



Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 14 January 2021¹

Case C-64/20

UH

v

An tAire Talmhaíochta Bia agus Mara, Éire agus an tArd-Aighne

(Request for a preliminary ruling from the Ard-Chúirt (High Court, Ireland))

(Reference for a preliminary ruling – Directive 2001/82/EC – Language requirements with regard to the packaging and labelling of veterinary products – Discretion of national courts to refuse relief – Direct effect – Primacy – Procedural autonomy – Effective judicial protection)

I. Introduction

1. There is no shortage of issues invoked in the present case. If placed together and played simultaneously, they generate a genuine EU law constitutional polyphony: direct effect, primacy, procedural autonomy, effective judicial protection, the overall effectiveness of national enforcement of EU law, all of them accompanied by an (alleged) right to receive information in one's language and the Union's multilingualism.

2. When listening attentively, there is one dominant tune which nonetheless emerges: do those principles, in particular the effectiveness of national enforcement of EU law, preclude national rules that provide a discretionary power to a court to determine whether to grant relief, and if so, the form of that relief, to an applicant who claims that the authorities have not transposed a directive correctly, despite the action being (apparently) well founded? That tune reverberates a rather well-known theme: what are the reasonable limits to the requirement of an effective enforcement of EU law at national level?

II. Legal framework

A. EU law

3. Title V 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,² entitled 'Labelling and package insert', includes Articles 58 to 64.

¹ Original language: English.

² OJ 2001 L 311, p. 1, as subsequently amended.

4. Article 58(1) of Directive 2001/82 lists the information that, save exceptions, ‘shall appear in legible characters’ on the packaging of medicinal products. Pursuant to Article 58(4) of that directive, the particulars mentioned in paragraph 1(f) to (l) of the same provision ‘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(1) of Directive 2001/82 states that, as regards ampoules, ‘the particulars listed in the first paragraph of Article 58(1) shall be given on the outer package’. It then lists the particulars that are necessary on the containers. Article 59(3) of Directive 2001/82 provides that ‘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 Directive 2001/82 states that ‘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. ... 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’. Article 61(2) of Directive 2001/82 lists the information that, at the very least, the package leaflet must contain..

7. Recitals 52 and 53 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/EC³ 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. ...

(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.’

8. Article 7 of Regulation 2019/6, entitled ‘Languages’, states:

‘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.’

9. In accordance with its Article 160, Regulation 2019/6 shall apply from 28 January 2022.

B. National law

10. According to the referring court, many statutory instruments were adopted in order to transpose Directive 2001/82. However, as regards the language of the packaging, which gave rise to the main proceedings, the relevant provisions are to be found in Statutory Instruments (“SI”) 144/2007 and 786/2007. Under those instruments, the particulars required under the provisions of Directive 2001/82 may be in Irish or in English.

³ OJ 2019 L 4, p. 43.

III. Facts, national proceedings and the questions referred

11. The applicant in the main proceedings is a native Irish speaker. He owns a pet dog, for which he purchases veterinary medicinal products. The applicant complained to the Aire Talmhaíochta, Bia agus Mara, Éire (the Minister for Agriculture, Food and the Marine, Ireland), that the information accompanying the veterinary products was solely in English and not in both official languages of the State: Irish and English. In his view, that constituted an infringement of Directive 2001/82.

12. On 14 November 2016, the applicant brought an application before the Ard-Chúirt (High Court, Ireland) seeking leave for judicial review regarding the Minister's failure to transpose Directive 2001/82 correctly in respect of the language requirements contained therein. That leave was granted and proceedings were thus brought against the Aire Talmhaíochta, Bia agus Mara, Éire (the Minister for Agriculture, Food and the Marine, Ireland) as well as the Ard-Aighne (the Attorney General) and Ireland. The case was heard on 24 and 25 July 2018.

13. The applicant sought the following forms of relief arising from the alleged failure of Ireland to transpose the directive correctly: (i) a declaration that the applicable national legislation does not transpose Title V (Articles 58 to 61) of Directive 2001/82 correctly or at all; (ii) a declaration that Irish law must ensure that the appropriate particulars on the package leaflets and packaging in question in Title V of Directive 2001/82 are in the official languages of the State, that is to say, in both Irish and English, on veterinary medicinal products placed on the market in the State; and (iii) a declaration that the Irish authorities must amend national law to ensure a correct transposition of the provisions of Title V of Directive 2001/82.

14. Before the Ard-Chúirt (High Court), the applicant mainly relied on (i) the direct effect of the provisions of Directive 2001/82 concerning the language requirements (that those provisions are clear, precise and unconditional), (ii) the primacy of EU law over national law (the national court could thus apply the EU provisions, setting aside the contrary Irish provisions), and (iii) the right to effective judicial review (an effective judicial remedy should be available to him and the national court should thus grant the relief sought).

15. For their part, the respondents acknowledged that, under national law, an applicant who successfully challenges the decision of a public authority by means of judicial review is *usually* entitled to relief. However, they argued that this is not an absolute entitlement and, in the main proceedings, it is justifiable to refuse any form of relief. They contend that, in this case, although there may be some benefit were relief granted to the applicant, it would nonetheless be very limited in terms of its value, owing to the imminent entry into force of Regulation 2019/6. In addition, the respondents contended that there is a strong possibility in this case, if relief were granted, that it would have a serious impact on third parties. If suppliers and distributors of veterinary medicinal products were to decide to withdraw from the Irish market due to the requirement to print the text of instruction leaflets and packaging in both official languages, it is clear that this would have grave consequences for animal health, as well as economic consequences, which would be detrimental to many individuals.

16. On 26 July 2019, the Ard-Chúirt (High Court) ruled that the applicant had standing since Article 58(4), Article 59(3), and Article 61(1) of Directive 2001/82 ('the EU provisions at issue') were clear, precise and unconditional. The applicant was therefore in a position to invoke them against the respondents. That court also ruled that Ireland had failed to transpose the directive correctly as regards the language requirements, in so far as the national law at issue (namely, SI 144/2007 and SI 786/2007) allowed the information to be provided in English only, instead of requiring both Irish and English.

17. However, the Ard-Chúirt (High Court) also noted that, during the proceedings, Regulation 2019/6 was adopted, which contains new provisions relating to the use of languages for veterinary medicinal products. According to that regulation, when it becomes applicable (on 28 January 2022), the information on the packaging may be permitted to be provided in English only. Against that backdrop, that court wondered whether it would be worthwhile granting the relief sought by the applicant in the light of that forthcoming change, despite Ireland being in breach of EU law.

18. That court points out that there are long-established grounds in Irish law under which courts may exercise discretion with regard to the choice of whether, and if so, how to grant appropriate relief to a successful applicant. Those grounds include various factors, for example: (1) undue delay in bringing proceedings; or (2) failure to seek other, more appropriate remedies, such as an appeal; or (3) a lack of candour on the part of the applicant; or (4) failure by the applicant to act in good faith; or (5) prejudice to third parties, or (6) where granting of relief would serve no useful purpose.

19. Accordingly, harbouring doubts as to whether EU law precludes national procedural rules such as those at issue in the main proceedings, the Ard-Chúirt (High Court, Ireland) decided to stay the proceedings and refer the following questions to the Court of Justice 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 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 Irish as well as English, in Ireland?’

20. Written observations have been submitted by the applicant, Ireland, the Polish Government and the European Commission.

IV. Analysis

A. Admissibility

21. Ireland and the Polish Government submit that the reference is inadmissible.

22. First, Ireland argues that it has duly transposed the EU provisions at issue. The text of Directive 2001/82 is ambiguous as to whether or not there is a requirement that all the official languages must be used for the information appearing on the packaging and labelling of veterinary medicinal products where there are several official languages in a Member State. Accordingly, Ireland’s decision to implement the said directive in a manner which permitted the use of only one of its official languages would fall within its margin of discretion in transposing the directive.

23. Second, Ireland submits that it is clear, on the basis of the express purpose of Directive 2001/82, that the rights flowing from it are not linguistic or cultural rights, but rather rights concerning access to information on veterinary medicinal products. Such rights would only be infringed if an applicant were in possession of packaging or labelling which he could not fully understand. However, the applicant in the main proceedings did not claim to have been faced with packaging or labelling that he could not fully understand.

24. For its part, the Polish Government argues that 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, that government contends that the applicant's action is destined to fail. Even if one were to suppose 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, it is not, in view of its nature, a right that may be relied on against the Irish authorities. The obligation to label these products in the Irish language rests on the shoulders of private entities, namely the producers and distributors of these products. However, the applicant cannot assert his right to information in Irish vis-à-vis veterinary medicinal products against the producers and distributors of these products, since a directive cannot of itself create obligations on the part of an individual and cannot therefore be relied on as such against him.

25. As far as admissibility of the present request for a preliminary ruling is concerned, these arguments fail to convince.

26. In my view, the arguments raised by both Ireland and the Polish Government pertain to the merits of the applicant's action in the main proceedings at national level. The objections raised by Ireland concern a preliminary matter of substance, which has, nonetheless, not been raised by the referring court. The same is true as regards the objections raised by the Polish Government. The question of whether EU law requires the national court to grant any specific remedy is again very much an issue of substance in these proceedings, not a matter of admissibility. The Court has consistently stated that arguments which concern matters of substance cannot affect the admissibility of the questions referred.⁴

27. Moreover, according to 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. That presumption cannot be rebutted by the possibility that the applicant could be ultimately unsuccessful in the main proceedings before the national court, in particular if a certain interpretation of the EU law at issue is embraced by the Court.⁵

28. For those reasons, I shall now turn to the substance of the two questions referred.

B. Substance

1. Preliminary remarks

29. In the present case the applicant relies on – and the referring court invokes – some of the most important structural principles of EU law: direct effect, primacy, effective judicial review, and procedural autonomy. At first sight, the issues raised by these proceedings may thus appear quite complicated. However, upon closer inspection, the key question emerges rather clearly.

⁴ See, for example, 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).

⁵ More amply and with further references, see recently for instance my Opinion in *C-505/19, Bundesrepublik Deutschland (Interpol red notice)* (EU:C:2020:939, point 34 and the case-law cited).

30. As I understand it, in the main proceedings the applicant essentially sought three forms of relief: (i) a declaration that national law is incompatible with EU law, (ii) a declaration that national law should comply with EU law and, finally, (iii) a declaration that the national authorities must amend national law accordingly.

31. It is not entirely clear to me whether those three forms of relief are to be granted simultaneously or whether the referring court can freely choose among them. For the sake of this Opinion, I shall assume that the referring court has significant room for manoeuvre in that regard. Indeed, the referring court states that, under national law, it enjoys a discretionary power to *choose* the relief it considers to be the most appropriate in view of the circumstances and, as the case may be, to even *refuse* to grant any form of relief altogether.⁶ That court thus wonders whether that remains equally true where an applicant derives his rights from EU law.

32. Against that background, it seems to me that, from an EU law perspective, issues relating to procedural autonomy and effective judicial protection are at the heart of the dispute. The two questions referred can thus be treated jointly, and re-formulated as follows: does EU law, and in particular the principles of procedural autonomy and effective judicial protection, preclude a national legislation or practice according to which national courts enjoy a discretionary power to determine whether to grant relief, and if so, the form of that relief, in respect to an applicant claiming that the authorities have not transposed a directive correctly, where the action is well-founded?

33. In answering that question, this Opinion is structured as follows: I shall start by laying down the relevant legal framework of analysis, in order to explain how the present case will be assessed (2). Next, I will briefly illustrate how, in past cases, the Court has applied that framework to specific cases (3). On that basis, I shall set out some transversal themes and guidelines that may be of use to the referring court (4). In so far as it will ultimately be for the referring court to draw the consequences for the case at issue in the main proceedings, I will conclude with some case-specific considerations (5).

2. *The relevant framework: 'Rewe' effectiveness and effective judicial protection under Article 47 of the Charter*

34. According to settled case-law, directly applicable rules of EU law which are an immediate source of rights and obligations for all concerned, whether Member States or individuals, must deploy their full effects, in a uniform manner in all Member States, as from their entry into force and *throughout the duration of their validity*.⁷

35. It is also settled case-law that any national court, hearing a case within its jurisdiction, has, as an organ of a Member State, the obligation pursuant to the principle of sincere cooperation set out in Article 4(3) TEU, *fully to apply* the directly applicable law of the Union and to protect the rights which the latter confers upon individuals, disapplying any contrary provision of national law.⁸

⁶ See above, point 18 of this Opinion.

⁷ See, to that effect, judgments of 9 March 1978, *Simmenthal* (106/77, EU:C:1978:49, paragraphs 14 to 15); of 19 June 1990, *Factortame and Others* (C-213/89, EU:C:1990:257, paragraph 18); and of 8 September 2010, *Winner Wetten* (C-409/06, EU:C:2010:503, paragraph 54).

⁸ See, to that effect, judgments of 9 March 1978, *Simmenthal* (106/77, EU:C:1978:49, paragraphs 16 and 21); of 19 June 1990, *Factortame and Others* (C-213/89, EU:C:1990:257, paragraph 19); and of 8 September 2010, *Winner Wetten* (C-409/06, EU:C:2010:503, paragraph 55).

36. It follows from the above that any *provision* of a national legal system and any legislative, administrative or *judicial practice* which might impair the effectiveness of EU law by withholding from the national court having jurisdiction to apply such law the power to do everything necessary at the moment of its application to set aside national legislative provisions which might prevent directly applicable EU rules from having full force and effect are incompatible with the requirements which are the very essence of EU law.⁹

37. However, how full must the full effect of directly applicable EU rules be for it to be fully effective? Unless, by default, ‘full’ must mean everything, anything, and beyond, there is in fact no independent EU law yardstick of full effectiveness. Instead, there is a case-by-case assessment normally carried out by cross-reference to the national legislative framework at issue in a given case.

38. That is inevitable if the default principle of the national enforcement of EU law rules is the national procedural autonomy. The initial reference yardstick remains the given national one. According to settled case-law, in the absence of EU legislation, it is for each Member State to designate the courts and tribunals having jurisdiction and to lay down the detailed procedural rules governing actions at law for safeguarding the rights which individuals derive from EU law. Nevertheless, those rules must be no less favourable than those governing similar domestic actions (the requirement of *equivalence*) and must not render impossible in practice or excessively difficult the exercise of rights conferred by EU law (the requirement of *effectiveness*).¹⁰

39. In the present proceedings, the issue of *equivalence* obviously does not arise. The referring court’s doubts stem from the very fact that the national procedural rules at issue apply not only to situations governed by national law, but also to situations governed by EU law.

40. The real issue is, therefore, that of *effectiveness*.

41. However, in a case such as the one at issue, the requirement of effectiveness, understood as a condition for the application of the principle of procedural autonomy, and thus sometimes referred to as ‘Rewe-effectiveness’,¹¹ in practice overlaps with the fundamental right to an *effective judicial remedy* under Article 47 of the Charter. Indeed, the applicant alleges that the application of the national procedural rules at issue deprives him of an adequate remedy to ensure protection of the (substantive) right he derives from the EU provisions at issue: to have the information accompanying the veterinary medicinal products in both official languages (Irish and English) of the State.

42. As I pointed out in my Opinion in *Banger*, the relationship between the principle of effectiveness, as one of the dual requirements arising under the procedural autonomy of the Member States, and the principle of effective judicial protection, as a fundamental right later enshrined in Article 47 of the Charter, is perhaps not (yet) entirely clear.¹² It can hardly be disputed that, at the very least, the two principles overlap to a large extent with regard to their substance.

43. Furthermore, as far as the type of assessment to be carried out is concerned, they could be seen as mandating an examination of a given situation from two complementary angles: (Rewe-)effectiveness focuses on the *structural* level (existence, in general, of adequate remedies in the type of situation at issue), whereas effective judicial protection under Article 47 of the Charter pays closer attention to the *individual* level (existence, *in concreto*, of adequate remedies for the person concerned).

⁹ See, to that effect, judgments of 9 March 1978, *Simmenthal* (106/77, EU:C:1978:49, paragraph 22); of 19 June 1990, *Factortame and Others* (C-213/89, EU:C:1990:257, paragraph 20); and of 8 September 2010, *Winner Wetten* (C-409/06, EU:C:2010:503, paragraph 56).

¹⁰ Among many, see the recent judgment of 24 October 2018, *XC and Others* (C-234/17, EU:C:2018:853, paragraphs 21 to 22 and the case-law cited).

¹¹ Since being first articulated in judgment of 16 December 1976, *Rewe-Zentralfinanz and Rewe-Zentral* (33/76, EU:C:1976:188).

¹² C-89/17, EU:C:2018:225, points 99 to 107.

44. The principle of effective judicial protection is a general principle of EU law, now enshrined in Article 47 of the Charter. It requires, in particular, the existence of adequate remedies of a judicial nature against any decisions of national authorities that may breach the rights and freedoms that individuals derive from EU law.¹³ In that context, the national court seized of the dispute must, *inter alia*, have the power to consider all the questions of fact and law that are relevant to the case before it.¹⁴

45. Yet, the scope and intensity of the review that a national court is to carry out in order to comply with Article 47 of the Charter varies depending on the specific context and the relevant circumstances of each case.¹⁵ As the Court has repeatedly stated, the elements that must be taken into account encompass, *inter alia*, ‘the nature of the act at issue, the context in which it was adopted and the legal rules governing the matter in question’.¹⁶

46. There is, naturally, abundant case-law on (Rewe-)effectiveness, which over the past decade has essentially been taken over by effective judicial protection under Article 47 of the Charter. However, that deeply case-specific case-law can hardly be considered consistent.

3. Past case-law: stringency, leniency, and something in between

47. The case-law assembled over the years varies.¹⁷ Being so case-specific, that case-law resists generalisation. Examples may be found for different approaches. They range from a rather Member States-friendly position where equivalence is generally enough, to uncompromising assertions of effectiveness, where a Member State must go (far) beyond what is normally possible under its national law.

48. On one side of the spectrum we find the cases in which the Court has accepted the national procedural rules at stake, after making the fulfilment of the condition of equivalence the focal point of its analysis. Here, the assessment of the condition of effectiveness has received a notably light touch.¹⁸ In that connection, the Court made clear that the principle of equivalence cannot be interpreted as an obligation for the Member States to extend their most favourable national procedural regime to all actions based on EU law.¹⁹ This ‘lenient’ standard of review appears to have been mostly employed *vis-à-vis* concepts and mechanisms of procedural law that are common to all Member States’ legal orders, being intrinsic to any judicial system (such as *res judicata*, time-limits, and so forth).

13 See, among many, judgments of 29 November 2018, *Bank Tejarat v Council* (C-248/17 P, EU:C:2018:967, paragraph 79), and of 31 January 2019, *Islamic Republic of Iran Shipping Lines and Others v Council* (C-225/17 P, EU:C:2019:82, paragraph 62).

14 See, to that effect, judgments of 6 November 2012, *Otis and Others* (C-199/11, EU:C:2012:684, paragraph 49), and of 17 December 2015, *Imtech Marine Belgium* (C-300/14, EU:C:2015:825, paragraph 38).

15 See, with further references, my Opinion in *Banger* (C-89/17, EU:C:2018:225, point 104).

16 See, to that effect, judgments of 18 July 2013, *Commission and Others v Kadi* (C-584/10 P, C-593/10 P and C-595/10 P, EU:C:2013:518, paragraph 102), and of 26 July 2017, *Sacko* (C-348/16, EU:C:2017:591, paragraph 41).

17 Legal scholarship has suggested that there would be waves or changes of tack in terms of approach, swinging back and forth between more and less intervention on the side of the Court over time. See, for instance, Dougan, M., *National Remedies Before the Court of Justice: Issues of Harmonisation and Differentiation*, Hart Publishing, Oxford, 2004, pp. 227 – 233 or Tridimas, T., *The General Principles of EC Law*, 2nd Ed, Oxford University Press, Oxford, 2006, pp. 420 – 422.

18 See, *inter alia*, judgments of 1 December 1995, *Van Schijndel and Van Veen* (C-430/93 and C-431/93, EU:C:1995:441); of 24 October 1996, *Kraaijeveld and Others* (C-72/95, EU:C:1996:404); and of 17 March 2016, *Bensada Benallal* (C-161/15, EU:C:2016:175).

19 See, to that effect, judgments of 15 September 1998, *Edis* (C-231/96, EU:C:1998:401, paragraph 36), and of 1 December 1998, *Levez* (C-326/96, EU:C:1998:577, paragraph 42).

49. On the opposite side of the spectrum one finds cases such as *Simmenthal*, *San Giorgio*, *Factortame*, *Cartesio*, *Elchinov*, or *Klausner*,²⁰ where the Court categorically insisted on a robust vision of effectiveness. Those cases typically concerned situations in which a type of remedy did not exist in the national legal order, while the national practice at issue was perceived to result in systemic obstacles to the full effectiveness of EU law or to a prompt and complete protection of the individuals whose rights were adversely affected.

50. Moreover, as concerns the context of the present case more specifically, a rather strict approach has also been embraced by the Court in various cases where the issue raised by the referring courts concerned the effects, *ratione temporis*, of judgments finding an incompatibility of national law with EU law. In cases such as *Winner Wetten*, *Filipiak*, *Gutiérrez Naranjo*, or *Association France Nature Environment*,²¹ the Court essentially refused the possibility that national courts, including national supreme courts or constitutional courts, had power to delay the effects of a finding of incompatibility of a national measure with EU law or to create a transitory regime, in order to fill an alleged legal vacuum. Any such decision would, according to the Court, correspond to a temporal limitation of the effects of an interpretation of a rule of EU law, which is something for the Court alone to decide. On the other hand, as a matter of context, it is to be equally acknowledged that an important element common to these cases have been the proper respect for, or even implementation of, previous judgments of the Court at stake in these cases.

51. Finally, in between those two extremes, one finds those cases where the Court took some middle ground position. Often, the Court attempted to arrive at ‘Solomonic’ decisions endorsing Member States’ national rules, whilst limiting their autonomy as to how those remedies are to be used. Cases such as *Fantask*, *Melki and Abdeli*, *DEB*, *Lesoochranárske zoskupenie VLK*, offer good examples in point.²²

52. A number of recent decisions of the Court seem to build on the latter strand of case-law. In those cases, the Court required national courts to make use of the full potential offered by their national procedural rules, in order to achieve the objectives pursued by the relevant EU provisions, but *only in so far as* such interpretative exercise was consistent with the principle of legality, and did not give rise to any infringement of fundamental rights.²³

53. All in all, the ‘Rewe/Simmenthal contradiction’,²⁴ pulling in different directions as far as the requirement of *equivalence* (or the prohibition of discrimination), on the one hand, and the requirement of *effectiveness*, on the other hand, are concerned, is still very much present in the test of national procedural autonomy. However, more and more, internal limits to an unqualified assertion of effectiveness are being expressly acknowledged as a result of the principle of legality and the protection of fundamental rights (and perhaps also of a grain of common sense).²⁵

20 Respectively, judgments of 9 March 1978, *Simmenthal* (106/77, EU:C:1978:49, paragraphs 14 to 15); of 9 November 1983, *San Giorgio* (199/82, EU:C:1983:318); of 19 June 1990, *Factortame and Others* (C-213/89, EU:C:1990:257, paragraph 18); of 16 December 2008, *Cartesio* (C-210/06, EU:C:2008:723); of 5 October 2010, *Elchinov* (C-173/09, EU:C:2010:581); and of 11 November 2015, *Klausner Holz Niedersachsen* (C-505/14, EU:C:2015:742).

21 Respectively, judgments of 19 November 2009, *Filipiak* (C-314/08, EU:C:2009:719); of 8 September 2010, *Winner Wetten* (C-409/06, EU:C:2010:503); of 21 December 2016, *Gutiérrez Naranjo and Others* (C-154/15, C-307/15 and C-308/15, EU:C:2016:980); and of 28 July 2016, *Association France Nature Environnement* (C-379/15, ECLI:EU:C:2016:603)

22 Respectively, judgments of 2 December 1997, *Fantask and Others* (C-188/95, EU:C:1997:580); of 22 June 2010, *Melki and Abdeli* (C-188/10 and C-189/10, EU:C:2010:363), of 22 December 2010, *DEB* (C-279/09, EU:C:2010:881); and of 8 November 2016, *Lesoochranárske zoskupenie VLK* (C-243/15, EU:C:2016:838).

23 See, in particular, judgments of 5 December 2017, *M.A.S. and M.B.* (C-42/17, EU:C:2017:936); of 17 January 2019, *Dzivev and Others* (C-310/16, EU:C:2019:30); and of 19 December 2019, *Deutsche Umwelthilfe* (C-752/18, EU:C:2019:1114).

24 See notably Prechal, S., ‘Community Law in National Court: The Lessons from Van Schijndel’ *Common Market Law Review* vol. 35, 1998, p. 687.

25 Possibly also called a ‘rule of reason’, ‘proportionality’, or simply a ‘reasonable balance’ to be reached amongst the interests at stake – see already Opinion of Advocate General Jacobs in Joined Cases *van Schijndel and van Veen* (C-430/93 and C-431/93, EU:C:1995:185, point 31), and Opinion of Advocate General Jacobs in *Peterbroeck* (C-312/93, EU:C:1994:184, point 40).

4. *The structural level: a case-by-case assessment*

54. In my view, the EU principles and the case-law just illustrated lead to the conclusion that there can be *no blanket, general* answer to the question of whether EU law precludes a national legislation or practice according to which national courts enjoy a discretionary power to determine whether to grant relief, and if so, the form of that relief, in respect to an applicant claiming that the authorities have not transposed a directive correctly, where the action is well founded.

55. It simply depends on the individual case. I fail to see any reason why EU law should, *as a matter of principle*, preclude such a legislation or practice. The Court has consistently stated that each case which raises the question of whether a national procedural provision renders application of EU law impossible or excessively difficult ‘must be analysed by reference to the role of that provision in the procedure, its progress and its special features, viewed as a whole, before the various national instances. In the light of that analysis, the basic principles of the domestic judicial system, such as protection of the rights of the defence, the principle of legal certainty and the proper conduct of procedure, must, where appropriate, be taken into consideration’.²⁶

56. What is thus required, as a matter of EU law, is a reasonable correlation between the rights, the infringement, and the type and scope of remedies or relief to be awarded, in the light of the facts and circumstances of a case. Each case is to be assessed in its own context and proportion. That requirement is, in my view, not limited to EU law only, but is inherent in any modern European system of law. I do not think that the much revered effectiveness of EU law should be invoked as a means of *de facto* returning, before a national court in which EU law is potentially at stake, to a tied, inflexible, and, as a consequence therefore, wholly disproportionate manner of judging, which is reminiscent of criminal sentencing in 17th and 18th century England.

57. Accordingly, it seems to me that it is the very case-law of the Court that in fact requires national courts to take into account, when exercising their discretion with regard to relief and remedies sought, elements such as those indicated by the referring court: undue delay in bringing proceedings, failure to seek other more appropriate remedies, a lack of candour on the part of the applicant, failure by the applicant to act in good faith, prejudice to third parties, and where granting of relief would serve no useful purpose. Taking those elements into account does not, *per se*, deprive an applicant of judicial protection, or render ineffective the substantive rights of which an applicant seeks protection.

58. On the contrary, by taking the aforementioned elements into account, the national court is doing nothing more than carrying out its judicial function which is to find, for each dispute, the most appropriate solution by looking at the specific context and all the relevant circumstances. Again, the principles of effectiveness of EU law and of effective judicial protection cannot be interpreted as imposing upon national courts any (senseless) automaticity.

59. True, the fact that the discretion of the national courts concerns not only the *form* of relief to be granted, but also whether it would be worthwhile to grant *any relief at all*, may suggest that, at least in some cases, an individual is completely deprived of any form of judicial protection and the effectiveness of the relevant EU rules would not be ensured.

60. Nevertheless, in my view, that would not be a reasonable conclusion. Indeed, to the best of my knowledge, there are procedural principles or mechanisms in all legal systems that are designed to avoid situations in which a blind and automatic application of the rules would produce an unjust or disproportionate outcome, or lead to a solution that serves no useful purpose. In that regard, I can think of, for example, rules relating to the sound administration of justice and judicial economy, or

²⁶ See especially judgments of 14 December 1995, *van Schijndel and van Veen* (C-430/93 and C-431/93, EU:C:1995:441, paragraph 19), and of 14 December 1995, *Peterbroeck* (C-312/93, EU:C:1995:437, paragraph 14). More recently, see judgment of 2 April 2020, *CRPNPAC and Vueling Airlines* (C-370/17 and C-37/18, EU:C:2020:260, paragraph 93).

rules against abuse of rights or of process, and frivolous or vexatious litigation. Accordingly, there is nothing intrinsically unlawful in the fact that, despite an applicant formally acting within his rights and his claims being well founded, in very exceptional cases (and I place emphasis on very exceptional cases), he may not obtain the form of relief that he sought. Again, whether that outcome might be justified depends on the circumstances and the context of each individual case.

61. I therefore conclude that an assessment of the compatibility with EU law of national procedural legislation or practice, such as that at issue – be it under the (more structure-oriented) condition of effectiveness as part of the principle of procedural autonomy, or under the (more individual-right-oriented) principle of effective judicial protection – is to be normally carried out on a case-by-case basis. What is, to my mind, crucial, is that, in each case, the national court should be allowed to find a reasonable (or proportional) relationship between the nature and importance of the right invoked; the seriousness of the infringement or the significance of the harm suffered; and the type of remedy or relief sought. All that should be measured and evaluated within the factual and legal situation at stake.

62. In the light of the foregoing, I take the view that the Court should provide an answer to the referring court that EU law, and in particular the principles of procedural autonomy and effective judicial protection, do not preclude, certainly not per se, a national legislation or practice according to which national courts enjoy a discretionary power to determine whether to grant relief, and if so, the form of that relief, in respect to an applicant claiming that the authorities have not transposed a directive correctly, where the action is well founded. It is for the referring court to ensure that there is, on the facts and the context of each individual case before it, a reasonable relationship between the nature of the rights invoked, the seriousness of their infringement or harm suffered, and the type of remedy sought, and by way of a consequence of the relief, that it decides to grant (or, as the case may be, not grant) in favour of the applicant.

63. What that entails for the dispute at issue in the main proceedings is an assessment that the referring court is clearly best placed to make. However, with a view to providing that court with some useful guidance, I will now offer some additional considerations, keeping in mind certain specific features of the case at hand.

5. The context of the present case: rights, infringement, remedies

64. In the main proceedings, the referring court will essentially have to determine whether (any, some, or all of) the three forms of relief sought by the applicant constitute a just and proportionate outcome for the protection of the rights invoked by the applicant.

65. Of course, that is the case under the assumption that the EU provisions at issue have direct effect. As to the structure of the relationship, it is indeed true that the respondents are public authorities and, according to settled case-law, the provisions of a directive may be relied upon by individuals against such authorities where the State has failed to transpose them by the end of the period prescribed.²⁷

66. However, whether the provision(s) of EU law at issue are endowed with direct effect, and precisely what the content of the directly effective rule is, is a different matter. According to settled case-law, an EU law provision has direct effect whenever, as far as its subject matter is concerned, it is sufficiently clear, precise and unconditional to be relied on against a conflicting national measure, or in so far as the provision defines rights which individuals are able to assert against the State.²⁸

²⁷ See, to that effect, for example, judgment of 24 January 2012, *Dominguez* (C-282/10, EU:C:2012:33, paragraph 33 and the case-law cited).

²⁸ See, among many, judgments of 19 January 1982, *Becker* (8/81, EU:C:1982:7, paragraph 25), and of 15 April 2008, *Impact* (C-268/06, EU:C:2008:223, paragraphs 56 to 57).

67. In the present case, the referring court appears to have settled the matter at a preliminary stage already by finding that, as submitted by the applicant, the EU provisions at issue are sufficiently clear, precise and unconditional to trigger direct effect. The referring court has not asked this Court to examine that issue and I shall respect that decision, despite that issue being raised and put forward by Ireland for the purpose of admissibility.²⁹ I would, nonetheless, note two elements.

68. First, precision of the rule, as a condition for direct effect, means that the content of the obligation incumbent on the Member State is indeed clear. The scope of a directly effective rule must not necessarily textually coincide with the entirety of the legal proposition. Thus, it is certainly possible to extract from a larger proposition a narrower, self-standing rule reflecting the minimal obligation incumbent on a Member State. That rule must, however, be clear and precise as to its scope and content.³⁰

69. Second, when carrying out such an analysis with regard to a rule contained in a directive, it serves to be mindful that the default constitutional position for the transposition of a directive is the Member State's choice and autonomy, provided, naturally, that the directive itself does not preclude that choice. By contrast, if any such choice and discretion is to be granted by a regulation, the text of the regulation must state so expressly. This fact might be particularly relevant when assessing the scope of a given obligation following a change in the type of EU legal source governing an area, in particular, as has recently been the case in a number of areas of EU law,³¹ when the regulatory instrument in a certain field has changed from a directive to a regulation.

70. Be that as it may, there is another aspect which deserves consideration. The nature of the right at stake is one of the elements that is normally to be taken into account³² in order to determine the appropriate remedy that the individual affected must be ensured. Indeed, the nature and the importance of the right at stake are at the input stage of the overall assessment equation to be taken into account by a national court.³³ I believe that in the present case, that element merits some consideration, to which I now turn.

(a) What rights? Linguistic rights in EU law

71. At the outset, there is hardly any doubt that linguistic diversity is particularly valued in the European Union. According to Article 3 TEU, the Union must 'respect its rich cultural and linguistic diversity' and 'ensure that Europe's cultural heritage is safeguarded and enhanced'. To that end, the Union must, pursuant to Article 165(2) TFEU, promote the teaching and dissemination of the languages of the Member States.

72. Respect for linguistic diversity is also enshrined in Article 22 of the Charter. Moreover, Article 21 of the Charter prohibits any discrimination based on the ground of, inter alia, language.

73. Furthermore, multilingualism has been a core principle of the European Union's functioning, early evidence of which is the adoption of Regulation No 1 in 1958.³⁴

²⁹ See above, points 22 and 23 of this Opinion.

³⁰ In more detail and with further references, see also my Opinion in *Klohn* (C-167/17, EU:C:2018:387, points 36 to 46).

³¹ See, for a recent example, my Opinion in *Fashion ID* (C-40/17, EU:C:2018:1039, points 45 to 48).

³² See, by analogy, judgment of the European Court of Human Rights ('ECtHR'), 20 March 2008, *Budayeva and others v. Russia* (CE:ECHR:2008:0320JUD001533902, § 191).

³³ See above, points 54 to 62 of this Opinion.

³⁴ EEC Council: Regulation No 1 determining the languages to be used by the European Economic Community (OJ 1958 17, p. 385), as subsequently amended.

74. However, while these principles and their value are indeed of the utmost importance, it has also been recognised that language policy involves making choices which are, at times, also politically and socially delicate. In view of this, both the EU legislature and the EU Courts have consistently adopted a rather cautious, diplomatic and pragmatic approach with regard to languages, at EU level, and also when that level is likely to have repercussions at Member States level.

75. At the level of the Union's internal functioning, the system has never been overly rigid. To begin with, even with regard to EU official languages, exceptions have been made recently, with regard, notably, to Irish³⁵ or Maltese.³⁶ More importantly for the purposes of the present case, the Court has consistently dismissed the idea that, as a matter of EU law, there must be absolute equality of all official languages.³⁷ The maxim of equal authenticity of all language versions or the principle of non-discrimination between the official languages of the Union does not mean that 'all official languages must in all circumstances be treated equally for all purposes'.³⁸ Differentiated regimes, at EU level, are thus permissible, provided there are sufficient justifications for that.

76. In addition, when called upon to recognise and uphold linguistic rights flowing from EU law, the EU Courts have striven to ensure that the individuals affected are protected,³⁹ while leaving the competent (EU or national) authorities some room for manoeuvre.

77. For example, in *Skoma-Lux*, the Court held that a (then) Community regulation that was not published in the official language of a Member State could not be enforced against an individual living in that State.⁴⁰ However, the Court refrained from deriving any more significant consequence, in relation to the validity or the applicability of the act, from the absence of publication. Thus, EU law unpublished in the (one and only) language of a Member State in fact remained valid law of that Member State. It is just that no obligations could be imposed on individuals on the basis of that law.⁴¹

78. This tendency is probably even more apparent where the Court is faced with national measures which reflect national policy choices. It should not be overlooked, in that regard, that language policy at national level falls, by and large, within the competences of the Member States. Indeed, pursuant to Article 6 TFEU, the Union only has the competence to carry out actions to support, coordinate or supplement the actions of the Member States in the fields of culture and education. After all, language policy cannot but reflect the history, culture, traditions and society of each country.

35 See Article 2 of Council Regulation (EC) No 920/2005 amending Regulation No 1 of 15 April 1958 determining the language to be used by the European Economic Community and Regulation No 1 of 15 April 1958 determining the language to be used by the European Atomic Energy Community and introducing temporary derogation measures from those Regulations (OJ 2005 L 156, p. 3), later again prolonged by Council Regulation (EU) No 1257/2010 extending the temporary derogation measures from Regulation No 1 of 15 April 1958 determining the languages to be used by the European Economic Community and Regulation No 1 of 15 April 1958 determining the languages to be used by the European Atomic Energy Community introduced by Regulation (EC) No 920/2005 (OJ 2010 L 343, p. 5). In general, see Report from the Commission to the Council on the Union institutions' progress towards the implementation of the gradual reduction of the Irish language derogation, COM(2019) 318 final.

36 Council Regulation (EC) No 930/2004 of 1 May 2004 on temporary derogation measures relating to the drafting in Maltese of the acts of the institutions of the European Union (OJ 2004 L 169, p. 1).

37 See, to that effect, judgments of 9 September 2003, *Kik v OHIM* (C-361/01 P, EU:C:2003:434), paragraphs 82 to 94); of 12 May 2011, *Polska Telefonia Cyfrowa* (C-410/09, EU:C:2011:294, paragraph 38); and of 26 March 2019, *Commission v Italy* (C-621/16 P, EU:C:2019:251, paragraphs 89 to 97). See also, more generally, my Opinion in *Commission v Italy* (C-621/16 P, EU:C:2018:611, points 153 to 179).

38 I borrow this expression from the Opinion of Advocate General Jacobs in *Kik v OHIM* (C-361/01 P, EU:C:2003:175, point 50).

39 The judgments of 28 November 1989, *Groener* (C-379/87, EU:C:1989:599); of 24 November 1998, *Bickel and Franz* (C-274/96, EU:C:1998:563); of 6 June 2000, *Angonese* (C-281/98, EU:C:2000:296); and of 27 March 2014, *Ruffer* (C-322/13, EU:C:2014:189) offer good examples of that.

40 Judgment of 11 December 2007 (C-161/06, EU:C:2007:773). Another example in point is offered by the judgment of 20 May 2003, *Consorzio del Prosciutto di Parma and Salumificio S. Rita* (C-108/01, EU:C:2003:296).

41 Further, see also judgment of 10 March 2009, *Heinrich*, (C-345/06, EU:C:2009:140). However, see (not in the context of a temporal failure to translate and publish legislation in the aftermath of an enlargement of the Union, but when legislation is intentionally and presumably forever to be kept secret, the much more convincing) Opinion of Advocate General Sharpston in *Heinrich* (C-345/06, EU:C:2008:212).

79. The EU Courts have therefore been reluctant to interfere excessively with national choices or impose far-reaching obligations upon Member States. By way of example, in *UTECA*, the Court found national legislation that required television broadcasters to commit a specific proportion of their revenue to the pre-funding of European cinematographic films and TV films the original language of which was one of the official languages of the Member State concerned to be compatible with EU law.⁴² In *Runevič-Vardyn*, the Court ruled that EU law did not preclude national authorities from refusing to amend the forenames and surnames of the interested parties as entered on the birth and marriage certificates on the ground that national legislation provided that the forenames and surnames of natural persons must be entered in those documents in accordance with the rules governing the spelling of the official national language.⁴³ More generally, the Court has consistently stated that the protection and promotion of one or more official languages of a Member State may justify derogations to the rules on free movement, and declared national measures adopted for that purpose incompatible with EU law only when found to be disproportionate to that aim.⁴⁴

80. I draw two conclusions from the case-law illustrations set out above. First, although there is no doubt that language rights are of the utmost importance in the Union, and individuals are certainly entitled to obtain protection against any breach of those rights, there are no automatic consequences that stem from their potential breach. In that respect, the EU Courts have generally preferred a balanced and nuanced approach, in which the specific circumstances of each case have been duly considered, and weighted one against the other, in order to reach a fair (and not disruptive) outcome.

81. Second, that approach has been embraced not only with regard to the use of languages vis-à-vis specific sectoral or area-dependent rules (such as the above quoted examples from the free movement case-law), but also with regard to constitutional choices. Thus, in other words, if even the structural or constitutional cases show a fair degree of flexibility and absence of any automatic outcome in terms of results, it would be rather surprising to insist that a discreet, secondary law regime in a specific regulatory field would suddenly give rise to an absolute linguistic right.

82. Against this background, I shall now turn to other variables in the equation before the referring court. Metaphorically: if on one side of the scale there is a potential breach of a language right such as that deriving from the EU provisions at issue, what type of remedies should the national court place on the other side of the scale in order to arrive at a balanced solution in the main proceedings?

(b) What form of relief?

83. At the outset, I must point out that the present case does not concern the conditions in which EU law requires national law to create new remedies in order to fill a legal gap in judicial protection,⁴⁵ unlike what was argued by the Polish Government.⁴⁶ This case only concerns the way in which the existing remedies, already available in a Member State's legal system, are to be employed when the case before the national court concerns rights based on EU law. There is, accordingly, no need to discuss whether and, if so, when a Member State may be obliged, as a matter of EU law, to establish a judicial remedy enabling national courts to adopt decisions which – like an injunction or an immediate executive order – compel the competent (legislative or administrative) authorities to amend national law without further ado.

⁴² Judgment of 5 March 2009 (C-222/07, EU:C:2009:124).

⁴³ Judgment of 12 May 2011 (C-391/09, EU:C:2011:291).

⁴⁴ See, for example, judgments of 16 April 2013, *Las* (C-202/11, EU:C:2013:239), and of 21 June 2016, *New Valmar* (C-15/15, EU:C:2016:464).

⁴⁵ On that matter, see judgments of 19 June 1990, *Factortame and Others* (C-213/89, EU:C:1990:257); of 13 March 2007, *Unibet* (C-432/05, EU:C:2007:163); and of 3 October 2013, *Inuit Tapiriit Kanatami* (C-583/11 P, paragraphs 103 to 104).

⁴⁶ See above, point 24 of this Opinion.

84. The question raised by the referring court is of a different nature. That court stated that, under national law, there are a set of rules which provide for a remedy in the specific case. However, it wonders whether that set of rules could be used and applied in exactly the same way if the applicant's claims were not based on national law, but on EU law. The referring court is unsure as to whether that set of rules is to be set aside 'in the name of' the effective enforcement of EU law or the effective legal protection of the individuals.

85. That being said, it hardly needs to be pointed out that the referring court cannot, in the main proceedings, ensure the full and immediate satisfaction of the applicant's substantive rights through the combined process of disapplying national law and applying EU law directly. The referring court cannot order the pharmaceutical companies to comply with the obligation flowing from Article 58(4), Article 59(3) and Article 61(1) of Directive 2001/82. Those companies are not defendants in those proceedings.

86. In addition, any such action against them would be very unlikely to succeed since the Court has consistently excluded the possibility that non-transposed directives may deploy a *horizontal* direct effect, and, as such, be relied upon against individuals.⁴⁷ Also, more recently in *Popławski*, the Court reiterated that 'even a clear, precise and unconditional provision of a directive does not allow a national court to disapply a provision of its national law which conflicts with it, if, in doing so, an additional obligation were to be imposed on an individual.'⁴⁸

87. Any form of protection of the applicant's right in the main proceedings is thus necessarily indirect and deferred in time. The applicant seeks a declaration that the national law at issue is incompatible with the provisions of Directive 2001/82, and should therefore be amended by the competent national authorities. I understand that only then, and as a consequence of the ensuing change in the national rules, could the pharmaceutical companies be obliged to comply with the new rules for the future.

88. In the light of the above, what remedies, and more specifically, what form of relief should the national court provide?

89. On the one hand, for the reasons illustrated in points 71 to 82 of this Opinion, the type and gravity of the alleged breach and the consequences of that breach are, probably, not such as to command some draconian form of relief. Accordingly, the referring court may well come to the conclusion that it would be disproportionate to grant all three forms of relief sought by the applicant at the same time. In particular, the applicant's request that the referring court declare that the Irish authorities *must* amend national law to ensure a correct transposition of the provisions of Title V of Directive 2001/82 might, perhaps also in the light of the principle of separation of powers,⁴⁹ go beyond what is necessary to ensure protection of the applicant's right.

90. On the other hand, however, should the applicant's claims prove to be well-founded, which is nonetheless for the referring court to determine, I fail to see how the outcome of those the proceedings could be considered just and proportionate if he were to leave the courtroom completely empty-handed.

47 See, inter alia, judgments of 2 February 1986, *Marshall* (152/84, EU:C:1986:84, paragraph 48); of 14 July 1994, *Faccini Dori* (C-91/92, EU:C:1994:292); and of 22 January 2019, *Cresco Investigation* (C-193/17, EU:C:2019:43, paragraph 72).

48 Judgment of 24 June 2019 (C-573/17, EU:C:2019:530, paragraph 67).

49 A principle which the Court considered to be flowing from the principle of the rule of law: see, to that effect, judgments of 10 November 2016, *Poltorak* (C-452/16 PPU, EU:C:2016:858, paragraph 35), and 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 124).

91. The right to an effective remedy must necessarily imply that the competent court is, in principle, to deal with the substance of the relevant complaint and grant appropriate relief,⁵⁰ and that that relief be duly executed.⁵¹ The right to a judge would be rendered meaningless if a successful party were denied any form of satisfaction in response to a breach of their rights, absent, of course, any exceptional circumstance warranting that.

92. Are there, in the present case, any such exceptional circumstances?

93. In the case at hand, the Irish authorities invoke two main reasons for opposing the granting of any relief. The first pertains to the sound administration of justice and judicial economy: granting of relief would serve no useful purpose since the applicant understands the information in English. Moreover, a new EU rule compatible with the current provisions of national law will soon enter into force. The second concerns a possible prejudice to third parties: the risk that producers and distributors of veterinary medicinal products may temporarily leave the Irish market in order to avoid additional costs, thereby harming animal health.

94. In principle, I agree with Ireland that sound administration of justice and judicial economy,⁵² and/or the need to prevent a risk of shortage of veterinary medicinal products,⁵³ are in themselves, and in general, interests deserving of protection. As such, a national court may therefore take them into account when exercising its discretion. However, it is for the referring court to verify whether, *in the present circumstances*, the actual use of the referring court's discretion in order to refuse any relief whatsoever would provide a meaningful contribution to the protection of those interests and, in any event, would not go beyond what necessary to that end.

95. Since there is, to date, still more than one year before the entry into force of the new EU regulation, it is difficult to perceive this period of time as being completely negligible. It might again be recalled that EU provisions must deploy their full effects 'as from their entry into force and throughout the duration of their validity'.⁵⁴ It may be true that the applicant understands the information in English. That may perhaps be taken as an element which suggests that the infringement is of a less severe nature and there is a lesser urgency in finding some form of redress. By contrast, I have greater doubts that that element may be considered as the (sole) basis to justifying a refusal to grant the applicant any form of protection of his rights, once that element presented no issues in terms of standing for the applicant and the case is now being assessed on merits.

96. Moreover, the alleged negative consequences for the third parties and the State are neither immediate nor flowing automatically from any decision taken by the referring court in the context of the present proceedings. Pursuant to the principle of primacy of EU law, a conflict between a provision of national law and a directly applicable provision of EU law is to be resolved by a national court applying the latter, if necessary by refusing to apply the conflicting national provision. But that statement of the Court was made and repeated⁵⁵ in the context of judicial proceedings, that are *inter partes* proceedings, the outcome of which is normally binding on the parties to the dispute. It has not

50 See, to that effect, ECtHR, 30 October 1991, *Vilvarajah and Others v. the United Kingdom*, CE:ECHR:1991:1030JUD001316387, § 122).

51 See, for a review of the relevant ECtHR case law, my Opinion in *Torubarov* (C-556/17, EU:C:2019:339, points 60 to 62).

52 To that effect, see, inter alia, judgment of 12 February 2015, *Baczó and Vizsnyiczai* (C-567/13, EU:C:2015:88, paragraph 51).

53 To that effect, see, inter alia, judgment of 16 September 2008, *Sot. Lélós kai Sia and Others* (C-468/06 to C-478/06, EU:C:2008:504, paragraph 75).

54 See above, point 34 of this Opinion.

55 See above, points 34 to 36 of this Opinion.

been stated, however, that a judicial conflict must be resolved, as a matter of EU law, by a declaration that the national provision is null, invalid or non-existent.⁵⁶ Indeed, the powers of the national courts and tribunals are a matter to be determined by each Member State. Direct effect and primacy do not require that the judicial decisions in question be endowed with some form of *erga omnes* effect.⁵⁷

97. In the light of the above, I wonder whether – assuming the referring court’s assessment with regard to the interpretation of the EU provisions at issue is correct – the granting of relief through a mere declaration that the national provisions at issue do not transpose Directive 2001/82 correctly may not be the most appropriate form of relief. On the one hand, it records the possible infringement invoked and provides some form of moral satisfaction to the applicant,⁵⁸ while perhaps opening up the potential for him to claim damages for any harm incurred should the conditions for State liability be satisfied.⁵⁹ On the other hand, that form of relief is rather limited in scope and effects, especially vis-à-vis third parties, and less intrusive with regard to the Irish legislative and administrative authorities.

98. However, as repeatedly mentioned throughout this Opinion, all these matters are indeed for the referring court to assess and to balance. All the points discussed in this section were simply to confirm that there are a range of conceivable solutions. The overall bottom line of this Opinion is that, in my view, EU law does not take away, even if rights based on EU law are at stake, the discretion a national court is normally endowed with for finding a case-appropriate and proportionate outcome to an individual case, including the choice of relief to be granted to the applicant, provided of course that his action is well founded on merits.

V. Conclusion

99. I propose that the Court answer the question referred for a preliminary ruling by the Ard-Chúirt (High Court, Ireland) as follows:

- EU law, and in particular the principles of procedural autonomy and effective judicial protection, do not preclude a national legislation or practice according to which national courts enjoy a discretionary power to determine whether to grant relief, and if so, the form of that relief, in respect to an applicant claiming that the authorities have not transposed a directive correctly, where the action is well founded.
- It is for the referring court to ensure that there is, on the facts and the context of each individual case before it, a reasonable relationship between the nature of the rights invoked, the seriousness of their infringement or harm suffered, and the type of remedy sought, and by way of a consequence of the relief, that it decides to grant (or, as the case may be, not grant) in favour of the applicant.

⁵⁶ See judgment of 19 November 2009, *Filipiak* (C-314/08, EU:C:2009:719, paragraphs 82 to 83).

⁵⁷ See, to that effect, judgment of 4 December 2018, *The Minister for Justice and Equality and Commissioner of the Garda Síochána* (C-378/17, EU:C:2018:979, paragraphs 33 to 34).

⁵⁸ In that connection, I would point out that, in the context of actions for non-contractual liability of the European Union, symbolic forms of compensation or the mere recording in the judgment of the unlawful event might constitute satisfactory compensation for the purposes of Article 340 TFEU: see, inter alia, judgments of 14 June 1979, *V. v Commission* (18/78, EU:C:1979:154, paragraph 19); of 9 July 1981, *Krecké v Commission* (59/80 and 129/80, EU:C:1981:170, paragraph 74); and of 9 July 1987, *Hochbaum and Rawes v Commission* (44/85, 77/85, 294/85 and 295/85, EU:C:1987:348, paragraph 22). This practice appears consistent with that of the ECtHR: see, among others, judgments of 23 November 1976, *Engel and Others v. the Netherlands* (CE:ECHR:1976:1123JUD000510071, §§ 10 to 11); of 17 October 2002, *Agga v. Greece* (CE:ECHR:2002:1017JUD005077699, §§ 65 to 66); and of 30 November 2004, *Vaney v. France* (CE:ECHR:2004:1130JUD005394600, §§ 55 to 57).

⁵⁹ See judgments of 19 November 1991, *Francovich and Others* (C-6/90 and C-9/90, EU:C:1991:428), and of 5 March 1996, *Brasserie du pêcheur and Factortame* (C-46/93 and C-48/93, EU:C:1996:79).