



**A Member State court is required to exercise the power conferred on it by national law to make a declaration that that Member State has failed correctly to transpose a directive and is required to take remedial steps in that regard**

*That court cannot disregard the obligation imposed on that Member State to transpose a directive on the ground that that transposition is purportedly disproportionate as a result of forthcoming changes in the requirements arising from EU law*

UH, an Irish citizen and a native Irish speaker from the Galway Gaeltacht (the Irish-speaking region of Co. Galway, Ireland), claimed that the information accompanying veterinary medicinal products was written exclusively in the English language. He takes the view that Directive 2001/82<sup>1</sup> requires that information to be in both of the official languages of Ireland, namely Irish and English. On 14 November 2016, UH requested that the Ard-Chúirt (High Court, Ireland) make a declaration that Directive 2001/82 was incorrectly transposed and that Ireland was under an obligation to amend its legislation accordingly.

The Ard-Chúirt found that Irish legislation on the labelling and package leaflet of veterinary medicinal products did not comply with the language requirements set out in the Directive and, therefore, infringed Article 288 TFEU.<sup>2</sup> Nonetheless, that court noted that Regulation 2019/6,<sup>3</sup> which is to apply from 28 January 2022, allows for information which must appear on the outer packaging, inner packaging and the package leaflet for veterinary medicinal products to be provided in the Irish or the English language. It therefore took the view that the applicant would obtain only a limited and temporary benefit from any amendment to Irish law in order to comply with the directive, while the suppliers and distributors of veterinary medicinal products would be faced with difficulties that could entail serious consequences for animal health and for the economic and social circumstances in Ireland.

Having been requested to give a preliminary ruling by that same court, **the Court holds 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 was adopted in order to repeal 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.**

<sup>1</sup> 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 provides, inter alia, that the outer packaging or containers of veterinary medicinal products must bear compulsory information relating to the medicinal products, for example, the name, strength, form, composition, production batch, authorisation number, species of animal and dosage. Article 58(4) of the directive provides that this information must be written 'in the language or languages of the country in which they are placed on the market.'

<sup>2</sup> Article 288(3) TFEU provides that 'a directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods'.

<sup>3</sup> 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 (OJ 2019, L 4, p. 43). Article 7(1) of that regulation provides that the compulsory particulars shall be drafted in 'an official language or languages of the Member State where the veterinary medicinal product is made available on the market.'

## Findings of the Court

The Court recalls that the obligation on Member States to achieve the result envisaged by a directive and their duty to take all appropriate measures, whether general or particular, is binding on all the authorities of Member States including, for matters within their jurisdiction, the courts.<sup>4</sup> Furthermore, the Court finds that 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.

In the present case, the referring court found that Directive 2001/82 had been incorrectly transposed. **The Court notes in that regard that 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.** Until Directive 2001/82 is repealed by that regulation, the provisions of the directive remain binding. **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.**

Consequently, the Court holds that Article 288 TFEU precludes a national court of a Member State from disregarding the obligation imposed on that Member 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. The referring court is therefore required to take all the appropriate general and particular measures to ensure that the result prescribed by that directive is attained and, accordingly, to make the declaration requested.

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**NOTE:** A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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<sup>4</sup> In that regard, it should be noted that the second paragraph of Article 4(3) TEU provides that 'the Member States shall take any appropriate measure, general or particular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the Union.'