Court of Justice EU, 10 October 2016, Servoprax v Roche Diagnostics

UNFAIR COMMERCIAL PRACTICES

- **Parallel importer of a self-diagnosis device is not obliged to carry out a new assessment in the importing Member State to certify the conformity of the labelling and the translation of the instructions for its use, when that device has already been subject to a conformity assessment by a notified body and it bears a CE marking**

In the light of the foregoing, the answer to the question referred is that Article 9 of Directive 98/79 must be interpreted as meaning that it does not require a parallel importer of a device for self-diagnosis for measuring blood sugar that bears a CE marking and that was the subject of a conformity assessment by a notified body to undertake a further assessment in order to certify the conformity of the labelling of that device and the instructions for its use as a result of their translation into the official language of the Member State of importation.

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Court of Justice EU, 10 October 2016
(R. Silva de Lapuerta, President of the Chamber, E. Regan, J.-C. Bonichot, E. Sharpston)
JUDGMENT OF THE COURT (First Chamber)
10 October 2016 (*)
(Reference for a preliminary ruling — Approximation of laws — In vitro diagnostic medical devices — Directive 98/79/EC — Parallel imports — Translation by the importer of the information and instructions for use provided by the manufacturer — Supplementary conformity assessment procedure)
In Case C‑277/15,
REQUEST for a preliminary ruling under Article 267 TFEU, from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 30 April 2015, received at the Court on 9 June 2015, in the proceedings
Servoprax GmbH
v
Roche Diagnostics Deutschland GmbH,
THE COURT (First Chamber),
composed of R. Silva de Lapuerta, President of the Chamber, E. Regan, J.-C. Bonichot, A. Arabadjiev and C.G. Fernlund (Rapporteur), Judges
Advocate General: E. Sharpston,
Registrar: K. Malacek, Administrator,
having regard to the written procedure and further to the hearing on 6 April 2016,
after considering the observations submitted on behalf of:
– Servoprax GmbH, by M. Merx, Rechtsanwalt,
– Roche Diagnostics Deutschland GmbH, by U. Grundmann, Rechtsanwalt,
– the German Government, by T. Henze and A. Lippstreu, acting as Agents,
– the Lithuanian Government, by D. Kriaučiūnas, A. Svinkūnaitė and R. Butvydytė,
acting as Agents,
– the European Commission, by C. Hermes and P. Mihaylova, acting as Agents,
after hearing the Opinion of the Advocate General at the sitting on 16 June 2016,
gives the following
Judgment
1. This request for a preliminary ruling concerns the interpretation of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ 1998 L 331, p. 1).
2. The request has been made in proceedings between Servoprax and Roche Diagnostics Deutschland GmbH ('RDD'), concerning the conditions for placing on the German market in vitro diagnostic medical devices imported from another Member State.
Legal context
3. Recitals 3, 5 and 6 of Directive 98/79 are worded as follows:
'(3) ... the harmonisation of national legislation is the only means of removing such barriers to free trade and of preventing new barriers from arising; ... this objective cannot be achieved in a satisfactory manner by other means by the individual Member States; ... this Directive lays down only such requirements as are necessary and sufficient to ensure, under the best safety conditions, free movement of the in vitro diagnostic medical devices to which it applies;
...
(5) ... in vitro diagnostic medical devices should provide patients, users and third parties with a high level of health protection and attain the performance levels originally attributed to them by the manufacturer; ... therefore, maintenance or improvement of the level of health protection attained in the Member States is one of the main objectives of this Directive;
(6) ... in accordance with the principles set out in the [Council resolution of 7 May 1985 on a new approach to technical harmonisation and standards (OJ 1985 C 136, p. 1)] rules regarding the design, manufacture and packaging of relevant products must be confined to the provisions required to meet the essential requirements; ... because they are essential, such requirements should replace the corresponding national provisions;
... the essential requirements, including requirements to minimise and reduce risks, should be applied with discretion, taking into account the technology and practice at the time of design and technical and economic considerations compatible with a high level of protection of health and safety'.

4. Article 1(2)(f) of that directive defines the concept of 'manufacturer' as follows:
'... the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;
...'
5. Article 2 of that directive, headed *'Placing on the market and putting into service'*, provides:
'Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose. This involves the obligation of Member States to monitor the security and quality of these devices. This Article applies also to devices made available for performance evaluation.'
6. Article 3 of that directive, headed *'Essential requirements'*, provides:
'Devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.'
7. Article 4 of Directive 98/79, headed *'Free movement'*, provides:
'1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 16 if these devices have undergone conformity assessment in accordance with Article 9.
...
4. Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official language(s) when a device reaches the final user. Provided that safe and correct use of the device is ensured, Member States may authorise the information referred to in the first subparagraph to be in one or more other official [EU] language(s).
In the application of this provision, Member States shall take into account the principle of proportionality and, in particular:
(a) whether the information can be supplied by harmonised symbols or recognised codes or other measures;
(b) the type of user anticipated for the device.
...'
8. Article 9(3) and (11) of that directive, that article being headed 'Conformity assessment procedures' provides:
'3. For all devices referred to in List B in Annex II other than those intended for performance evaluation, the manufacturer shall for the purposes of affixing the CE marking, follow either:
(a) the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance) or;
(b) the procedure relating to EC type-examination set out in Annex V couplet with:
(i) the procedure relating to EC verification set out in Annex VI, or
(ii) the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).
...
11. The records and correspondence relating to the procedures referred to in paragraphs 1 to 4 shall be in an official language of the Member State in which the procedures are carried out and/or in another [EU] language acceptable to the notified body.'
9. Article 16 of that directive, headed *'CE marking'*, provides:
'1. Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.
2. The CE marking of conformity, as shown in Annex X, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and on the instructions for use. The CE marking of conformity must also appear on the sales packaging. The CE marking shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes III, IV, VI and VII.
3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.'
10. Devices for self-diagnosis for measuring blood sugar are covered by List B in Annex II to Directive 98/79, Annex II being headed *'List of devices referred to in Article 9(2) and (3).'*
11. Annex I to Directive 98/79, headed *'Essential requirements'*, provides in Section A.1, that section being headed *'General requirements'*:
'The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the

benefits to the patient and be compatible with a high level of protection of health and safety.'

12. Under point 8 of Section B of Annex I to Directive 98/79, that section being headed *'Design and Manufacturing Requirements'*:

'Information supplied by the manufacturer

8.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the data on the label and in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices.

Instructions for use must accompany or be included in the packaging of one or more devices.

In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.

The decision whether to translate the instructions for use and the label into one or more languages of the European Union shall be left to the Member States, except that, for devices for self-testing, the instructions for use and the label must include a translation into the official language(s) of the Member State in which the device for self-testing reaches its final user.

...'

13. Annex IV to Directive 98/79, headed ' EC Declaration of Conformity' (Full quality assurance system), provides in point 1 :

'The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the devices concerned, as specified in section 3, and is subject to audit as laid down in section 3.3 and to the surveillance as specified in section 5. In addition, the manufacturer must follow, for devices covered by Annex II, List A, the procedures laid down in sections 4 and 6.'

14. Under point 1 of Annex V to Directive 98/79, headed *'EC Type-examination'*:

'EC type-examination is the part of the procedure whereby a notified body ascertains and certifies that a representative sample of the production envisaged fulfils the relevant provisions of this Directive.'

The request to reopen the oral procedure

15. By document lodged at the Court's Registry on 12 July 2016, RDD requested that a further hearing be set for oral argument and, in the event that the oral part of the procedure had already been declared closed, that the Court order the oral part of the procedure to be reopened. In support of that request, RDD claims, in essence, that **the Opinion delivered by the Advocate General** is based on errors of fact with respect to the description of its business and that of Roche Diagnostics GmbH, its parent company.

16. That request was made after the Advocate General had delivered **her Opinion** and, therefore, after the oral part of the procedure was declared closed in accordance with Article 82(2) of the Court's Rules of Procedure. The request must therefore be understood as a request to reopen the oral procedure.

17. It should be noted that the Court may, at any time, after hearing the Advocate General, order that the oral procedure be reopened, in accordance with Article 83 of its Rules of Procedure, in particular if it considers that it lacks sufficient information or that the case must be dealt with on the basis of an argument that has not been debated by the parties or the interested persons referred to in Article 23 of the Statute of the Court of Justice of the European Union.

18. In the present case, the Court, after hearing the Advocate General, considers that it has all the information necessary to answer the question raised by the referring court and that the case does not have to be decided in the light of a new fact of such a nature as to have a decisive bearing on its decision or of an argument which has not been debated before it.

19 That being the case, the request is rejected.

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

20. RDD markets two types of test strips manufactured by Roche Diagnostics for use for selftesting of blood sugar. Those products were subject to a conformity assessment undertaken by a notified body in the United Kingdom and bear a CE marking.

21. In Germany, RDD sells those products with labelling and instructions for use in German and, as the units of measurement, 'mmol/l' and 'mg/dl'. Roche Diagnostics places those products on the United Kingdom market using, as the sole unit of measurement, 'mmol/l'.

22. Servoprax purchases in the United Kingdom the two types of test strips manufactured by Roche Diagnostics in order to re-sell them in Germany. Servoprax adds to those products a label and instructions for use in German. In the period between the month of June and the autumn of 2010, the threshold values for the devices marketed by Servoprax were stated solely in 'mmol/l', as applies for those sold in the United Kingdom.

23. RDD served notice on Servoprax that it could not market those products in Germany unless it submitted them for a supplementary conformity assessment. Servoprax then made use of a notified body established in the Netherlands. On 13 December 2010 that body certified the products concerned.

24. RDD brought an action before the Landgericht (Regional Court, Germany) seeking primarily an order that Servoprax should pay damages for the loss sustained due to the sale of the products concerned prior to 13 December 2010. That action was dismissed.

25. RDD brought an appeal against that decision. The appeal court held that Servoprax had contravened the national legislation on the labelling of in vitro diagnostic medical devices.

26. An appeal on a point of law having been brought before it by Servoprax, the referring court considers that the outcome of the dispute depends on the interpretation of Directive 98/79. That court considers that RDD's claims should be upheld if Servoprax, in marketing the products concerned prior to 13 December 2010, was in breach of the national provisions on the labelling of in vitro diagnostic medical devices.
27. The referring court notes that it is stated in point 8.1 of Annex I.B to Directive 98/79 that one of the essential requirements prescribed in Article 3 of that directive is that each device must be accompanied by the information that is needed to use it safely and properly, taking account of the training and knowledge of the potential users, and that serves to identify the manufacturer. That information comprises the data on the labelling and in the instructions for use, which must include a translation into the official language or languages of the Member State in which the device to be used for self-diagnosis reaches the final user.
28. Since the labelling and instructions for use are covered by the conformity certification and examination procedures laid down in Annexes IV and V to Directive 98/79 and the information forms part of the essential requirements, within the meaning of Article 3 of, and Annex I to, that directive, the referring court considers that a parallel importer may not place on the market in Germany in vitro diagnostic medical devices for self-testing of blood sugar levels that have been relabelled and supplied with German-language instructions for use unless a supplementary conformity assessment has taken place.
29. In the view of the referring court, the exception provided for in Article 1(2)(f) of Directive 98/79, for the benefit of a person who, while not a manufacturer, assembles or adapts, to their intended purpose, devices already on the market for an individual patient, is not applicable in this case. A broad interpretation of that exception would come up against the fact that the reproduction of the labelling and the instructions for use of a corresponding product, without any checks by a notified body, could endanger the health of patients. In this case, the products at issue marketed in Germany contain as the sole unit of measurement only 'mmol/l'. Patients would therefore be required to make a conversion into 'mg/dl' in order to use those test strips in a device that contained only measurements in 'mg/dl'.
30. According to the referring court, the fact that the instructions for use attached by Servoprax correspond word for word to that used by RDD should not be a point in the parallel importer's favour. In the course of the additional procedure, the conformity review could be restricted to checking whether the information on the labelling and in the instructions for use do in fact correspond to the information that has already been the subject of the assessment carried out by the manufacturer.
31. In those circumstances the Bundesgerichtshof (Federal Court of Justice, Germany) decided to stay the proceedings before it and to refer the following questions to the Court for a preliminary ruling:
'(1) In the case of an in vitro diagnostic medical device for self-testing blood sugar levels which has undergone a conformity assessment by the manufacturer in accordance with Article 9 of Directive 98/79/EC in Member State A (specifically: in the United Kingdom), which bears the CE marking of conformity in accordance with Article 16 of that directive and which meets the essential requirements set out in Article 3 of, and Annex I to, that directive, is a third party required to subject that device to a new or supplementary conformity assessment in accordance with Article 9 of Directive 98/79/EC before it places the device on the market in Member State B (specifically: in the Federal Republic of Germany) in packaging which contain instructions in the official language of Member State B, which differs from the official language of Member State A (specifically: German as opposed to English) and the instructions for the use of which are enclosed in the official language of Member State B rather than in that of Member State A?
2) Does it make any difference in this case whether the instructions for use enclosed by the third party correspond word-for-word to the information which the manufacturer of the device uses for the purpose of distribution in Member State B?'

Consideration of the questions referred for a preliminary ruling

32. By its two questions, which can be examined together, the referring court seeks, in essence, to ascertain whether Article 9 of Directive 98/79 must be interpreted as meaning that it requires a parallel importer of a self-diagnosis device for the measurement of blood sugar, which bears a CE marking and which has been the subject of a conformity assessment by a notified body, to undertake a further assessment to obtain certification of the conformity of the labelling and instructions for use of that device because of their translation into the official language of the Member State of importation.
33. In order to answer the question referred, it is useful to recall the obligations imposed by Directive 98/79 on manufacturers and parallel importers for the purposes of assessment of the conformity of a device to be used for self-diagnosis, such as that at issue in the main proceedings.
34. In that regard, it must be noted that the objective of Directive 98/79, which constitutes a harmonisation measure adopted under Article 100A of the EC Treaty (later Article 95 EC), is to promote the free movement of in vitro diagnostic medical devices that conform to the requirements of that directive in order to replace the various laws, regulations and administrative measures in force in the Member States which create barriers to free trade.
35. Directive 98/79 harmonises the essential requirements which must be met by the in vitro diagnostic medical devices falling within the scope of that directive. Once those devices comply with the harmonised standards and are certified in accordance

with the procedures provided for by that directive, they must be presumed to comply with those essential requirements and therefore be deemed to be appropriate for the use for which they are intended.

36. To that effect, Article 16(1) of Directive 98/79 provides that all devices, other than those for performance evaluation, which are considered to meet the essential requirements referred to in Article 3 of that directive, must bear the CE marking of conformity when they are placed on the market. Article 4(1) of that directive prohibits Member States from creating any obstacle to the placing on the market of devices bearing the CE marking if those devices have undergone conformity assessment in accordance with Article 9 of that directive.

37. It therefore follows from those provisions that in vitro diagnostic devices the conformity of which with the essential requirements of Directive 98/79 has been certified and which bear a CE marking must be allowed to move freely throughout the European Union, and no Member State can impose a requirement that such a product should undergo a further conformity assessment procedure (see, by analogy, judgment of 14 June 2007, Medipac-Kazantzidis, C-6/05, EU:C:2007:337, paragraph 42). That is why Directive 98/79 makes no provision for any mechanism for the review of conformity that is additional to or that supplements the mechanisms provided for in Article 9 of that directive.

38. As regards the language requirements for the marketing of in vitro diagnostic devices, Article 9(11) of Directive 98/79 requires records and correspondence relating to the conformity assessment procedures to be written *'in an official language of the Member State in which the procedure are carried out and/or in another language [of the European Union] acceptable to the notified body'*. That provision therefore does not impose a requirement that the assessment records be written in each of the official languages of the Member States in which it is intended that an in vitro diagnostic device will be sold.

39. Article 4(4) of Directive 98/79 provides, however, that the Member States may require that, when a device reaches the final user, the information that is needed to ensure that the device can be used properly and safely, taking account of the training and knowledge of the potential users, and that serves to identify the manufacturer, should be written in their official languages. In the specific case of devices intended for self-diagnosis, that option is converted to an obligation. It follows from a combined reading of Article 4(4) of Directive 98/79 and the last subparagraph of point 8.1 of Annex I.B to that directive that a product of that kind must be accompanied by instructions for use and labelling in the official language or languages of the Member State in which the device reaches the final user.

40. It must be emphasised that the rules referred to in paragraphs 37 and 39 of this judgment apply without distinction to the manufacturer and to the parallel importer of an in vitro diagnostic device. The prohibition imposed on the Member States, not to require a further conformity assessment, concerns all the devices that bear a CE marking and that have been subject to a conformity assessment procedure in accordance with Article 9 of Directive 98/79. Likewise, the option for, or, in the case of devices intended for self-diagnosis, the obligation on, the Member States, to require that, when an in vitro diagnostic device reaches the final user, the information needed for the safe use of that device should be translated into the official language or languages of that Member State, applies to all devices, whether they are sold by the manufacturer or by a third party.

41. It follows from the foregoing that, while the Member States are obliged, in the case of a self-diagnosis device such as that at issue in the main proceedings, to require that information to be translated into their official languages, they cannot go so far as to require the importer of such a device, that bears a CE marking and that has undergone conformity assessment by a notified body, to submit that device to a notified body for an assessment of the conformity of alterations caused by that translation requirement.

42. The referring court asks nonetheless whether, as claimed by RDD, for reasons of patient safety, the parallel importer of an in vitro diagnostic medical device who adds a label and instructions for use written in the language of the Member State of importation should be treated in the same way as a manufacturer and, consequently, should undertake a supplementary conformity assessment.

43. However, as the Advocate General stated in **point 27 of her Opinion**, the obligation to undertake a conformity assessment laid down in Article 9 of Directive 98/79 is imposed solely on a manufacturer. As defined in Article 1(2)(f) of that directive, that concept means the person who places a device on the market under his own name. When a person purchases in a Member State in vitro diagnostic devices after they have been placed on the EU market by their manufacturer in order thereafter to re-sell them in another Member State, but makes no alteration to their original packaging or presentation other than to attach a label and instructions for use written in the official language(s) of the Member State of importation, hat person cannot be regarded as having repackaged that device or having placed it on the *market 'under his own name'*.

44. That being the case, the parallel importer of devices intended for self-diagnosis, such as those at issue in the main proceedings, unless he markets those devices under his own name, cannot be regarded as a 'manufacturer', within the meaning of Article 1(2)(f) of Directive 98/79. Consequently, that importer cannot be required to submit the devices concerned for a further conformity assessment procedure under Article 9 of that directive in order to certify the conformity of the alterations made to the labelling of that device and the instructions for its use as a result of their translation into the official language of the Member State of importation.

45. In any event, as regards the fears expressed by the referring court in relation to the failure of the devices imported by Servoprax to use both units of measurement ('mmol/l' and 'mg/dl') displayed on the devices sold in Germany by RDD, it must be stated that there is nothing in the documents submitted to the Court to indicate that such a presentation is contrary to German law. The German Government, at the hearing, moreover expressly denied the existence, under national law, of a prohibition on selling devices for measuring blood sugar that have 'mmol/l' as the sole unit of measurement.

46. If it were to be established that certain devices intended for use for self-diagnosis and bearing a CE marking, such as those at issue in the main proceedings, might compromise health or safety, it must be recalled that Directive 98/79, one of whose main objectives is, as stated in recital (5) thereof, the maintenance or improvement of the level of health protection attained in the Member States, provides for the adoption of safeguard measures. Article 8 of that directive imposes on Member States that have identified risks to the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, the obligation to take all appropriate interim measures to withdraw those devices from the market, or prohibit or restrict their being placed on the market or put into service. In those circumstances, the Member State concerned is required under that provision to notify the Commission immediately of the measures taken, indicating in particular the reasons for its decision.

47. That safeguard mechanism is complemented by the vigilance procedure provided for in Article 11 of Directive 98/79. That procedure requires Member States to take the necessary steps to ensure that any information brought to their knowledge regarding, inter alia, *'any inadequacy in the labelling or the instructions for use [of devices bearing the CE marking] which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health'* should be immediately notified to the European Commission and to the other Member States and should be recorded and evaluated centrally.

48. The combination of those safeguard and vigilance procedures accordingly makes it possible to protect the health and safety of individuals, while limiting the adverse effects on the free movement of goods that would be entailed by the application of national measures requiring an importer to undertake a supplementary conformity assessment with respect to the alterations made to the labelling of a device and the instructions for its use in order to comply with the language requirements of the State of importation.

49. In that regard, the Commission submits, referring by analogy to the Court's case-law on the application of trademark law to the repackaging of products, more specifically **the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282)** and the order of 11 December 2002, Merkur Chemical (C-134/00, not published, EU:C:2002:743), that a manufacturer may not object to the affixing by a parallel importer of a label or the attachment of a translation of the instructions for use, provided that that importer has taken the trouble to notify in advance that manufacturer of the placing of the repackaged product for sale, in order to enable the manufacturer to verify the accuracy of that information and to ensure the safety of the product and of patients. That verification would extend to units of measurement and would offer an effective answer to concerns in relation to the health of patients.

50. However, **as stated by the Advocate General in point 46 of her Opinion**, there is no legal basis in EU law as it stands for the mechanism of advance notification thus advocated by the Commission. There is no provision in Directive 98/79 from which it can be inferred that such a mechanism was established, even implicitly, by the EU legislature.

51. Further, it would be contrary to the structure and the objectives of Directive 98/79 to accord to the manufacturer of an in vitro diagnostic device the right to be notified in advance of a parallel import solely because of the fact that that device bears a CE marking. A CE marking does not confer on the manufacturer, who affixes it to an in vitro diagnostic device after having submitted that device for a conformity assessment in accordance with Article 9 of Directive 98/79, any exclusive right comparable to that provided by a trademark to its proprietor.

52. In the light of the foregoing, the answer to the question referred is that Article 9 of Directive 98/79 must be interpreted as meaning that it does not require a parallel importer of a device for self-diagnosis for measuring blood sugar that bears a CE marking and that was the subject of a conformity assessment by a notified body to undertake a further assessment in order to certify the conformity of the labelling of that device and the instructions for its use as a result of their translation into the official language of the Member State of importation.

Costs

53. 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 (First Chamber) hereby rules:

Article 9 of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices must be interpreted as meaning that it does not require a parallel importer of a device for self-diagnosis for measuring blood sugar that bears a CE marking and that was the subject of a conformity assessment by a notified body to undertake a further assessment in order to certify the conformity of the labelling of that device and the instructions for its use as a result of their translation into the official language of the Member State of importation.

*Language of the case: German

OPINION OF ADVOCATE GENERAL SHARPSTON
delivered on 16 June 2016 (1)
Case C-277/15
Servoprax GmbH
v
Roche Diagnostics Deutschland GmbH
(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))
(Directive 98/79/EC on in vitro diagnostic medical devices – Parallel distribution within the internal market – Attachment to the outer packaging of medical devices for self-testing of blood sugar levels of another linguistic version of the manufacturer's information on the label and the instructions for use – New or supplementary conformity assessment procedure)

1. A manufacturer subjects test strips for use with an in vitro diagnostic medical device to a conformity assessment in one Member State. The labelling and instructions for use are in the language of that Member State. The test strips are approved and receive CE marking.

Its distribution company in another Member State markets the same test strips there, with a label and instructions for use in the language of that second Member State. A parallel distributor buys the test strips in the first Member State with labelling and instructions for use in the language of that Member State, but adds product information on the outer packaging and encloses instructions for use that correspond word-for-word to the instructions enclosed with the test strips distributed by the manufacturer's distribution company in the second Member State. It then distributes the test strips on the market of that second Member State. The distribution company challenges the lawfulness of its competitor's activity, arguing that the parallel distributor is acting as a 'manufacturer' within the meaning of Article 9 of the Directive on in vitro diagnostic medical devices ('the Directive') (2) and that a new or supplementary conformity assessment procedure is therefore required for that distribution activity. This reference from the Bundesgerichtshof (Federal Court of Justice, Germany) offers the Court its first opportunity to interpret the Directive, which aims both to remove barriers to the free movement within the single market of devices bearing the CE marking and to ensure a high level of health protection.

Legal background

EU law

2. The Directive harmonises national rules regarding the safety, health protection and performance, characteristics and authorisation procedures for in vitro diagnostic medical devices and lays down such requirements as are necessary and sufficient to ensure free movement of the products falling within its scope under the best safety conditions. (3) One of the directive's main objectives is to ensure that in vitro diagnostic medical devices provide patients, users and third parties with a high level of health protection and attain the performance levels originally attributed to them by the manufacturer. (4)

3. Article 1 of the Directive provides:

'1. This Directive shall apply to in vitro diagnostic medical devices ...

2. For the purposes of this Directive, the following definitions shall apply:

...

(b) "in vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

– concerning a physiological or pathological state,

...

(d) "device for self-testing" means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

...

(f) "manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. [(5)]

This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

...

(i) "placing on the market" means the first making available in return for payment or free of charge of a device other than a device intended for performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(j) "putting into service" means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.

...'

4. Pursuant to Article 2, Member States must take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose. To this

end, Member States are required to monitor the security and quality of these devices.
5. In accordance with Article 3, in vitro diagnostic medical devices must meet the essential requirements set out in Annex I which apply to them, taking account of their intended purpose.
6. Under part A, section 1, of Annex I ('Essential requirements'), in vitro diagnostic medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.
7. Pursuant to part B, section 8.1, of Annex I, each device must be accompanied by the information necessary for its safe and proper use, taking into account the training and knowledge of the potential users, and identify the manufacturer. (6) This information comprises the data on the label and the instructions for use. (7) For devices for self-testing,
the label and instructions for use must include a translation into the official language(s) of
the Member State in which the device for self-testing reaches its final user. (8)
8. Article 4 of the Directive provides:
'1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking ... if these devices have undergone conformity assessment in accordance with Article 9.
...
4. Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official language(s) when a device reaches the final user.
...'
9. It follows from Article 9(3) read in conjunction with the ninth indent of List B in Annex II that the manufacturer of self-testing devices for the measurement of blood sugar must, for the purposes of affixing the CE marking, follow either the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance) or the procedure relating to the EC-type examination set out in Annex V, coupled with the procedure relating to EC verification set out in Annex VI, or the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).
10. Article 9(11) requires the records and correspondence relating to conformity assessment procedures to be in an official language of the Member State in which the procedures are carried out and/or in another EU language acceptable to the notified body.
11. Article 11 ('Vigilance procedure') provides in particular:
'1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of [the] Directive, regarding the incidents mentioned below involving devices bearing the CE marking is recorded and evaluated centrally:
(a) ... any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health;
...
3. After carrying out an assessment, if possible together with the manufacturer, Member States shall ... immediately inform the Commission and other Member States of the incidents referred to in paragraph 1 for which appropriate measures, including possible withdrawal, have been taken or are contemplated.'
12. Article 15(1) requires the Member States to notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 9 and the specific tasks for which the bodies have been designated.
13. Article 16(1) states that devices, other than devices for performance evaluation, considered to meet the relevant essential requirements set out in Annex I must bear the CE conformity marking when they are placed on the market.

German law

14. The German Law on medical products (Medizinproduktegesetz) and the German Medical Products Regulations (Medizinprodukte-Verordnung) implement, in particular, Articles 2, 3 and 16 of the Directive. Thus, in accordance with the first sentence of paragraph 6(1) of the German Law on medical products, in vitro diagnostic medical devices may be placed on the market in Germany only if they bear the CE marking. Under paragraph 6(2), medical products may receive the CE marking only if the essential requirements applicable to them have been satisfied. Paragraph 5(2) of the German Medical Products Regulations requires products intended for the measurement of blood sugar to be subject to one of the conformity assessment procedures referred to in Article 9(3) of the Directive.

Factual background, procedure and questions referred

15. Roche Diagnostics GmbH ('Roche'), a subsidiary of Hoffmann-La Roche AG, manufactures test strips for diabetics for use with its electronic blood sugar measurement devices, in order to enable them to self-test their blood sugar levels. Before placing the test strips on the market, under the designations 'Accu-Chek Aviva' and 'Accu-Chek Compact', Roche submitted those products to a conformity assessment by a notified body in the United Kingdom, in accordance with Article 9 of the Directive. The label and instructions for use were thus in English. The test strips received CE marking and could therefore in principle move freely within the European Union. Nothing in the

material submitted to the Court suggests that the CE marking was (for whatever reason) wrongly affixed to the products or that the conformity assessment was in some way deficient or flawed.

16. Roche Diagnostics Deutschland GmbH ('Roche Deutschland'), a distribution company of Roche, markets Accu-Chek Aviva and Accu-Chek Compact in Germany, with labelling and instructions for use in German. Thus, when marketed in Germany the test strips have information in German on the outer packaging and instructions for use in German enclosed in the sales packaging. The test strips boxes also contain a control solution for verifying the accuracy of the blood sugar measurement device. Thus, before measuring his blood sugar level, the patient places a drop of the control solution on a test strip and inserts it into the measurement device. The value measured is compared with the threshold values indicated on the box of test strips. If the value measured is outside the threshold values, it means that the blood sugar measurement device is not sufficiently accurate. The blood sugar measurement devices which Roche Deutschland markets in Germany use either 'mmol/l' (millimoles/litre) or 'mg/dl' (milligrams/decilitre) as the unit of measurement. (9) The threshold values on test strip boxes which it markets in that Member State are therefore indicated in both units of measurement. By contrast, the same blood sugar measurement devices and test strips marketed by Roche in the United Kingdom use 'mmol/l' as the only unit of measurement.

17. Servoprax GmbH ('Servoprax') distributed in Germany Accu-Chek Aviva and Accu-Chek Compact that had been manufactured for the United Kingdom market. On the new labels in German which it attached to the outer packaging of these products, Servoprax identified itself as their 'importer and distributor' in Germany. The labels attached to the outer packaging of Accu-Chek Aviva also contained information in German describing the product, its purpose and how to use it. Servoprax included with all products a document in German corresponding word-for-word to the instructions for use provided with the test strips distributed by Roche Deutschland in Germany. Between June 2010 and the autumn of that year, the Accu-Chek Aviva which Servoprax distributed in Germany only mentioned 'mmol/l' as the unit of measurement.

18. Roche Deutschland challenged Servoprax's distribution activity. It argued that Servoprax could not sell the Accu-Chek Aviva and Accu-Chek Compact test strips it had purchased in the United Kingdom on the German market without a new or supplementary conformity assessment procedure under Article 9 of the Directive. It therefore served a warning on Servoprax in respect of that parallel distribution. Without prejudice to its legal position, Servoprax subjected those products to a new conformity assessment procedure carried out by a notified body in the Netherlands and received the certification applied for on 13 December 2010.

19. Roche Deutschland initiated judicial proceedings in Germany against Servoprax seeking the provision of information, the payment of compensation and the reimbursement of legal costs. The judgment rejecting that action at first instance was reversed on appeal in respect of distribution which took place prior to 13 December 2010. Servoprax appealed to the Bundesgerichtshof (Federal Court of Justice).

20. The Bundesgerichtshof (Federal Court of Justice) considers that the outcome of that appeal turns on the interpretation of Articles 1(2)(f), 2, 3, 4(1), 9(3) and 16 of, and Annexes I and IV to VII to, the Directive. It therefore stayed the proceedings and requested a preliminary ruling on the following questions:

'In the case of an in vitro diagnostic medical device for self-testing blood sugar levels which has undergone a conformity assessment by the manufacturer in accordance with Article 9 of [the Directive] in Member State A (specifically: in the United Kingdom), which bears the CE marking of conformity in accordance with Article 16 of that directive and which meets the essential requirements set out in Article 3 of, and Annex I to, that directive, is a third party required to subject that device to a new or additional conformity assessment in accordance with Article 9 of [the Directive] before it places the device on the market in Member State B (specifically: in the Federal Republic of Germany) in packaging which contains instructions in the official language of Member State B, which differs from the official language of Member State A (specifically: German as opposed to English) and the instructions for the use of which are enclosed in the official language of Member State B rather than in that of Member State A? Does it make any difference in this case whether the instructions for use enclosed by the third party correspond word-for-word to the information which the manufacturer of the device uses for the purpose of distribution in Member State B?'

21. Written observations were submitted by Servoprax, Roche Deutschland, the German and Lithuanian Governments and the European Commission. With the exception of the Lithuanian Government, the same parties made oral submissions at the hearing on 6 April 2016.

Assessment

Preliminary remarks

22. It is common ground that test strips for the self-testing of blood sugar levels are devices for self-testing within the meaning of Article 1(2)(d) of the Directive and must therefore undergo conformity assessment in accordance with Article 9(3) of that directive. (10)

23. The Directive pursues a double objective, as it seeks both to ensure free movement of in vitro diagnostic medical devices within the internal market and to ensure that those devices provide patients, users and third parties with a high level of health protection. (11)

24. The system of CE marking of conformity set out in Article 16 of the Directive reflects both those objectives. On the one hand, devices considered to

meet the essential requirements in Annex I must bear the CE marking of conformity when they are placed on the market. Both conformity assessment procedures to which that provision refers involve intervention by a notified body. They also entail an examination of the label and instructions for use. (12)

25. On the other hand, there is a reward for fulfilling those formalities. Once the devices have undergone conformity assessment and thus bear the CE marking, (13) Member States may not create any obstacle to placing them on the market or putting them into service within their territory, (14) subject only to the safeguard clause in Article 8 and the vigilance procedure in Article 11 of the Directive. (15)

26. The questions referred to the Court essentially ask for guidance on the following issue. Where a parallel distributor has purchased products covered by the Directive that have already undergone a conformity assessment and bear the CE conformity marking and, in order to market them in another Member State, attaches a new label and encloses instructions for use in the official language of that Member State which are materially identical to what the manufacturer provides when it distributes its own products through its own distributor, is the parallel distributor required to put the CE-marked products it wishes to sell through a new or supplementary conformity assessment procedure before it can lawfully market them?

27. The requirement laid down by Article 9 of the Directive to submit any device covered by that directive to a conformity assessment procedure only applies to 'the manufacturer' of that device. The meaning of that concept is therefore central to providing an answer to that question.

Interstate movements of in vitro diagnostic medical devices bearing the CE marking in the European Union

28. Article 9(11) of the Directive requires the records and correspondence relating to the conformity assessment procedures to be *'in an official language of the Member State in which the procedures are carried out and/or in another [EU] language acceptable to the notified body'* (emphasis added). Therefore, as the main proceedings indeed illustrate, a conformity assessment procedure does not concern different language versions of the label and instructions for use of a device with a view to its being marketed in various Member States. Requiring every notified body to be able to carry out conformity assessment procedures in the various official languages of all the Member States in which the manufacturer intended to market a new device would be inconsistent with the plain wording of Article 9(11). It would also be virtually impossible to implement in practice.

29. The Directive does not moreover require a manufacturer whose device has already undergone conformity assessment by a notified body in one Member State to subject that device to new or additional conformity assessment in another Member State where he also intends to market it, even where that Member State uses a different official language. It follows from Article 4(1) that, once a device has undergone conformity assessment and bears the CE marking, Member States may not create any obstacle to placing it on the market or putting it into service in their territory, subject only to the safeguard clause in Article 8 and the vigilance procedure in Article 11. It would plainly be incompatible with that free movement objective to interpret Article 9 of the Directive as requiring the manufacturer to subject a CE-marked device to a new or supplementary conformity assessment every time he wished to market it in a Member State with a different official language than that in which the original conformity assessment was carried out.

30. The Directive however strikes a careful balance between the free movement objective and the health protection objective. Thus, it follows from Article 4(4) that the free movement rule under Article 4(1) is without prejudice to the possibility for Member States to require, inter alia, that the information needed to use a device safely and properly or the compulsory information on the label (16) be given in their official language(s) when the device reaches the final user. The directive itself converts that option into an obligation for devices for self-testing. Under Article 3 read together with the sixth subparagraph of part B, section 8.1, of Annex I, a manufacturer marketing a self-testing device is required to provide with it a translation of the label and instructions for use into the official language(s) of the Member State(s) in which the device in question reaches its final user. (17) Again, that does not involve a new or supplementary conformity assessment procedure.

31. Do the same principles apply when an independent distributor markets devices which have received CE marking following a conformity assessment procedure in one Member State in a different Member State and provides a translation of the label and the instructions for use into the official language of the second Member State?

32. In my view, the answer is 'yes'. That results first of all from a reading of various provisions of the Directive taken together.

33. It appears from the definition in Article 1(2)(f), first subparagraph, of the Directive that the act of placing a product on the market under one's own name serves to identify who is a 'manufacturer'. (18) The same holds true for Article 1(2)(f), second subparagraph, which subjects natural or legal persons who assemble, package, process, fully refurbish and/or label one or more ready-made products and/or assign them to their intended purpose to the same obligations as 'manufacturers' only to the extent that they place products on the market under their own name.

34. According to Article 1(2)(i), a device is placed on the market once it is first made available with a view to distribution and/or use in the internal market. Where a manufacturer, under his own name, sells devices to an independent economic operator who intends to distribute them in another Member State, the devices are first placed on the market by the manufacturer, not by the independent economic operator.

35. I therefore reject Roche Deutschland's submission that, when Servoprax added a label and instructions for use in German to the devices for self-testing which it distributed in Germany, Servoprax acted as a 'manufacturer' placing those devices on the German market. It appears clear from the material available to the Court that Servoprax did not place those devices on the market under its own name but rather sold them in Germany after they had already been 'placed on the market' in another Member State. It is true that Servoprax clearly identified itself as the importer and distributor of the devices in Germany. That does not imply however that it marketed them in that Member State 'under its own name', which would have required that Servoprax held itself out to the purchasers as the devices' manufacturer. (19)
36. Consequently, in circumstances such as those in the main proceedings, the distributor cannot be regarded as either a 'manufacturer' within the meaning of Article 1(2)(f), first subparagraph, of the directive or a person subject to the same obligations as manufacturers pursuant to Article 1(2)(f), second subparagraph, of that Directive. (20) Accordingly, such a distributor is not required to subject the devices which it sells in the European Union to a new or supplementary conformity assessment procedure in accordance with Article 9 of the Directive.
37. That corresponds in essence to the Commission's recommendation in its Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (the 'proposal for a new regulation'). (21) The Commission there suggests that a distributor should be subject to the obligations incumbent on manufacturers (including regarding conformity assessment) (22) if he modifies a device already placed on the market or put into service in such a way that compliance with requirements applicable to that device pursuant to the regulation may be affected. (23) However, that does not apply where the distributor merely provides a translation of the label and instructions for use supplied by the manufacturer relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State. (24)
38. In my view it is immaterial whether the instructions for use which the distributor attaches to the devices marketed in the Member State of distribution do or do not correspond word-for-word to the instructions for use which the manufacturer provides with those devices in that Member State. That has no bearing on whether the distributor places the device on the market in his own name. It is therefore irrelevant for the purposes of ascertaining whether he is required to subject the device to a new conformity assessment in accordance with Article 9 of the Directive.
39. Furthermore, the conclusion that I have reached does not compromise the Directive's objective of ensuring a high level of health protection.
40. According to Article 3 of the Directive, devices must meet the essential requirements set out in Annex I which are applicable to them, taking into account their intended purpose. (25) Consequently, in a situation such as that in the main proceedings, the distributor has to ensure that the instructions for use and the label of the device for self-testing which it sells in a Member State contain all the information needed to use the device safely and properly and include a translation into the official language(s) of that Member State. (26) This echoes the requirements applicable to the manufacturers themselves when they extend their marketing of a device for self-testing to other Member States in the European Union. (27)
41. The various enforcement mechanisms are such as to encourage compliance with those requirements.
42. Thus, a distributor who is in breach could be held responsible for any damage caused by its negligence and, consequently, be required to compensate victims (private enforcement).
43. In addition, Article 2 of the Directive requires Member States to ensure that devices comply with the security and quality requirements which it lays down when the devices are placed on the market. In my view, having regard to the Directive's objective of ensuring a high level of health protection, that involves monitoring the security and quality of devices which independent distributors (such as Servoprax) sell on their territory, including as regards the quality and accessibility of the information needed to use the devices safely and properly (public enforcement). (28)
44. That monitoring duty is supplemented by the vigilance procedure set out in Article 11 of the Directive, which requires Member States to record and evaluate centrally any information brought to their knowledge concerning, inter alia, 'any inadequacy in the labelling or the instructions for use' of a device bearing the CE marking which is liable to threaten the life of a patient, user or other persons or to lead to a serious deterioration in their state of health, and to inform the Commission (and other Member States) immediately if appropriate measures (including possible withdrawal of the device from the market) have been taken or are contemplated. As I see it, that vigilance procedure should be activated if a Member State becomes aware that a distributor has sold an in vitro diagnostic medical device on its territory with a label and/or instructions for use that are liable to result in a serious risk for human health and safety.
45. That said, I cannot agree with the Commission when it contends that, in a situation such as that in the main proceedings, the distributor is required to give prior notice to the manufacturer of the in vitro diagnostic medical device before repackaging it and putting it on sale, so that the manufacturer can verify whether the labelling and information provided with the device comply with all applicable requirements. (29) The Commission here sought to draw an analogy between CE conformity marking and the protection due to trade mark owners when their trade-marked pharmaceutical products give rise to parallel distribution within the internal market. (30) The Commission also submits that this corresponds in

essence to what is envisaged in the proposal for a new regulation.
46. I see no basis in EU law as it stands today for a pre-notification procedure such as that set out in the previous point.
47. The trade mark case-law to which the Commission refers cannot lead to such a result by analogy. The pre-notification and pre-authorisation procedure which developed through that case-law aims to reconcile free movement of pharmaceutical products with the legitimate interest of trade mark owners to be protected in particular against repackaging by parallel distributors such as either to affect the original condition of the product or to damage the reputation of the trade mark. (31) That legitimate interest results from the specific subject matter of the trade mark, which is, inter alia, to guarantee to the owner that he has the exclusive right to use that trademark for the purpose of putting a product on the market for the first time and therefore to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products bearing it illegally. (32) Whilst the Court concluded that, as a result of the free movement of goods, the trade mark owner might not rely on his rights as owner in order to oppose the marketing under his trade mark of products repackaged by a parallel importer, it also deemed it necessary to protect the owner against any misuse of his trade mark. (33)
48. CE marking on a product confers no such exclusive right on the product's manufacturer. The purpose of CE marking is different. As is clear from Article 30(3) of Regulation (EC) No 765/2008, (34) affixing CE marking to a product merely indicates that the manufacturer 'takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing', including thus, where appropriate, requirements under the Directive on in vitro diagnostic medical devices. (35) That commitment does not confer on the manufacturer an exclusive right justifying requiring an independent distributor, in a situation such as that in the main proceedings, to obtain the manufacturer's authorisation before marketing the device in the Member State of distribution. That conclusion is of course without prejudice to the duties which I have identified at **point 40 of this Opinion** and which (according to the law already in force) bear on the distributor in such circumstances.
49. Finally, the parties have devoted some attention to the difference in the units of measurement relating to the threshold values for the control solution appearing on the Accu- Chek Aviva marketed by Roche Deutschland on the German market (that is to say both mmol/l and mg/dl) and on the same product sold by Servoprax in that Member State from June 2010 to the autumn of that year (mmol/l only). At the hearing, Roche Deutschland confirmed in essence that the unit of measurement 'mg/dl' was added to the test strips which it sold in Germany in order to take into account usages and legal requirements in that Member State. It also indicated that that unit of measurement formed part of the conformity assessment conducted by the notified body in the United Kingdom, in addition to 'mmol/l'. Roche Deutschland argued on that basis that patient safety might be compromised by Servoprax's activities and that, for that reason, a supplementary conformity assessment was necessary.
50. I do not agree.
51. First of all, I note that Roche Deutschland's submission that it is not legal to market Accu-Chek Aviva and Accu-Chek Compact in Germany only with 'mmol/l' as a unit of measurement was flatly contradicted by the German Government at the hearing. There is moreover nothing in the material before the Court to suggest that such a prohibition exists in Germany.
52. Next, in any event the devices Servoprax distributed on the German market bore the CE marking and had undergone conformity assessment in accordance with Article 9. The manufacturer of those devices thus took responsibility for their conformity with all applicable requirements under the Directive. (36) Accordingly, the devices could be marketed throughout the European Union without a new or supplementary conformity assessment, subject (in particular) to compliance with the requirements in the first, second and sixth subparagraphs of part B, section 8.1, in Annex I to the Directive. As I have explained, a distributor acting in breach of those requirements would run the risk of a civil action and might also be subject to enforcement measures by the competent national authorities. (37)
53. At the hearing, Roche Deutschland also sought to rely on Laboratoires Lyocentre. (38) The Court there examined whether the classification of a product in one Member State as a medical device bearing the CE marking, in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, (39) precluded the competent authorities of another Member State from classifying the same product, on the basis of pharmacological, immunological or metabolic action, as a medicinal product within the meaning of Article 1(2)(b) 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. (40) Whilst answering 'no' to that question, the Court emphasised that, prior to reclassifying the product, the competent national authorities had first to apply the procedure for wrongly affixed CE marking set out in Article 18 of Directive 93/42. By contrast, the present case is not one in which the authorities of a Member State take the view that CE marking has been wrongly affixed on a device marketed on that Member State's territory, or that it has been affixed in accordance with the Directive on in vitro diagnostic medical devices on a product that is not in fact covered by that directive. (41) On the contrary, there is no suggestion that CE marking has been wrongly affixed or affixed inappropriately on the test strips at issue in the main proceedings. (42)

Conclusion

54. In the light of the foregoing considerations, I suggest that the Court should rule as follows in answer to the questions raised by the Bundesgerichtshof (Federal Court of Justice, Germany):

1) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, as last amended by Commission Directive 2011/100/EU of 20 December 2011, must be interpreted as not requiring a parallel distributor to subject in vitro diagnostic medical devices to a new or supplementary conformity assessment procedure in the official language(s) of the Member State in which that parallel distributor intends to market them, where the devices in question have already undergone, in accordance with Article 9 of Directive 98/79, conformity assessment in another Member State and in another language, and thus bear the CE marking of conformity, and the parallel distributor attaches to those devices a new label and instructions for use in that (those) official language(s).

2) It is immaterial whether the instructions for use which the parallel distributor attaches to the devices marketed in the Member State of distribution do or do not correspond word-for-word to the instructions for use which the manufacturer provides with those devices when marketing them in that Member State.

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1 – Original language: English.

2 – Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 (OJ 1998 L 331, p. 1). The version of that directive relevant to the facts in the main proceedings is that last amended by Commission Directive 2011/100/EU of 20 December 2011 (OJ 2011 L 341, p. 50).

3 – Recitals 2 and 3.

4 – Recital 5.

5 – See also recital 19, which provides that ‘manufacturing ... also includes the packaging of the medical device, insofar as such packaging is related to the safety and performance aspects of this device’.

6 – First subparagraph.

7 – Second subparagraph.

8 – Sixth subparagraph.

9 – 1 mmol/l equals approximately 18 mg/dl.

10 – Annex II, List B, ninth indent.

11 – Recitals 2, 3 and 5.

12 – See Annex IV, section 3.2.c, and Annex V, section 3, read together with Annex III, section 3, 12th indent.

13 – It appears from the material available to the Court that the Accu-Chek Aviva and Accu-Chek Compact which Servoprax purchased for the purposes of parallel distribution in Germany fulfilled those conditions.

14 – Article 4(1) of the Directive.

15 – See, on that latter procedure, point 44 of this Opinion.

16 – Part B, sections 8.1 and 8.4, of Annex I.

17 – Monitoring compliance with that requirement forms part of the duties of the Member States resulting from Article 2 of the Directive. See point 43 of this Opinion.

18 – That latter element is also in essence part of the definition of ‘manufacturer’ under Article R1(3) in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ 2008 L 218, p. 82), which refers to the marketing of a product by a natural or legal person ‘under his own name or trade mark’.

19 – Had that been the case, Servoprax would indeed have been required to fulfil the same obligations as the manufacturer subject to the conditions in Article 1(2)(f) of the Directive.

20 – It is therefore unnecessary to explore the exception contained in the second sentence of the second subparagraph of Article 1(2)(f) of the Directive, which is concerned with persons who, while not manufacturers, assemble or adapt devices already on the market to their intended purpose for an individual patient.

21 – COM(2012) 541 final. On 24 May 2016, the Dutch presidency of the Council and representatives of the European Parliament reached a political agreement on a new regulation concerning in vitro medical devices (see: Council press release, ‘Medical devices: deal reached on new EU rules’, 25 May 2016, www.consilium.europa.eu/en/policies/new-rules-medical-in-vitro-diagnostic-devices/). At the time of writing, however, the agreement still had to be approved by the Council’s Permanent Representatives Committee and by the European Parliament’s Committee on Environment, Public Health and Food Safety.

22 – Article 40 of the draft regulation.

23 – See point (c) of the first subparagraph of Article 14(1) of the draft regulation.

24 – Article 14(2)(a) of the draft regulation. However, under the draft regulation, the distributor is required to indicate the activity which he carries out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established, either on the device or, where that is not possible, on its packaging or in a document accompanying the device (Article 14(3), first subparagraph). Furthermore, the distributor must have in place a quality management system that includes procedures which ensure, inter alia, that the translation of information is accurate and up-to-date (Article 14(3), second subparagraph).

25 – That rule applies regardless of whether the devices are ‘placed on the market’ or are ‘put into service’.

26 – Part B, section 8.1, first and sixth subparagraphs, of Annex I. See, by analogy, the judgment of 8 September 2005 in Yonemoto, C‑40/04, EU:C:2005:519, paragraphs 47 and 48. There may be cases where – unlike in the main proceedings – the

manufacturer does not market the device in the Member State where an independent distributor distributes it. The manufacturer's information on the label and in the instructions for use may therefore not be available in the official language(s) of that Member State. The distributor is then required to produce that information by translating the information available with the device into another language.

27 – See point 30 above. It also echoes Decision No 768/2008, which requires distributors, in particular, to 'act with due care in relation to the requirements applicable' and, before making a product available on the market, to 'verify that the product bears the required conformity marking or markings' and that it is 'accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market' (Article R5(1) and (2) in Annex I to Decision No 768/2008). However, Decision No 768/2008 merely sets out the common framework of general principles and reference provisions for drawing up future EU legislation harmonising the conditions for marketing products. It does not itself create obligations for distributors in a situation such as that in the main proceedings.

28 – Annex I, part B, section 8.1.

29 – It was unclear from the Commission's submissions at the hearing whether the Commission was advancing that argument on the basis of the law currently in force or the proposal for a new regulation.

30 – See, inter alia, the judgments of 23 May 1978 in Hoffmann-La Roche, 102/77, EU:C:1978:108; 11 July 1996 in Bristol-Myers Squibb and Others, C‑427/93, C‑429/93 and C‑436/93, EU:C:1996:282; and 23 April 2002 in Boehringer Ingelheim and Others, C‑143/00, EU:C:2002:246.

31 – Judgments of 23 May 1978 in Hoffmann-La Roche, 102/77, EU:C:1978:108, paragraphs 7 to 12, and 23 April 2002 in Boehringer Ingelheim and Others, C‑143/00, EU:C:2002:246, paragraphs 61 and 62.

32 – Judgment of 11 July 1996 in Bristol-Myers Squibb and Others, C‑427/93, C‑429/93 and C‑436/93, EU:C:1996:282, paragraph 44.

33 – Judgments of 23 May 1978 in Hoffmann-La Roche, 102/77, EU:C:1978:108, paragraphs 11 and 12, and 11 July 1996 in Bristol-Myers Squibb and Others, C‑427/93, C‑429/93 and C‑436/93, EU:C:1996:282, paragraphs 68 and 69.

34 – Of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ 2008 L 218, p. 30). Regulation No 765/2008 lays down the general principles of CE marking (Article 1(4)).

35 – That is consistent with the definition of 'CE marking' as 'a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing' (Article 2(20) of Regulation No 765/2008).

36 – See point 48 of this Opinion.

37 – See points 42 and 43 of this Opinion.

38 – Judgment of 3 October 2013 in Laboratoires Lyocentre, C-109/12, EU:C:2013:626.

39 – OJ 1993 L 169, p. 1.

40 – OJ 2001 L 311, p. 67.

41 – Article 17 of the Directive on in vitro diagnostic medical devices specifically governs the issue of wrongly affixed CE marking.

42 – See point 15 of this Opinion.