Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

17 March 2021 *

(Reference for a preliminary ruling – Article 288 TFEU – Directive 2001/82/EC – Community code relating to veterinary medicinal products – Articles 58, 59 and 61 – Information to be provided on outer packaging, immediate packaging and the package leaflet for veterinary medicinal products – Obligation to provide information in all the official languages of the Member State in which the product is marketed – National legislation providing that the information may be provided in one or other of the official languages of the Member State – National court hearing an action for a declaration that the Member State had failed correctly to transpose Directive 2001/82/EC and that the competent national authorities must amend the national legislation)

In Case C-64/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Ard-Chúirt (High Court, Ireland), made by decision of 20 January 2020, received at the Court on 6 February 2020, in the proceedings

UH

v

An tAire Talmhaíochta, Bia agus Mara,

Éire,

An tArd-Aighne,

THE COURT (First Chamber),

composed of J.-C. Bonichot, President of the Chamber, L. Bay Larsen, C. Toader, M. Safjan (Rapporteur) and N. Jääskinen, Judges,

Advocate General: M. Bobek,

Registrar: A. Calot Escobar,

having regard to the written procedure,

* Language of the case: Irish.

after considering the observations submitted on behalf of:

– UH, by D. Mac Cárthaigh, abhcóide, and S. Ó Tuathail, abhcóide sinsir,

– Ireland, by M. Browne, M. Teahan and A. Joyce, acting as Agents, assisted by C. Ó hOisín, abhcóide sinsir, and T. O'Malley, abhcóide,

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

– the European Commission, by C. Cunniffe, L. Haasbeek and F. Erlbacher, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 14 January 2021,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 288 TFEU, and of Article 58(4), Article 59(3) and Article 61(1) 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 2001 L 311, p. 1), as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 58) ('Directive 2001/82').

2 The request has been made in proceedings between UH and the Aire Talmhaíochta, Bia agus Mara, Éire (Minister for Agriculture, Food and Marine Affairs, Ireland), Éire (Ireland) and the Ard-Aighne (Attorney General, Ireland), concerning the compatibility with the language requirements laid down by Directive 2001/82 of the Irish legislation on the labelling and package leaflet of veterinary medicinal products.

Legal context

European Union law

Directive 2001/82

3 Title V of Directive 2001/82, entitled 'Labelling and package insert', includes, inter alia, Articles 58, 59 and 61 thereof.

4 Article 58(1) and (4) of that directive provides:

'1. Except in the case of the medicinal products referred to in Article 17(1), the competent authority shall approve the immediate packaging and outer packaging of veterinary medicinal products. Packaging shall bear the following information, which shall conform with the particulars and documents provided pursuant to Articles 12 to 13d and the summary of product characteristics, and shall appear in legible characters:

(a) the name of the medicinal product, followed by its strength and pharmaceutical form; The common name shall appear if the product contains only one active substance and its name is an invented name.

(b) A statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names;

(c) Manufacturer's batch number;

(d) Marketing authorisation number;

(e) Name or corporate name and permanent address or registered place of business of the marketing authorisation holder and, where appropriate, of the representative designated by the marketing authorisation holder;

(f) The species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;

(g) The withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero;

(h) Expiry date, in plain language;

(i) Special storage precautions, if any;

(j) Specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place;

(k) Particulars required to be indicated pursuant to Article 26(1), if any;

(l) The words 'For animal treatment only' or, in the case of the medicinal products referred to in Article 67, the words 'For animal treatment only – to be supplied only on veterinary prescription'.

[…]

4. 'The particulars mentioned in paragraph 1(f) to (l) shall appear on the outer package and on the container of the medicinal products in the language or languages of the country in which they are placed on the market.'

5 Article 59 of Directive 2001/82 provides:

'1. As regards ampoules, the particulars listed in the first paragraph of Article 58(1) shall be given on the outer package. On the immediate packaging, however, only the following particulars shall be necessary:

– name of veterinary medicinal product,

– quantity of the active substances,

– route of administration,

– manufacturer's batch number,

– date of expiry,

– the words 'For animal treatment only'.

2. As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in paragraph 1, the requirements of Article 58(1), (2) and (3) shall apply only to the outer package.

3. The particulars mentioned in the third and sixth indents of paragraph 1 shall appear on the outer package and on the immediate packaging of the medicinal products in the language or languages of the country in which they are placed on the market.'

6 Article 61(1) of that directive provides:

'The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed.'

7 The information to be included in that leaflet is set out in Article 61(2)(a) to (i) of that directive.

Regulation (EU) 2019/6

8 Recitals 52, 53 and 96 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (2019) (OJ 2019 L 4, p. 43) read:

'(52) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced …. Care should be taken so that those rules do not jeopardise public or animal health or environmental safety.

(53) In addition, Member States should be able to choose the language of the text used in the summary of product characteristics, labelling and package leaflet of veterinary medicinal products authorised in their territory.

…

(96) Taking into account the main changes that should be made to the existing rules, and aiming to improve the functioning of the internal market, a regulation is the appropriate legal instrument to replace Directive 2001/82/EC in order to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.'

9 Article 7 of that regulation, entitled 'Languages', provides:

'1. The language or languages of the summary of the product characteristics and the information on the labelling and on the package leaflet shall, unless the Member State determines otherwise, be an official language or languages of the Member State where the veterinary medicinal product is made available on the market.

2. Veterinary medicinal products may be labelled in several languages.'

10 The first paragraph of Article 149 of that regulation states:

'Directive 2001/82/EC is repealed.'

11 Under Article 160 of that regulation, entitled 'Entry into force and application':

'This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 28 January 2022.'

Irish law

12 Directive 2001/82 was transposed into the Irish legal order by Rialacháin na gComhphobal Eorpach (Leigheasanna Ainmhithe) 2007 (I. R. Uimh 144 of 2007) (European Communities (Animal Remedies) Regulations 2007 (S.I. No. 144/2007)), and then, after those regulations were

repealed, by Rialacháin na gComhphobal Eorpach (Leigheasanna Ainmhithe) (Uimh. 2), 2007 (I.R. Uimh. 786 of 2007) (European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No 786/2007)).

13 The latter regulation provides that the information which must appear on outer packaging, immediate packaging and the package leaflet for veterinary medicinal products 'shall be in English or Irish'.

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

14 The applicant in the main proceedings, who is an Irish citizen and a native Irish speaker, originates from the Galway Gaeltacht (the Irish-speaking region of Galway, Ireland). He speaks Irish at home and at work. He conducts all of his official business in the Irish language in so far as the resources are available to that end. He has a pet dog and, accordingly, requires veterinary medicinal products. His complaint is that the information accompanying veterinary medicinal products is written exclusively in the English language and not, as required by Directive 2001/82, in both of the official languages of Ireland, namely the Irish and English languages.

15 Following an exchange of correspondence between the parties to the main proceedings, on 14 November 2016 the applicant in the main proceedings lodged an application with the Ard-Chúirt (High Court, Ireland) for permission to bring judicial review proceedings concerning the incorrect transposition, by the Minister for Agriculture, Food and Marine Affairs, of Directive 2001/82 with regard to the language requirements laid down by that directive. That permission was granted and the case was heard before the referring court on 24 and 25 July 2018.

16 The applicant in the main proceedings asked that court, in particular, to declare that Directive 2001/82 had been incorrectly transposed into Irish law and that Ireland was under an obligation to amend its national legislation so that the information covered by that directive was provided in the two official languages of the State, that is to say, in both the Irish and English languages, for veterinary medicinal products placed on the market in the State, with the requirement that the two language versions be provided in the same font, while clear precedence is to be given to the Irish language version, since that is the national language and the first official language.

17 On 26 July 2019, after upholding the interest of the applicant in the main proceedings in bringing proceedings, on the ground that the provisions of Directive 2001/82 on languages were clear, precise and unconditional and finding that the national legislation did not comply with those provisions, the referring court observed, however, that, as from 28 January 2022, the date on which, in accordance with Article 160 thereof, Regulation 2019/6 came into force, the information required to appear on outer packaging, internal packaging and package leaflets for veterinary medicinal products could be drafted in the Irish or the English language. That court therefore considered whether, notwithstanding the infringement of EU law in the present case, it had a discretion that permitted it, in an appropriate manner, not to grant the remedy sought, in the same way as a national court is permitted to do where there is an infringement of national law, and invited the parties to the main proceedings to make any observations in that respect.

18 The applicant in the main proceedings submitted that such discretion could not be allowed in the event of an infringement of EU law, owing to the principles of direct effect and primacy, the right to effective judicial protection, laid down in Article 47 of the Charter of Fundamental Rights of the European Union, and respect for the rule of law.

19 For their part, the Aire Talmhaíochta, Bia Agus Mara, Éire (Minister for Agriculture, Food and Marine Affairs, Ireland), Eire (Ireland) and the Ard-Aighne (Attorney General, Ireland), the defendants in the main proceedings, pointed out that, even if an applicant successfully challenges the decision of a public authority by means of judicial review, the court hearing the case may, at its discretion, refuse to grant the measures sought by the applicant, having regard to certain circumstances, such as where those measures would serve no purpose or would prejudice a third party.

20 In the present case, the benefit that the applicant in the main proceedings could derive from the requested measures is very limited owing to the entry into force of Regulation 2019/6 with effect from 28 January 2022. Furthermore, granting those measures could lead to suppliers and distributors of veterinary medicinal products to withdraw from the Irish market in view of the constraints the obligation to provide the information in the Irish and the English languages would entail, which would have serious consequences for animal health and on economic and social circumstances.

21 In the light of the arguments put forward before it, the referring court wishes to ascertain whether a refusal to grant the measures sought by the applicant in the main proceedings would not infringe EU law.

22 In those circumstances, the Ard-Chúirt (High Court) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Does a national court have discretion to refuse relief in spite of its decision that national law has failed to give effect to a particular aspect of a directive of the European Union (EU) and, if the court does have that discretion, what are the appropriate factors that should be taken into account in relation to the discretion and/or is the national court entitled to take into account those same factors which it would take into account if it were dealing with a breach of national law?

(2) Would the principle of direct effect in EU law be undermined if the national court refused to grant relief in this case due to the entry into force of Article 7 of [Regulation 2019/6] (the application of which is deferred until 28 January 2022), in spite of the fact that the national court decided that national law has failed to give effect to the duty in Articles 61(1), 58(4) and 59(3) of Directive 2001/82, that duty being that the packaging and labelling of veterinary products must be in the official languages of the Member State, that is to say, in Ireland, in the English language as well as the Irish language?’

Consideration of the questions referred

Admissibility

23 In their written observations, Ireland and the Polish Government call into question the admissibility of the questions referred for a preliminary ruling.

24 Ireland submits, first, that it has properly transposed the provisions of Directive 2001/82 at issue in the main proceedings, the text of which is ambiguous, the decision of that Member State to implement them in a way which allows only one of its official languages to be used being a matter that falls within its discretion.

25 Second, the express purpose of that directive makes it clear that the rights flowing from it constitute not linguistic or cultural rights, but rather rights concerning access to information on veterinary medicinal products. Such rights would only be infringed if a consumer were in possession of packaging or labelling which he or she could not fully understand. However, the applicant in the main proceedings does not claim to have been faced with packaging or labelling that he could not fully understand.

26 According to the Polish Government, EU law does not require national courts to grant relief which consists in ordering the competent national authorities to amend national law so as to bring it into line with EU law. In any event, the action in the main proceedings cannot succeed. Even supposing that the right to have the information accompanying veterinary medicinal products available in the Irish language derives from unconditional and sufficiently precise provisions of Directive 2001/82, that right may not, given its nature, be relied on against the Irish authorities. The obligation to label those products in the Irish language would fall on private entities, namely the producers and distributors of those products, against which the applicant cannot rely on the provisions of a directive.

27 In that regard, as the Advocate General observed in point 26 of his Opinion, the arguments raised by both Ireland and the Polish Government relate to the substance of the action brought by the applicant in the main proceedings. It must however be recalled that arguments which concern matters relating to the substance of an action cannot affect the admissibility of the questions referred (see, to that effect, the judgment of 19 November 2019, *A.K. and Others (Independence of the Disciplinary Chamber of the Supreme Court)* (C-585/18, C-624/18 and C-625/18, EU:C:2019:982, paragraph 111).

28 Moreover, according to the Court's settled case-law, questions as to the interpretation of EU law which are referred by a national court in the factual and legislative context which that court is responsible for defining, and the accuracy of which is not for this Court to verify, enjoy a presumption of relevance (judgment of 2 February 2021, *Consob*, C-481/19, EU:C:2021:84, paragraph 29). That presumption of relevance cannot be rebutted by the possibility that the applicant might ultimately be unsuccessful in the main proceedings before the national court, in particular on the basis of an interpretation of EU law adopted by the Court.

29 In the light of the foregoing, the questions referred for a preliminary ruling must be declared admissible.

Substance

30 By its two questions, which it is appropriate to examine together, the referring court asks the Court, in essence, whether Article 288 TFEU must be interpreted as precluding a national court – which, in the context of proceedings laid down in national law for that purpose, finds that the Member State to which it pertains has failed to fulfil its obligation to transpose correctly Directive 2001/82 – from refusing, on the ground that it appears to it that the national legislation is consistent with Regulation 2019/6 which repeals that directive and will be applicable with effect from 28 January 2022, to make a declaration that that Member State has not correctly transposed that directive and is required to take remedial steps in that regard.

31 In that regard, it must be recalled that the Member States' obligation arising from a directive to achieve the result envisaged by that directive and their duty, under Article 4(3) TEU and Article 288 TFEU, to take all appropriate measures, whether general or particular, to ensure the

fulfilment of that obligation is binding on all the authorities of Member States including, for matters within their jurisdiction, the courts (judgments of 19 April 2016, *DI*, C-441/14, EU:C:2016:278, paragraph 30 and the case-law cited; of 4 October 2018, *Link Logistik N&N*, C-384/17, EU:C:2018:810, paragraph 57, and of 13 December 2018, *Hein*, C-385/17, EU:C:2018:1018, paragraph 49).

32 In the present case, it is apparent from the order for reference that Irish law allows individuals to obtain a judicial declaration that Ireland has not correctly transposed a European Union directive and is required to transpose that directive, while leaving it open to the national courts to refuse to make such a declaration, on the grounds established by that law.

33 In that regard, it should nevertheless be recalled that, as the referring court has found that Directive 2001/82 was incorrectly transposed, it is required to take all the appropriate general and particular measures to ensure that the result prescribed by that directive is attained (see, to that effect, judgment of 24 October 1996, *Kraaijeveld and Others*, C-72/95, EU:C:1996:404, paragraph 55).

34 The fact that the Irish legislation is already compatible with Regulation 2019/6, which will apply with effect from 28 January 2022, cannot call into question the finding that that legislation is incompatible with EU law before that date or, a fortiori, justify such incompatibility.

35 Until Directive 2001/82 is repealed by that regulation, the provisions of the directive remain binding for so long as the Court of Justice has not ruled that they are invalid (see, to that effect, judgments of 13 February 1979, *Granaria*, 101/78, EU:C:1979:38, paragraph 5, and of 21 September 1989, *Hoechst* v *Commission*, 46/87 and 227/88, EU:C:1989:337, paragraph 64).

36 Accordingly, the Court alone may, exceptionally and for overriding considerations of legal certainty, grant a provisional suspension of the effects of a rule of EU law with regard to a national law that is contrary to it (see, to that effect, judgment of 28 July 2016, *Association France Nature Environnement*, C-379/15, EU:C:2016:603, paragraph 33 and the case-law cited).

37 In those circumstances, Article 288 TFEU precludes a national court of a Member State from disregarding the obligation imposed on that state to transpose a directive on the ground that that transposition is purportedly disproportionate as it might prove costly or serve no purpose on account of the forthcoming application of a regulation intended to replace that directive, with which the law of that Member State is fully compatible.

38 It follows that, under Article 288 TFEU, the referring court, which has found that the national legislation is incompatible with Directive 2001/82, is required to uphold the application for a declaration that Ireland is under an obligation to remedy the incorrect transposition of that directive.

39 It follows from all of the foregoing that Article 288 TFEU must be interpreted as precluding a national court – which, in the context of proceedings laid down in national law for that purpose, finds that the Member State to which it pertains has failed to fulfil its obligation to transpose correctly Directive 2001/82 – from refusing, on the ground that it appears to it that the national legislation is consistent with Regulation 2019/6 which repeals that directive and will be applicable with effect from 28 January 2022, to make a declaration that that Member State has not correctly transposed that directive and is required to take remedial steps in that regard.

Costs

40 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 288 TFEU must be interpreted as precluding a national court – which, in the context of proceedings laid down in national law for that purpose, finds that the Member State to which it pertains has failed to fulfil its obligation to transpose correctly 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, as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 – from refusing, on the ground that it appears to it that the national legislation is consistent with Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 which repeals that directive and will apply with effect from 28 January 2022, to make a declaration that that Member State has not correctly transposed that directive and is required to take remedial steps in that regard.

[Signatures]