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Danish perspectives on navigating virtual marketing of pharmaceutical products in the EU

Milla Clara de Place Bjørn*

This article explores the regulations governing online pharmaceutical advertising in Europe and demonstrates some of the challenges medical companies may encounter when engaging in online activities. With multi-jurisdictional reach, uncertainty arises regarding which rules to follow and what they require when pharmaceutical products are advertised online. The article discusses the primary legislative framework regulating the marketing of medicines in the EU in Directive 2001/83/EC (The Community Code Directive). Further, it deals with Directive 2000/31/EC (The eCommerce Directive) and its ambiguous formulation of the country-of-origin principle in Article 3. The question arises as to the true intent of Article 3: Is the country-of-origin principle designed to always enforce the law of the country of origin, or is it intended merely to eliminate any regulations that could disadvantage the service provider compared to the legislation in the country where the provider is established? Is the primary objective behind Article 3 solely to highlight the freedoms within the EU without stating explicit rules, or does it extend beyond primary law? This article concludes that the eCommerce Directive applies to the virtual marketing of medicinal products in the EU, even though the Community Code Directive is *lex specialis* and *lex posterior*. Further, the article finds that the country-of-origin principle in the eCommerce Directive must be understood as internationally mandatory, prevailing ordinary rules of conflict in EU legislation and national provisions.

* Law student at the Faculty of Law, University of Copenhagen.

1. Introduction

Pharmaceutical companies established in the EU must be aware of the risk of being subject to the laws of another State's regulation when they communicate online. Due to the borderless nature of cyberspace, these service providers might find themselves subject to many laws – an uncertainty that could discourage business.[1] Through compliance programs and standard operating procedures, globally oriented companies can ensure that they do not inadvertently act in violation of the rules in the other Member States[2]. These strategies lead to enormous costs for global medical companies and even restrictions on the freedom to provide services and goods within the internal market.[3] This is especially critical to small- and medium-sized corporations whose willingness to dare internet commerce is even more hindered by this legal uncertainty due to their inability to pay significant sums of money in advance to research different legislative possibilities.[4]

This issue was exemplified in a legal dispute between a smaller international pharmaceutical company established in Denmark and a German competitor.[5] The German company claimed injunctive relief in Germany because of statements made on the Danish company's online website. The German pharmaceutical company claimed that the various statements on the website were unlawful according to German public law. The German party argued that according to Article 6 in the Rome II Regulation German law was applicable in the dispute. Article 6 prescribes that the law applicable to non-contractual obligations arising from unfair competitive behaviour is the law of the country in whose territory the competitive relation or collective interests of consumers have been or are likely to be effective. Thus, the German party sought injunctive relief, contending that Article 6 of the Rome II Regulation warranted the application of German law over statements on the Danish party's website.

The Danish company argued against this claim and stated that if Article 6 were to apply, any pharmaceutical company established in the EU would have to carry

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[1] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[2] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, p. 97 (2021).

[3] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[4] *Id.* p. 3.

[5] Hanseatic Higher Regional Court. Ref.: 3 U 91/21 312 O. 115/20 LG Hamburg. 02.06.2022.

out compliance reviews based on legislation in all 27 EU Member States[6]. This would be burdensome and might contradict the free movement of information society services and the objectives of various EU directives. As evident by Article 27 of the Rome II Regulation, the Regulation is not intended to prejudice the application of provisions of Community law which lay down conflict of law rules[7] to non-contractual obligations concerning particular matters. The Danish pharmaceutical company further argued that Recital 35 in the Rome II Regulation explicitly states that the application of provisions in the Regulation should not restrict the free movement of goods and services as regulated by Community instruments, such as the eCommerce Directive. The eCommerce Directive introduces a significant modification to the principle of applicable law in Article 6 of the Rome II Regulation by establishing *the country-of-origin principle*.[8] According to this principle, any provider of an information society service is subject to the law of the Member State in which it is established and not the laws of the EU Member States where its services are provided. Applying this principle in the dispute between the pharmaceutical companies would make Danish law applicable. As a result, the German competitor would be unable to invoke a breach of its national laws.

The case was ultimately brought before the German Appeal Court[9], which decided to lift the preliminary injunction in favour of the Danish pharmaceutical company. However, the court did not answer whether German law was applicable in the dispute. Instead, it simply stated that the international jurisdiction of

[6] Hanseatic Higher Regional Court. Ref.: 3 U 91/21 312 O. 115/20 LG Hamburg. 02.06.2022. Paragraph 5.

[7] Conflict of law rules: sometimes used interchangeably with "choice of laws rules" or "private international law rules". Conflict of law is a set of rules used to select which jurisdiction's laws to apply in a lawsuit. Conflict of law questions most frequently arise in lawsuits in the federal courts that are based on diversity jurisdiction, where the plaintiff and defendant are from different states. In these lawsuits, the courts are often confronted with the question of which jurisdiction's laws should apply. The choice of law rules establishes a method by which the courts can select the appropriate law.

[8] The country-of-origin principle is found in Article 3 of Directive 2000/31/EC and will be dealt with later in this article.

[9] Hanseatic Higher Regional Court. Ref.: 3 U 91/21 312 O. 115/20 LG Hamburg. 02.06.2022.

German courts under Article 7(2)[10] of the EU Regulation no. 1215/2012[11] could not be invoked. Thus, the German authorities lacked international competence to adjudicate the case. At the time of writing[12], the case is on hold without definitive answers concerning whether the country-of-origin principle applies when pharmaceutical companies market their products online. The judgment clearly shows that there is a gap in the understanding of which legislation is applicable when medicinal products are marketed online. As of today[13], there are no EU judgments concerning the interpretation of the country-of-origin principle in the eCommerce Directive.

Digital communication, including online advertising, is the primary tool pharmaceutical companies use to communicate with the purchasers of medical products. Finding a set of rules applicable to online communication is difficult since the internet constitutes a global system without national frontiers[14]. As this judgment illustrates, the ubiquity of information on the internet poses problems for these companies, leaving questions concerning the country-of-origin principle unanswered.

With multi-jurisdictional reach, uncertainty arises regarding which rules to follow and what they require when pharmaceutical products are advertised online.[15] The question arises as to the true nature of the rule in Article 3 of the e-Commerce Directive; Is the intention behind the country-of-origin principle always to make the law of the country of origin applicable, or is the intention instead solely to put a stop to any rules that could be considered disadvantageous to the service provider in comparison with the law from the State where the provider is established? Is the primary objective behind Article 3 solely to point

[10] Article 7: "A person domiciled in a Member State may be sued in another Member State [...]

(2) in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred or may occur;"

[11] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

[12] November 30, 2023.

[13] *Id.*

[14] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[15] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, p. 92 (2021).

out the freedoms of the EU without stating any rules itself, or does it go further than primary law?

The following Section 2 will discuss the legal framework governing virtual marketing of pharmaceutical products, focusing on defining key terms and principles such as *medicinal products*, *pharmaceutical advertising*, and *the country-of-origin principle*. Section 4 utilises this legal framework and scholarly contributions on the topic at hand to identify, analyse, and synthesise the content of the law. Section 4 will evaluate the findings from the previous sections. Section 5 will conclude that the eCommerce Directive applies to the digital advertising of medicinal products in the EU and will establish that the country-of-origin principle in the eCommerce Directive must be understood as internationally mandatory, prevailing ordinary rules of conflict in EU legislation and national provisions.

2. Legal Framework and Definitions

The virtual marketing of pharmaceutical products in the European Union is regulated by key legislative frameworks. Directive 2001/83/EC[16] (the Community Code Directive) provides the harmonised basis for the pharmaceutical legislation across the EU Member States, while Directive 2000/31/EC[17] (the eCommerce Directive) provides the regulatory framework for information society services provided on the internet.

In the year 2022, the European Commission enacted two significant regulations: 2022/9257EC[18] (The Digital Markets Act – 'DMA') and 2022/2065/EC[19] (The Digital Services Act – 'DSA'). The critical question arises as to whether these two acts provide any insights into the interpretation of the

[16] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to pharmaceutical products for human use.

[17] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.

[18] REGULATION (EU) 2022/1925 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act).

[19] REGULATION (EU) 2022/2065 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act)

country-of-origin principle outlined in the eCommerce Directive. While the DMA and DSA do interact with the eCommerce Directive and complement it in various aspects, these two distinctive pieces of legislation do not replace or override the country-of-origin principle. Instead, they introduce targeted and updated rules for specific digital platforms and services while preserving the core principles of the Directive. Thus, while the DMA and DSA both interact with the eCommerce Directive, they do not provide clarity on the interpretation of the country-of-origin principle. The forthcoming analysis will consequently solely focus on the interaction between the Community Code Directive and the eCommerce Directive with the aim to discern the correct interpretation of the country-of-origin principle when pharmaceutical products are marketed online.

The DMA primarily addresses the conduct of large online platforms with significant market power, referred to as 'gatekeepers'[20]. While it is conceivable that certain large medicinal companies may fall under the definition of gatekeepers within the scope of the DMA[21], the act solely introduces additional obligations concerning e.g., data sharing[22], interoperability[23], and non-discrimination rules[24]. Similarly, the DSA does not replace or alter the country-of-origin principle but supplement the eCommerce Directive with new obligations related to content

[20] 2022/9257/EC Article 1(2):

> This Regulation shall apply to core platform services provided or offered by gatekeepers to business users established in the Union or end users established or located in the Union, irrespective of the place of establishment or residence of the gatekeepers and irrespective of the law otherwise applicable to the provision of service.

[21] Cf. 2022/9257/EC Article 3, cf. Article 2(1).

Article 3(1):

> "An undertaking shall be designated as a gatekeeper if:
>
> (a) it has a significant impact on the internal market;
>
> (b) it provides a core platform service which is an important gateway for business users to reach end users; and
>
> (c) it enjoys an entrenched and durable position, in its operations, or it is foreseeable that it will enjoy such a position in the near future."

[22] See 2022/9257/EC Article 5(2).

[23] See e.g., 2022/9257/EC Article 7 and pr. 64.

[24] See e.g., 2022/9257/EC Article 6(5) and Article 6(11-12), see also pr. 61 and 105.

moderation[25], transparency[26], and user rights[27]. Furthermore, Article 2(3)[28] in the DSA explicitly states that the regulation does not affect the application of the eCommerce Directive. This is cemented in Recital 9 in the DSA, stating that the act does not preclude the application of the country-of-origin principle in the eCommerce Directive.[29]

2.1. The Community Code Directive (Directive 2001/83/EC)

The Community Code Directive provides the regulatory framework for pharmaceutical products authorised by the Member States and codifies various medicinal products to enable patients' access to safe treatments within a fair common market.[30] The directive establishes a dual marketing authorisation system for pharmaceutical products in the EU. Although there are four different routes to obtain a marketing authorization (MA), this system broadly categorises them into two main paths: authorisation by competent national authorities of Member States or centralised authorisation by the European Commission based on advice from the European Medicines Agency (EMA).

2.1.1. Defining Medicinal Products and advertising

'Medicinal products' are defined in the Community Code Directive's Article 1 as either[31]

(i) a substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(ii) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring,

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[25] See e.g., 2022/2065/EC Article 14(1) and Article 15 (1). See also pr. 66.

[26] See e.g., 2022/2065/EC Article 15 and 24. See also pr. 40. See also pr. 49.

[27] See e.g., 2022/2065/EC Article 1(1) and Article 14 (4), pr. 47.

[28] 2022/2065/EC Article 2(3): "This Regulation shall not affect the application of Directive 2000/31/EC".

[29] Recital 9:"(...) This should not preclude the possibility of applying national legislation applicable to providers of intermediary services, in compliance with Union law, including Directive 2000/3/EC, in particular its Article 3, where the provisions of national law pursue other legitimate public interest objectives than those pursued by this Regulation."

[30] C. Mellein and J. Schwarze, *Targeted Review of EU Pharmaceutical Legislation – The Community Code on Medicinal Products Needs to Remain a Directive*, European Pharmaceutical Law Review, vol. 5, no.1, 4-20 (2021).

[31] Directive 2001/83/EC, Article 1, litra a-b.

> correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis.

'Drug advertising' is defined in the Community Code Directive's Article 86(1) as any form of door-to-door information, canvassing activity or motivation aiming at the prescription, supply, sale, or use of medicinal products. Advertising of a medicinal product includes, among other activities: *(i)* advertising of medical products addressed to the general public, *(ii)* visits paid by sales representatives selling medicinal products to persons authorised to write prescriptions, *(iii)* supply and samples and *(iv)* sponsorship to scientific congresses with the participation of persons authorised to prescribe or to supply medicinal products, and, in particular, converting travelling and accommodation expenses connected with such congresses.[32] The definition of pharmaceutical advertising presented in the Community Code Directive refers to all medicines, both prescription-only and non-prescription pharmaceutical products. However, the rules governing what is allowed in advertising differ depending on whether the medicine is prescription-only or over-the-counter.

The term 'advertising' is defined differently across jurisdictions, and some states have introduced far-reaching rules on direct-to-consumer advertisements for prescription medicines[33]. Thus, the applicable rules on pharmaceutical advertising must be scrutinised in each instance. In Denmark, the Ethical Committee for the Pharmaceutical Industry (ENLI), the Danish Medicines Agency and Danish courts determine on a case-by-case basis whether disseminating information about a pharmaceutical product constitutes advertising of such products[34]. In case C-421/07, *Damgaard*[35], the European Court of Justice (ECJ) delineated the scope of the advertising concept within the field of pharmaceutical products. In the judgment, the ECJ held that the definition of advertising in Article 86(1) is to be construed broadly, including disseminating information about a pharmaceutical

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[32] Article 86(1), Directive 2001/83/EC.

[33] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, 92 – 97 (2021).

[34] K. L. Nilsson and C. M. Svane, *A Challenge to the Country of Origin-Principle. Website Marketing, The Saga Continues,* European food and feed law review, vol. 7, no. 4, pp. 201-207 (2012).

[35] Case C-421/07: Judgment of the Court (Second Chamber) of 2 April 2009 (reference for a preliminary ruling from the Vestre Landsret - Denmark)) - Criminal proceedings against Frede Damgaard.

product even by a third party acting independently on his initiative for non-commercial purposes.[36]

Even though the definition of pharmaceutical advertising is broad, Article 86(2) of the Community Code Directive states some activities that are not covered by the term, including *(i)* labelling packages and the accompanying leaflets, *(ii)* correspondence accompanied by a material of a non-promotional character essential to provide an answer for a specific enquiry concerning a particular medicinal product, *(iii)* factual and abounding information announcements and reference material relating to, e.g., package changes, warnings against adverse reaction as part of general drug precautions, amongst other things.[37]

2.2. The eCommerce Directive (Directive 2001/31/EC)

Directive 2000/31/EC[38] establishes a general legal framework for information society services covering a wide range of economic activities which takes place online[39]. The objective is to contribute to the development of electronic commerce by removing obstacles such as diverging national rules and legal uncertainty as to which national laws apply, thus creating a legal framework to ensure the free movement of information society services.[40]

With the goal of the eCommerce Directive in mind, it becomes evident that such promotion of electronic commerce will be best served by providing a territory within the European Community where the information society service providers do not have to expend time or money determining what law might apply and what requirement then need to be respected.[41] The internal market is especially critical

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[36] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021).

[37] A. Czerw and U. Religioni, *Legislative and non-legislative regulations concerning Rx drug advertisement in the European Union and the United States--comparative analysis*, Acta Pol Pharm, vol 69, no. 4, pp. 779-87 (2012).

[38] Directive 2000/31/EC of the European Parliament and of the Council of 7 June 2000 on certain legal aspects of information society services, in particular electronic commerce

[39] C. Ionescu-Dima, *Legal Challenges Regarding Telemedicine Services in the European Union, eHealth: Legal, Ethical and Governance Challenges*, Springer, Berlin, Heidelberg, p. 117 (2012).

[40] Directive 2000/31/EC, recitals 2,5 and 6.

[41] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. 2-3 (2005).

to small- and medium-sized corporations whose willingness to dare internet commerce is even more hindered by this legal uncertainty due to their inability to pay significant sums of money in advance to research different legislative possibilities.[42]

Specific issues are altogether excluded from the field of application of the eCommerce Directive. Article 1(5) clearly states that the Directive does not apply to taxation, cartel law, gambling activities etc. In addition, the Directive does not apply to questions relating to information society services covered by the Directives on protecting personal data and privacy in the telecommunications sector[43].

2.2.1. Defining Information Society Services

The eCommerce Directive applies to 'information society services' within the coordinated field. Information society services are defined in Article 1(2) of the eCommerce Directive, as amended by Article 2(a) of Directive 98/48/EC.[44] Information society services are described as a "service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services", excluding, for instance, broadcasting services[45]. It comprises a great variety of online economic activities, e.g., the sale of goods or services, online newspapers, marketing or publicity services, auction markets or free lotteries.[46] Information society services are interpreted broadly, and as we will see in Section 3.1., the advertising of pharmaceutical products constitutes an information society service within the coordinated field. The eCommerce Directive does not apply to information society services where the service provider is established outside the EU or information society services that are aimed only at third countries but where the service provider is established in the EU area.

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[42] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 3 (2005).

[43] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, p. 197 (2004).

[44] Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

[45] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021).

[46] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

2.2.2. Defining the Country-of-Origin Principle

'The country-of-origin principle' found in the eCommerce Directive's Article 3 alters the principle of territorial sovereignty by establishing that the law of the state where the service provider is established shall apply to the requirements that the service provider has to comply with.[47] According to the country-of-origin principle, a provider of society services is subject to domestic control and, thus, the law of the EU Member State in which it is established. The provider is consequently not subject to the laws of the state where the services are provided, also referred to as the 'forum state'. The country-of-origin principle is not an exception to the sovereign concept but seeks to harmonise applicable law.[48]

According to Article 3, paragraphs 1 and 2 of the eCommerce Directive, the country-of-origin principle consists of two central elements[49]:

1. Each Member State shall ensure that information society services provided by a service provider established on its territory comply with the national provisions applicable in the Member State in question, which fall within the coordinated field.
2. Member States may not restrict the freedom to provide information society services from another Member State for reasons falling within the coordinated field.

While the first paragraph in Article 3 enounces the country-of-origin principle, the second paragraph correlatively declares the principle of the free movement of information society services. With this statement, the Directive seeks to set up a system of mutual recognition within the European Community. The Member State where the service is established must thus ensure that the provider respects all legal rules of that State, which constitutes sufficient control.[50] Consequently, other Member States usually cannot impose other requirements or respect further rules when the service provider crosses the border but rather trust other countries' legislation and control to protect general interests.

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[47] *Id.*

[48] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021).

[49] Article 3(3) makes certain exceptions from article 3(1-2) which are listed in the annex of Directive 2000/31/EC.

[50] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

The technique of exclusive control by the Member State in which the service provider is established, in addition to mutual recognition of this control by the other Member States, has been used by secondary Community law in other directives.[51] Nevertheless, the country-of-origin principle in the eCommerce Directive goes even further since it not only applies where questions of public law, namely requirements of access to the market, are at stake. Instead, the principle covers all services of the information society in all areas of law falling within the coordinated field, meaning that public, private and penal laws are concerned.[52]

Article 3(4)(a) allows Member States to set up more restrictive rules concerning information society services if those are justified as necessary to preserve some vital interests in the forum country, including 'ordre public', protecting national health, public security, or protection of consumers.[53] These measures must only be invoked when a service provider hurts any of the interests mentioned above or poses a threat to do so. In addition, these measures must be proportionate, cf. Article 3(4)(a)(iii). If a Member State invokes one of the justifications listed in Article 3(4)(a), it must notify the Commission and the country of origin about its intentions, cf. Article 3(4)(b).

Further, the Member State must preliminarily ask the country of origin to take those measures, and it may only proceed if the country did not adequately act on the preliminary call or ultimately failed to do so. Derogation from this procedure is only possible in urgent situations, and even then, notification to the Commission and the country of origin must be made, cf. Article 3(6).

Recent developments have clarified the extend of derogation from the country-of-origin principle in Article 3(4) through the judgment in case C-376/22, *Google Ireland Limited and Others v Kommunikationsbehörde Austria (Komm*

[51] Examples include Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, COM(2011)0367: GREEN PAPER Modernising the Professional Qualifications Directive and Directive 2001/40/EC of 28 May 2001 on the mutual recognition of decisions on the expulsion of third country nationals.

[52] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[53] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

Austria).[54] In this judgment, the Court ruled that general and abstract measures aimed at a category of information society services described in general terms and applying without distinction to any provider of that category of services do not fall within the concept of measures against a 'given information society service' within the meaning of Article 3(4).[55]

Instead, any restrictive measures must be specific to individual services, thus ensuring that Member States cannot impose broad, blanket restrictions on categories of information society services form other Member States under Article 3(4). By limiting the scope of Article 3(4) to specific, individualised measures, the ruling supports the principle of mutual recognition and the free movement of information society services within the EU.

In conclusion, these narrowly circumscribed possibilities to deviate from the country-of-origin principle in the coordinated field show very well the force of this principle and its importance for the EU legislator and the ECJ.

2.2.3. Defining Choice of Law Rules

'Choice of law rules' govern the legal relationships of private law nature featuring an international aspect. The term is sometimes used interchangeably with 'conflict of laws rules' or 'private international law rules'. Choice of law questions frequently arise in national lawsuits based on diversity in jurisdiction, where the plaintiff and defendant are from different states. In these lawsuits, the courts are often confronted with the question of which jurisdiction's laws should apply.[56] The choice of law rules establishes a method by which the courts can select the appropriate law.

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[54] Judgment of the Court (Second Chamber) of 9 November 2023, Google Ireland Limited and Others v Kommunikationsbehörde Austria (Komm Austria), Case C-376/22, ECLI:EU:C:2023:835. The case concerned Google Ireland Limited, Meta Platforms Ireland Limited and Tik Tok Technology Limited, who challenged the Austrian Federal Law on measures for the protection of users of communication platforms. This law imposed obligations on service providers to monitor and notify allegedly unlawful content, which these companies argued was incompatible with the country-of-origin principle established by Directive 2000/31/EC.

[55] Case C-376/22, para 60.

[56] Lawshelf, Erie Doctrine and Choice of Law – Choice of Law, https://lawshelf.com/coursewarecontentview/erie-doctrine-and-choice-of-law-choice-of-law (accessed Nov. 20, 2022)

3. Analysis and Discussions[57]

Most authors agree that the country-of-origin principle applies to the online marketing of medicines.[58] Both the Community Code Directive and the eCommerce Directive are applicable when examining which State has jurisdiction over the matter at hand. The academic debate concerning the qualification of the country-of-origin principle is, on the contrary, huge. According to most authors, it does not seem possible to derive general rules of conflict from the primary law's definition hereof.[59]

Many, including e-service providers, advocate that Article 3 in the eCommerce Directive should be understood as a new choice of law rule designating the law of the place of establishment of the service provider as applicable.[60] Thus, one interpretation of Article 3 suggests that the country-of-origin principle establishes a rule of conflict that supersedes national or EU choice of law rules[61]. However, Article 1(4) of the eCommerce Directive explicitly states that no additional rules on private international law are created.[62]

The Directive is not a work of absolute clarity, and questions arise, especially regarding Article 1(4). The relationship between the country-of-origin principle and the conflict of the laws, in general, seems to stem from the qualification to be given.[63] The importance of the doctrine becomes evident; thus, an evaluation is

[57] The forthcoming evaluation extensively draws on references from N. Höning and M. Hellner, acknowledged as the most authoritative sources presently available. The author is mindful of the fact that these sources are more than 20 years old, and it is acknowledged that this temporal distance may impose limitations on the relevance and currency of information.

[58] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021). Höning, *supra* note 3. M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[59] *Id.*

[60] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 17, note 78 (2005).

[61] Private international law: see note 9.

[62] Article 1(4): "This directive does not establish additional rules on private international law, nor does it deal with the jurisdiction of the Courts."

[63] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 16 (2005).

necessary. Three interpretations of the country-of-origin principle in the eCommerce Directive seem to prevail in the academic debate:

(i) The country-of-origin principle establishes a new choice of law rule.[64]

(ii) The country-of-origin principle sets out certain limitations to applying the designated choice of law rule.[65]

(iii) The country-of-origin principle makes the law in the service provider's country mandatory and thus applicable irrespective of which Member State has jurisdiction.[66]

3.1. Is the eCommerce Directive applicable to online advertising of medicines?

As stated above, the eCommerce Directive regulates e-commerce within the coordinated field. However, it does not explicitly state that it applies to pharmaceutical products. To determine if the eCommerce Directive applies, an analysis should be made as to whether virtual marketing of medicines falls within the definition of an information society service under the coordinated field. In judgment C-161/10, *Oliver Martinez*[67], the ECJ explicitly stated that the eCommerce Directive not solely applies to services but also to online sales of pharmaceutical products, which entails online marketing of such products.[68] Thus, prevailing case law in the EU prescribes that virtual marketing of medicines falls within the scope of the eCommerce Directive.

3.2. Does the Community Code Directive exclude the application of the eCommerce Directive?

In the C-347/05, *Gintec*[69], the ECJ established that the Community Code Directive brings complete harmonisation in the field of medicinal products and

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[64] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 17, note 78 (2005).

[65] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 21, note 102 (2005).

[66] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 26, note 130 (2005).

[67] C-161/10, Oliver Martinez, and Robert Martinez v. MGN Limited, paras 31-32 .

[68] *Id.*

[69] Judgment of the Court (Second Chamber) of 8 November 2007. Gintec International Import-Export GmbH v Verband Sozialer Wettbewerb eV. Case C-374/05.

that it expressly lists the cases in which Member States are authorised to adopt provisions departing from the rules in the Directive. Meanwhile, although the Community Code Directive harmonises the rules on pharmaceutical advertising, it only governs some aspects of it.

The Community Code Directive does not, for instance, address if a product that undergoes clinical development may or will constitute a medicinal product within the meaning of the Directive. It is up to the authorities and courts of each Member State to assess what constitutes a medicinal product in such situations. Further, the Community Code Directive prohibits the advertising of prescription medicines to all persons other than healthcare professionals.[70] However, the Community Code Directive does not further clarify when a person is qualified to be a healthcare professional, and Member States may include a definition hereof in their national legislation. For example, the Danish law explicitly defines healthcare professionals in The Danish Medicines Act (Lægemiddelloven) § 66, stk. 2.[71]

While Articles 86-100 in the Community Code Directive harmonise the advertising of particular medicinal products, they do not govern the choice of law rules concerning online activities. Thus, online pharmaceutical advertising is not harmonised under the Community Code Directive. It will be shown in the later sections of this article that the eCommerce Directive governs the digital marketing of medicines in the EU. Case law has verified that online sales services relating to medicinal products constitute an information society service within the meaning of Article 2(h) ('the coordinated field') in the eCommerce Directive, see *A v Daniel B and Others*[72].

Ultimately, although the Community Code Directive is *lex specialis* and *lex posteriori* to the eCommerce Directive, it does not render the eCommerce Directive inapplicable for the virtual marketing of medicines. As long as virtual marketing falls within the scope of the eCommerce Directive and is not explicitly regulated by the Community Code Directive, its provisions are applicable.

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[70] Article 88 Directive 2001/83/EC.

[71] Lovbekendtgørelse 2018-01-16 nr. 99 om lægemidler.

[72] Judgment of the Court (Third Chamber) of 1 October 2020. A v Daniel B and Others. Case C-649/18, para 33: "It follows that an online sales service relating to medicinal products, such as that at issue in the main proceedings, may constitute an information society service, within the meaning of Article 2(a) of Directive 2000/31 and, therefore, may be within the scope of that directive as regards the requirements applicable to that service, which come within the 'coordinated field', within the meaning of Article 2(h) of that directive."

3.3. What is the scope of the country-of-origin principle?

As we saw earlier, the eCommerce Directive applies to the virtual marketing of medicines. It is thus relevant to analyse the scope of the country-of-origin principle laid down in the Directive's Article 3.

A question that has caused quite a debate is whether the eCommerce Directive has established a particular choice of law rule for electronic commerce services.[73] The issue lies in the fact that the Directive, on the one hand, established what to many appears to be a particular choice of law rule for electronic commerce, designating the law of the service provider as applicable, but on the other hand, explicitly refutes that it does so.[74] Academics, governments, businesses, and practitioner's organisations have for years insisted that there is an urgent need for the Commission to clarify the relationship between the country-of-origin principle set down in internal market instruments and rules on the conflict of laws.[75]

It has been submitted that Article 3(1) of the eCommerce Directive is a choice of law rule designating the law of the country applicable. However, if read this way, that would not rhyme well with Article 1(4) of the Directive, which stipulates that:

> "This Directive does not establish additional rules on private international law nor does it deal with the jurisdiction of Courts."

If the eCommerce Directive gives birth to a choice of law rule while it purports not to create any additional rules of private international law, that would, to put it mildly, appear to be an issue.[76] It would be a problem on a theoretical level relating to the internal coherence of the law since provisions should not contradict themselves. Furthermore, there is the practical problem concerning which law should apply – that of the country of origin or that stipulated by national or EU

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[73] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021). N Höning, *supra* note 3. M. M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[74] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 194 (2004).

[75] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[76] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 198 (2004).

choice of law rules.[77] The three main interpretations of Article 3 will in the forthcoming sections be clarified further.

3.3.1. The country-of-origin principle as a new conflictual rule

Despite the wording in Article 1(4) in the eCommerce Directive, many authors believe that the country-of-origin principle creates a new rule of conflict[78]. It bypasses ordinary conflict rules, applying only the substantive law of the provider's establishment country. The free movement of services reveals collisions of two different legislations: the country of origin and the country of destination, requiring conflictual rules for resolution.[79] The country-of-origin principle prevails over the ordinary rules of private international law, ensuring the Directive's goal of allowing e-commerce users free access to the common market.[80]

Recital 22 of the eCommerce Directive, according to which 'information society services should in principle be subject to the law of the Member State in which the service provider is established', indicates that a choice of law rule is intended, irrespective of the fact that Article 1(4) of the Directive makes the opposite interpretation[81]. Furthermore, the Commission's visions are said to be unmistakably acknowledged since the main goal of the Directive, which is the establishment of a free circulation of internet services between Member States, is best served from the point of view of the provider's interest.[82]

Understanding Article 3 of the Directive as a conflictual rule derives from the political reasoning that applying the law of the forum State would be burdensome for service providers who would have to know and respect a multitude of different national legislations.[83] Requiring compliance with the laws of all Member States poses significant costs for online pharmaceutical providers. This is especially important for small- or medium-sized corporations who are even less willing to

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[77] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[78] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 17, note 78 (2005).

[79] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[80] Id.

[81] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 202-203 (2004).

[82] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[83] Id.

promote activities at a high price and less interested in taking that risk than big corporations with money and expanded multi-state relationships.[84]

While the eCommerce Directive disclaims qualification as private international law, this disclaimer does not alter the conflictual nature of the country-of-origin principle[85]. Analogously, the country-of-origin principle is likened to Magritte's painting of a pipe, and underneath it is written: "*This is not a pipe*"[86]. This perspective also holds true for contract law's exclusion or penalty clauses. In assessing a court's authority over a specific clause, it interprets its substance rather than relying on what the parties have called it.[87]

The qualification of the principle as a rule of conflict is also supported by the exemptions to Article 3 in the Annex of the eCommerce Directive. For instance, the country-of-origin principle does not apply to the choice of law in contract law. This exemption excludes parts of private international law and would be superfluous if the principle itself were not a choice of law rule.[88] These exemptions prove that the principle regulates the whole system, especially the conflict of law.

In a 2018 non-public decision, the Danish Medicines Agency (Lægemiddelstyrelsen) seemingly recognises the country-of-origin principle as a choice of law rule. [89] The judgment concerned a Spanish pharmaceutical company's marketing of its products through a Danish website. Some products could not legally be sold in Denmark, but the Agency determined that, according to the country-of-origin principle, the company was subject to Spanish law and exempt from Danish advertising regulations.[90] This implies a direct Danish stance on the choice of law. Additionally, the Danish law implementing the eCommerce

[84] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 18 (2005).

[85] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[86] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. p. 16 (2005).

[87] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. 19 (2005).

[88] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[89] Dræbye Gantzhorn, M., & Bjerrum, E. *Pharmaceutical Advertising in Digital Media: A Danish Perspective*. European Pharmaceutical Law Review Volume 5, Issue 2, pp. 92 – 97 (2021).

[90] *Id.*

Directive[91] expressly exempts service providers from other EU countries offering information society services from complying with Danish rules in the coordinated area, even if targeting Denmark.

Understanding the country-of-origin principle solely as referencing the law of origin simplifies its application. This approach eliminates the need for ordinary conflict of law rules, streamlining the process for judges who can directly apply the law of the service provider's country of origin.[92] The advantage for service providers lies in increased foreseeability and jurisdictional security, alleviating the burden of learning and adhering to other Member States' legislation. This might create possibilities for many more corporations that otherwise would not have taken their chances to engage in internet commerce.[93]

3.3.2. The corrective functioning of the country-of-origin principle

Other authors give the wording in Article 1(4) in the eCommerce Directive more emphasis and consequently do not view Article 3(1-2) as norms of conflict.[94] Although the private international law rules can be influenced by Community law, one cannot conclude that, in general, they can be considered rules of conflict.[95] These rules should be seen as corrective to ensure that the internal market is not harmed.

Ordinary rules of private international law still need to apply, and the country-of-origin principle solely plays a partial role when determining which state's law is applicable. Determining the jurisdictional reach of each Member State should follow a two-step test: First, the ordinary rules of the conflict determine which national law can be applied to a particular question of law. An example of ordinary choice of law rules can be found in Article 6 of the Rome II Regulation. Second, after finding the law applicable to that situation, it must be determined if applying it would somehow restrict the provider´s services in a way that its national law would not[96]. If this is the case, the foreign national law must be avoided or

[91] Lovbekendtgørelse 2018-01-16 nr. 99 om lægemidler.

[92] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[93] *Id.*

[94] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 21, note 102 (2005).

[95] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 22 (2005).

[96] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

modified to benefit the provider's national jurisdiction so that free circulation can be guaranteed.[97]

This interpretation of the country-of-origin principle is based on several considerations. Certain authors have considered the nature of the provisions found in primary EU law. The country-of-origin principle in the eCommerce Directive is understood as a concretion of Articles 28 and 49 in the EU Treaty and cannot go beyond them[98]. Accordingly, national rules on jurisdiction and applicable law are utilised. Still, the law they designate is only applied to the extent that it does not restrict the freedom to provide information society services for the state of origin. Concerning the free movement of services, it has been clearly stated that even legislation from the service provider's home country can be considered an obstacle[99]. Comparison between jurisdictions is needed in all situations – whether in front of a foreign or national jurisdiction[100].

A strong argument that Article 3 is not a choice of law rule is found in the structure of the eCommerce Directive. Article 1(4) first defines the Directive's scope and objective, which would indicate that Article 1(4) is intended to limit the meaning of the country-of-origin principle in Article 3 – depriving it of any possible choice of law character. Further, if the Community legislator intended to create a choice of law rule, it would have done so explicitly, as in the Insurance Directives.[101] In addition, the title of Article 3 is not "Country-of-Origin Principle" but "Internal Market". Article 3 does not mention the law that ought to be applied, but only that the Member States should not restrict the services in the coordinated field.[102]

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[97] Id.

[98] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[99] ECJ regarding article 49 CE.

[100] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[101] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[102] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

Article 3 of the eCommerce Directive establishes a 'most favourable law principle'.[103] If the forum State has stricter rules than the country of origin, the stricter rules may not apply. Comprehending the country-of-origin principle as a corrective measure amounts comparison of legislation to find which law is most beneficial for the provider. A judge in the destination country must decide upon which legislation to apply by following the two-step test, determining the applicable law, and ensuring it is not more restrictive than the provider's country of establishment. This ensures that the less restrictive law prevails.[104] Simultaneously, the judge in the country of origin must ensure compliance with national provisions for information society services.[105]

This interpretation of the eCommerce Directive counteracts the race to the bottom issue.[106] Since the laws in the country of origin solely apply if they are favorable, it does not matter where the service provider is established. On the other hand, service providers in intra-state relations will not benefit from the favorable application of the less restrictive law.[107] They would have to compete with providers from the other Member States on the same market under more unfavorable legal conditions since they must comply with the stricter national legislation.

3.3.3. Internationally mandatory rules

Some authors do not agree with either of the proposed hypotheses mentioned above.[108] They argue that Article 3(1) of the eCommerce Directive not only sets certain limitations to the application of the designated law but also has an effect on the question of which law is applicable.[109] The country-of-origin principle may

[103] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[104] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 25 (2005).

[105] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[106] *Id.*

[107] *Id.*

[108] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 26, note 130 (2005).

[109] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

have this effect without being a choice of law rule as such. Further, the country-of-origin principle must go beyond being a mere corrective rule since it is the legislative intent that 'information society services should, in principle, be subject to the law of the Member State in which the service provider is established, cf. Recital 22[110]. Against this background, it is first submitted that the rules within the 'coordinated field' are to be treated as mandatory rules overriding any choice of law rules.

Substantive law rules with a defined territorial field of application are so-called *internationally mandatory rules.* In Article 7(1) of the 1980 Rome Convention[111], mandatory rules are defined as 'rules [that] must be applied whatever the law specified by choice of law rules'. Those rules that form part of the coordinated field should be held to be territorially applicable to services provided by service providers established within the territory of the Member State in question.[112] Thus, it can be argued that Article 3 of the eCommerce Directive is internationally mandatory and, therefore, must be applied regardless of which state's law would otherwise be designated according to national or EU law. This would offer a solution that would satisfy both the presumption in Recital 22 that the law of the service provider should apply and the statement in Article 1(4) that no new rules of private international law are established.[113]

In the joined cases *eDate Advertising and Martinez*[114] the German Federal Court of Justice essentially asked the ECJ if the provisions in the eCommerce Directive should be interpreted as rules requiring the application of the law of the place where the service provider is established.[115] The ECJ found that the Directive does not lay down a conflict of laws rule leading to the application of the law of

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[110] Recital 22, Directive 2000/31/EC.

[111] 1980 Rome Convention on the law applicable to contractual obligations.

[112] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 209 (2004).

[113] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 193-213 (2004).

[114] Joined Cases C-509/09 & 161/10, eDate Advertising v. X and Oliver Martinez and Robert Martinez v. MGN Limited, Judgment of the Court of Justice (Grand Chamber) of 25 October 2011, nyr.

[115] J. Kuipes, *Joined Cases C-509/09 & 161/10, eDate and Olivier Martinez v. MGN Limited, Judgment of the Court of Justice (Grand Chamber) of 25 October 2011,* nyr. Common Market Law Review, vol 49, pp. 1211-1232 (2012).

the Member State in which the service provider is established. However, after confirming that the Directive does not require the adoption of the country-of-origin principle as a conflict of laws rule, it added a caveat.[116]

The ECJ drew a parallel to the *Ingmar* case[117], which concerned the mandatory nature of articles 17-19 of the Agency Directive.[118] The Court stated that the parties could not avoid the application of the mandatory provisions of a directive necessary to achieve the objectives of the internal market[119]. According to the ECJ, the free movement of information society services would only be fully guaranteed if service providers ultimately comply with stricter requirements than those applicable to them in the Member State in which they are established[120].

Applying Article 3(1) would not ensure the free movement of services. If service providers faced stricter requirements in the host Member State, it would impede this goal.[121] Article 3 thus precludes, subject to derogations authorised by the conditions set out in Article 3(4), a provider of an electronic commerce service from being made subject to stricter regulatory framework in the host Member State.[122] The judgment implies that if a pharmaceutical company were sued in its home country, adherence to that State's law is not a matter of choice but compliance with international mandatory rules.[123] Further, as introduced in Section 2.2.2, the ECJ has emphasised in its recent ruling that the country-of-origin principle within the e-Commerce Directive that Member States cannot adopt general and abstract measures aimed at categories of information society services. The judgment reinforces the interpretation that the country-of-origin principle should be regarded as an internationally mandatory rule, ensuring that service providers are subject to the regulations of their home country.

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[116] *Id.*

[117] Case C-381/98 Ingmar GB Ltd v. Eaton Leonard Technologies Inc [2000] ECR 1-9305.

[118] Council Directive 86/653/EEC of 18 December 1986 on the coordination of the laws of the Member States relating to self-employed commercial agents, OJ L 302, 31 December 1986, pp. 17-21.

[119] Case C-381/98 Ingmar GB, para 67.

[120] J. Kuipes, *supra* note 115.

[121] *Id.*

[122] Case C-381/98 Ingmar, para 67.

[123] K. Karaseiwicz, *Country of origin principle in the E-commerce Directive: is it of any significance?* Journal of International Trade Law and Policy, Emrald Group Publishing Limited vol. 7, no. 1, 46-60 (2008).

4. Evaluation

The country-of-origin principle in the eCommerce Directive poses difficult questions in determining its real meaning.[124] Today, 24 years after the birth of the Directive, authors from all over Europe are still in intense debate about the principle's qualification, revealing the deficits of its formulation. Whether the principle is a rule of conflict, a corrective measure or internationally mandatory, the objective remains clear.[125] Promoting the internal market is crucial to support the information society service providers and enable them to compete with those of third countries.

It has been argued that Article 3 of the eCommerce Directive creates a choice of law rule designating the law of the country of establishment of an electronic service provider as applicable to a wide range of questions. However, it is not the present author's belief that the legislation is some 'personal law' that the service provider can bring beyond its national borders. Indeed, this approach ensures the service provider more legal certainty since the provider would not have to consider foreign legislation. However, understanding Article 3 as a choice of conflict might disadvantage providers established in countries where the level of protection and restriction is high.[126] A provider from a country with strict legislation might be discriminated against since it will have to compete against providers from other countries with laws that are much less restrictive and, thus, more favorable. The logical step for the provider established in a well-regulated and restricted Member State would likely be to emigrate to a Member State with more beneficial regulations. This situation is also referred to as a 'race to the bottom issue'[127]. The consequence might be that the legislative tendency in well-regulated Member States shifts, resulting in more provider-friendly rules to the detriment of other categories of citizens concerned or protected by the more restrictive rules, such as consumers and companies that do not market their products online.

Further, the EU legislator clearly and unmistakably states in Article 1(4) and Recital 23 that no new private international law rules are created. Article 1(4) is situated in the first article, which defines the Directive's scope and objective, and must therefore limit the meaning of Article 3. Advocate General Cruz Villalón

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[124] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[125] *Id.*

[126] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 20 (2005).

[127] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

adopted a literal interpretation of Article 1(4) of the eCommerce Directive in Opinion[128], para 68-81 connected to the cases *eDate Advertising and Martinez*. According to Advocate General Cruz Villalón, it is evident that a pure conflictual understanding must be objected to. As we saw in Section 3.3.3, this interpretation was adopted by the ECJ in that exact judgment.

Moreover, to comprehend Article 3 as a rule of conflict would leave Article 3(2) without much substance: If the principle enounced in paragraph 1 always declares the law of the establishment country as applicable, then why did the legislator mention that another Member State cannot restrict this law in paragraph 2?[129] The statement in paragraph 2 would be superfluous in admitting that the law of establishment is applicable in any case.

There are also certain obstacles when interpreting the country-of-origin principle as a simple corrective measure. The corrective approach would unavoidably lead to a comparison of the determined law and the law of the country of origin, culminating in applying the law more beneficial for the provider.[130] However, this most favorable law principle is likely to have been outside the objectives of the EU legislator: The fundamental objective is the promotion of the internal market and freedom of circulation, but not to support service providers in all circumstances at all costs. Such an interpretation would be to the detriment of everyone except the providers, who are protected and supported in a way which goes beyond the Directive's intention.

To support this argument, it may be highlighted that the German legislator once sought to introduce such a "principle of preference" in the Teledienstegesetz[131] to transpose the Directive. This initiative was later abandoned, and the Commission clarified that there was a risk of violating the eCommerce Directive.[132] The Commission thus showed that applying the least strict, most provider-friendly legislation was not within the Directive's intent. In addition, in applying ordinary private international law rules, the provider might again be

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[128] Opinion of Mr Advocate General Cruz Villalón delivered on 29 March 2011. eDate Advertising GmbH v X (C-509/09) and Olivier Martinez and Robert Martinez v MGN Limited (C-161/10).

[129] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[130] *Id.*

[131] Act on the Utilization of Teleservices (Gesetz über die Nutzung von Telediensten) 1997.

[132] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

confronted with a different set of laws whose consequences it might have difficulty foreseeing.[133] This approach would, therefore, not be consistent with the Directive's goal to minimize uncertainty and legal risks for service providers.

The third approach argues that the country-of-origin principle is mandatory, which makes the law in the home country applicable in all cases, given that it does not restrict the free movement of information society services. The eCommerce Directive's definition of the coordinated field in Article 2(h) supports the mandatory nature of Article 3(1): In the definition, a reference is made to general rules or material rules, and not conflictual ones. Thus, a service provider established on a particular Member State's territory can be assured that it is only required to comply with that particular state's national legislation. In that sense, Article 3(1) can be seen as a mandatory rule because it does not leave any space for comparison or other legislation to be applied[134].

Article 3(2) prohibits the restriction of the freedom to provide information society services by a State other than the provider's State of establishment.[135] The paragraph does not mention applicable law but solely declares that Member States cannot restrict the free movement of services falling in the coordinated field. Correlatively, the title of Article 3 is not "Country-of-Origin Principle" but "Internal Market". Therefore, the principle only applies where necessary for the optimal functioning of the Market. This means that if a provider is dealing in another State's market and this State's legislation is more advantageous, that legislation should also apply to the provider. The fact that the EU Treaty does not discriminate according to which Member State makes the restrictions does not go against this approach. A comparison between the different legislations is made effectively under Article 3(2) so that "export restrictions" are avoided. Thus, the legislation in the State of establishment does not hinder the provider's expansion of services outside its territory.[136]

The risk of a race to the bottom is still present since providers from countries with less restrictive rules will always have their legislation applied, making those countries more attractive for the providers. However, that risk is already in the

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[133] *Id.*

[134] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, pp. [i]-65 (2005).

[135] *Id.*

[136] N. Höning, *The European Directive on e-Commerce (2000/31/EC) and Its Consequences on the Conflict of Laws*, Global Jurist, vol. 5, no. 2, p. 35 (2005).

Directive, and it is still lower than it could be if the law of the home country were applicable in all circumstances.[137]

Of the various alternatives available, it is most plausible that the law in the foreign State is applied due to the general choice of law rules or that the law of the provider State is applied due to its mandatory nature. In practice, the difference between these approaches is somewhat limited[138]. On the one hand, it seems more reasonable to apply the latter solution as it does not add another "layer" of private international law rules to an already complex EU legal system. On the other hand, the first solution is more straightforward in its argumentation, making the country-of-origin principle more applicable in the practical world. Further, it seems doubtful that the EU legislator intended to create a rule with mandatory nature that would produce such complex academic debates.

The third thesis, declaring the country-of-origin principle internationally mandatory, serves the objective of the eCommerce Directive the best. This approach's most significant weakness lies in the fact that the theory behind it is probably only understood by a happy few specialists in private international law and that it depends on distinctions that could be contested.[139] However, its strength lies in the fact that it does preserve the theoretical consistency of the eCommerce Directive while recognizing the importance of mandatory rules. Nevertheless, the law stands, offering more questions than answers.

5. Conclusions

The dynamic interplay between the eCommerce Directive and the Community Code Directive forms a nuanced legal landscape for the digital marketing of medicinal products in the European Union. Prevailing case law in Denmark and the EU supports that the eCommerce Directive applies to the digital marketing of medicinal products within the coordinated field, highlighting its pivotal role in regulating online commerce. While the Community Code Directive harmonises rules of pharmaceutical advertising, it does not govern e-commerce-related situations, allowing the application of the eCommerce Directive when pharmaceutical products are advertised online.

The qualification of the country-of-origin principle in the eCommerce Directive remains a subject of spirited debate. In navigating this legal intricacy, the

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[137] *Id.*

[138] K. Karaseiwicz, *supra* note 123.

[139] M. Hellner, *The Country of Origin Principle in the E-commerce Directive – A Conflict with Conflict of Laws?* European Review of Private Law, vol. 12, no. 2, pp. 212 (2004).

present author contends that viewing Article 3 as an internationally mandatory rule aligns with its essence. This perspective maintains coherence with the objectives of the EU legislator, sidestepping the inclusion of a potentially divergent "most favorable law principle". Simultaneously, it does not contradict the Directive's Article 1(4).

Turning attention to the practical implications, the legal dispute between Danish and German medical companies sheds light on the real-world impact of the Directive. If Article 3 in the eCommerce Directive is construed as internationally mandatory, Danish law would prevail in this cross-border conflict. The provisions of the eCommerce Directive, governing virtual advertising of medicines in the EU, necessitate the application of the country-of-origin principle. This, in turn, must be understood as a mandatory rule, prevailing ordinary choice of law rules, including Article 6 in the Rome II Regulation. In this context, Danish law emerges as the prevailing jurisdiction in the dispute, provided it does not impose more stringent restrictions than German law, thereby upholding the principle of the free movement of society services within the EU.

In the current landscape, the aforementioned dispute underscores a crucial concern for pharmaceutical companies operating within the EU. The borderless realm of cyberspace poses a unique challenge, subjecting service providers to a myriad of laws and creating an atmosphere of uncertainty that may deter business. Adding to this complexity is the evident gap in understanding which jurisdiction applies when medicinal products are marketed online. The recent judgment highlights this challenge, revealing a lack of clarity in interpreting the country-of-origin principle outlined in the eCommerce Directive. Remarkably, there are currently no EU judgments addressing this interpretation, leaving the matter open for debate and contributing to a significant level of uncertainty.

To navigate this intricate legal terrain, globally oriented pharmaceutical companies can implement comprehensive compliance programs and standard operating procedures. These proactive measures ensure that these companies avoid inadvertent violations of rules across various Member States. However, the adoption of these strategies comes with significant costs, impacting the operational scope of global medical companies. This not only imposes financial burdens but may also restrict the freedom to provide services within the internal market. As legal uncertainties persist, the need for a strategic and compliance-focused approach becomes increasingly evident for pharmaceutical companies navigating the complexities of the evolving digital landscape.