

PLEA: Should online pharmacy services be prohibited?

Peter O'Sullivan

Introduction

Online pharmacy is an area which slowly began to emerge in Europe since the late 1990s.¹ It is marked by an unharmonized divide among Member States (MS), with some willing to embrace such new technologies, while others preserve their independent competences to regulate healthcare matters as they deem appropriate. This approach is arguably in conflict with the European ambition to complete the internal market and remove barriers to intra-Union trade.²

It is obvious *rogue* online pharmacies need to be prohibited, as they abide by no rigorous legal constraints, and oftentimes simply require nothing more than a pro-forma questionnaire³ or card details to authorise their transaction.⁴ This dangerous and potentially fatal criminal activity is under constant global surveillance, and has been augmented by the current COVID-19 pandemic as can be illustrated by INTERPOL's Operation Pangea, which last year shut down 113,020 illicit websites.⁵ This is in contrast to *legitimate* online pharmacies, where a myriad of benefits accrue to patients. These include, convenience and greater choice for disabled patients and those living in remote rural locations, privacy, and more competitive pricing.⁶ It is in fact arguable that by regulating and providing a legitimate online option for patients, the rampant flow of illegal trade may be curtailed. The obverse, according to a 2012 EAASM Report, gives rise to a degree of regulatory arbitrage. Countries enforcing a blanket

¹ Dan Twibell, "Europe takes to the Net" (2000) 20(8) *Pharmaceutical Executive* 116, where he observes that *Pharmacy2U* began its operations in November 1999. Other e-pharmacies mentioned included *Allcures* (UK-established January 2000), and *Pharmaworld* (Swiss - established in 1996).

² See further, Isidora Maletić, *The Law and Policy of Harmonisation in Europe's Internal Market* (Cheltenham, UK and Northampton, MA, USA: Edward Elgar 2013).

³ John Richard Castronova, "Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking" (2006) 27(2) *Journal of Legal Medicine* 207, citing evidence from an investigative journalist who obtained slimming tablets on completion of a questionnaire, where the details of a healthy seven-year-old child were inputted.

⁴ Bethany Lipman, "Prescribing Medicine for Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets" (2013) 50(3) *American Criminal Law Review* 545 at p550.

⁵ INTERPOL Press Release of Operation Pangea XIV, "Criminals continuing to cash in on COVID-19 on and offline" (8 June 2021) < <https://www.interpol.int/News-and-Events/News/2021/Thousands-of-fake-online-pharmacies-shut-down-in-INTERPOL-operation> > accessed 30 January 2022. In contrast to Operation IX in 2016 when a mere 4,932 websites were shut down (see further INTERPOL Press Release of Operation Pangea IX, "Online sale of fake medicines and products targeted in INTERPOL operation" (9 June 2016) < <https://www.interpol.int/en/News-and-Events/News/2016/Online-sale-of-fake-medicines-and-products-targeted-in-INTERPOL-operation> > accessed 6 February 2022.

⁶ Carlisle George, "Internet Pharmacies: Global threat requires a global approach to regulation" (2006) 4(1) *Hertfordshire Law Journal* 12, at p14.

ban on online prescription sales (e.g. Italy) are more prone to greater rogue websites, than markets where such practices are permitted (e.g. Germany).⁷

In this essay the pivotal case law and legislative endeavours thus far will be discussed. It will be argued in favour of a more harmonised approach among EU MS to allow the liberalisation of the *legitimate* online pharmacy market.

Jurisprudence:

The two significant cases, *DocMorris(No1)*⁸ and *DocMorris(No3)*,⁹ both relate to attempts by the well-known Dutch online pharmacy chain to gain greater access to German patients. Given the sheer dearth of any European-wide harmonised legislation on this matter, the Court of Justice of the European Union (CJEU) was constricted in its rulings.¹⁰ It could only resort to primary Treaty provisions of Articles 34 and 36 of the TFEU relating to free movement of goods (i.e. medicinal products) and permissible list of restrictions on such movement respectively.¹¹ The most pertinent derogation listed in Article 36 is the concern for “the protection of health and life of humans”.¹² The rationale of such derogations are described by Weatherill as:

*“striking a balance between the impetus towards free trade and the acceptance that MS retain a strictly defined competence lawfully to restrict free trade in order to protect certain domestic interests.”*¹³

Such a balancing of competing rights was at stake before the CJEU in *DocMorris(No1)*, where it considered whether the German national laws¹⁴ prohibiting the mail-order sale of both prescription and non-prescription medicinal products from

⁷ European Alliance for Access to Safe Medicines (EAASM), *Discounted or Dangerous* (Essex, UK: EAASM 2012) at p19-21.

⁸ Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV* [2003] ECR I-4887; [2005] 1 CMLR 46 [hereinafter “*DocMorris(No 1)*”].

⁹ Case C-148/15 *Deutsche Parkinson Vereinigung eV v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV* EU:C:2016:776; [2017] 2 CMLR 1 [hereinafter “*DocMorris (No 3)*”].

¹⁰ *supra* note 8 (*DocMorris (No 1)*) at paras 64-65. See further Maletić (*supra* note 2) at p8.

¹¹ Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47 [hereinafter “TFEU”] <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT> accessed on 30 January 2022.

¹² *ibid* at Article 36.

¹³ Stephen Weatherill, *Cases and Materials on EU Law* (10th edn, Oxford University Press 2012), at p279.

¹⁴ *Arzneimittelgesetz* (Law on Medicinal Products) [hereinafter “AMG”], *Federal Law Gazette (BGBl.) 1998 I, p.2649* at paras, 43(1) and 73(1). In 1998 the 8th amendment to the AMG was inserted, which provided for this explicit prohibition on the sale of medicines by the post (see wording of legislation at paras 23-27 of *DocMorris(No 1)*).

the Dutch e-pharmacy was compatible with the EU free trade Articles.¹⁵ In following the *Keck* precedent,¹⁶ the Court found that such a prohibition was a measure having equivalent effect to a quantitative restriction (MEQR) under Article 34, as it unfairly impeded foreign pharmacies any access to the German market.¹⁷ In order for this MEQR to be permitted *per* Article 36, it must be *necessary* and *proportionate* to achieve the public health protection objective.¹⁸ The Court held that there was no justification for the curtailment of non-prescription cross-border selling,¹⁹ but due to the stricter control requirements and greater inherent risk of prescription medicines such domestic prohibitions were permissible and within the discretion of each MS to opt to impose such a ban or not.²⁰ Birsch *et al.* note that while some considered the judgment's impact to be minimal because of the varying prescription rules across each MS in Europe, others in fact saw it as a "stepping stone" for a standardisation of these prescription requirements.²¹

As a result of *DocMorris (No I)*, Germany decided to amend its laws in 2003 and embrace a fully functional online pharmacy market allowing both prescription and non-prescription sales.²² This new era of liberalisation was ultimately short-lived due to the economic contentions concerning the equal applicability of German fixed pricing legislation on prescription sales to foreign cross-border pharmacies, which typically offer bonuses and discounts online.²³ This came to the fore in

¹⁵ *supra* note 8 (*DocMorris (No I)*) at para 43, the judgment refers to the old provision, i.e. Article 28 and 30 of EC Treaty, but for the purpose of this essay the new numbering of 34 and 36 TFEU will be used.

¹⁶ Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097 [hereinafter "*Keck*"]. For a recent analysis of the jurisprudence this case has spawned, see Ioannis Lianos, "In Memoriam Keck: the reformation of the EU law on the free movement of goods" (2015) 40(2) *European Law Review* 225.

¹⁷ *supra* note 8 (*DocMorris (No I)*), at para 74.

¹⁸ *ibid* at para 104 citing Case C-215/87 *Schumacher v Hauptzollant* [1989] ECR 617 at para 18; Case C-62/90 *Commission v Germany* [1992] ECR I-2575 at para 11). Note that in the Case C-322/01 *DocMorris (No I)* [2003] ECR I-14893, Opinion of Advocate General Stix-Hackl, where she sets out a three step proportionality test as follows: (1) *appropriateness*; (2) *necessity*; and (3) *reasonableness* (para 108) [hereinafter "Opinion of Advocate General Stix-Hackl"].

¹⁹ *ibid* at para 112-116.

²⁰ *ibid* at para 117. See further, Julia Hörnle, "Online Pharmacies - at the borderline of legality?" (2004) 6(6) *Electronic Business Law* 2.

²¹ Klaus M. Birsch and Claudia E. Haupt, "Information Technology Meets Healthcare: The Present and Future of German and European E-Health Initiatives" (2009) 12 *DePaul Journal of Healthcare Law* 105.

²² *Gesetz zur Modernisierung der gesetzlichen Krankenversicherung* (Law on Modernisation of Statutory Health Insurance Companies) [hereinafter "*GMC*"], *Federal Law Gazette (BGBl.) 2003 I, p.2190*, which by virtue of Article 23(4) inserts para 73(1)(1a), which permits cross-border sale of medicinal products, provided they comply with German law.

²³ *Arzneimittelpreisverordnung* (Regulation on the Prices of Medicines) [hereinafter "*AMPreisV*"], *Federal Law Gazette (BGBl.) 1980 I, p2147 (as amended)* (see para 30 *DocMorris (No I)*).

DocMorris(No3),²⁴ where the Court confirmed that the prescription medicines pricing measures were a *de facto* MEQR. It was stated that price competition is seen as a “more important factor” for an online pharmacy to maintain access to a foreign market than a local premises, who use online sales as an addendum to their “brick and mortar” establishment, and can further distinguish themselves with on-site advice and emergency supplies.²⁵ The German assertion that such price restrictions were *necessary* and *proportionate* under Article 36 to protect against “ruinous price competitions” and safeguard a stable supply of prescription medicinal products was considered “too tenuous.”²⁶ The Court in fact suggested that such online price competition may in fact be conducive to a more consistent supply by providing opportunities for the establishment of pharmacies in more remote areas to avail of higher prices.²⁷

The emerging narrative from the European Courts appears to be one in favour of liberalisation of the online pharmacy market rather than prohibition. The most recent *DocMorris (No3)* case concerning two MS both engaged in online prescription sales is a testament to this. Nordlander and Costesec consider this judgement to provide an “impetus for the creation of a truly EU-wide market for online sales of medicinal products.”²⁸

Legislative Measures:

In 2012 the European Commission following *DocMorris(No1)*, remarked on the “highly fragmented market” that exists currently for online pharmacies.²⁹ This leads to uncertainties for patients regarding the legitimacy of websites and does not prevent them from unconsciously purchasing from *rogue* sites.³⁰

²⁴ *supra* note 9 (*DocMorris (No3)*).

²⁵ *ibid* at para 24. See further *obiter dicta* of Opinion of Advocate General Szpunar describing the uniform pricing arrangement as “*indirect discrimination*”.

²⁶ *ibid* at 34, (citing Case C-421/09 *Humanplasma* [2010] ECR-I12869 at para 34, and Case C-333/14 *Scotch Whiskey* EU:C:2015:845, at para 33). See further *obiter dicta* of Opinion of Advocate General Szpunar.

²⁷ *ibid* at para 38.

²⁸ Kristina Nordlander and Dominique Costesec, “Deutsche Parkinson Vereinigung v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV” (2016) 16(6) *Leading Internet Case Law*, 12 at p13.

²⁹ European Commission, Staff Working Document and Communication, A coherent framework for building trust in the Digital Single Market for e-commerce and online services (SEC(2011) 1641 final) <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011SC1640&from=pt> accessed 6 February 2022.

³⁰ See further, European Alliance for Access to Safe Medicines (EAASM), *The Counterfeiting Superhighway* (Surrey, UK: Medicom Group Ltd 2008) at p27, it found that 62% of prescription-only medicines purchased online were fake or substandard.

The main legislation in the online pharmacy sphere is the enactment of the Falsified Medicines Directive,³¹ which amends the Community Code.³² The Directive requires the establishment of an EU-wide Common logo,³³ which is hyperlinked to the MS's competent authority.³⁴ This logo should assist the public in distinguishing between *legitimate* and *rogue* e-pharmacies. While this Directive is a welcome addition to the landscape, it does not affect the jurisprudence of *DocMorris(No1)* with MS still adopting divergent views. At present there are only six EU countries which permit cross-border prescription sales,³⁵ with the remainder simply permitting non-prescription sales due to the requirements of *DocMorris(No1)*.³⁶ Some even imposing a total prohibition on internet pharmacies.³⁷ Sadeleer³⁸ suggests that such prohibitive measures are rooted in “neo-protectionist policies” which are anti-competitive and are applied indiscriminately to both domestic and imported medicines.³⁹ Despite this disparate landscape, it should still be observed that countries who have opted for such liberalised regimes have flourished without endangering public health. For example, in Germany, *ABDA* reported in 2021 that there were 18,753 “brick and mortar” and 3,036 registered mail-order pharmacies.⁴⁰ Now it should be noted that in Germany's seventeen years of online pharmacy there have been attempts to reinstate a ban, but

³¹ European Parliament and Council Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] OJ L174/74 [hereinafter “Falsified Medicines Directive”].

³² European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67 [hereinafter “Community Code”].

³³ *ibid* note 34 (Falsified Medicines Directive) at Article 85c(1)(b) of Article 1(20), see further detail in the EU technical paper on the logo, available at https://ec.europa.eu/health/system/files/2016-11/logosancointernet_charte_v2_0.pdf accessed 6 February 2022.

³⁴ *ibid* at Article 85c(3).

³⁵ Denmark, Estonia, Finland, Germany, Netherlands, and Sweden. Since 31 January 2021 the UK no longer abides by EU pharmaceutical distance selling laws, see further GPhC, Internet Pharmacy (2021) <<https://www.pharmacyregulation.org/registration/internet-pharmacy>> accessed 6 February 2022.

³⁶ *supra* note 8 (*DocMorris (No 1)*).

³⁷ e.g. Cyprus.

³⁸ Nicolas de Sadeleer, “Restrictions on the Sale of Pharmaceuticals and Medical Devices such as Contact Lenses over the Internet and the Free Movement of Goods” (2012) 19 *European Journal of Health Law* 3.

³⁹ *ibid*.

⁴⁰ *ABDA (Bundesvereinigung Deutscher Apothekerverbände e. V)*, *German Pharmacies-Figures-Data-Facts* (2021), <https://www.abda.de/fileadmin/user_upload/assets/ZDF/ZDF21/ABDA_ZDF_2021_Brosch_english.pdf> accessed 6 February 2022.

none have prevailed so far.⁴¹ It is noted by Hancher and Sauter⁴² that “although MS are not obliged to liberalise, once they have done so this is difficult to turn back” (i.e. *liberalisation breeds liberalisation*).⁴³ This should be instructive to other MS considering opening up their e-pharmacy markets.

Conclusion:

This essay contextualised the many legal challenges *legitimate* online pharmacies face, and the emerging narratives emanating from the ECJ. There is an unfortunate tendency on the part of regulators to err on the side of prohibitive measures as a default position, without properly entertaining an alternative. Consider one of the central tenets of Locke’s philosophy:

*“So that, however it may be mistaken, the end of law is not to abolish or restrain, but to preserve and enlarge freedoms: for in all the states of created beings capable of laws, where there is no law, there is no freedom.”*⁴⁴

This is all the more relevant in the online pharmacy world of today, as digital populations of countries grow older,⁴⁵ are more forward thinking and consequently are more willing to embrace e-pharmacies over “*prohibitive protectionist reflexes*” (per Dr. Fuchs).⁴⁶

⁴¹ Kirsten Sucker-Sket, “Kein Rx-Versandverbot – und nun?” (*Daz.Online*, 28 October 2020) <<https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/10/28/kein-rx-versandverbot-und-nun>> accessed 6 February 2022.

⁴² Leigh Hancher and Wolf Sauter, “One foot in the grave or one step beyond? From Sodemere to Docmorris: the EU’s freedom of establishment case law concerning healthcare” (2009) *Tilburg Law and Economics Centre Discussion Paper* (Available on SSRN https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1429315 accessed 6 February 2022).

⁴³ *ibid* at p4, relying on Case C-141/07 *Commission v Germany* [2008] ECR I-06935, at para 41.

⁴⁴ *John Locke (Two Treatises of Government* (1690) Book 2, Ch. VI § 57).

⁴⁵ Emily Jackson, *Medical Law: text, cases, and materials* (4th edn, Oxford University Press 2016) at p557.

⁴⁶ Hinnerk Feldwisch-Drentrup, “Risikokapital statt Rx-Versandverbot” (*Daz.Online*, 12 June 2017) <https://www.deutsche-apotheker-zeitung.de/news/artikel/2017/06/12/risikokapital-statt-rx-versandverbot> accessed 6 February 2022: “mit offenen Armen und nicht mit protektionistischen Verbotreflexen begegnet werden”.