the drops to the tablets. Furthermore, use of the medicinal product in tablet form depended on the doctor's prescription and was an important and well-established alternative to the use of the pharmaceutical preparation in drop form.

18 By decision of 1 July 2016, the Federal Institute for Medicinal Products rejected the opposition filed by kohlpharma, stating, inter alia, that the amendments proposed by kohlpharma 'created uncertainty and undermined the patient's treatment compliance', which was incompatible with the 'requirement of safety of medicinal products'.

19 On 1 August 2016, kohlpharma brought an action against that decision before the referring court. In the context of that action, it claimed, inter alia, that it had complied with its obligations as a parallel importer, having adjusted the leaflet used in Italy to the stricter requirements in respect of the drops in Germany and that, as a result of that decision, its product was on the market accompanied by an outdated information leaflet.

20 Before that court, the Federal Institute for Medicinal Products submitted, first, that the dosage regimen for the drops contains requirements which cannot be met in the case of the tablets and, second, that the drops authorised in Germany differ from the drops authorised in Italy as regards the concentration of the active ingredient. Furthermore, it states that an individual dosage adjustment is impossible with the tablets and that parallel importers are not, according to the applicable legislation, under an obligation to submit periodic safety reports.

21 Nevertheless, as regards a possible justification of the contested national measure on the basis of the effective protection of the life and health of humans within the meaning of Article 36 TFEU, the referring court states that it does not find sufficient evidence of a risk to the effective protection of the life and health of humans, within the meaning of that article, capable of calling into question the validity of kohlpharma's parallel import licence.

22 Therefore, the question arises whether and under what conditions such a parallel import licence can be amended after the marketing authorisation of reference has expired. In the view of the referring court, such amendments are not automatically excluded and must be examined according to the same standards as those applying to the grant of a parallel import licence. Those amendments must thus be refused if one of the grounds for refusal provided for in Article 26 of Directive 2001/83 applies. As there is no longer a marketing authorisation of reference, however, that referring court is unsure on what criteria those amendments by the parallel importer can be justified.

23 In the present case, the amendments proposed by kohlpharma are based on a partial reproduction of the indications relating to the medicinal product in question in drop form, authorised in Germany, in respect of the tablets, in combination with the indications authorised in Italy. That approach was nevertheless rejected by the Federal Institute for Medicinal Products on the ground that it is incompatible with the regulatory concept of 'parallel import'.

24 In those circumstances, the Verwaltungsgericht Köln (Administrative Court, Cologne, Germany) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Do the principle of the free movement of goods laid down in Article 34 TFEU and the principles, developed on that basis, of the parallel import of medicinal products require the national authorising authority to consent to an amendment to the indications regarding the dosage of a parallel-imported medicinal product even if the marketing authorisation of reference has expired and the amendment is substantiated with an adoption of the indications regarding a domestically produced medicinal product with essentially the same active ingredient and different form of administration in combination with the indications approved in the exporting state for the parallel-imported medicinal product?

(2) Against the background of Articles 34 and 36 TFEU, can the national authority refuse to consent to such an amendment by noting that parallel importers are exempt from the obligation to submit periodic safety reports and, due to the lack of a domestic marketing authorisation of reference, there is no current data on the risk-benefit assessment, the existing domestic marketing authorisation concerns a different form of administration and relates to a different active ingredient concentration from the authorisation for the same form of administration in the exporting State, and the combination of two forms of administration in the information texts is moreover inconceivable?'

Consideration of the questions referred

25 As a preliminary point, it must be noted that, according to the Court's settled case-law, Directive 2001/83 cannot apply to a medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a medicinal product already covered by a marketing authorisation in that other Member State, because the imported medicinal product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation. Such a situation therefore falls under the provisions of the TFEU on the free movement of goods, including Articles 34 and 36 TFEU (judgment of 3 July 2019, *Delfarma*, C-387/18, EU:C:2019:556, paragraph 19 and the case-law cited), which, in essence, prohibit Member States, in principle, from imposing quantitative restrictions on imports and measures having equivalent effect, which may, however, be justified, inter alia, on grounds of the protection of health and life of humans.

26 The free movement of goods means that an operator who has bought a medicinal product lawfully marketed in one Member State under a marketing authorisation issued in that State can import that medicinal product into another Member State where it already has a marketing authorisation, without having to obtain such an authorisation in accordance with Directive 2001/83 and without having to provide all the particulars and documentation required by the directive for the purpose of determining whether the medicinal product is effective and safe. Therefore, a Member State must not obstruct parallel imports of a medicinal product by requiring parallel importers to satisfy the same requirements as those which are applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product, subject to the condition, however, that the import of that medicinal product does not undermine the protection of public health (judgment of 3 July 2019, *Delfarma*, C-387/18, EU:C:2019:556, paragraphs 21 and 22 and the case-law cited).

27 Consequently, the competent authorities of the Member State of importation must ensure, at the time of import and on the basis of the information in their possession, that the medicinal product imported as a parallel product and the medicinal product which is the subject of a marketing authorisation in the Member State of importation, even if not identical in all respects, have at least been manufactured according to the same formulation, have the same active ingredient and have the same therapeutic effect, and that the imported medicinal product does not pose a problem of quality, efficacy or safety. If all those criteria are satisfied, the medicinal product to be imported must be regarded as having already been placed on the market in that Member State and, consequently, must be entitled to benefit from the marketing authorisation issued for the medicinal product already on the market, unless there are countervailing considerations relating to the effective protection of the life and health of humans. Thus, that authority is required to authorise that medicinal product where it is convinced that that product, in spite of differences relating to the excipients, as the case may be, does not pose a problem of quality, efficacy or safety (judgment of 3 July 2019, *Delfarma*, C-387/18, EU:C:2019:556, paragraphs 23 and 24 and the case-law cited).

28 In the case which gave rise to the judgment of 10 September 2002, *Ferring* (C-172/00, EU:C:2002:474), the Court also held that Article 34 TFEU precludes national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof means that the parallel import licence for that product automatically ceases to be valid. Nevertheless, it held that, if it is demonstrated that there is in fact a risk to public health arising from the coexistence of two versions of the same medicinal product on the market in a Member State, such a risk may justify restrictions on the importation of the old version of the medicinal product in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that market (judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 46).

29 Despite the difference between the facts at issue in the case that gave rise to the judgment referred to in the preceding paragraph and those at issue in the main proceedings, the findings in that judgment apply *mutatis mutandis* to situations where the marketing authorisation of reference has expired and two versions of the same medicinal product do not coexist on the market of a Member State.

30 Like the withdrawal of a marketing authorisation at the request of its holder, the expiry of a marketing authorisation of reference does not in itself call into question the quality, efficacy and safety of a medicinal product covered by a parallel import licence on the basis of that marketing authorisation of reference, in particular where the medicinal product in question continues, as in the case in the main proceedings, to be lawfully marketed in the Member State of exportation under the marketing authorisation issued in that State and pharmacovigilance in the Member State of importation can be guaranteed through cooperation with the national authorities of the Member State of exportation (see, to that effect, judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraphs 36 and 38).

31 For those reasons, the circumstance that the medicinal product covered by a parallel import licence on the basis of that marketing authorisation of reference is, due to the expiry of that marketing authorisation, now the only one marketed in the Member State of importation, as is the case with the medicinal product at issue in the main proceedings, is not such as to generally allow for a departure from the principles identified in the judgment of 10 September 2002, *Ferring* (C-172/00, EU:C:2002:474).

32 Nevertheless, if there are no reasons of a general nature which could explain why the withdrawal of the marketing authorisation of reference should entail that of the parallel import licence, that does not preclude the existence, in specific circumstances, of reasons relating to the protection of public health which could justify the withdrawal of the parallel import licence (judgment of 8 May 2003, *Paranova Läkemedel and Others*, C-15/01, EU:C:2003:256, paragraph 31).

33 In the present case, it is apparent from the information provided by the referring court that the competent authority of the Federal Republic of Germany granted, on 17 September 1990, a parallel import licence covering the medicinal product Impromen 5 mg in tablet form, imported by kohlpharma from Italy, where that medicinal product was covered by a marketing authorisation, as the medicinal product Consilium 5 mg (Impromen 5 mg) was covered at the time by a marketing authorisation in Germany issued by the same authority, which was able to serve as a marketing authorisation of reference for that parallel import.

34 While the medicinal product Impromen 5 mg is still covered by a marketing authorisation in Italy, in Germany the marketing authorisation for the medicinal product Consilium 5 mg (Impromen 5 mg) expired on 30 June 2010. It is nevertheless apparent from the case-law cited in paragraphs 28 to 32 of the present judgment that the expiry of that marketing authorisation of reference cannot mean that Germany can regard kohlpharma's parallel import licence in that Member State as having automatically expired, since, in particular, the parallel import licence granted to kohlpharma is still valid, as the Federal Institute for Medicinal Products confirmed in response to a question put by the Court.

35 Thus, it is apparent from the information provided by the referring court that the questions referred to the Court do not relate to the parallel import licence but concern solely the authorisation of the amendment to the particulars and documents relating to the medicinal product imported by kohlpharma. By the decision at issue in the main proceedings, the Federal Institute for Medicinal Products refused to approve those amendments on the ground that, in essence, they are based on the indications relating to the pharmaceutical preparation Impromen Tropfen 2 mg/ml in drop form, which is the only form of that medicinal product currently authorised on the German market.

36 It is against that background that the referring court's questions should be examined.

37 It must thus be noted that, by those questions, which it is appropriate to examine together, the referring court asks, in essence, whether Articles 34 and 36 TFEU must be interpreted as precluding the competent authority of a Member State from refusing to approve amendments to the particulars and documents relating to a medicinal product which is covered by a marketing authorisation in another Member State and by a licence for parallel import into the first Member State, on the sole ground that the marketing authorisation of reference in the first Member State has expired and the proposed amendments are based on both the indications authorised in the other Member State for the parallel-imported medicinal product and the indications relating to a medicinal product with the same therapeutic indication and covered by a marketing authorisation in both Member States, which is essentially manufactured with the same active ingredient but in a different pharmaceutical form.

38 In that regard, it must be borne in mind that, in accordance with settled case-law, all measures of a Member State which are capable of hindering, directly or indirectly, actually or potentially, trade within the European Union are to be considered as measures having an effect equivalent to quantitative restrictions within the meaning of Article 34 TFEU (judgments of 11 July 1974, *Dassonville*, 8/74, EU:C:1974:82, paragraph 5, and of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 31).

39 National legislation which makes all amendments to the particulars and documents relating to a medicinal product that is the subject of a parallel import licence conditional on the competent authority's approval is capable of preventing the importer of that medicinal product from presenting its particulars and documents in the manner that it considers the most appropriate for the prescription of that medicinal product and, thus, of hindering the marketing of that product. Such legislation therefore constitutes, according to the case-law cited in the preceding paragraph, a measure having an effect equivalent to a quantitative restriction, within the meaning of Article 34 TFEU.

40 Under Article 36 TFEU, the need to protect health is capable of justifying such a measure. The Court has held on numerous occasions that the health and life of humans rank foremost among the assets and interests protected by the TFEU and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved (judgments of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraph 15, and of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 30).

41 Nevertheless, it is apparent from the Court's case-law that the principle of proportionality, which is the basis of the last sentence of Article 36 TFEU, requires that the power of the Member States to prohibit imports of products from other Member States be restricted to what is necessary in order to achieve the aims concerning the protection of health that are legitimately pursued. Therefore, national legislation or practice cannot benefit from the derogation laid down in Article 36 TFEU when the health and life of humans can be protected equally effectively by measures less restrictive of trade within the internal market (judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 34 and the case-law cited).

42 In the present case, the competent authority of the Member State of importation, namely the Federal Republic of Germany, refused to approve amendments to the particulars and documents relating to a medicinal product which is covered by a marketing authorisation in the Member State of exportation, in the present case the Italian Republic, and by a licence for parallel import into the Member State of importation, on the sole ground that the marketing authorisation of reference for that medicinal product in the latter Member State had expired and the amendments were based on indications relating to another medicinal product, which uses the same active ingredient in a different pharmaceutical form, in the present case drops rather than tablets, and which is covered by a marketing authorisation in both the Member State of exportation and the Member State of importation.

43 Furthermore, it must be noted that, first, the Federal Institute for Medicinal Products has confirmed that kohlpharma's parallel import licence is still valid and, second, the referring court has stated that there is insufficient evidence of a risk to the effective protection of the life and health of humans.

44 Having regard to those elements, the assessment of which it is for the referring court to carry out, it must be considered that the refusal of a competent authority of the Member State of importation to approve amendments to the particulars and documents relating to a medicinal product which is covered by a marketing authorisation in the Member State of exportation and by a licence for parallel import into the Member State of importation, on the sole ground that the marketing authorisation of reference in the Member State of importation has expired and the amendments are based on indications relating to another medicinal product, which uses the same active ingredient in a different pharmaceutical form and is covered by a marketing authorisation in both the Member State of exportation and the Member State of importation, cannot be regarded as an appropriate and necessary measure to achieve the objective of protection of health.

45 Failing such approval, the medicinal product which is the subject of a parallel import licence would continue to be marketed accompanied by particulars and documents which are outdated and therefore do not take account of possible new information relating to that medicinal product. Such a situation is also capable of posing health risks.

46 Since, in the Member State of importation, no medicinal product using the same active ingredient and presented in the same pharmaceutical form is available on the market, the possibility of relying, as regards the updating of the particulars and documents relating to a medicinal product which is the subject of a parallel import licence, on a medicinal product on the market which uses the same active ingredient but in a different pharmaceutical form cannot be automatically excluded.

47 The fact that parallel importers are not under an obligation to submit periodic safety reports, invoked by the Federal Institute for Medicinal Products before the referring court, also cannot justify a refusal to approve amendments to the particulars and documents relating to a medicinal product that is the subject of a parallel import licence.

48 Pharmacovigilance satisfying the relevant requirements of Directive 2001/83 can ordinarily be guaranteed for medicinal products that are the subject of parallel imports through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer in the Member States in which those medicinal products are still marketed on the basis of a marketing authorisation still in force (see, to that effect, judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 38).

49 It follows from all of the foregoing considerations that the answer to the questions referred is that Articles 34 and 36 TFEU must be interpreted as precluding the competent authority of a Member State from refusing to approve amendments to the particulars and documents relating to a medicinal product which is covered by a marketing authorisation in another Member State and by a licence for parallel import into the first Member State, on the sole ground that the marketing authorisation of reference in the first Member State has expired and the proposed amendments are based on both the indications authorised in the other Member State for the parallel-imported medicinal product and the indications relating to a medicinal product with the same therapeutic indication, which is covered by a marketing authorisation in the two Member States concerned and which is essentially manufactured with the same active ingredient but in a different pharmaceutical form, where the parallel import licence at issue is still valid and there is insufficient evidence of a risk to the effective protection of the life and health of humans.

Costs

50 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 (Fourth Chamber) hereby rules:

Articles 34 and 36 TFEU must be interpreted as precluding the competent authority of a Member State from refusing to approve amendments to the particulars and documents relating to a medicinal product which is covered by a marketing authorisation in another Member State and by a licence for parallel import into the first Member State, on the sole ground that the marketing authorisation of reference in the first Member State has expired and the proposed amendments are based on both the indications authorised in the other Member State for the parallel-imported medicinal product and the indications relating to a medicinal product with the same therapeutic indication, which is covered by a marketing authorisation in the two Member States concerned and which is essentially manufactured with the same active ingredient but in a different pharmaceutical form, where the parallel import licence at issue is still valid and there is insufficient evidence of a risk to the effective protection of the life and health of humans.

[Signatures]