Case Note

Now what, Doc? Regulation 1924/2006 Applies to Communications to Health Professionals (Case C-19/15)

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"*You shall do no injustice in court*"
(Leviticus, 19/15)

I. Introduction

In its Judgment of 14 July 2016[1], the Court of Justice of the EU ruled that commercial communications from food firms exclusively addressed to health professionals need to respect the rules of Regulation 1924/2006 on nutrition and health claims (hereinafter, "Regulation 1924/2006" or the "Regulation")[2].

However, the Court did not object to food companies communicating to health professionals "objective information" about "new scientific developments" (including references to illnesses) if such communications are of a "non-commercial nature"[3].

The ruling runs counter to the administrative practices of many EU countries, some of which have issued guidance expressly excluding communications to health professionals from the scope of application of Regulation 1924/2006[4], and the prevailing opinion of EU food law scholars[5]. It also entails paradoxical consequences, such as opening the door to advertising of food ingredients to the general public bypassing Regulation 1924/2006 altogether, or the possibility of using "objective information," including references to diseasesin connection with the health properties of food in the advertising of foods to health professionals and, arguably, to the final consumer.

Whilst allowing some kind of communications between food firms and health professionals, the ruling generates significant legal uncertainty because it does not give any criteria to define the main elements of such communications. What should be understood as "objective information", or in which cases are communications from the industry to health professionals of a "non-commercial nature"?

In view of the extended industry practice, especially in the case of functional foods, of having two

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1 Judgment of the Court (Third Chamber) of 14 July 2016 in Case C-19/15, Verband Sozialer Wettbewerb eV v Innova Vital GmbH, not published yet (hereinafter, the "Judgment").

2 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404/9 of 30 December 2006 – corrected by OJ L 12/3 of 18 January 2007).

3 See paragraphs 50 to 53 of the Judgment.

4 See, *inter alia, Food Standards Agency Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods, of November 2011: "*While the Regulation applies to claims made in commercial communications about foods it is our opinion that it will not control claims made in communications within trade (business to business), to doctors or other health professionals, or to their organisations, whether the claim is in the labelling, advertising or other presentation of the food. This is provided that the recipients are acting within the scope of their professional activities and that they are not being addressed as final consumers of the foods. It therefore follows that if the information were, at any time, conveyed to final consumers within a commercial context, any claims made would need to comply with the requirements of the Regulation." See also *Belgian Ministry of Health, note of September 27, 2013:* "While not explicitly mentioned [in Article 1(2)], the Belgian government considers that commercial communications not intended for the final consumer fall outside the scope of the Regulation. This interpretation follows from the principal purpose of the Regulation, in particular the protection of consumers against misleading information."

5 See, for example, Holle (*Health Claims Kompakt*, 2007), who holds that Regulation 1924/2006 is exclusively applicable to final consumers, Teufer, ZLR 2009, p. 581, Ballke, "Nutrition and health claims in b2b communications", EUFFLR 3, 2011 and Romero and Timmermans, "*But what is it, Doc*?" – Health Care Professionals under Regulation 1924/2006", EUFFLR 5, 2010. Finally, Meisterernst/Harber, Praxiskommentar Health&Nutrition Claims, 2008, art. 1 margin note 64 et seq., had in the past doubted that non-consumers were exempted from the scope of Regulation 1924/2006, but have since embraced the opposite view, see *Health and Nutrition Claims. Commentary on the Health REGULATION 1924/2006*, Lexxion, 2010.

different channels of communications, one with final consumers and another with health professionals, this article will attempt to shed some light on the aftermath of the ruling. First, the actual judgment will be discussed, and its consequences analyzed. Second, some guidance will be offered as to how to safely communicate about health properties of food to health professionals.

II. The Ruling

German firm Innova Vital GmbH, the director of which is a doctor, markets a food supplement containing vitamin D. The director of Innova sent a written communication exclusively to doctors stating that this product helped to prevent diseases caused by vitamin D deficiency[6]. A German association *Verband Sozialer Wettbewerb* challenged the ad based on an infringement of Regulation No 1924/2006.

As this question deals with the interpretation of whether commercial communications addressed exclusively to health professionals were caught by the Regulation, the German court referred it to the Court of Justice, for a preliminary ruling.

In essence, to answer the question the Court relied on a literal interpretation of Article 1(2) of Regulation 1924/2006 to conclude that the said rules cover commercial communications addressed exclusively to health professionals.

Article 1(2) states that "[t]his Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer". The concept of "final consumer" is defined in Regulation 178/2002[7] as "the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity".

According to the Court, "[...] Article 1(2) of Regulation No 1924/2006 does not include any details on the addressee of the commercial communication and makes no distinction according to whether that addressee is a final consumer or a health professional. It follows that [...] it is the product itself, and not the communication of which it is the subject matter, which must necessarily be aimed at consumers."[8]

Then, the Court went on to justify that this conclusion was not contrary to the *context or* the *objectives* of the Regulation. Thus, it stated that, "the absence of any reference to 'professionals' in [recitals 1, 9, 16, 29 and 36, and Article 5(2)] does not mean that that regulation does not apply to the situation where a commercial communication is addressed exclusively to health professionals. In such a situation, that communication between the food business operators and the health professionals covers principally the final consumer, in order that that consumer acquires the food which is the subject of that communication, following the recommendations given by those professionals."[9]

Furthermore, "health professionals may be considered to have scientific knowledge superior to that of a final consumer, understood as an average consumer, who is reasonably well informed and reasonably observant and circumspect, as stated in recital 16 of that regulation. However, those professionals cannot be regarded as being in a position to permanently have all specialised and up-to-date scientific knowledge necessary to evaluate each food and the nutrition or health claims used in the labelling, the presentation or advertising of those foods." It follows that "it cannot be ruled out that the health professionals themselves may be misled by nutrition or health claims which are false, deceptive, or even men-

6 The ad read as follows: "You are aware of the situation: 87% of children in Germany have blood vitamin D levels below 30 ng/ml. According to the German Food Association (Deutsche Gesellschaft für Ernährung, DGE), that level should be approximately 50 to 75 ng/ml. As has already been demonstrated in numerous studies, vitamin D plays an important role in the prevention of several illnesses, such as atopic dermatitis, osteoporosis, diabetes mellitus and MS [multiple sclerosis]. According to those studies, vitamin D deficiency in childhood is partly responsible for the subsequent development of those illnesses […] As a doctor specialising in immunology, I considered this issue and developed a vitamin D3 emulsion (Innova Mulsin® D3) which can be administered in the form of drops [...]. Benefits of Mulsin® emulsions: […] Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D3-deficient in winter) [...]. You can find out how to place direct orders and obtain free information material for your surgery by calling [...]". That written communication also contained images of the product in question, information on its composition, its selling price and the daily cost of treatment based on the recommended dose of one drop per day or as advised by a doctor. It stated that 'with a selling price of EUR 26.75, your patients are investing EUR 0.11 per day for balanced vitamin D3 supplement', see Opinion of Advocate General Saugmandsgaard Øe delivered on 18 February 2016 in Case C-19/15 *Verband Sozialer Wettbewerb e.V.* v *Innova Vital GmbH*, not published yet.

7 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1 of 1 February 2002.

8 See, along the same lines, Opinion of the Advocate General Saugmandsgaard Øe, point 39, *supra* note 6.

9 See paragraph 35 of the Judgment.

dacious. Therefore, those health professionals risk forwarding, in all good faith, incorrect information on foods which are the subject of a commercial communication to final consumers with whom they have a relationship. That risk is all the more remarkable as such professionals are likely, because of the relationship of trust which generally exists between them and their patients, to exercise significant influence over the latter."[10]

III. Analysis

In our view, this is a flawed legal analysis, which opens the door to paradox.

The Court has relied on a strictly literal reading of Article 1(2) of Regulation 1924/2006 to justify the application of Regulation 1924/2006 to communications to professionals. As it has been established *supra*, according to the Court, the phrase "to be delivered to the final consumer" refers to the foodstuffs themselves and not to the communications in connection thereto. It follows that there is no difference if the commercial communication aims at the final consumer or at professionals, for as long as the *products* themselves are delivered to the final consumer[11].

The most striking consequence of this reasoning is that *any* B2B commercial communication, not only those addressed to health professionals, would have to abide by the rules of Regulation 1924/2006, to the exclusion of the communications made by ingredients manufacturers, for as long as the ingredient object of the communication is not *intended to be delivered as such to the ultimate consumer* (as a single-ingredient product).

Think about probiotics, for example, which could be profusely advertised to the general public by their manufacturers without having regard to the hundreds of health claims rejected by EFSA. It is not difficult to think of companies then advertising their products as containing those ingredients. This would be, according to the letter of the ruling, a perfectly legitimate *modus operandi*.

In our opinion, such practical consequence, in addition to being inconsistent, would be difficult to justify based on the objectives of the Regulation.

As we have explained in the past[12], the reference to the concept of final consumer in Article 1(2) of the Regulation should exclude from its scope of application professionals (such as food traders, distributors, manufacturers of final products, etc.) acting within the scope of their professional activities. This dichotomy consumer vs professional lies in the very foundations of EU consumer protection law in the EU[13], as it has been expressly acknowledged by scholars[14]. The same principle applies to other regulated

10 See paragraphs 43 to 45 of the Judgment.

11 See paragraph 31 of the Judgment.

12 See Romero/Timmermans, *supra* note 5.

13 See, to this effect, Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council, OJ L 304, 22 November 2011, pp. 64–88, Article 2(1); Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours, OJ L 158/59 of 23 June 1990, Article 2(4); Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, OJ L 95/29 of 21 April 1993, Article 2(b); Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers, OJ L 80/27 of 18 March 1998, Article 2(e); Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees, OJ L 171/12 of 7 July 1999, Article 2(a); Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (hereinafter, the "Services Directive"), OJ L 376/36 of 27 December 2006, and the Directive on Electronic Commerce, and 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 ('Directive on electronic commerce'), OJ L 178 of 17 July 2000, pp. 1–16, Article 2(e); Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC, OJ L 271/16 of 9 October 2002, Article 2(e); and Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (hereinafter, the "Unfair Commercial Practices Directive"), OJ L 149/22 of 11 June 2005, Article 2(a).

14 According to the scholars, the various definitions referred to in the above mentioned acts share common characteristics which can be summarized as comprising all physical persons *acting outside their professional duties*, who receive goods or services for their *final use or consumption*, with the objective to meet personal or family needs. See, in this sense, González Vaqué, "La noción de consumidor normalmente informado en la jurisprudencia del Tribunal de Justicia de las Comunidades Europeas: la Sentencia Gut Springenhedie", *Derecho de los Negocios*, No 103 (April 1999), Palao Moreno, "La protección de los consumidores en el ámbito comunitario europeo" in Reyes López (ed.), *Derecho de Consumo*, Tirant lo Blanch, Valencia, 2002, pp. 39-40; Tenreiro, "Un Code de la consommation ou un Code autour du consommateur? Quelques réflexions critiques sur la codification et la notion du consommateur" in Krämer, Micklitz and Tonner (eds.), *Law and Diffuse Interests in the European Legal Order – Liber amicorum Norbert Reich*, Nomos, Baden-Baden, 1997, p. 348.

areas, such as prescription-only medicines, tobacco products, infant formulae and, to some extent, alcoholic beverages[15]: whilst promotion (in the form of advertising) to the general public is prohibited[16], it is allowed if addressed to *professionals*[17].

Considering that infant formulae, alcohol, tobacco or medicines involve higher health risks than regular foods and that their advertising to consumers is the object of a blanket ban, it is difficult to understand that communications to professionals is not subject to particular rules where for foods, with a much lower health risk, it is subject to the stringent rules of Regulation 1924/2006.

One cannot avoid wondering whether this whole body of EU consumer law was even considered by the Court, and whether the dichotomy consumer vs professional is still relevant for areas of consumer law where there is no specific mention of the latter.

Finally, as to the statement that health professionals "risk forwarding, in all good faith, incorrect information on foods which are the subject of a commercial communication to final consumers with whom they have a relationship" and "that risk is all the more remarkable as such professionals are likely, because of the relationship of trust which generally exists between them and their patients, to exercise significant influence over the latter"[18], suffice it to say that deontological and professional duties, as old as the Hippocratic Oath, require that health professionals read and verify the information before passing it onto consumers[19].

Regulation 1924/2006 was not conceived to encroach on the medical profession rules of conduct and ethical obligations (although perhaps we should interpret the ruling as an amendment of the Oath...).

IV. Practical Consequences: the Legal Framework to Communicate to Health Professionals after Case C-19/15

In any case, there is still light. As stated above, the Court did not object to food companies communicating to health professionals "*objective information* about *new scientific developments*", including references to illnesses, if this communication is of a "*non-commercial nature*"[20].

So, in practical terms, information about health properties of foods, including references to diseases, will be permitted when it is the following: (i) *objective*, (ii) intended for *health professionals* only, (iii) involves the use of a *technical or scientific terminology*, and (iv) of a *non-commercial nature*.

15 According to consistent case-law of the CJEU, a provision that limits the possibilities of advertising of alcoholic beverages as a means of combating alcoholism responds to public health concerns (cf. CJEU judgments of 10 July 1980, *Commission/France*, case 152/78, paragraph 17; of 25 July 1991, *Aragonesa de Publicidad Exterior and Publivía*, joined cases C-1/90 and C-176/90, paragraph 15; or 8 March 2001, *Konsummentombudsmannen vs Gourmet International Products AB*, C-405/98, paragraph 27). According to the CJEU's settled case-law, the freedom of expression may only be limited when justified by objectives in the public interest by a pressing social need and, in particular, proportionate to the legitimate aim pursued. The possibility of such a restriction has also been raised in relation to the advertising of tobacco products. Cf. the CJEU Judgement of 12 December 2006, *Germany vs European Parliament and Council of the European Union*, Case C-380/03, ECR [2006] Page I-11573, paragraph 155, and additionally: the Judgements of 26 June 1997, *Vereinigte Familiapress Zeitungsverlags- und -vertriebs GmbH v Heinrich Bauer Verlag*, Case C-368/95, ECR [1997] Page I-03689, paragraph 26; of 11 July 2002, *Mary Carpenter v Secretary of State for the Home Department*, Case C-60/00, ECR [2002] Page I-06279, paragraph 42; and of 12 June 2003 *Eugen Schmidberger, Internationale Transporte und Planzüge vs Republik* Österreich, Case C-112/00, ECR [2003] Page I-05659, paragraph 50.

16 *A fortiori,* in case of food products, it is not prohibited, but strictly limited by Regulation 1924/2006.

17 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28 November 2001, pp. 67–128 (hereinafter, the "Medicinal Products Directive") expressly prohibits advertising to the general public of medicinal products available on medical prescription-only, but allows advertising them to professionals ("persons qualified to prescribe or supply such products") (Article 88). Also, whilst Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127 of 29 April 2014, pp. 1–38, prohibits the advertising of tobacco products, it can be done so in publications intended exclusively for "professionals in the tobacco trade" (Article 3). Along the same lines, Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25 of 2 February 2016, pp. 1–29, restricts advertising of infant formula to "publications specialising in baby care and scientific publications".

18 See paragraphs 44 and 45 of the Judgment.

19 "I swear by Apollo the physician, and Asclepius, and Hygieia and Panacea and all the gods and goddesses as my witnesses, that, according to my ability and judgement, I will keep this Oath and this contract" (US National Library of Medicine, History of Medicine Division, 2002).

20 See paragraphs 50-53 of the Judgment.

It is thus necessary to explore these conditions in detail.

1. The Concept of "Objective Information"

It should be stated at the outset that the mere fact that the Court *acknowledges* the possibility that some sort of messages on the health properties of food can be made as "*objective information*" (as opposed to health claims) opens a very interesting debate – and probably some doors too. Arguably, the same analysis could be made following the Court's reasoning about the framework of advertising to the final consumer.

However, outside the specific case of information about "new scientific developments, involving the use of a technical or scientific terminology", it seems difficult to envisage a widespread use of this newly opened door.

This is why. Article 2(2)(5) of Regulation 1924/2006 defines "health claim" as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health". The World Health Organization defines "health" as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"[21]. A "claim", on its part, is "any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics" [Article 2(2)(1)].

It arises from the foregoing definitions that Regulation 1924/2006 does not require the relationship between food and health to be "beneficial" in order to be caught by the definition of "health claim"[22]. Indeed, the definition of both "claim" and "health claim" (and even of the very *relationship* between food and health) is very wide, as the Court itself has confirmed[23], and, catches, in principle, from objective and factual statements to purely promotional slogans as long as they deal with health.[24]

Even though the possibility to include objective information about health properties of foods is an interesting door that the Court has opened, it is now necessary to narrow the debate on its use in communications addressed to health professionals.

In view of the rather vague guidance offered by the Court, and taking into account the need to use language which *involves the use of a technical or scientific terminology*[25], we believe that resort to the pharmaceutical legal and regulatory framework will be useful for providing a safe harbour in the form of *best practices* which will, additionally, enhance the quality of the communications from food firms to health professionals, by adapting them to the standards known to the medical environment.

Several EU and national regulations, including an ill-fated European Commission's *Proposal for a Directive as regards information to the general public on medicinal products subject to medical prescription*[26] and deontological self-regulation instruments (such as codes of practices)[27], have developed quality criteria which complement the current legal frame-

21 See WHO, Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946. This definition was proposed for inclusion in Regulation 1924/2006 by the European Economic and Social Committee but this amendment was not retained in the final text adopted by the Council and the European Parliament (see Opinion on the Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods of 26 February 2004).

22 As opposed to the definition of nutrition claim, which does require a beneficial effect.

23 See, *inter* alia, C-544/10, Judgment of the Court (Third Chamber) of 6 September 2012, Deutsches Weintor eG vs Land Rheinland-Pfalz, paragraph 34.

24 On the other hand, factual, objective statements on the *characteristics of the ingredients* that do not relate to or imply a health or nutritional benefit fall outside the scope of the Regulation.

25 See Paragraph 53 of the Judgment.

26 The Proposal was based on Article 88(a) of the Medicinal Products Directive, which notes that "the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability". The reference to "other treatments" could be interpreted as extending this provision, *inter alia*, to foods which enter the medical environment, thus, the relevance of the application of this set of rules to the case at hand (see along the same lines, Amarilla Mateuu, "Diferencias entre Publicidad e Información", *El derecho a la información en salud alimentaria*, European Pharmaceutical Law Group, 2006). The Proposal, together with a twin proposal for a Regulation on the same topic, were finally withdrawn on 21 May 2014, OJ CL 153 of 21 May 2014, p. 3.

27 Resort to codes of practice and other types of self-regulatory instruments has been expressly backed up in several fields of consumer law. These codes of conduct should include rules for commercial communications relating to the regulated professions and rules of professional ethics and conduct of the regulated professions. See, *inter alia*, the Unfair Commercial Practices Directive (Directive 2005/29, cited in *supra* note 14), whose Article 3(8) encourages Member States to impose on professionals' conditions of establishment or of authorization regimes, or any *deontological codes of conduct* or other specific rules governing regulated professions, in order to uphold high standards of integrity on the professionals (see also Article 10).

work for communications between the pharmaceutical industry and the health professionals[28].

It arises from these instruments that communications are *objective* when they are focused on *informing and guiding* the health professionals to the *correct and safe use* of the foods, with particular reference to any possible adverse reactions derived from their consumption (or excess of consumption)[29]. Further, they should be based on facts and not influenced by prejudices and personal perceptions.

2. The Concept of "Technical or Scientific Terminology"

In order to comply with this requisite, it is also useful to refer to the regulatory instruments described *supra*. In a nutshell, it would be crucial that the information sent to health professionals is (i) *strictly related to their professional interest*, i.e. the provision of health care services and expert advice; and (ii) of *a scientific and factual nature*[30]. For these purposes, it would be advisable to follow recommendations contained in renowned guidelines on principles related to publication in medical journals, as they provide the highest standards to be achieved in the manner scientific communications should be conveyed.

Thus,

(i) Communications should be *evidence-based* and provide *scientific* and *educational information* and supporting medical research and education[31]. It is recommended that any relevant statement be adequately supported by scientific evidence and any reference to other scientific publications which support the evidence be attached, clearly identified or made available on request by the health professionals. Furthermore, quotations from scientific literature or from personal communications and artworks – including graphs, illustrations, photographs and tables taken from published studies – included in the communications should clearly indicate the precise source and be faithfully reproduced[32]. Also, the communications should not appear as the ownership of an independent editing company if the food firm provides financial support necessary to publish the document[33].

(ii) Communications should also be *unbiased*, i.e. impartial, non-directive and balanced, encouraging the rationale use of the foods by presenting them objectively and *without exaggerating their properties*[34].

(iii) Finally, communications should be *up-to-date* when they are factually correct and *not misleading* – by distortion, exaggeration, undue emphasis, omission or in any other way[35].

3. The Requisite of the Communications Being "Intended for Health Professionals only"

In our view, communications are *health professional-oriented* when they are *exclusively* addressed and distributed to the healthcare community. That is, specific education should be required for the correct interpretation of the information, e.g. with references to scientific vocabulary not usually used by the general public[36].

An illustrative example of whether communications, and *in casu*, a leaflet, is addressed to the health professionals or the general public can be found in a resolution of Autocontrol, the Spanish self-regulato-

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28 Usually, these quality criteria refer to information that is conveyed to patients and not to health professionals. Logically, application of these principles to the case at hand results in the adaptation of some provisions thereof. One of the suggestions envisaged by the European Commission is to create an EU Advisory Committee which would provide a model code of conduct using the quality criteria, upon which national models could be based.

29 Article 93(3) of the Medicinal Products Directive.

30 See Article 10 of Regulation (EU) 2016/127, cited in *supra* note 18.

31 International Federation of Pharmaceutical Manufacturers Associations (IFPMA), "Code of Practice", 2012 (hereinafter, the "IFPMA Code"), Article 2, Section 2(1).

32 Except where adaptation or modification is required in order to comply with the relevant rules, in which case it must be clearly stated that the artwork has been adapted and/or modified.

33 IFPMA Code, Q&A Section.

34 Article 87 of the Medicinal Products Directive.

35 International Research-Based Pharmaceuticals Manufacturers Association (IRPMA), "Code of Marketing Practices", Section 4(2). Descriptions such as 'no side effects' should generally be avoided and should always be adequately qualified. Furthermore, the word "new" must not be used to describe any product or presentation which has been generally available or any therapeutic indication which has been generally promoted for more than one or two years, cfr. European Federation of Pharmaceutical Industries and Associations (EFPIA), "Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals", Article 9, Sections 3(07) and 3.08; as well as "*Código español de buenas prácticas de promoción de medicamentos y de interrelación de la industria farmacéutica con los profesionales sanitarios*", Article 3(6).

36 Farmaindustria, Unidad de Supervisión deontológico de la Industria Farmacéutica, "Código Español de buenas prácticas para la promoción de los medicamentos", Section V.

ry body, related to an appeal by *Farmaindustria* – the Spanish association of the pharmaceutical industry – against Bayer for the presumed responsibility for the elaboration of two leaflets related to a contraceptive pill which included references to the National Association for Women's Health Development (*Asociación Nacional para el Desarrollo de la Mujer*)[37].

The Jury analyzed whether the leaflet, elaborated under the responsibility of Bayer, had to abide by the deontological code for the promotion of medicinal products (*Código de Buenas Prácticas para la Promoción de los Medicamentos*). To do so, two cumulative criteria needed to be fulfilled: (i) an objective criterion: the leaflet should be promotional (as opposed to informative) in nature; and (ii) a subjective criterion: the intended addresses of the leaflet should be health professionals.

a. The "Objective" Criterion

With regard to the first criterion, the Jury in Plenary considered that there were sufficient elements to support the argument that the leaflets were *promotional* and not *informative* in nature, since the references therein: (i) qualified the product as "new"; (ii) persistently emphasized the positive aspects of the pills – without making reference to any secondary or adverse effect –; (iii) were formulated in a singular manner, that is, without reference to contraceptive pills in general but with a clear reference to a particular pill; and (iv) included the presence of distinctive signs of the Product – e.g. the logo. Moreover, only one laboratory at the time, Bayer, commercialized those pills (since it had patented the use of the active substance at hand).

b. The "Subjective" Criterion

With regard to the second criterion, the Jury in Plenary ruled that, in order to consider whether the promotional activity at hand was addressed to health professionals, it had to be *specifically* (as opposed to *exclusively*) addressed to health professionals. According to the Plenary Jury, in order to decide whether this criterion was fulfilled, it had to be shown that the promotional campaign was *health professionals-oriented,* which the Plenary Jury confirmed by taking into account various elements.

(i) First, despite the fact that the leaflets seemed to be addressed to the general public – since they included the statement "Consult your doctor" – there were abundant references to the main active substance of the pill – patented by Bayer – instead of references to the brand name of the product: "it is hardly explicable that a promotional material, supposedly addressed at women who use contraceptive pills refers at all times to the active substance (drospirenona) of the medicine which is being promoted, active substance which said users will usually not recognize and not associate to any given brand. On the other hand, there is a reasonable expectation that doctors will associate drospirenone to Bayer contraceptive pills". Therefore, the leaflets were, at least indirectly, addressed to health professionals, so that health professionals could use them in their office hours with patients or so that patients would necessarily need to address the health professionals for explanations about the identity of the pill the leaflets referred to, in which case the health professionals would recommend the consumption of Bayer's pill. The message contained in the leaflets was therefore addressed to health professionals and not to patients themselves;

(ii) The leaflets included distinctive signs that the health professionals would also use to promote the pill among the health professionals in further venues (e.g. National Congress of Gynaecologists). Further, this coincidence appeared among the various communications sent by Bayer to health professionals and not among the various communications sent by Bayer to female consumers (e.g. packaging);

(iii) Finally, the leaflets had been distributed only in healthcare offices, clinics, familiar planning centres, etc. where they could reach health professionals with the authority to prescribe anticonceptive pills, and did not limit them to a diffusion which would (exclusively and) circumstantially reach health professionals as potential members of the general public[38].

37 See Autocontrol Resolution of 24 April 2008, *Unidad de Supervisión Deontológica (de Farmaindustria) vs. Química Farmacéutica Bayer*, S.L (hereinafter, the "BAYER Appeal") which upheld the Resolution of the Fifth Chamber of the Jury of Autocontrol of 3 April 2008 (hereinafter, the "BAYER Resolution").

38 This reasoning is in line with the doctrine that expresses that the average consumer test should refer to a consumer with a prudent active attitude but without the need to conduct an exhaustive investigation to be adequately informed (Article 15 of the Regulation). Cfr. González Vaqué, *supra* note 14.

4. The Concept of "Commercial Communication"

Second, and of equally difficult assessment, is defining the requisite of communications being of a "non-commercial nature" in order to escape the application of Regulation 1924/2006.

As the Court itself stated, neither the Regulation nor the General Food Law define the concepts of *commercial* or *non-commercial communications*[39]. According to the definition laid down in other EU regulations, *commercial communications* are "any form of communication designed to promote, directly or indirectly, the goods, services or image of an undertaking, organisation or person engaged in commercial, industrial or craft activity or practising a regulated profession".[40]

It arises from this definition that the *promotional purpose* (whether direct or indirect) is the main criterion to differentiate commercial from non-commercial communications. Therefore, its scope of application is very wide, catching, "any form of communication" conveyed by a firm which purports at promoting its products, even indirectly.

This broad interpretation is further reinforced by the fact that only communications compiled *in an independent manner, particularly when provided for non-financial consideration,* are excluded from the definition of *commercial communications*[41]. Also, Regulation 1924/2006 merely refers to "dietary guidelines or advice issued by public health authorities and bodies", or "information in the press and in scientific publications" as examples of *non-commercial communications*.

Arguably, any form of communication by a food business operator in connection with their products (including to health professionals) could be presumed to be made with an *intention to promote* them (in this case, *indirectly*, by means of enhancing their credibility and reputation among health professionals).

In the absence of recommendations from the Court, special attention should be paid to the criteria described *supra* in connection with the *objective* nature of the information conveyed (as described in point IV (iii) (a) *supra*).

V. Conclusions

As we have developed above, the ruling ignores the fundamental legal dichotomy between consumers and professionals that illustrates EU consumer laws, and encroaches on the medical professional and ethical rules. It yields paradoxical consequences that are inconsistent with the objectives of the Regulation. For these reasons we consider it flawed.

By stating boldly that the phrase "to be delivered to the final consumer" in Article 1(2) of the Regulation refers to the foodstuffs themselves and not to the communications in connection thereto, the Court has opened the door to ingredient manufacturers willing to advertise the health properties of their products without having to observe the rules of Regulation 1924/2006[42], or using messages on the health properties of food outside the scope of the Regulation, as "objective information".

On the other hand, it can be maintained that both the opinion of A. G. Saugmandsgaard Øe and the ruling itself deal with the easily answered question of whether it is possible to circumvent Regulation 1924/2006 by using health professionals as *intermediaries* between food firms and the final consumer, rather than by communicating with health professionals *per se*.

This may be the reason why the Court decided to grant a special status to the communications to health professionals, in a difficult legal pirouette which entails allowing these communications to bypass the Regulation and, for example, refer to treatment of diseases, provided the four conditions described in the last section are met.

Obviously, a case-by-case analysis will be needed to determine whether this is the case in a particular

39 See paragraphs 25 to 30 of the Judgment.

40 The Services Directive, *supra* note 13. On its part, the Medicinal Products Directive defines advertising of medicinal products as "any form of door-to-door information, canvassing activity or inducement designed *to promote* the prescription, supply, sale or consumption of medicinal products" (emphasis added).

41 Article 2(f) of Directive on Electronic Commerce and Article 4(12) of the Services Directive.

42 However, other provisions such as the general principle of not misleading the consumer as enshrined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 295, 12.11.2011, pp. 18-63 and in Regulation 178/2002, *supra* note 8. The rules of Directive 2005/29/EC on unfair business-to-consumer commercial practices, *supra* note 13, would also be applicable.

situation. For example, what is the status of a website addressed to health professionals, alongside the website addressed to consumer? What about press releases or, in general, communications in the press?

The overall assessment needs to take into account many elements, such as whether specific education is required for the correct interpretation of the information, whether there are references to scientific vocabulary not usually used by the general public, whether reference is made to the active substances of the products, instead of to their commercial names or brands, or which are the distribution channels (clinics, private hospitals, consultation offices, etc.). All these factors will ultimately determine whether communications are considered objective information and non-commercial and, thus, allowed even if not complying with the Regulation.

As always, interesting days ahead...