Reports of Cases

OPINION OF ADVOCATE GENERAL
SZPUNAR
delivered on 2 June 2016[1]

Case C-148/15

Deutsche Parkinson Vereinigung eV
v
Zentrale zur Bekämpfung unlauteren Wettbewerbs eV
(Request for a preliminary ruling
from the Oberlandesgericht Düsseldorf

(Higher Regional Court, Düsseldorf, Germany))

(Free movement of goods — Articles 34 and 36 TFEU — State fixed-prices for prescription-only medicinal products — Measure having equivalent effect to a quantitative restriction — Selling arrangement — Justification on ground of public health)

I – Introduction

1. Questions on Article 36 TFEU[2] occupied the Court before those on direct effect or primacy.[3] Adjudicating between the Union interest of free movement and Member States' interests when pursuing non-economic public policy aims is a delicate task which the passage of time has not diminished. On the contrary, the same legal questions resurface in the context of different factual circumstances. The present case bears testimony to the fact that the Treaty provisions on the internal market and, in particular, those relating to the free movement of goods continue to be at the core of the EU legal edifice and the EU's economic constitution.

2. The present preliminary reference by the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, hereafter 'OLG Düsseldorf') which seeks to ascertain whether a system under which prescription-only medicinal products can be made subject to uniform prices is in accordance with Articles 34 and 36 TFEU provides a neat illustration of the relevance of the provisions on free movement of goods.

1 — Original language: English.

2 — Formerly Article 30 EC (Amsterdam) and Article 36 EEC (Rome).

3 — The first judgment on Article 36 TFEU (then EEC), *Commission* v *Italy* (7/61, EU:C:1961:31), was delivered on 19 December 1961, whereas the judgment in *van Gend & Loos* (26/62, EU:C:1963:1) dates from 5 February 1963 and the one in *Costa* (6/64, EU:C:1964:66) from 15 July 1964.

3. Quite apart from this, and in a less obvious manner, this case provides yet another example of the value of the preliminary reference procedure. Further to divergence in the case-law of two of the highest German courts, the Bundessozialgericht and the Bundesgerichtshof, as to the legality of the provisions in question under Articles 34 and 36 TFEU, the Joint Chamber of the Superior Federal Courts [4] held that those provisions are in conformity with EU law. [5] Were it not for the OLG Düsseldorf which, in my view, correctly harbours doubts as to this conformity, the case would have never reached the Court.

4. Finally, we should call a spade a spade: this is the third time that the Court is called upon to assess the compatibility of a German measure with the Treaty provisions on free movement where the Dutch pharmacy DocMorris is endeavouring to obtain access to the German market. In the first case, *Deutscher Apothekerverband eV* v *0800 DocMorris NV and Jacques Waterval*, [6] the Court was called upon to examine whether a German prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the Member State concerned was in conformity with Articles 34 and 36 TFEU. The Court found that, while the measure in question constituted a measure having equivalent effect in the sense of Article 34 TFEU, Article 36 TFEU could be relied upon with respect to medicinal products subject to prescription in Germany, but not to those not subject to prescription. The second case, joined cases *Apothekerkammer des Saarlandes and others* v *Saarland, Ministerium für Justiz, Gesundheit und Soziales* (C-171/07) and *Helga Neumann-Seiwert* v *Saarland, Ministerium für Justiz, Gesundheit und Soziales* (C-172/07), [7] dealt with the question whether the Treaty provisions on establishment [8] precluded German legislation which prevents persons not having the status of pharmacist from owning and operating pharmacies (the so-called 'Fremdbesitzverbot'). The Court found that freedom of establishment did *not* preclude the 'Fremdbesitzverbot'.

5. Further to the first DocMorris case, Germany altered its legislation and allowed for mail order, not only of non-prescription, but also of prescription-only medicinal products. On the basis of the information provided to the Court, it appears that, at least for some time, there were no rules on uniform prices as regards prescription-only medicinal products imported from other Member States. Later on, such rules were also to apply to such products. This leads us to the legal framework.

II – Legal framework

A – *German law on medicinal products*

6. The first sentence of Paragraph 78(1) of the Arzneimittelgesetz (Law on medicinal products; 'AMG') provides:

'The Ministry for Economics and Technology shall be authorised to establish

1. price margins for medicinal products which are distributed in wholesale commerce or in pharmacies or which are re-sold by veterinary surgeons …'

4 — This Joint Chamber, which is foreseen in Article 95(3) of the German Basic Law (Constitution) and which, by virtue of that provision aims 'to preserve the uniformity of decisions' of the German highest courts, is an ad-hoc body which is only convened on the extraordinary occasion that the highest German courts differ in their case-law. It takes a binding decision on the case. Its precise tasks and composition are fleshed out in a dedicated law, the 'Gesetz zur Wahrung der Einheitlichkeit der Rechtsprechung der obersten Gerichtshöfe des Bundes' of 19 June 1968, BGBl. I, p. 661-664.

5 — See GmS-OGB, Order of 22 August 2012, available at: https://openjur.de/u/617231.html. In fact, this decision, which is the latest one to be delivered by that body, constitutes but the 14th decision since the creation of the Joint Chamber in 1968, see https://openjur.de/gericht_e-235-0-ed-desc.html.

6 — Judgment of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664).

7 — Judgment of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316).

8 — Articles 49 and 54 TFEU.

7. Paragraph 78(2) of the AMG is worded as follows:

'Prices and price margins shall take account of the legitimate interests of consumers of medicinal products, veterinary surgeons, pharmacies and the wholesale trade. A uniform pharmacy retail price shall be guaranteed for medicinal products that may not be sold other than through pharmacies. …'

8. Given that the case-law of the German highest courts was conflicting as to whether that provision applied also to prescription-only medicinal products obtained, by way of mail order, from pharmacies established in another Member State, the German legislature, by law of 19 October 2012,[9] inserted the following sentence in Paragraph 78(1) of the AMG: 'The Arzneipreisverordnung, adopted on the basis of the first sentence, applies also to medicinal products introduced within the scope of the present Law pursuant to point 1a of Paragraph 73(1).' Point 1a of Paragraph 73(1) of the AMG, to which reference is made, concerns medicinal products that are dispensed to end consumers in Germany by mail order from a pharmacy established in another Member State.

9. Moreover, given the conflicting case-law of the highest German courts, by order of 22 August 2012 the Joint Chamber of the Superior Federal Courts held that the AMG, also in its earlier wording, was to be interpreted to this effect.

B – *German Regulation on the pricing of medicinal products*

10. The Arzneimittelpreisverordnung (Regulation on the pricing of medicinal products) provides, to the extent relevant here, that the manufacturer must establish a price for its medicinal products (Paragraph 1) to which wholesaler additions (Paragraph 2) and pharmacy additions (Paragraph 3) are added. This regulation does not apply to medicinal products not requiring a prescription. In addition, point 2 of Paragraph 7(1) of the Heilmittelgesetz (Law on medicinal products) prohibits the grant of discounts.

III – Facts, procedure and questions referred

11. Deutsche Parkinson Vereinigung eV (hereafter 'DPV'), a registered association, is a self-help organisation whose objective is to improve the lives of patients with Parkinson's disease and those of their families. By letter of July 2009, promoting a cooperative venture between DPV and the Dutch mail-order pharmacy DocMorris, DPV informed its members of a bonus system under which various bonuses would be provided to members of DPV when purchasing from DocMorris certain prescription-only medicinal products for Parkinson's disease available only through pharmacies.

12. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV ('ZBW'), an association combating unfair competition, considers the promotion unfair pursuant to Paragraph 4(11) of the Gesetz gegen den unlauteren Wettbewerb (Law against unfair competition; 'UWG') in conjunction with the former version of Paragraph 78 of the AMG and Paragraphs 1 and 3 of the Arzneimittelpreisverordnung and now, after amendment, in conjunction with the fourth sentence of Paragraph 78(1) of the AMG, as the bonus system promoted runs contrary to the establishment of a uniform retail price to be observed by pharmacies, as required by legislation.

13. The Landgericht (Regional Court) upheld ZBW's claim and ordered DPV, when operating in a competitive market in the context of a cooperation with the mail-order pharmacy DocMorris, not to recommend the bonus system of that pharmacy, where this is done by means of a letter such as that triggering the present dispute. The Landgericht held that the application for an injunction was well

9 — See Article 1, point 62, of the Zweites Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften, 19. Oktober 2012, BGBl. I, p. 2192-2227, at p. 2212.

founded because, in sending its contested letter, DPV had infringed point 2 of Paragraph 8(3), Paragraph 3 and Paragraph 4(11) of the UWG in conjunction with Paragraph 78 of the AMG and Paragraphs 1 and 3 of the Arzneimittelverordnung. It held that the letter constituted commercial conduct on the part of DPV that was unfair because the bonus system promoted was prohibited under competition rules. Moreover, the Landgericht continued by holding that, at the material time, the legislative rules at issue were applicable also to supplies effected by DocMorris, which is not established on German territory. This is now from the effect of the fourth sentence of Paragraph 78(1) of the AMG, as amended on 26 October 2012.

14. DPV lodged an appeal against that judgment, maintaining its view that the ZBW's claim should be dismissed.

15. It is in the context of these proceedings that, by order of 24 March 2015, received at the Court on 30 March 2015, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) referred the following questions for a preliminary ruling:

'(1) Must Article 34 TFEU be interpreted as meaning that a system of fixed prices laid down by national law applicable to prescription-only medicinal products constitutes a measure having equivalent effect within the meaning of Article 34 TFEU?

(2) If the Court answers Question 1 in the affirmative:

Is the system of fixed prices for prescription-only medicinal products justified under Article 36 TFEU on grounds of the protection of health and life of humans if that system is the only means of ensuring a consistent supply of medicinal products to the population across the whole of Germany, in particular in rural areas?

(3) If the Court also answers Question 2 in the affirmative:

What is the degree of judicial scrutiny required when determining whether the condition mentioned in Question 2 is in fact satisfied?'

IV – Analysis

A – *Question 1 – Restriction on the free movement of goods*

16. Does a system of fixed prices laid down by national law applicable to prescription-only medicinal products constitute a measure having equivalent effect within the meaning of Article 34 TFEU?

1. Dassonville

17. The definition of a measure having equivalent effect to a quantitative restriction is so well known that it hardly needs to be recalled. Since *Dassonville* the Court has held that 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions'.[10] Nowadays, the Court tends to refer to 'measures' rather than 'trading rules enacted by

10 — See judgment of 11 July 1974 in *Dassonville* (8/74, EU:C:1974:82, paragraph 5).

Member States',[11] though it does revert to the traditional *Dassonville* formula at times.[12] The purpose of Article 34 TFEU et seq has been neatly summarised by the Court as follows: 'It has been established in the case-law since the judgment … *Dassonville* … that Articles [34 and 35 TFEU], taken in their context, must be understood as being intended to eliminate all barriers, whether direct or indirect, actual or potential, to trade flows in intra-Community trade.'[13]

18. Fixed prices are a thorn in the flesh of any economic operator not present on a market, given that competition, is, by its very essence, determined by price. By depriving an economic operator of the possibility of undercutting a certain price, it is deprived of a factor allowing it to be competitive. Goods originating from Member States other than Germany therefore face difficulties when entering the German market. The provisions at issue are liable to reduce imports into Germany.

19. Ergo, under *Dassonville*, the provisions at issue qualify as constituting a measure having equivalent effect. They are more than capable of hindering trade. This has also been evidenced by the decline in sales of DocMorris in Germany of prescription-only medicinal products, further to the introduction of the provisions under examination.

2. Keck

20. Next, we have to examine whether the German provisions in question constitute a 'certain selling arrangement' within the meaning of the *Keck and Mithouard* case-law. If so, the consequence would be that it would fall outside the scope of the Treaty provisions on the free movement of goods.

21. In what is arguably the most contested judgment in the domain of free movement of goods under the Treaty,[14] the Court famously held that 'contrary to what has previously been decided, the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the *Dassonville* judgment …, so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States'.[15] The Court went on to state that 'provided that those conditions are fulfilled, the application of such rules to the sale of products from another Member State meeting the requirements laid down by that State is not by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products. Such rules therefore fall outside the scope of Article [34 TFEU].'[16]

11 — See, by way of example, judgments of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 66) and of 15 November 2007 in *Commission* v *Germany* (C-319/05, EU:C:2007:678, paragraph 80).

12 — See for instance judgments of 16 January 2014 in *Juvelta* (C-481/12, EU:C:2014:11, paragraph 16), of 10 February 2009 in *Commission* v *Italy* (C-110/05, EU:C:2009:66, paragraph 33) and of 30 April 2009 in *Fachverband der Buch- und Medienwirtschaft* (C-531/07, EU:C:2009:276, paragraph 16).

13 — See judgment of 12 June 2003 in *Schmidberger* (C-112/00, EU:C:2003:333, paragraph 56).

14 — See, among many, Mattera, A., 'De l'arrêt "Dassonville" à l'arrêt "Keck": l'obscure clarté d'une jurisprudence riche en principes novateurs et en contradictions', *Revue du marché unique européen*, 1994, n° 1 pp. 117-160; Gormley, L., 'Reasoning Renounced? The Remarkable Judgment in Keck & Mithouard', *European Business Law Review*, 1994, pp. 63-67; Steindorff, E., 'Unvollkommener Binnenmarkt', *Zeitschrift für das gesamte Handelsrecht und Wirtschaftsrecht*, 1994, pp. 149-169; Lenz, C.O., 'Ein undeutlicher Ton', *Neue juristische Wochenschrift*, 1994, pp. 1633-1634. For a defence of *Keck*, see Joliet, R. [one of the sitting judges on that judgment], 'Der freie Warenverkehr: Das Urteil Keck und Mithouard und die Neuorientierung der Rechtsprechung', *Gewerblicher Rechtsschutz und Urheberrecht, internationaler Teil*, 1994, pp. 979-987.

15 — See judgment of 24 November 1993 in *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905, paragraph 16).

16 — See judgment of 24 November 1993 in *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905, paragraph 17).

22. I understand *Keck* as a legitimate answer of the Court to an ever-growing reliance, by economic operators, on Article 34 TFEU in order to have set aside by a national court any measure impeding them in the pursuit of their economic activity.[17] The trouble appears to me to have been less the number of cases brought, but rather the issues they entailed.[18] A very broad interpretation of the scope of Article 34 TFEU meant that the Court increasingly had to deal with issues only marginally related to the actual free movement of goods, but rather to delicate societal choices such as opening hours of shops on Sundays and so forth.

23. Yet, the instances in which the Court has, in effect, applied the *Keck* exception are rare and, moreover, the Court has never positively defined what exactly it understands by a 'selling arrangement'.[19] Since they do exist, however, *Keck* is still alive and must be examined in the case at issue.[20]

24. Provisions, such as the ones in question, relating to the fixing of prices of certain products might not, at first sight, constitute 'rules that lay down requirements to be met by … goods (such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging)'.[21] Moreover, with regard to national provisions on book pricing, the Court has held that in so far as they 'do not concern the characteristics of those goods, but solely the arrangements under which they may be sold' they 'must be regarded as concerning selling arrangements within the meaning of *Keck and Mithouard*'.[22]

25. Even if, in that same case, the Court went on to find that the provisions in question constituted all the same a measure having equivalent effect, in so far as they created 'for imported books, a distinct regulation, which has the effect of treating products from other Member States less favourably',[23] I would not have gone as far as to make the initial statement that a measure on price fixing constitutes a selling arrangement. A fixed-price imposed on a specific product comes extremely close to a rule on presentation, labelling or packaging. After all, products often have a physical price tag on them, which forms part of the packaging. Moreover, any measure which regulates one of the major aspects of a product, the price, is, in my view, more than a selling arrangement. Measures on price directly affect the competitive advantage of an economic operator and are far more severe from the perspective of economic operators and free movement rules, than, say, a prohibition of sale at a loss or provisions regulating opening hours of shops. They should not be seen as a 'selling arrangement'. I therefore have a fundamental difficulty with qualifying a measure fixing a price as a selling arrangement, with the consequence that one has thereafter to analyse whether the measure impedes market access and/or is discriminatory.

26. Rather, it would be sufficient, in my view, to check whether the conditions of the *Dassonville* formula have been fulfilled or not. Be that as it may, taking into account the existing case-law, I shall analyse the provisions in question as if they constituted a 'selling arrangement'.

17 — Advocate General Tesauro captured the immediate pre-Keck mood well, when he stated, fittingly and rhetorically, in his Opinion in *Hünermund and Others* (C-292/92, EU:C:1993:863, point 1): 'Is [Article 34 TFEU] a provision intended to liberalise intra-Community trade or is it intended more generally to encourage the unhindered pursuit of commerce in individual Member States?'

18 — See also Weiler, J.H.H., 'The constitution of the common market place', in P. Craig, G. de Búrca, *The evolution of EU law*, Oxford University Press, 1999, pp. 349-376, at p. 370.

19 — See, among many, Kellerhals, A., 'Das Binnenmarktrecht der Warenverkehrsfreiheit', in Müller-Graff, P.-Chr. (ed.), *Europäisches Wirtschaftsordnungsrecht (Enzyklopädie Europarecht, Band 4)*, Nomos, Baden-Baden, 2015, pp. 357-396, at p. 376.

20 — And yet, the *Keck* formula should not be applied mechanically. The purpose of identifying selling arrangements is not to exclude them completely from the scope of Article 34 TFEU, but rather to introduce a presumption that such rules do not restrict trade between Member States within the meaning of *Dassonville*. See Szpunar, M., *Promocja towarów w prawie wspólnotowym*, Kraków, 2002, p. 185.

21 — Terminology used in the *Keck* judgment itself, see judgment of 24 November 1993 in *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905, paragraph 15).

22 — See judgment of 30 April 2009 in *Fachverband der Buch- und Medienwirtschaft* (C-531/07, EU:C:2009:276, paragraph 20).

23 — See judgment of 30 April 2009 in *Fachverband der Buch- und Medienwirtschaft* (C-531/07, EU:C:2009:276, paragraph 22).

27. A uniform pharmacy retail price, such as the one in the case at issue undoubtedly applies, in law, to both German and non-German pharmacies and, by extension, both to German and imported products.

28. Germany argues that the same can be said of the position in fact. The Joint Chamber of the Superior Federal Courts also takes the view that the fixed-price system applies in law and in fact equally to domestic and foreign pharmacies. [24]

29. By contrast, the European Commission considers there to be a measure having equivalent effect. It takes the view that the fixed-price system imposes a greater burden on foreign pharmacies as they can offset the disadvantage of being able to obtain access to the German market only via mail order only by means of the advantage of being permitted to sell their products in accordance with the pricing rules of the Member State of their establishment. In contrast, for German pharmacies, mail order is simply an additional distribution channel.

30. As DPV, the Dutch Government and the Commission correctly point out, pharmacies not located in Germany have only one means to gain access to the German market, namely via the internet. The main reason for this is the German 'Fremdbesitzverbot', that is to say that the right to own and operate a pharmacy is restricted to pharmacists alone. [25] An internet-pharmacy located outside Germany which intends to market its products in Germany therefore sees its access to the German market impeded if it cannot compete on price.

31. But the case at issue goes further than that.

32. Measures that apply in law but not in fact in the same way are habitually known as indirectly discriminatory measures. Establishing any kind of discrimination is always a delicate matter. It hinges on the comparator to be applied, as the case at issue neatly illustrates. If one takes as the comparator, as the Joint Chamber does, internet pharmacies, then it is difficult to detect an indirect discrimination. Both a pharmacy based in Hamburg (DE) and one based in Heerlen (NL) that intend to supply patients in Trier (DE) will be, de facto, treated in the same way.

33. However, this is not the right angle from which to examine the question of (indirect) discrimination in the case at issue.

34. Surely, it is not *internet* pharmacies that should be compared but pharmacies *in general*. And then a different picture emerges, for the simple reason that, as DPV correctly points out, German and non-German pharmacies rely on the internet to varying degrees. A pharmacy already present in Germany will, typically, if at all, resort to the internet in a limited capacity only, whereas a pharmacy based outside Germany does not have any means other than the internet to serve patients based in Germany. In other words, while for a German pharmacy, delivery by way of mail order constitutes but an additional channel of distribution, for a non-German one it is the only channel of distribution.

35. In *Deutscher Apothekerverband*, the Court found that a prohibition on mail-order delivery of pharmaceutical products was '*more* of an obstacle to pharmacies outside Germany than to those within it'. [26] It went on to state that although there is little doubt that as a result of the prohibition, pharmacies in Germany cannot use the extra or alternative method of gaining access to the German market consisting of end consumers of medicinal products, they are still able to sell the products in their

24 — GmS-OGB, Order of 22 August 2012, paragraph 47, available at: https://openjur.de/u/617231.html.

25 — As opposed to a capital company lawfully operating a pharmacy in another Member State. The 'Fremdbesitzverbot' has been held by the Court to be compatible with the Treaty provisions on freedom of establishment: see judgment of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 61).

26 — See judgment of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 74). Emphasis added.

dispensaries. However, for pharmacies not established in Germany, the internet provides a more significant way to gain direct access to the German market. A prohibition which has a greater impact on pharmacies established outside German territory could impede access to the market for products from other Member States more than it impedes access for domestic products. [27]

36. In *Ker Optika*, the Court extended such reasoning to a prohibition on selling contact lenses by mail order. It held that such a prohibition deprived traders from other Member States of a particularly effective means of selling those products and thus significantly impeded access of those traders to the market of the Member State concerned. [28]

37. In a situation where the effect of a measure is to block or at least reduce market access for internet pharmacies, which are typically foreign, so as to maintain a viable structure of physical pharmacies, I deem it impossible to speak of an indistinctly applicable selling arrangement. Ergo, I would hold that the German measure in question, by indirectly discriminating against non-German pharmacies, does not constitute a 'certain selling arrangement' in the sense of *Keck and Mithouard* and does constitute a barrier to trade of medicinal goods from other Member States.

38. This brings me to a final consideration on the classification of the German provisions: my finding is fully in line not only with the letter of *Keck and Mithouard* but also with its rationale, described above. Sensitive matters of a non-economic nature which are only marginally linked to free movement as such (and which are non-discriminatory) should be left to Member States. I do not see any room for such sensitivity when the effect of the measure is to limit competition and the market access of foreign economic operators. Such a measure is a far cry from rules on sale at a loss, [29] Sunday trading cases, [30] or cases on restrictions on advertising. [31]

B – *Questions 2 and 3 – Justification on grounds of public health*

39. By its second and third questions, which should be examined together, the referring court in essence seeks to ascertain whether the provisions in question are justified on the ground of 'protection of health and life of humans' under Article 36 TFEU. [32]

27 — See judgment of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 74). A comparable argument is made in legal writing where it is stated that a fixed retail price can have negative consequences on imports, resulting from a restriction on the competitive advantage of an importer, see Müller-Graff, P.-Chr., in von der Groeben, H., Schwarze, J., Hatje, A. (eds), *Europäisches Unionsrecht (Kommentar)*, 7th ed., Nomos, Baden-Baden, Artikel 34 AEUV, point 143. See also Becker, U., in Schwarze (ed.), *EU-Kommentar*, 3rd ed., Nomos, Baden-Baden, Artikel 34 AEUV, point 69.

28 — See judgment of 2 December 2010 in *Ker-Optika* (C-108/09, EU:C:2010:725, paragraph 54). In that judgment the Court examined the question of market access and discrimination together, as it seems to be doing frequently.

29 — See judgment of 24 November 1993 in *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905).

30 — See judgments of 23 November 1989 in *B & Q* (C-145/88, EU:C:1989:593) of 16 December 1992 in *B & Q* (C-169/91, EU:C:1992:519) (both already pre-Keck) and of 2 June 1994 in *Punto Casa and PPV* (C-69/93 and C-258/93, EU:C:1994:226) (post-Keck).

31 — See judgments of 15 December 1993 in *Hünermund and Others* (C-292/92, EU:C:1993:932, paragraph 21), and of 9 February 1995 in *Leclerc-Siplec* (C-412/93, EU:C:1995:26, paragraph 21). Besides, the Court has found some advertising restrictions to constitute a measure having equivalent effect, namely when they did impede access to a market, see, e.g., judgment of 8 March 2001 in *Gourmet International Products* (C-405/98, EU:C:2001:135, paragraph 21).

32 — As it has been established that the measure is indirectly discriminatory, only the written grounds of justification, listed in Article 36 TFEU can be relied upon by Germany and no mandatory requirements, developed by the Court on the basis of the *Rewe-Zentral "Cassis de Dijon"* case-law (judgment of 20 February 1979, 120/78, EU:C:1979:42).

1. Ground of justification invoked: public health

40. Since *De Peijper*, the first case on the public health exception, the Court has consistently ruled that 'health and the life of humans rank first among the property or interests protected by Article 36 [TFEU] and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure …'. [33]

41. Germany, which relies on this ground of justification, stresses that the measure in question is necessary in order (1) to ensure a consistent supply of pharmaceutical products throughout Germany, (2) to ensure the quality of such supply and to protect patients and (3) to control cost developments in the health sector.

42. The last sub-ground of justification cannot be invoked. Given that Article 36 TFEU is 'directed to eventualities of a non-economic kind', [34] measures designed to reduce the cost of social security schemes may not be justified under the head of health under Article 36 TFEU. [35] Only the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest, [36] which, given the exceptional nature of that ground of justification is clearly not the case here. [37] Quite apart from that, if prices were not fixed and competition increased, this could actually result in lower prices which could be beneficial for social security systems.

43. As for the other two sub-grounds of justification, the Court has acknowledged, that, in principle, the head of justification 'health' includes measures relating to the need to provide individual advice to the customer and to ensure his protection when he is supplied with medicines and to the need to check that prescriptions are genuine and to guarantee that medicinal products are widely available and sufficient to meet requirements. [38]

2. Proportionality

44. Against this background, I should like to examine the proportionality of the German measure with respect to the necessity of ensuring a consistent supply of pharmaceutical products throughout Germany, the quality of such supply and the protection of patients. In doing so, I shall examine the suitability, and the necessity, of the contested provisions.

33 — See judgment of 20 May 1976 in *de Peijper* (104/75, EU:C:1976:67, paragraph 15). See also judgments of 7 March 1989 in *Schumacher* (215/87, EU:C:1989:111, paragraph 17); of 16 April 1991 in *Eurim-Pharm* (C-347/89, EU:C:1991:148, paragraph 26); of 10 November 1994 in *Ortscheit* (C-320/93, EU:C:1994:379, paragraph 16); and of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 103).

34 — See already the very first case on Article 36 TFEU (at the time, EEC): judgment of 19 December 1961 in *Commission* v *Italy* (7/61, EU:C:1961:31, p. 329).

35 — See judgment of 28 April 1998 in *Decker* (C-120/95, EU:C:1998:167, paragraphs 39 and 40).

36 — See judgment of 28 April 1998 in *Decker* (C-120/95, EU:C:1998:167, paragraph 39). The Court takes the same approach in relation to the freedom to provide services: see judgment of 28 April 1998 in *Kohll* (C-158/96, EU:C:1998:171, paragraph 41).

37 — Strictly speaking and in line with the *Cassis de Dijon* case-law of the Court, in order to be justified as an overriding reason in the general interest (or in the older case-law: mandatory requirement), the measure in question would have to be indistinctly applicable to domestic and foreign products which is, as we have seen above not the case here. That said, I am not sure whether the Court still maintains such a strict stance, in particular when it comes to measures which are discriminatory in fact, but not in law. See e.g. judgment of 30 April 2009 in *Fachverband der Buch- und Medienwirtschaft* (C-531/07, EU:C:2009:276, paragraphs 22 and 34), even if *in casu* (paragraphs 35 and 36) the Court held the measure in question to be disproportionate under the overriding reason of 'protection of books as cultural objects'.

38 — See judgments of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 106) and of 11 September 2008 *Commission* v *Germany* (C-141/07, EU:C:2008:492, paragraph 47) in relation to the free movement of goods. The Court has subsequently extended this reasoning to freedom of establishment: see, for instance judgments of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 28); of 1 June 2010 in *Blanco Pérez and Chao Gómez* (C-570/07 and C-571/07, EU:C:2010:300, paragraph 64); of 5 December 2013 in *Venturini and Others* (C-159/12 to C-161/12, EU:C:2013:791, paragraph 42); and of 13 February 2014 in *Sokoll-Seebacher* (C-367/12, EU:C:2014:68, paragraph 25).

45. On a general note, Germany [39] does not present this case as a typical case in which an application of the free movement rules would lead to disastrous consequences in Germany. [40] The issue does not appear to be one of mutual recognition or mutual trust. [41] Germany's line of argumentation is more fundamental: too much alleged competition, including lower prices for patients and a higher degree of free movement of medicinal products between other Member States and Germany would have negative consequences for the protection of public health in Germany. Inevitable market failure would lead to a concentration of pharmacies in certain areas, leaving behind the remote, the immobile, the vulnerable and the old.

46. Germany is afraid that with increased competition German traditional retail pharmacies committed to a high degree of professionalism in the advice and consultancy they offer to consumers would have to lower the quality of such services in order to keep up with competition.

47. It is for me difficult to conceive how, with increased competition, pharmacists would lower the quality of their services. I would expect the opposite to be the case. In this context, I allow myself to refer to Advocate General Poiares Maduro who makes a similar argument with incisiveness and elegance in *Blanco Perez*. [42]

a) Suitability

48. To meet the requirement of proportionality, the measure must, first, be suitable (or appropriate or adequate) [43] for securing the attainment of the objective pursued. Such suitability for securing attainment of the objective relied upon is accepted only if the measure at issue genuinely reflects a concern to attain that objective in a consistent and systematic manner. [44] In general, the Court accords a wide discretion to Member States at this stage. [45] If the national measure has no effect on the ground for justification, then the measure in question is not suitable. The same goes for a measure adopted on the basis of a manifest error of assessment. [46]

39 — See, by contrast, the German submission relating to the prohibition of the sale by mail order of medicinal products, in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 80).

40 — Other than cutthroat price competition, see immediately below.

41 — Which would have been, in my view, very difficult to construe in any event in an age where there is a mutual recognition of professional qualifications, in particular those of doctors and pharmacists, by virtue of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22).

42 — See Opinion of Advocate General Poiares Maduro in Joined Cases *Blanco Pérez and Chao Gómez* (C-570/07 and C-571/07, EU:C:2009:587, point 26): 'no basis appears to exist in the record to say that increased competition will lead the pharmacists to lower the quality of their services. I cannot but notice, in this respect, that there is a degree of inconsistency in the rationale behind large parts of the reasoning of some of the parties and the Member States. At times, pharmacists are portrayed as being primarily motivated by financial gain to the extent that they would all seek to practise only in heavily populated areas and, if subject to competition, ready to allow profit to prevail over their professional obligations. At other times, when in possession of a "monopolist" position in a populated area, pharmacists are assumed to conduct their business dominated by their professional obligations and devoted primarily to the provision of quality pharmaceutical services. In the arguments of several of the parties, competition appears to transform saints into sinners.'

43 — In my understanding, English terminology in this respect is used interchangeably. My personal preference goes for the term 'suitable', which is, moreover the term used by the EU legislator in the 'Services directive', see Article 15(3)(c) of Directive 2006/123 of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36). See also Barnard, C., *The substantive law of the EU. The four freedoms*, Oxford University Press, 4th ed., 2013, p. 177, who employs all three terms in the context of Article 36 TFEU.

44 — See judgments of 21 December 2011 in *Commission* v *Austria* (C-28/09, EU:C:2011:854, paragraph 126) and of 3 March 2011 in *Kakavetsos-Fragkopoulos* (C-161/09, EU:C:2011:110, paragraph 42) with respect to the free movement of goods. See also judgments of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 42) and of 13 February 2014 in *Sokoll-Seebacher* (C-367/12, EU:C:2014:68, paragraph 39) with respect to the freedom of establishment, and of 16 December 2010 in *Josemans* (C-137/09, EU:C:2010:774, paragraph 70) with respect to the freedom to provide services.

45 — See judgment of 15 September 1994 in *Houtwipper* (C-293/93, EU:C:1994:330, paragraph 22).

46 — See judgment of 15 September 1994 in *Houtwipper* (C-293/93, EU:C:1994:330, paragraph 22).

i) Consistent supply

49. ZBW and the German Government take the view that the provisions in question are suitable for ensuring the consistent and comprehensive supply of medicinal products throughout the German territory.

50. Moreover, the Joint Chamber, having regard to the discretion afforded to the legislature, has deemed the system justified on the basis that no alternative system is apparent that, in the interests of a reliable and high-quality supply of medicinal products to the population, is equally capable as the fixed-price system of counteracting the risk of cutthroat price competition between pharmacies, of ensuring a consistent supply of prescription-only medicinal products to the entire population and of reducing the risk of misuse or overuse of medicinal products. [47]

51. The link between the German measure and the purported goal, that is the consistent supply of pharmaceutical products appears to me to be too tenuous, which leads me to believe that the measure in question is unsuitable to attaining the purported objectives, for the following reasons.

52. First, as the Commission correctly points out, it is not the number of pharmacies that automatically implies that there is a consistent and comprehensive coverage across the German territory. Who can tell whether it is precisely remote areas and/or areas in which many elderly people live which will be better served if the number of pharmacies is higher? On the contrary, price competition among pharmacies could be conducive to a consistent coverage of medicinal products. I would assume that by allowing internet pharmacies to compete, remote areas will be better served. People with reduced mobility could greatly benefit from being able to place orders online and having them delivered directly to their home. Even if they are not accustomed to the alleged intricacies of ordering online, they will often have someone at their side (a carer, a (grand)child, a neighbour etc.) who is.

53. Secondly, as regards prescription-only medicinal products it is less the pharmacies one should concentrate on, but the number of doctors. *Ländlicher Ärztemangel*, that is a lack of doctors, particular in remote areas is, surely, at the root of the problem, not the number of pharmacies. Typically, where there is no doctor to prescribe medicinal products, there will be no pharmacy.

54. Thirdly, as regards the more delicate and sensitive matter of supply in emergency situations, it should not be forgotten that Germany has addressed this issue with a dedicated law, the Apothekennotdienstsicherstellungsgesetz. [48] This law, which has as its aim to ensure a comprehensive and consistent supply of medicinal products all over Germany, in particular rural areas, outside regular opening hours of pharmacies, provides for financial assistance to pharmacies providing such emergency supply through a fund administered by the Deutscher Apothekerverband. A charge is levied on medicinal products sold. Incidentally, on the basis of the information available, it appears that medicinal products imported into Germany are also subject to this charge, which means that foreign pharmacies selling their products on the German market contribute financially to this fund. [49]

55. I cannot see how the provisions under examination would have an additional impact on ensuring consistent supply of medicinal products.

47 — See GmS-OGB, Order of 22 August 2012, paragraph 50, available at: https://openjur.de/u/617231.html.

48 — See Gesetz zur Förderung der Sicherstellung des Notdienstes von Apotheken (Apothekennotdienstsicherstellungsgesetz – ANSG) of 15 July 2013, BGBl. I, p. 2420, available at: http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl113s2420.pdf.

49 — See point 5.8 of the rules of procedure of the said fund, available at http://www.dav-notdienstfonds.de/wp-content/uploads/2016/02/VERFAHRENSORDNUNG-V-2-0-16_02_03.pdf.

ii) Quality of supply

56. As regards quality of supply, it cannot be stressed enough that we are dealing with prescription-only medicinal products. I would, in this context, like to recall the Court's judgment in *Venturini*, where it held that 'the number of establishments which sell prescription-only medicinal products, including those the cost of which is borne not by the national health service but wholly by the purchaser, is of little importance. Since only doctors are authorised to prescribe those medicinal products, neither owners of pharmacies nor owners of ["para-pharmacies"] have, in any event, any direct influence on the volume of sales of those medicinal products and cannot therefore contribute to their possible overconsumption'.[50] Ergo, the price of a medicinal product has no effect on the quantity of prescription-only medicinal products that are supplied to a patient. Pharmacists' hands are bound.

iii) 'Uncertainty as to the existence or extent of risks to human health'

57. Moreover, it should be kept in mind that the burden of proof of justification and proportionality lies on Germany. It is for that Member State to prove the suitability of the measure in question. Germany has not submitted any evidence in support of its provisions. Instead, it points to the Court's consistent case-law, according to which 'where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent'. In this context, it also refers to the precautionary principle.

58. This assertion merits closer examination.

– Origin: case-law on precautionary principle

59. The said passage is indeed regularly resorted to by the Court. It finds its origins in the case-law on the precautionary principle. To my knowledge, it was first employed by the Court in relation to the EU institutions in 1998 in two judgments in the context of the BSE crisis.[51] Since then, it has been used both in relation to measures of the EU institutions or to measures of Member States, in derogation of the rules on free movement. All cases were ones where there was indeed no scientific certainty as to the existence or extent of a risk to human health. Typically cases arose in the area of vitamin or otherwise enriched foodstuffs,[52] novel foods,[53] labelling requirements applicable to foods and food ingredients consisting of, or derived from, GMOs[54] and, again, BSE.[55]

60. There have been occasions where an Advocate General has referred to the precautionary principle, but not the Court.

50 — See judgment of 5 December 2013 in *Venturini and Others* (C-159/12 to C-161/12, EU:C:2013:791, paragraph 57).

51 — See judgments of 5 May 1998 in *National Farmers' Union and Others* (C-157/96, EU:C:1998:191, paragraph 63) and of 5 May 1998 in *United Kingdom* v *Commission* (C-180/96, EU:C:1998:192, paragraph 99): 'Where there is uncertainty as to the existence or extent of risks to human health, *the institutions* may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.' Emphasis added.

52 — Judgment of 23 September 2003 in *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 49). See also Opinion of Advocate General Mischo in *Commission* v *Denmark* (C-192/01, EU:C:2002:760, point 102): 'It therefore seems to me that a *plausible* public-health risk is enough, according to the precautionary principle, to allow a Member State to adopt measures on the basis of [Article 36 TFEU]. Moreover, the greater the scientific uncertainty, the broader the discretion of the Member States, which are responsible for protecting public health.'

53 — See judgment of 9 September 2003 in *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 111).

54 — Judgment of 26 May 2005 in *Codacons and Federconsumatori* (C-132/03, EU:C:2005:310, paragraph 61).

55 — Judgment of 12 January 2006 in *Agrarproduktion Staebelow* (C-504/04, EU:C:2006:30, paragraph 39).

61. For instance, Advocate General Tizzano in a case on compound animal feedingstuffs, proposed to the Court that it refute the application of the precautionary principle and specified that the EU Directive in question was 'not a specific provisional risk management measure which prohibits specific products or practices the harmful nature of which is the subject of scientific uncertainty. Rather, Directive 2002/2/EC [56] is a legislative measure which is general in its scope and, with a view to improving the level of public health protection (see the fourth and fifth recitals in the preamble), harmonises the requirements relating to the labelling of feedingstuffs in a manner more restrictive than that obtaining hitherto.' [57] Without even mentioning the precautionary principle, the Court followed the Advocate General's reasoning and held the directive in question not to be disproportionate. [58]

– Extension to pharmacies

62. In 2009, matters took a certain turn in the case-law of the Court. It began referring to 'uncertainty as to the existence or extent of risks to human health' in different contexts from the ones described above.

63. *Commission* v *Italy* concerned legislation which restricted the right to operate a private retail pharmacy to natural persons who have graduated in pharmacy and to operating companies and firms composed exclusively of members who are pharmacists, and legislative provisions which made it impossible for undertakings engaged in the distribution of pharmaceutical products ('distribution undertakings') to acquire stakes in companies which operate municipal pharmacies. [59] *Apothekerkammer des Saarlandes and Others* was about national rules limiting pharmacy ownership to pharmacists. [60]

64. In both these cases the Court, by referring to case-law on the precautionary principle, used the said formula. It did not, however, further mention that principle as such.

65. However, the Court made an important qualification by adding the following: (1) a Member State may take the measures that reduce, as far as possible, a public-health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public; [61] (2) attention is to be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods; [62] (3) those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered; [63] (4) overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied. [64]

56 — Directive of the European Parliament and of the Council of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs and repealing Commission Directive 91/357/EEC (OJ 2002 L 63, p. 23).

57 — Opinion of Advocate General Tizzano in *ABNA and Others* (C-453/03, EU:C:2005:202, point 129).

58 — See judgment of 6 December 2005 in *ABNA and Others* (C-453/03, C-11/04, C-12/04 and C-194/04, EU:C:2005:741, paragraph 57 et seq.)

59 — See judgment of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315).

60 — See judgment of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316).

61 — See judgments of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315, paragraph 54) and of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 30).

62 — See judgments of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315, paragraph 55) and of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 31).

63 — See judgments of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315, paragraph 56) and of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 32).

64 — See judgments of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315, paragraph 57) and of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 33).

66. In those cases, the Court found that, as a result, Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. [65]

67. In *Blanco Pérez and Chao Gómez*, the Court even dropped the qualification referred to in the previous point but one. Asked to what extent a Member State could regulate in order to prevent a concentration of pharmacies in certain areas, the Court repeated the said formula [66] before going on to state that a Member State may in view of the risk that some parts of its territory will be left with too few pharmacies, adopt legislation under which one pharmacy may be set up in relation to a certain number of inhabitants. [67]

68. The same statement was repeated in *Venturini*. [68]

– In casu: no uncertainty as to the existence or extent of risks to human health

69. The extension of the said formula to pharmacies since 2009 is unfortunate for it blurs the origin of the said formula and what the precautionary principle is really about: risk management in the context of scientific uncertainty. It applies both where the extent of a risk is *uncertain* and where there is *doubt* as to its very *existence*. However, it does not come into play in a situation of uncertainty surrounding the effectiveness of a policy option aimed at tackling a previously identified hazard. [69] Precaution is not to be confused with prevention. In the latter concept, there is no element of uncertainty as to the existence or extent of a risk. In prevention, the danger is identified. [70]

70. Yet, the cases since 2009, referred to above, related to pharmacies and involve no scientific uncertainty whatsoever about the health risk of misuse or overconsumption of pharmaceutical products. Moreover, such products are already legally on the market following a strict marketing process. The uncertainty is confined to the viability or effectiveness of the measure envisaged.

71. The precautionary principle does, therefore, not play a role in deciding the case at issue. As a consequence, I would deem it expedient for the Court to dispense with, as support of argument, the formula of 'uncertainty as to the existence or extent of risks to human health'.

65 — See judgments of 19 May 2009 in *Commission* v *Italy* (C-531/06, EU:C:2009:315, paragraph 58) and of 19 May 2009 in *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316, paragraph 34).

66 — See judgment of 1 June 2010 in *Blanco Pérez and Chao Gómez* (C-570/07 and C-571/07, EU:C:2010:300, paragraph 74).

67 — See judgment of 1 June 2010 in *Blanco Pérez and Chao Gómez* (C-570/07 and C-571/07, EU:C:2010:300, paragraphs 75 and 76). By contrast, such statements do not appear in the Opinion of Advocate General Poiares Maduro on those joined cases (C-570/07 and C-571/07, EU:C:2009:587).

68 — See judgment of 5 December 2013 in *Venturini and Others* (C-159/12 to C-161/12, EU:C:2013:791, paragraph 60).

69 — See Alemanno, A., The Precautionary principle, in Baudenbacher, C. (ed.), *The Handbook of EEA Law*, Springer, 2016, p. 839-851, at p. 848.

70 — See Alemanno, A., Le principe de précaution en droit communautaire: stratégie de gestion des risques ou risqué d'atteinte au Marché intérieur?, in *Revue du droit de l'Union européenne*, 2001, pp. 917-953, at p. 929.

iv) Burden of proof

72. As already stated, the burden of proof why a measure on the basis of Article 36 TFEU is justified lies on the Member State. This constitutes consistent case-law of the Court.[71] As is put illustratively in authoritative legal writing on the matter, 'the Court has not shied away from applying this rule in cases where human life is at stake'.[72] Importantly, it is applied both in the context of preliminary references and of infringement proceedings. Over the years, the Court has refined this principle to one imposing specific obligations on Member States. It has held that a risk 'must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research'.[73]

73. It now regularly employs the following formula: 'The reasons invoked by a Member State by way of justification must thus be accompanied by an analysis of the appropriateness and proportionality of the measure adopted by that State and by specific evidence substantiating its arguments.'[74]

74. Such proof has not been furnished.

75. The German provisions are therefore not suitable to attaining the objective of public health.

b) Necessity

76. Given that I come to the conclusion that the German provisions are not suitable to attaining the purported aims, I can be more brief at this stage.

77. As DPV points out, prior to the adoption of the provisions in question, the German Government had for some time advocated a system providing for *maximum* instead of *fixed* prices. From the perspective of mail-order pharmacies and the free movement of medicinal products throughout the Union, this is a less restrictive measure, for it allows mail-order pharmacies to compete on price.

78. It is obviously not for the Court to interfere in national political and democratic processes and to prejudge certain political choices. Suffice it to state, however, that, as we have just seen, there are measures that are conceivable and that could be taken instead of a system of fixed prices.

c) Further considerations on proportionality

79. Finally on proportionality, I would like to put my above reasoning in the context of a passage in the first DocMorris judgment. As is well known, the Court, at paragraph 119 of that judgment ruled that 'the need to be able to check effectively and responsibly the authenticity of doctors' prescriptions and to ensure that the medicine is handed over either to the customer himself, or to a person to whom its collection has been entrusted by the customer, is such as to justify a prohibition of mail-order sales'.[75] On the basis of this passage, one might wonder: can one allow such a prohibition while at the same time advocating the unsuitability of a measure which is the 'lesser evil' from the perspective of the internal market?

80. The answer is: 'yes, one can'.

71 — See already judgment in *Denkavit Futtermittel* (251/78, EU:C:1979:252, paragraph 24). See also judgment of 23 December 2015 in *Scotch Whisky Association and Others* (C-333/14, EU:C:2015:845, paragraph 53).

72 — See Enchelmaier, S., in Oliver, P. (ed.), *Oliver on free movement of goods in the European Union*, 5th ed., Hart Publishing, Oxford, 2010, point 8.13.

73 — See judgment of 14 July 1994 in *van der Veldt* (C-17/93, EU:C:1994:299, paragraph 17).

74 — See, by way of example, with respect to protection of health in the context of Article 36 TFEU: judgments of 26 April 2012 in *ANETT* (C-456/10, EU:C:2012:241, paragraph 50) and of 7 June 2007 in *Commission* v *Belgium* (C-254/05, EU:C:2007:319, paragraph 36). See also judgment of 15 November 2007 in *Commission* v *Germany* (C-319/05, EU:C:2007:678, paragraph 88).

75 — Judgment of 11 December 2003 in *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 119).

81. Once a Member State has, of its own volition, decided to allow mail-order sales of prescription-only medicinal products, that measure has to be analysed on its own merits for suitability, coherence and consistency. If this were not the case, a Member State, just because it has allowed for such sales would have *carte blanche*, without any possibility of judicial scrutiny, and foreign economic operators could not benefit from their subjective rights enshrined in the fundamental freedoms, in particular (and *in casu*) from Article 34 TFEU.

V – Conclusion

82. In the light of the foregoing considerations, I propose that the Court answer the questions referred by the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) as follows:

Articles 34 and 36 TFEU preclude a system of fixed prices, laid down by national law, applicable to prescription-only medicinal products such as the one contained in Paragraph 78 of the German Arzneimittelgesetz, in combination with the German Arzneimittelpreisverordnung.