**Case C-354/25 [Waisrinter]** [i]

**Request for a preliminary ruling**

**Date lodged:**

27 May 2025

**Referring court:**

Bundesverwaltungsgericht (Germany)

**Date of the decision to refer:**

20 March 2025

**Appellant on a point of law:**

R. SpA

**Respondent on a point of law:**

Bundesrepublik Deutschland

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**Bundesverwaltungsgericht (Federal Administrative Court)**

**ORDER**

[…]

In the administrative proceedings

of R. S.p.A.

applicant, appellant

and appellant on a point of law,

[…]

a n d

the Federal Republic of Germany,

[i] The name of the present case is a fictitious name. It does not correspond to the real name of any party to the proceedings.

represented by the Federal Institute for Drugs

and Medical Devices,

[…] Bonn,

defendant, respondent

and respondent on a point of law,

[…]

intervener:

A. AG,

[…]

the Third Chamber of the Federal Administrative Court, further to the hearing held on 13 March 2025, […]

on 20 March 2025 made

the following order:

The proceedings are stayed.

The following questions on the interpretation 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 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, p. 1) and the interpretation of Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU) are referred to the Court of Justice of the European Union for a preliminary ruling pursuant to Article 267 TFEU:

1. Do the labelling requirements laid down in Articles 54, 55(3) and 63(1) of Directive 2001/83/EC apply to a medicinal product for which a marketing authorisation has been issued in a Member State and the importation of which into another Member State constitutes a parallel import in relation to a medicinal product already covered by a marketing authorisation in that second Member State?

2. Must Article 63(3) of Directive 2001/83/EC be interpreted as meaning that a medicinal product is not intended to be delivered directly to the patient if it is classified as a medicinal product subject to medical prescription?

3. Does Article 63(3) of Directive 2001/83/EC have direct effect, meaning that an operator wishing to import into Germany a medicinal product from another Member State may rely on that provision before the German courts against the defendant Federal Republic of Germany which has not transposed that provision into national law or has not transposed it fully?

4. Do Articles 34 and 36 TFEU preclude provisions of national and of EU law, which require the labelling of immediate packaging with certain minimum particulars in the language of the Member State of importation, being applied to a medicinal product imported in parallel, if it is not possible to relabel the immediate packaging of the medicinal product imported in parallel in order to comply with those labelling requirements because of a significant impairment to its shelf life which would result from this?

## Grounds

### I

1 The dispute concerns the labelling of a medicinal product imported in parallel.

2 The applicant is the holder of the German marketing authorisation for the medicinal product … This medicinal product subject to medical prescription is indicated for the treatment of advanced prostatic cancer. It consists of a syringe (syringe A) prefilled with 440 mg of solvent and another syringe (syringe B) prefilled with 28.2 mg of … in powder form. To produce the ready-to-use injection solution, the syringes are screwed together and the liquid contained in syringe A is expressed into syringe B. The syringes each come in a thermoformed packaging tray, which is sealed with a film. The two packaging trays are in an outer carton. The medicinal product is intended for single use only; according to the package leaflet, the solution must be prepared and used immediately once the tray packaging has been opening.

3 In 2009, the intervener applied for marketing authorisation for the medicinal product … imported in parallel from Italy into Germany. The application made reference to the medicinal product … already authorised in the Federal Republic of Germany. The Federal Institute for Drugs and Medical Devices (‘the BfArM’), the competent authority of the defendant Federal Republic of Germany, granted the requested authorisation to the intervener in July 2010. In 2012, the intervener provided notification of its intention to also import the medicinal product … from Romania and Poland. In July 2014, it applied for the authorisation to be renewed for the medicinal products imported in parallel, again referring to the medicinal product … authorised in Germany as the reference medicinal product. The BfArM renewed the parallel import authorisation by means of the contested decision of

8 September 2014. That decision contained the following ‘Note on the wording of particulars intended for the container (syringes)’:

> ‘Opening the thermoformed trays encasing syringe A and syringe B impacts the shelf life of the medicinal product. Therefore, the parallel importer should not open the thermoformed trays in order to label the syringes in accordance with Paragraph 10(8) of the Arzneimittelgesetz (German Medicinal Products Act, ‘the AMG’). In order to ensure that the medicinal product and the different syringes A and B are marked so that they can be clearly identified, the parallel importer must ensure, by means of documented samples (GMP), that at least the following particulars appear in Latin characters on the syringes of the medicinal product imported in parallel:
>
> - name of the medicinal product and strength
> - identification of syringes A or B enabling the two syringes to be clearly distinguished from each other
> - batch number
> - expiry date.’

4 The former holder of the German marketing authorisation, that is to say the legal predecessor of the current applicant, lodged an objection against that decision and, after this was rejected by decision of 22 May 2015, brought an action before the Verwaltungsgericht (Administrative Court). This action relied on non-compliance with the labelling requirements laid down in the third sentence of Paragraph 10(8) of the AMG. The Administrative Court dismissed the action as inadmissible for lack of standing. In the course of the appeal proceedings, the current applicant stated it had acquired the marketing authorisation from the former applicant and was taking over the proceedings. The Oberverwaltungsgericht (Higher Administrative Court) dismissed the applicant’s appeal by means of the contested judgment of 14 December 2021, on the grounds that the action was admissible but unfounded. The issue of whether the contested authorisation and its renewal was unlawful by virtue of non-compliance with labelling requirements could be left open. In any event, the applicant’s own rights would not be infringed as a result of this. The labelling provisions laid down in Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG or Article 55(3) of Directive 2001/83/EC were not intended to protect the holder of the marketing authorisation for the reference medicinal product in the Member State of importation, but only to inform and protect patients.

5 In its appeal on a point of law, the applicant claims, inter alia, that the contested decision is unlawful because the authorisation was granted despite non-compliance with the labelling provisions laid down in the third sentence of Paragraph 10(8) of the AMG, its rights being infringed as a result. In accordance with the special characteristics of parallel importation, the authorisation refers to

the applicant's marketing authorisation for the (original) medicinal product already placed on the market in Germany. The applicant should have to tolerate this only if the medicinal product imported in parallel complies with the provisions of the AMG.

6 The defendant and the intervener defend the judgment of the Higher Administrative Court. The defendant also considers the contested authorisation decision to be lawful, on the grounds that, in the interest of the free movement of goods, the BfArM may, in justified exceptional cases, allow the parallel importer not to label the immediate container with particulars in German. This is what happened here, as opening the thermoformed trays would impact the shelf life of the medicinal product. Paragraph 10(8) of the AMG is to be interpreted as permitting different requirements supported by Paragraph 28(1) of the AMG in such exceptional cases.

II

7 The proceedings shall be stayed and a preliminary ruling obtained from the Court of Justice of the European Union pursuant to Article 267(3) of the Treaty on the Functioning of the European Union. The interpretation of the Union law that is decisive for the outcome of the dispute is not so obvious as to leave no scope for any reasonable doubt (see CJEU <Grand Chamber>, judgment of 6 October 2021 – C-561/19 [ECLI:EU:C:2021:291], Consorzio – paragraph 39).

8 The applicant's admissible action for annulment is well-founded under the first sentence of Paragraph 113(1) of the Verwaltungsgerichtsordnung (Code of Administrative Court Procedure, 'the VwGO') if the authorisation renewal granted to the intervener is unlawful and the applicant's own rights are infringed as a result. It is not possible to determine whether the authorisation renewal was unlawful without having an answer to the questions referred.

9 1. The applicant claims that the decision of 8 September 2014, renewing the authorisation granted in 2010, was unlawful because, by means thereof, the intervener was authorised to place on the market the medicinal product … imported from Italy, Poland and Romania, even though the labelling of each imported medicinal product failed to satisfy the legal requirements.

10 Pursuant to point (7) of the first sentence of Paragraph 25(2) of the AMG, in the version promulgated on 12 December 2005 (Bundesgesetzblatt (Federal Law Gazette; 'BGBl.') I, p. 3394), as last amended, as of the relevant date when the decision on the objection was adopted, by the Erstes Pflegestärkungsgesetz (First Act to Strengthen Long-term Care) of 17 December 2014 (BGBl. I, p. 2222), authorisation for a medicinal product may be refused, in particular where the placing on the market of the medicinal product would be in breach of statutory provisions. According to the first sentence of Paragraph 31(3) of the AMG, renewal of an authorisation is also excluded in this case.

11 Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG may be considered statutory provisions that could be infringed by the placing on the market of the medicinal product … imported in parallel from Italy, Poland and Romania. Paragraph 10(1) of the AMG stipulates, inter alia, that finished medicinal products falling under the scope of the Medicinal Products Act – disregarding exceptions that are not relevant here – may only be placed on the market provided that certain mandatory particulars are provided on the containers and, where used, on the outer packaging, in readily comprehensible German. The third sentence of Paragraph 10(8) reduces the mandatory particulars to be provided for, inter alia, containers having a nominal fill volume of not more than 10 millilitres.

12 (a) The alleged infringement of the labelling requirements laid down in Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG only leads to the renewal of the authorisation granted to the intervener being unlawful if the labelling requirements also apply to the authorisation for a medicinal product imported in parallel or its renewal, i.e. if – as here – a medicinal product covered by a marketing authorisation in one Member State 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.

13 The wording of the provision provides no definitive answer to this; the general scheme of the AMG would militate in favour of the requirements also applying to medicinal products imported in parallel. The question is, however, whether Union law requires another interpretation. Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG serve to transpose Articles 54, 55(3) and 63(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 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, p. 1) which is the version relevant here. Article 54 of Directive 2001/83/EC stipulates that certain mandatory particulars must appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging. Article 63(1) of Directive 2001/83/EC stipulates that the particulars shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. Article 55(3) of Directive 2001/83/EC stipulates that the following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed: the name of the medicinal product as laid down in Article 54(a) and, if necessary, the route of administration, the method of administration, the expiry date, the batch number and the contents by weight, by volume or by unit.

14 One argument against the applicability of the provisions of Directive 2001/83/EC could be that, according to the case-law of the Court of Justice of the European Union, the Directive 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. Rather, such a situation falls under the provisions of the TFEU on the free movement of goods (CJEU, judgement of 8 October 2020 – C-602/19 [ECLI:EU:C:2020:804], kohlpharma – paragraph 25). The authorisation for the imported medicinal product must therefore be granted where the competent authority of the Member State of importation has satisfied itself that the medicinal product imported in parallel 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, and the competent authority is convinced that that imported product, in spite of differences relating to the excipients, does not pose a problem of quality, efficacy or safety (CJEU, judgment of 8 October 2020 – C-602/19, kohlpharma – paragraph 27). The Court of Justice has not yet had to rule on whether compliance with the labelling requirements must also be examined. However, in the case of the parallel import of a veterinary medicinal product it saw nothing to justify the non-application of the stringent provisions (no longer in force) of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, p. 1) concerning, for example, the labelling and package leaflet in the case of the parallel import (CJEU, judgment of 27 October 2016 – C-114/15 [ECLI:EU:C:2016:813], Audace – paragraph 56). In the view of the present Chamber, the same should apply to medicinal products for human use.

15 (b) If the first question is answered in the affirmative, i.e. the labelling requirements are applicable, it must be found that the medicinal product … imported in parallel from Italy, Poland and Romania fails to meet the requirements laid down in Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG. The syringes are containers within the meaning of Paragraph 10(1) of the AMG or immediate packaging within the meaning of Article 1(23) and Article 55(1) of Directive 2001/83/EC. They are covered by the third sentence of Paragraph 10(8) of the AMG because, having regard to the weight of the syringe contents, their respective nominal fill volumes are not more than 10 millilitres. Pursuant to Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG, such containers must at least state the following in German:

- the name of the medicinal product, followed by details of the strength and pharmaceutical form and, if applicable, the indication that it is intended for administration to babies, children or adults unless this information is already included in the name (Paragraph 10(1), first sentence, point (2), first clause of the AMG),

- the batch identification, if the medicinal product is placed on the market in batches, with the abbreviation ‘Ch.-B.’; if it cannot be placed

on the market in batches, the date of manufacture (Paragraph 10(1), first sentence, point (4) of the AMG),

- the content by weight, nominal volume or number of items (Paragraph 10(1), first sentence, point (6) of the AMG),

- the method of administration (Paragraph 10(1), first sentence, point (7) of the AMG) and

- the expiry date with the indication ‘verwendbar bis’ (to be used by) (Paragraph 10(1), first sentence, point (9) of the AMG).

16 That these particulars are not present on the syringes of the medicinal product … imported in parallel is undisputed. The syringes display no particulars in German, in particular not the information ‘subcutaneous administration’ required under Paragraph 10(1), first sentence, point (7) of the AMG.

17 (c) The decisive question here is therefore whether the BfArM was allowed to waive compliance with the labelling requirements.

18 By means of its ‘Note on the wording of particulars intended for the container (syringes)’ reproduced above, the BfArM waived the need to specify, as required by the third sentence of Paragraph 10(8) of the AMG, the intended use of the medicinal product for particular patient groups, the content by weight, nominal volume or number of units, the method of administration, the designation ‘Ch-B.’ for the batch identification and the wording ‘verwendbar bis’ for the expiry date. With respect to the name of the medicinal product and its strength, the batch identification and the expiry date, still required under the provision, it waived the need for labelling in German.

19 There is no legal basis for this in national law; in particular, waiving the labelling requirements cannot be supported by Paragraph 28 of the AMG. It could, however, be permitted by Article 63(3) of Directive 2001/83/EC.

20 (aa) Article 63(3) of Directive 2001/83/EC, in the version applicable in the present case, is worded as follows:

> ‘Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.’

21 (1) In so far as the BfArM has waived the need for certain particulars entirely, the basis for this might be found in the first sentence of Article 63(3) of Directive 2001/83/EC. Waiving the use of the German language for the remaining particulars might be based on the second sentence of Article 63(3) of Directive 2001/83/EC. Since there were no availability problems, the prerequisite for this would have to be that the medicinal product … imported in parallel was not intended to be delivered directly to the patient as of the relevant date when the decision on the objection was adopted. The present Chamber is of the view that it is insufficiently clear how this criterion is to be interpreted.

22 First of all, a medicinal product is not intended to be delivered directly to the patient if it is classified as a medicinal product subject to medical prescription (see Article 70 et seq. of Directive 2001/83/EC). This interpretation is supported by the fact that the original version of Article 63(3) of Directive 2001/83/EC of 6 November 2001 (OJ L 311, p. 67) enabled an exemption from certain labelling requirements 'when the product is not intended to be delivered to the patient for self-administration'. The term 'self-administration' usually describes self-treatment by the patient with medicinal products without medical prescription. If a medicinal product is subject to prescription, it is therefore not delivered for self-administration in this sense. The amendment to Article 63(3) of Directive 2001/83/EC by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, p. 34) removed the term 'self-administration'. There is no explanation as to why; it cannot be ruled out that the EU legislature intended merely to make a linguistic change and not a substantive amendment. If the newly introduced term of 'direct delivery of a medicinal product' is still to be understood in the sense of delivery for self-administration, this would not exist if delivery to the patient were subject to medical prescription. According to this interpretation, the medicinal product … imported in parallel would be covered by Article 63(3) of Directive 2001/83/EC, since it is subject to medical prescription.

23 However, it also cannot be ruled out that the legislature intended to make a substantive amendment by amending Article 63(3) of Directive 2001/83/EC by Directive 2004/27/EC. On that basis, a medicinal product could not be intended to be delivered directly to the patient if it is not handed over to the patient, that is to say, if the patient does not gain power of control over it. Such an interpretation is supported by the fact that the German version of the Commission's original proposal, presented on 26 November 2001, for a Directive amending Directive 2001/83/EC (COM(2001) 404 final; OJ L 2002 C 75 E, p. 216) enabled an exemption from certain labelling requirements 'when the medicinal product is not intended to be delivered to the patient'. It was only during the course of the legislative procedure that the word 'directly' was added. This appeared for the first time in Common Position (EC) No 61/2003 of 29 September 2003 adopted by the Council (OJ C 297 E, p. 41); there is no explanation as to why. A corresponding amendment can also be found in the French version of the documents; the original Commission draft still spoke of 'lorsque le médicament

n'est pas destiné à être fourni au patient', whereas in the Common Position the provision is worded 'lorsque le médicament n'est pas destiné à être fourni directement au patient'. The same is true of the Italian version of the documents, the initial draft stating: '…, se il medicinale non è destinato ad essere fornito al paziente'. In the Common Position, the phrase has been moved to the beginning of the paragraph and the word 'direttamente' added: 'Se il medicinale non è destinato ad essere fornito direttamente al paziente, …'. In contrast, the English version of the Commission's proposal read 'when the product is not intended to be delivered directly to the patient' from the outset. The wording of the English version 'delivered directly to the patient' in the original version of the Commission's proposal was therefore expressed in the German version as 'delivered to the patient'. It cannot therefore be ruled out that the insertion of the German word 'direkt' (and 'directement' in the French version and 'direttamente' in the Italian version) was merely a linguistic adjustment and not a substantive amendment. If Article 63(3) of Directive 2001/83/EC were to be interpreted as meaning that the medicinal product must not be intended to be handed over to the patient, that provision would not apply in the present case, since, in accordance with Paragraph 43 of the AMG, the medicinal product … imported in parallel import can be handed over by the pharmacy to the patient.

24 Finally, an interpretation is also possible according to which a medicinal product is not intended to be delivered directly to the patient if it is not intended to be administered by the patient himself. Although Directive 2001/83/EC draws a distinction between delivery as an activity in the context of distribution (see, in particular, Article 1(17), Article 3(2), Article 70 et seq.) and the administration of the medicinal product, for example oral or external administration (see, inter alia, Article 11(4.2), Article 14(1), Article 54(a)), the original English version of Article 63(3) of Directive 2001/83/EC (OJ L 311, p. 67) can be used to support this interpretation. According to that provision, it was possible to grant an exemption to labelling requirements 'when the product is not intended to be delivered to the patient for self-administration'. This could have meant that the product was intended to be delivered directly to the patient for self-administration. The Italian version ('… se il medicinale non è destinato ad essere fornito al paziente per l'autosomministrazione') also supports that interpretation. Whether this interpretation of the term is correct depends, in turn, on the extent to which it can be assumed that the legislature intended to make a substantive amendment with the change in wording brought about by Directive 2004/27/EC. In addition, it is necessary to clarify the relationship between the terms 'Selbstmedikation' (in the original German version of Directive 2001/83/EC, see above) and 'self-administration' (in the original English version) and 'autosomministrazione' (in the original Italian version). If the requirement laid down in Article 63(3) of Directive 2001/83/EC were to be understood in the aforementioned sense, an exemption from the labelling requirements in the present case could probably not be supported by this provision. The draft package leaflet for the medicinal product … imported in parallel, which was available to the BfArM at the relevant time, stated that … was usually administered by a doctor or nurse, who also prepared the ready-to-use solution. If the patient wanted to produce the ready-to-

use solution himself, he should ask the doctor to explain exactly how he should proceed. The medicinal product was therefore also intended to be used by the patient himself – albeit in exceptional cases.

25 (2) If the second question is answered in the affirmative, the medicinal product … imported in parallel is covered by the provision of Article 63(3) of Directive 2001/83/EC. In order to apply in the present proceedings, the provision of the Directive would also have to have direct effect. According to the case-law of the Court of Justice, whenever the provisions of a directive appear, so far as their subject matter is concerned, to be unconditional and sufficiently precise, they may be relied upon before the national courts by individuals against the State where the latter has failed to implement the directive in domestic law by the end of the period prescribed or where it has failed to implement the directive correctly (settled case-law, see CJEU, judgment of 8 March 2022 – C-205/20 [ECLI:EU:C:2022:168], Bezirkshauptmannschaft Hartberg-Fürstenfeld – paragraph 17 and the case-law cited). Whether this applies to Article 63(3) of Directive 2001/83/EC cannot, in the opinion of the present Chamber, be answered with sufficient clarity. However, the period prescribed for implementing the provision in the version that is relevant here, i.e. as amended by Directive 2012/26/EU of 25 October 2012 (OJ L 299, p. 1), which ran until 28 October 2013 according to Article 2(1) thereof, had already expired by the date relevant here in May 2015, without the German legislature having implemented the provision in domestic law. The Chamber also assumes that the direct application of the provision in the present proceedings is not precluded by the fact that the application of Article 63(3) of Directive 2001/83/EC would not benefit the applicant. Although a directive cannot impose obligations on an individual, but can only confer rights (CJEU, judgment of 17 July 2008 – C-152/07 to C-154/07 [ECLI:EU:C:2008:426], Arcor and others – paragraph 35), it seems to be decisive in the present third-party action for annulment, however, that the intervener may rely on Article 63(3) of Directive 2001/83/EC against the defendant. The question arises, however, whether the provision is unconditional as far as its subject matter is concerned or whether it merely gives the Member States the option left to their discretion to provide for a corresponding derogation. Article 63(3) of Directive 2001/83/EC is not addressed to the Member States, but to the competent authorities. The German legislature seems to understand the rule in the sense of an option; thus, when inserting Paragraph 10(1a) of the AMG, which partially transposed Article 63(3) of Directive 2001/83/EC into German law in 2020, it stated that it was using ‘making use of the option for a corresponding provision provided for in Article 63(3) of Directive 2001/83/EC’ (Bundestag document 19/17155, p. 124).

26 (bb) If the second and/or third questions are answered in the negative, waiving the labelling requirements laid down in Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG and the provisions of the underlying directive, namely Articles 54, 55(3) and 63(1) of Directive 2001/83/EC, could nevertheless be justified if Articles 34 and 36 TFEU were to preclude the application of the labelling provisions. This Chamber assumes that the application of the labelling

requirements in the case to be decided here is to be regarded as a measure having equivalent effect to quantitative restrictions within the meaning of Article 34 of the TFEU. Since opening the thermoformed trays in order to relabel the syringes so that they are marked in compliance with the labelling requirements would, according to the findings of the Higher Administrative Court, which are binding on the Chamber pursuant to Paragraph 137(2) of the VwGO, significantly impair the shelf life of the medicinal product and is therefore not possible, the labelling requirements would preclude the parallel import of … from Italy, Poland and Romania. The question of whether such a restriction on the free movement of goods is justified under Article 36 of the TFEU on grounds of the protection of health and life of humans cannot be answered with sufficient clarity in the Chamber's view.

27 2. The questions raised are relevant to the decision to be given. Outside these questions, no grounds for the unlawfulness of the decision of 8 September 2014 are apparent. If the renewal of the authorisation for the medicinal product … imported in parallel from Italy, Poland and Romania is unlawful by virtue of non-compliance with the labelling requirements under Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG, the applicant's own rights are infringed as a result of this, which is a prerequisite under the first sentence of Paragraph 113(1) of the VwGO. The provisions on the authorisation of a medicinal product, in conjunction with the labelling requirements in Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG, are also intended to protect the holder of a medicinal product authorisation from a situation where a medicinal product imported in parallel can be placed on the market, referencing the holder's authorisation, but the immediate packaging of imported product is not labelled in German in accordance with the regulations.

28 According to the case-law of the Court of Justice, it follows from the provisions of the TFEU 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/EC 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 (settled case-law, see, for example, CJEU, judgment of 8 October 2020 – C-602/19, kohlpharma – paragraph 25 et seq., and the case-law cited). The authorisation for a medicinal product imported in parallel may be granted in a simplified procedure when the information necessary for the purpose of protecting public health is already available to the competent authorities of the Member State of importation as a result of the first placing on the market of a product in that Member State (COM(2003) 839 final 7 et seq.). The simplified procedure is essentially limited to verifying whether there are therapeutically relevant differences between the imported medicinal product and the reference medicinal product (Federal Ministry of Health, Notice on the authorisation for a medicinal product imported in parallel under a simplified procedure of 6 November 1995, BAnz (Federal Gazette) 1996

p. 398). The reference to the medicinal product authorised in the Federal Republic of Germany thus enables the importer to place the product on the market, without having to prove that the medicinal product is effective and safe. The holder of the marketing authorisation for the reference medicinal product must fundamentally tolerate that the parallel importer is linked to his authorisation and must accept the facilitation of the parallel import associated with this. In return, however, the holder can demand that the authorisation for the imported medicinal product is only granted if it is labelled in German in accordance with the requirements of Paragraph 10(1) and the third sentence of Paragraph 10(8) of the AMG. Although the labelling requirements apply to all medicinal products, the absence of container labelling in German in the present case results from the fact that the medicinal product was imported from a non-German-speaking Member State of the European Union. The specific connection between the parallel import and the reference medicinal product is also reflected in the parallel importer's obligation to notify the holder of the marketing authorisation for the reference medicinal product in accordance with Article 76(3) of Directive 2001/83/EC and the first sentence of Paragraph 67(7) of the AMG. The simplified procedure described was also applied to the authorisation of the medicinal product … imported in parallel and to the renewal of the authorisation. The intervener's applications for authorisation and renewal each referred to the medicinal product … authorised in the Federal Republic of Germany.

[…]