Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

3 July 2019 *

(Reference for a preliminary ruling — Articles 34 and 36 TFEU — Free movement of goods — Measure having equivalent effect to a quantitative restriction — Protection of health and life of humans — Parallel import of medicinal products — Reference medicinal products and generic medicinal products — Requirement that the imported medicinal product and that which has been granted a marketing authorisation in the Member State of importation are both reference medicinal products or are both generic medicinal products)

In Case C-387/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court, Warsaw, Poland), made by decision of 18 April 2018, received at the Court on 12 June 2018, in the proceedings

Delfarma sp. z o.o.

v

Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych,

THE COURT (Fifth Chamber),

composed of E. Regan, President of the Chamber, C. Lycourgos, E. Juhász, M. Ilešič and I. Jarukaitis (Rapporteur), Judges,

Advocate General: G. Hogan,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Delfarma sp. z o.o., by J. Dudzik, radca prawny,

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

– the Czech Government, by M. Smolek and J. Vláčil, acting as Agents,

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

* Language of the case: Polish.

– the Italian Government, by G. Palmieri, acting as Agent, and M. Russo, avvocato dello Stato,

– the European Commission, by K. Herrmann, E. Manhaeve and A. Sipos, acting as Agents,

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

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 Delfarma sp. z o.o. and Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland) ('the President of the Office') concerning the refusal to issue a parallel import licence for a generic medicinal product.

Legal context

EU law

3 Under Article 6(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 (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'):

'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 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 No 726/2004 (OJ 2007 L 324, p. 121)].

…'

4 Article 8(3) of that directive sets out the particulars and documents which must accompany the application for authorisation to place a medicinal product on the market 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.

5 Article 10 of that directive reads as follows:

‘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 8 years in a Member State or in the [European Union].

…

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. …

…’

Polish law

6 Article 2(7b) of the Ustawa — Prawo farmaceutyczne (Pharmaceutical Law), of 6 September 2001(‘the Law on medicinal products’), defines the concept of ‘parallel imports’ as follows:

‘… each action within the meaning of Article 72(4) involving import from European Union Member States or member states of the European Free Trade Agreement (EFTA) — parties to the Agreement on the European Economic Area — of a medicinal product that meets all of the following conditions:

(a) the imported medicinal product has the same active substance or active substances, at least the same indications up to level 3 of the ATC/ATCvet code (code of the international anatomical therapeutic chemical classification of medicinal products/code of the international anatomical therapeutic chemical classification of veterinary medicinal products), the same strength, the same route of administration and the same form as a medicinal product authorised for marketing in the territory of the Republic of Poland or has a similar form which does not result in any therapeutic differences compared to the medicinal product authorised for marketing in the territory of the Republic of Poland;

(b) the imported medicinal product and the medicinal product authorised for marketing in the territory of the Republic of Poland are both reference medicinal products or are both generic medicinal products in the country from which the product is imported and in the territory of the Republic of Poland, respectively.’

7 Article 21a(5) of the Law on medicinal products provides:

‘If the President of the Office is unable, based on the documentation held, to determine whether the differences between the medicinal product imported in parallel and the medicinal product authorised for marketing in the territory of the Republic of Poland could be considered significant from the point of view of the safety or efficacy of this product, the President of the Office shall request additional documentation other than that defined in paragraphs 7 and 8 from the competent authorities of the

European Union Member State or of the member state of the European Free Trade Association (EFTA) — party to the Agreement on the European Economic Area — from which the medicinal product in question is imported.'

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

8 Delfarma is a company engaged in the parallel import of medicinal products on the Polish market. Delfarma submitted an application to the President of the Office for the issue of a licence for parallel import from the United Kingdom of the following medicinal product: 'Sumamed, Azithromycinum, Film-Coated Tablets, 500 mg' ('Sumamed'), known in the United Kingdom as 'Azithromycin 500 mg Film-Coated Tablets' ('Azithromycin'). In its application, Delfarma stated that Azithromycin, which is authorised in the United Kingdom, and Sumamed, which is authorised in Poland, were totally identical.

9 By decision of 13 June 2017, the President of the Office rejected that application on the basis of Article 2(7b) of the Law on medicinal products, after stating that Azithromycin had been authorised in the United Kingdom on the basis of abridged documentation as a product equivalent to a reference medicinal product, whereas Sumamed had been placed on the market in Poland on the basis of full documentation as a reference medicinal product. In the grounds for his decision, the President of the Office observed, inter alia, that the prohibition on quantitative restrictions on imports and measures having equivalent effect deriving from Article 34 TFEU did not preclude the application of prohibitions and restrictions justified on the grounds of the protection of health and life of humans.

10 Delfarma requested a review of its application, asking the President of the Office to refrain from applying Article 2(7b)(b) of the Law on medicinal products on the ground that that provision introduces a restriction on the free movement of goods prohibited by Article 34 TFEU. In support of that request Delfarma, first, challenged the finding that the equivalent of a reference medicinal product and a reference medicinal product cannot be regarded as identical or similar for the sole reason that they have been authorised on the basis of different documentation. Second, it argued that the additional requirement, laid down in Article 2(7b)(b) of the Law on medicinal products, pursuant to which the imported medicinal product and the medicinal product authorised in the importing State must be in the same registration category of medicinal products, was formal in nature and was not justified on grounds of protection of public health.

11 By a decision of 3 August 2017, the President of the Office confirmed his previous decision, holding that the documentation relating to a reference medicinal product was not evidence of the quality, safety and efficacy of an equivalent reference medicinal product, and that the placing on the market of a medicinal product for which the competent authority did not hold documentation which was capable of verifying such data constituted a threat to life and health, which justified the requirement laid down in Article 2(7b)(b) of the Law on medicinal products.

12 In support of its action against that decision before the referring court, Delfarma criticised the President of the Office for failing to compare the two medicinal products concerned although he had information obtained from the competent authority in the United Kingdom and that, under Article 21a(5) of the Law on medicinal products, he had the option to request further information from that authority if he considered it necessary. Delfarma asserts that the President of the Office wrongly held that Article 2(7b)(b) of that law was justified on ground of safety, as his interpretation of that provision led him to exclude the option of carrying out an examination as to whether those two medicinal products are therapeutically identical, and it led to a decision which constitutes a restriction on the free movement of goods which is not justified on the basis of Article 36 TFEU.

13 The referring court considers that the outcome of the dispute in the main proceedings requires a decision as to whether the FEU Treaty precludes the application of Article 2(7b)(b) of the Law on medicinal products, according to which the failure to comply with the requirement laid down may constitute an exclusive, independent basis for a refusal to issue a parallel import licence for a medicinal product.

14 It appears to the referring court that the case-law of the Court adopts a strict position regarding the imposition of restrictions on the free movement of goods in relation to pharmaceutical products. Therefore, it has doubts as to whether EU law permits the refusal to issue a parallel import licence for a medicinal product on the sole ground that the application does not satisfy an additional formal requirement, such as that laid down in Article 2(7b)(b) of the Law on medicinal products, which requires that the imported medicinal product and the medicinal product already authorised in the Member State of importation have been granted a marketing authorisation on the basis of identical documents.

15 The referring court asks, in particular, about the compatibility of such a provision with the principle of proportionality, which authorises the issue of a parallel import licence for a medicinal product to be refused in the absence of identical documentation, while under national law the President of the Office may request the competent authorities of the Member State of exportation to send him the relevant documentation in order to compare the medicinal products at issue.

16 In those circumstances the Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court, Warsaw, Poland) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

‘Does EU law, and in particular [Articles 34 and 36 TFEU], preclude national legislation whereby the marketing authorisation in a Member State for a medicinal product imported in parallel cannot be granted quite simply because the medicinal product imported in parallel has been authorised in the Member State of exportation as an equivalent to a reference medicinal product, namely on the basis of an abridged dossier, whereas in the Member State of importation this medicinal product has been authorised as a reference medicinal product, namely on the basis of a full dossier, and the authorisation is refused without examining whether both products are essentially therapeutically identical and without the national authority applying — despite this being possible — for documentation to the appropriate authority in the Member State of exportation?’

Consideration of the question referred

17 By its question, the referring court asks essentially whether Articles 34 and 36 TFEU must be interpreted as precluding the legislation of a Member State, such as that at issue in the main proceedings, which requires, for the issue of a parallel import licence for a medicinal product, that that medicinal product and the medicinal product which has been granted a marketing authorisation in that Member State are both reference medicinal products or both generic medicinal products and which, therefore, prohibits the issue of a parallel import licence for a medicinal product if it is a generic medicinal product, whereas the medicinal product already authorised in that Member State is a reference medicinal product.

18 In that connection, it should be noted, that, under Article 6(1), first subparagraph, of Directive 2001/83, no medicinal product may be placed on the market of a Member State for the first time unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with that directive, or an authorisation has been granted in accordance with Regulation No 726/2004. Applications for marketing authorisations must be accompanied by the information and documents listed in Article 8(3) of the directive, even where the medicinal product concerned is already the subject of an authorisation issued by the competent authority of another Member State

(see, to that effect, judgments of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 19; of 16 December 1999, *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 23; and of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 19).

19 However, it is clear from the case-law of the Court that 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 FEU Treaty on the free movement of goods (see, to that effect, judgments of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 21, and of 16 December 1999, *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 27; see also, as regards plant protection products, judgment of 6 November 2014, *Mac*, C-108/13, EU:C:2014:2346, paragraph 27 and the case-law cited, and, as regards veterinary medicinal products, judgment of 27 October 2016, *Audace and Others*, C-114/15, EU:C:2016:813, paragraph 51 and the case-law cited).

20 It should be recalled that, according to 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 (see, to that effect, judgments of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraph 12, and of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 31 and the case-law cited).

21 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 information and documentation required by the directive for the purpose of determining whether the medicinal product is effective and safe (see, to that effect, judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 21 and the case-law cited).

22 It follows from Articles 34 and 36 TFEU that 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. However that is subject to the condition that the import of that medicinal product does not undermine the protection of public health (see, to that effect, judgment of 16 December 1999, *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 40).

23 Accordingly, 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 (see, to that effect, judgments of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 26, and of 16 December 1999, *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 45).

24 If, on completion of its examination, the competent authority of the Member State of importation finds that all the criteria mentioned in the preceding paragraph of the present judgment 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 (see, to that effect, judgments of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 29; see also, as regards plant protection products, judgments of 11 March 1999, *British Agrochemicals Association*, C-100/96, EU:C:1999:129, paragraph 36, and of 6 November 2014, *Mac*, C-108/13, EU:C:2014:2346, paragraph 28). Thus, that authority is required to authorise a medicinal product imported as a parallel product which satisfies those criteria where it is convinced that that product, in spite of differences relating to the excipients, does not pose a problem of quality, efficacy or safety (judgment of 16 December 1999 *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 45).

25 Based on the case-law of the Court, the Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, of 30 December 2003 (COM(2003) 839 final), states, in point 3 thereof, 'in particular, when the information necessary for the purposes of protecting public health is already available to the competent authorities of the Member State of destination as a result of the first marketing of a product in this Member State, a parallel imported medicinal product is subject to a licence granted on the basis of a proportionally simplified procedure provided [that] the imported product has been granted a marketing authorisation in the Member State of exportation [and that] the imported product is sufficiently similar to a product that has already received marketing authorisation in the Member State of destination even if there are differences relating to the excipients'.

26 In the present case, it is common ground that Article 2(7b)(b) of the Law on medicinal products, which requires, for the issue of a parallel import licence for a medicinal product in Poland, that that medicinal product and the medicinal product which has been granted a marketing authorisation in that Member State are both reference medicinal products or both generic medicinal products and which, therefore, prohibits the issue of a parallel import licence for a medicinal product where it is a generic medicinal product while the medicinal product already authorised in that Member State is a reference medicinal product, impedes access to the market concerned of that generic medicinal product and, therefore, constitutes a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 34 TFEU, unless it is justified by considerations relating to the protection of health and life of humans referred to in Article 36 TFEU.

27 The Polish Government claims that that requirement is justified by considerations relating to the protection of health and life of humans. In its view, that requirement is one of the elements guaranteeing that the medicinal products at issue are essentially similar, which is impossible if they are the subject of different registrations based on different documentation. That would be the case even if the President of the Office obtained full documentation from the Member State of exportation relating to the imported medicinal product because, in order to confirm the bioequivalence of the medicinal products at issue, the reference medicinal product authorised in that Member State would have to be identical to the reference medicinal product authorised in Poland. Thus, that requirement prevents the marketing of medicinal products for which the President of the Office does not have documentation on the basis of which their similarity to the medicinal products issued with a marketing authorisation in Poland can be confirmed and on the basis of which their safety and efficacy can be guaranteed.

28 The Polish Government adds that the competent authority of the Member State of importation should not have to request the production of full documentation relating to the imported medicinal product, having regard to the simplified procedure for parallel imports as compared with the marketing authorisation procedure laid down by Directive 2001/83. Furthermore, in the absence of the requirement laid down in Article 2(7b)(b) of the Law on medicinal products, there would be a risk of circumvention of that latter procedure, according to the Polish Government, since the parallel import procedure would allow the same result to be achieved at a lower cost and more quickly.

29 In that connection, although it is true that, among the goods or interests protected by Article 36 TFEU, the protection of health and life of humans is ranked in first position and that it is for the Member States, within the limits imposed by the FEU Treaty, to decide the level of protection they wish to afford, in particular, as regards how strict the checks to be carried out are to be, the fact remains that, in accordance with settled case-law, a measure having equivalent effect to a quantitative restriction on imports can be justified, for example, on grounds of the protection of the health and life of humans, within the meaning of that article, only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it (see, to that effect, judgments of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraphs 15 to 17, and of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 33).

30 Article 36 TFEU cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required (judgment of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraph 18).

31 In the present case, it must be recalled, first, as indicated by the referring court, that Article 2(7b)(b) of the Law on medicinal products lays down a formal requirement, non-compliance with which may in itself constitute a ground for refusal to issue a parallel import licence for a medicinal product. Thus, by virtue of that provision, the competent national authority may refuse to issue such a licence without even examining the information it holds regarding the medicinal products concerned for the purpose of determining whether the latter are similar, whereas it follows from the case-law set out in paragraphs 23 and 24 of the present judgment that that court is required to undertake such an examination.

32 Second, it does not appear, in a situation such as that at issue in the main proceedings, in which the imported medicinal product is a generic medicinal product whereas the medicinal product already authorised in the Member State of importation is a reference medicinal product, that the documentation relating to that generic medicinal product submitted by the importer and the documentation relating to the reference medicinal product held that authority are automatically insufficient and that more extensive documentation, including that relating to the reference medicinal product which has been granted a marketing authorisation in the Member State of exportation, is necessary in every case in order to verify whether those medicinal products have at least been manufactured in accordance with the same formula and using the same active substance, and that they have the same therapeutic effects.

33 Moreover, as regards the information necessary for the examination of an application for a parallel import licence for a medicinal product, the Court has already observed that the competent national authorities have available to them legislative and administrative means of compelling the manufacturer or his duly appointed representative to supply information in their possession which the authorities consider necessary and that simple cooperation between the authorities of the Member States would enable them to obtain the necessary substantiating documents on a reciprocal basis (see, to that effect, judgments of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraphs 26 and 27, and of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraphs 27 and 28; see also, as regards plant protection products, judgment of 6 November 2014, *Mac*, C-108/13, EU:C:2014:2346, paragraph 36 and the case-law cited).

34 The Court states that when the applicant does not have access to all the necessary information but provides data that make it at least plausible that the two medicinal products do not differ significantly for the purpose of assessing their safety and efficacy, the competent authorities must act in such a way that their decision as to whether to extend to the second medicinal product the marketing authorisation granted to the first one is taken on the basis of the fullest information possible,

including information which is available to them or which they could have obtained through cooperation with the health authorities in other Member States (judgment of 1 April 2004, *Kohlpharma*, C-112/02, EU:C:2004:208, paragraph 20).

35 It follows that it is for the competent national authority, if it considers that it has insufficient information to determine the similarity of the imported medicinal product to the reference medicinal product already authorised in the importing Member State, to request the importer to provide further information and, where appropriate, to request the competent national authority of the Member State of exportation, in the context of the cooperation between Member States, for the documents necessary for the verifications, including, if necessary, those relating to the reference medicinal product which has been granted a marketing authorisation in that Member State. Such verifications, which according to the referring court are provided for in Article 21a(5) of the Law on medicinal products, cannot be regarded as a burden which clearly exceeds the limits of what can reasonably be required.

36 Therefore, it is only if, in spite of those verifications, that the competent national authority still lacks sufficient information or, in any event, if, after the necessary verifications have been undertaken, it has doubts as to whether the imported medicinal product poses a problem in relation to quality, efficacy and safety, it must, in accordance with the case-law set out in paragraphs 22 to 24 of the present judgment, refuse the issue of the parallel import licence for the medicinal product.

37 In that connection, it must be observed that, in the case in the main proceedings, the President of the Office already had full documentation relating to the reference medicinal product Sumamed which has been granted a marketing authorisation in Poland, and that the refusal to grant a parallel import licence was based not on the ground mentioned in the preceding paragraph of the present judgment, but only on the fact that those medicinal products are not in the same registration categories, one being a reference medicinal product and the other a generic medicinal product.

38 It follows that the requirement laid down in Article 2(7b)(b) of the Law on medicinal products, in so far as it prevents any examination of the similarity of the medicinal products at issue and is based on a presumption that the documentation on which the necessary verifications are carried out are insufficient or that there is a risk that they may be insufficient, goes beyond what is necessary to achieve the objective of the protection of health and life of humans relied on.

39 Furthermore, neither is that requirement necessary to avoid the risk of circumvention of Directive 2001/83, since in order to avoid being subject to the marketing authorisation procedures laid down in that directive, the imported medicinal products must correspond strictly to the criteria set out in paragraph 23 of the present judgment, and whether those criteria are met must be verified in each case by the competent national authority.

40 Having regard to all of those considerations, that requirement cannot be regarded as being justified on the basis of Article 36 TFEU.

41 Consequently, the answer to the question referred is that Articles 34 and 36 TFEU must be interpreted as meaning that they preclude the legislation of a Member State such as that at issue in the main proceedings, which requires, for the issue of a parallel import licence for a medicinal product, that that medicinal product and the medicinal product which has been granted a marketing authorisation in that Member State are both reference medicinal products or both generic medicinal products and which, therefore, prohibits the issue of any parallel import licence for a medicinal product where it is a generic medicinal product whereas the medicinal product previously authorised in that Member State is a reference medicinal product.

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 (Fifth Chamber) hereby rules:

Articles 34 and 36 TFEU must be interpreted as precluding the legislation of a Member State, such as that at issue in the main proceedings, which requires, for the issue of a parallel import licence for a medicinal product, that that medicinal product and the medicinal product which has been granted a marketing authorisation in that Member State are both reference medicinal products or both generic medicinal products and which, therefore, prohibits the issue of any parallel import licence for a medicinal product where it is a generic medicinal product whereas the medicinal product previously authorised in that Member State is a reference medicinal product.

[Signatures]