Case Notes

Synthetic Marijuana Not a "Medicinal Product"

*Joasia Luzak**

Joined Cases C-358/13 and C-181/14, Markus D. and G.

Substances which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health do not fall within the scope of the definition of a "medicinal product" in the Directive 2001/83 (official headnote).

Consumer safety and medicines control legislation is not suitable to penalise the introduction of new psychoactive substances on European markets (author's headnote).

Art 1(2)(b) Directive 2001/83

I. Introduction

European and national legislators seem to be losing the fight against the use of narcotics. The latest European Drug Report[1] indicates that the drug problem in the European Union grows, also in complexity, due to the increased use of synthetic drugs on the European market.[2] The United Nations Single Convention on Narcotic Drugs[3] and the United Nations Convention on Psychotropic Substances[4] prohibit the unauthorised supply and possession of certain drugs.

These international rules allow the Member States to effectively enforce their anti-narcotics policies, however, only against the established drugs that these conventions identify. Meanwhile, the marketing, sale and use of the so-called new psychoactive substances, designed to circumvent the anti-narcotics legislation, have not yet been regulated in the international arena.[5]

Just in 2013 the European watchdogs identified 81 of such new drugs, with 29 among them being synthetic cannabinoids (or "synthetic weed", "synthetic marijuana", "spice").[6]

The synthetic cannabinoids' design allows them to mimic the effects of cannabis, often even enhancing its regular psychoactive impact. Therefore, synthetic cannabinoids' users may experience an increased or accelerated state of intoxication in comparison with 'natural' cannabis' users.[7] Initially, researchers developed synthetic cannabinoids as a valid substitute for cannabis that they could use,

* Assistant Professor, Centre for the Study of European Contract Law, University of Amsterdam, the Netherlands, j.a.luzak@uva.nl.

1 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), "European Drug Report: Trends and developments", 2014, available on the Internet at: <http://www.emcdda.europa.eu/publications/edr/trends-developments/2014> (last accessed on 5 November 2014).

2 EMCDDA, "European Drug Report out today – Europe's drugs problem 'increasingly complex'", New Release No 3/2014, available on the Internet at: <http://www.emcdda.europa.eu/news/2014/3> (last accessed on 5 November 2014).

3 United Nations Single Convention on Narcotic Drugs, 30 March 1961, in force 13 December 1964, *UN Treaty Series*, vol. 520, p. 151.

4 United Nations Convention on Psychotropic Substances, 21 February 1971, in force 16 August 1976, *UN Treaty Series*, vol. 1019, p. 175.

5 The European institutions are currently in the process of adopting new measures that could provide the EU with a quicker and smarter system to protect consumers from potentially harmful substances being sold to them. In 2011 the European Commission published a report on the functioning of the Decision 2005/387/JHA calling for the revision of this measure (COM(2011)430 final). The resulting thereof two legislative proposals have been endorsed by the European Parliament in April 2014 and await approval by the Council: Regulation on new psychoactive substances (COM(2013)619 final) and Directive amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the con-

among others, to study its addictive and therapeutic properties.[8] However, they have quickly identified many adverse side effects of the synthetic cannabinoids' use that so far proved difficult to separate from their desired therapeutic properties.[9] Adverse side effects include, but are not limited to nausea, intense vomiting, heart-racing, disorientation, delusions and even cardiac arrest and their intensity vary, depending on the chemical composition of a particular synthetic cannabinoid and its content in a product offered on the market.[10] Usually, consumers purchase a herbal mixture, which only partially consists of synthetic marijuana. Importantly, these herbal products generally lack proper labelling and use instructions, which may additionally endanger consumers.[11]

While the European institutions agree that synthetic cannabinoids should not be given a free access to the European market and that European consumers should be discouraged from using them, so far they have failed to adopt strict measures that could stop or slow down their trade.[12] They only managed to issue Decision 2005/387/JHA[13] that was supposed to facilitate the Member States in keeping up-to-date with the new drugs appearing on the market. Due to the existence of this lacuna, the Member States became creative in penalising the supply of synthetic cannabinoids.[14] The EMCDDA's report identifies three types of national responses to combat the use of new drugs: using consumer safety or medicines control legislation (e.g. in Poland, Germany); extending or adapting existing drug laws or processes (e.g. in the UK, Cyprus); designing new legislation (e.g. in Portugal, Slovakia, Poland and Romania). In the joined cases *Markus D. and G* the Court of Justice of the European Union (hereafter, the "CJEU") had a chance to determine the validity of the first approach. That is to say, whether the national enforcement authorities and courts could use consumer safety and medicines control legislation to penalise and control new synthetic drugs' supply on their markets.

II. Facts

In case C-358/13 the German regional court (Landgericht) in Lüneburg sentenced Markus D. to one year and nine months of imprisonment on probation.[15] The verdict followed a finding that Markus D. placed an unsafe medicinal product on the market. Namely, in his shop "G. – Alles rund um Hanf" ("G. – All about hemp") he sold to consumers small bags containing herbs to which synthetic cannabinoids had been added.[16] The bags were labelled as air fresheners, not meant for human consumption. The label did not indicate what active substances, if any, were added to the herbs or what their dosage might have been. During the proceedings Markus D.

stituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drugs (COM(2013)618 final).

6 EMCDDA, "European Drug Report out today…", *supra* note 2.

7 EMCDDA, "Perspectives on Drugs: Synthetic cannabinoids in Europe", last update 27 May 2014, available on the Internet at <http://www.emcdda.europa.eu/topics/pods/synthetic-cannabinoids> (last accessed on 5 November 2014); Andrea Rael, "What Is Synthetic Marijuana And How Does It Compare To Traditional Marijuana?", Huffington Post, 9 November 2013, available on the Internet at <http://www.huffingtonpost.com/2013/09/11/synthetic-marijuana_n_3908171.html> (last accessed on 5 November 2014); Alice G. Walton, "Why Synthetic Marijuana Is More Toxic To The Brain Than Pot", Forbes, 28 August 2014, available on the Internet at <http://www.forbes.com/sites/alicegwalton/2014/08/28/6-reasons-synthetic-marijuana-spice-k2-is-so-toxic-to-the-brain/> (last accessed on 5 November 2014). See also: EMCDDA, "European Drug Report: Trends and developments", *supra* note 1, p. 36.

8 Michelle Hunter, "Clemson University professor created synthetic marijuana for abuse research", 29 July 2012, available on the Internet at <http://www.nola.com/crime/index.ssf/2012/07/clemson_university_professor_c.html> (last accessed on 5 November 2014); Mark Schone and Anna Schecter, "Legalize Marijuana, Says Inventor of 'Spice' Chemicals", ABC News, 7 June 2011, available on the Internet at <http://abcnews.go.com/Blotter/legalize-marijuana-inventor-spice-chemicals/story?id=13782613> (last accessed on 5 November 2014).

9 EMCDDA, "Analysis: synthetic cannabinoids in Europe", last update 27 May 2014, available on the Internet at < http://www.emcdda.europa.eu/topics/pods/synthetic-cannabinoids> (last accessed on 5 November 2014).

10 Case C-358/13 and C-181/14, Markus D. and G., ECLI:EU:C:2014:2060, at para. 13. See also: EMCDDA, "Perspectives on Drugs…", *supra* note 7, p. 3.

11 Opinion AG Bot, Case C-358/13 and C-181/14, Markus D. and G., ECLI:EU:C:2014:1927, para. 23. See also: Andrea Rael, "What Is Synthetic Marijuana…", *supra* note 7; Alice G. Walton, "Why Synthetic Marijuana Is More Toxic…", *supra* note 7.

12 European Commission, "Responding to new drugs", available on the Internet at <http://ec.europa.eu/justice/anti-drugs/new-drugs/index_en.htm> (last accessed on 5 November 2014). See also note 5.

13 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ 2005 L 127/32.

14 EMCDDA, "European Drug Report: Trends and developments", *supra* note 1, p. 69.

15 Case C-358/13 and C-181/14, *supra* note 10, para. 16.

16 Ibid., *supra* note 10, para. 11.

admitted he knew that his consumers used these bags as a substitute for marijuana.[17] At the time, Germany did not classify synthetic cannabinoids as narcotics and, therefore, could only penalise Markus D. if the herbal mixtures he sold could qualify as an unsafe medicinal product.[18]

In the second joined case, case C-181/14, the German regional court (Landgericht) in Itzehoe sentenced G. to four years and six months of imprisonment and fined him € 200.000, again for selling unsafe medicinal products.[19] In this case, Mr G. used his online shop to sell similar herbal mixtures to the above-described.[20]

Both defendants appealed from their respective judgments and the German Supreme Court (Bundesgerichtshof) posed a question to the CJEU whether a substance that merely modifies human physiological functions, without providing a therapeutic benefit to its users, could qualify as a medicinal product. The answer to this question should clarify whether substances such as synthetic cannabinoids, which are consumed purely for intoxication purposes and which could endanger consumer health, could count as medicinal products just on account of their impact on consumers' physiology. Only if the CJEU answered in the positive, the Member States could continue to use the European rules prohibiting the introduction of unsafe medicinal products to the market to control and penalise the supply of synthetic cannabinoids to consumers.

III. Judgment

The CJEU did not agree with the German government as to the classification of synthetic cannabinoids as medicinal products. Germany and a few other Member States claimed that Article 1(2)(b) of the Directive 2001/83[21], which defines medicinal products by their functions, does not require a medicinal product to yield a therapeutic benefit to its users. They made this claim based on the neutral notion of *modification of physiological functions* of human beings, which the European legislator employed in this provision to illustrate one of the required functions of a medicinal product.[22] The CJEU, however, emphasised the importance of a conjunctive analysis of Article 1(2)(b) of the Directive 2001/83 together with its point (a), as well as the need for a teleological approach to this provision's interpretation.[23]

Article 1(2)(a) of the Directive 2001/83 defines medicinal products by their presentation and clearly requires them to benefit human health. That is to say, such products' presentation needs to refer to them possessing *properties for treating or preventing disease in human beings*.[24] If a medicinal product is not advertised as such, it may still fall within the Directive's scope if a given substance could be used to *restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis*. Only the word *modify* in this provision has a neutral connotation. All other requirements listed therein highlight the importance of a medicinal product's curative, beneficial action on human health.[25] As Advocate General (hereafter, the "AG") Bot mentions in his opinion, the CJEU's previous case law suggests that even if a product provided consumers with a general health benefit this would not suffice to qualify it as a medicinal product. A medicinal product needs to clearly influence treating or preventing diseases.[26] Considering the need for consistency in the interpretation of the notion of "medicinal products", as well as the clear objective of the Directive 2001/83 to safeguard public health, the CJEU determines that this notion may not apply to substances, which do not provide any immediate or long-term benefits to human health, even if they may modify certain physiological functions of human beings.[27]

The fact that the German legislator did not set up any criminal sanctions for the marketing or supplying of synthetic cannabinoids, cannot justify the

17 Ibid., *supra* note 10, para. 12.

18 Ibid., *supra* note 10, para. 15.

19 Ibid., *supra* note 10, para. 21.

20 Ibid., *supra* note 10, para. 19.

21 European Parliament and the Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311/67.

22 Opinion AG Bot, *supra* note 11, para. 33.

23 Case C-358/13 and C-181/14, *supra* note 10, paras. 29, 32. Contrary to often applied separate interpretation of these notions, see e.g.: Rolf-Georg Müller, "Arzneimittelrecht: Synthetische Cannabinoide keine Arzneimittel", 19 *Europäische Zeitschrift für Wirtschaftsrecht* (2014), p. 745.

24 Case C-358/13 and C-181/14, *supra* note 10, para. 34.

25 Ibid., *supra* note 10, paras. 31, 35-36.

26 Opinion AG Bot, *supra* note 10, para. 43. See also: Case C-319/05, Commission v. Germany, ECLI:EU:C:2007:678, para. 64.

27 Case C-358/13 and C-181/14, *supra* note 10, para. 38. See also recital 2 preamble of the Directive 2001/83.

broadening of the interpretation of the notion of a "medicinal product", pursuant to the CJEU.[28] Even if a narrower definition disallows German authorities to penalise the marketing or supplying of such new drugs, its use supports consistent application of consumer safety and medicines control legislation. As AG Bot emphasises in his opinion, the purpose of the Directive 2001/83 is to ascertain that safe and effective medicinal products are eventually placed on the market and permitted to move freely in the EU. Contrary to that objective, the national governments sought exclusion from the market rather than access to it for synthetic narcotics.[29]

IV. Comment

The most recent findings of the EMCDDA show that Member States stopped waiting for the European institutions to provide market restrictions or prohibitions for new synthetic drugs and instead started either expanding existing anti-narcotics measures or adopting new ones.[30] The CJEU's judgment in the case *Markus D. and G.* strengthens the need for such measures to be adopted, since the Court clearly prohibits national courts to apply consumer safety and medicines control legislation as a temporary solution in the anti-narcotics fight. The Court may, however, be overly optimistic in assuming that either national or European legislators could come up with effective criminal sanctions to prevent or even restrain further marketing of new psychoactive substances. Producers of such substances keep on altering their design in order to fall outside the current legislation's scope.

Consumer safety could, therefore, increase if the Court interpreted EU law in a way that allowed the Member States to adopt any measures necessary to control synthetic cannabinoids' presence on the internal market. However, AG Bot validly raised the issue of legitimacy not only for the CJEU but also for other European institutions to address this matter. The CJEU briefly mentions the fact that the synthetic weed's consumption occurs purely for a recreational and not a therapeutic purpose without pausing to address the issue of its potential lack of competence to adjudicate under such circumstances.[31] AG Bot indicates in his opinion that if consumers of such drugs are almost exclusively interested in their psychoactive effects, specifically intoxication, such recreational instances of the synthetic cannabinoids' use would fall outside the legal economic sphere of the internal market and, therefore, the European institutions would not be competent to regulate on this matter.[32] If the new psychoactive drugs do not benefit consumers' health and the Member States' intention is to criminalise them instead of ascertaining they comply with specific, high consumer protection standards prior to their introduction to the internal market, then indeed their regulation exceeds the EU institutions' purview.

It should be noticed that the CJEU's arguments raised to justify why a medicinal product should always provide a therapeutic benefit to consumers are of a very general nature. In this regard, the AG Bot's opinion is more convincing by adopting a teleological approach and invoking the historical development of the notion of a "medicinal product". He refers to previous CJEU case law that already required producers of medicinal products to be able to prove specific beneficial actions that a given substance could have on human health, before it could qualify as a medicinal product.[33] However, neither AG Bot nor the CJEU mention that the purpose of the Directive 2001/83 is also to regulate a situation when a "medicinal product" proves to be unsafe for human consumption, for example, by *proving to be harmful under normal conditions of use* or by *lacking in therapeutic efficacy*, pursuant to Article 117 (1) of the Directive 2001/83. The delineation of medicinal products cannot be accurate when the CJEU does not specifically address these EU law provisions that could undermine its interpretation of the notion of a "medicinal product" as applying only to substances with beneficial therapeutic effects.[34] To illustrate, the CJEU could have decided that the distinction between medicinal products as referred to in Article 117 (1) of

28 Case C-358/13 and C-181/14, *supra* note 10, paras. 48-49.

29 Opinion AG Bot, *supra* note 11, para. 47.

30 EMCDDA, "European Drug Report: Trends and developments", *supra* note 1, p. 69.

31 Case C-358/13 and C-181/14, *supra* note 10, para. 46.

32 Opinion AG Bot, *supra* note 11, paras. 29, 48.

33 Opinion AG Bot, *supra* note 11, para. 43. See also: Case C-319/05, Commission v. Germany, ECLI:EU:C:2007:678, para. 64. See also: Rolf-Georg Müller, "Arzneimittelrecht…", *supra* note 23, p. 744-745.

34 See also: Jörn Patzak, Mathias Volkmer und Andreas Ewald, "Neue psychoaktive Substanzen sind keine Funktionsarzneimittel", 8 *Neue Zeitschrift für Strafrecht*, (2014), p. 464.

the Directive 2001/83 and synthetic cannabinoids lied therein that with regards to the first ones the initial tests showed that they provided consumers with therapeutic benefits and only when they have been introduced to the market as medicinal products, their subsequent use and further tests proved them to be more harmful than beneficial. If synthetic drugs from the first tests showed mostly harmful influence on human health, this could then exclude them from the scope of Article 117(1) of the Directive 2001/83.

V. Conclusion

The two European legislative proposals that are to apply to new psychoactive substances await their fate in the Council. The deliberations thereon have already been scheduled to take place, but due to this year's EU elections the discussions were postponed. However, even if these measures will be adopted AG Bot claims that they will not solve the issues raised in the case of *Markus D. and G.*, since the new measures only aim at putting market restrictions on such substances like synthetic cannabinoids and not at prohibiting them altogether.[35] The national enforcement authorities and courts will thus still have a role to play in ensuring consumer safety against such substances. The CJEU's judgment removes only one of the instruments that were at the Member States' disposal to penalise and control the supply of new synthetic drugs.

35 Opinion AG Bot, *supra* note 11, paras. 53-56.