Medicinal Claims

Prohibition, Enforcement and Delineation: Food in Fact but Medicine in Law?

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Under EU medicinal law, substances presented as having properties for treating or preventing disease are medicinal products by virtue of their presentation. EU food law prohibits attributing to any food the property of preventing, treating or curing a disease. However, if certain conditions are fulfilled, it is allowed to make health claims for foods. Authorities in the Netherlands take the position that the EU prohibition on medicinal claims for foods is redundant because all products with such claims are medicinal products by virtue of their presentation. Thus, claims not (fully) authorised are enforced as infringements on medicinal law. The author systematically and comparatively analyses the food law prohibition on medicinal claims in relation to the concept of medicinal product by presentation. He argues that the presentation criterion is structural in nature and depends on the overall impression an averagely well-informed consumer acquires regarding a product. The prohibition on medicinal claims is behavioural in nature. It is possible to promise consumers too much regarding beneficial properties of a food without actually making them believe that the food is a medicinal product. The author argues against the Dutch interpretation and in favour of an interpretation adhered to by most other EU Member States.

I. Introduction

The EU Regulation on Food Information to Consumers in Article 7 holds a prohibition of medicinal claims. For several years now, the Netherlands (the Ministry of Health in particular) has taken the view that this prohibition is redundant because all products for which medicinal claims are made by definition would be medicinal products by presentation.

Against this background, this contribution discusses the prohibition of medicinal claims for foods and the presentation criterion for medicinal products in relation to each other.

II. The Prohibition of Medicinal Claims

Article 7(3) of Regulation (EU) 1169/2011 on Food Information to Consumers (hereinafter: FIC) reads:

> Subject to derogations provided for by Union law applicable to natural mineral waters and foods for particular nutritional uses, food information shall

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not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties.

An equivalent provision regarding the labelling of food supplements can be found in Article 6(2) of Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

Claims attributing the property of preventing, treating or curing a human disease are often (and also in this article) referred to as '*medicinal claims*'.[1]

III. Redundant?

The Dutch Ministry of Public Health, Welfare and Sports (VWS;[2] hereinafter the Ministry of Health) expressed its view for the first time in 2009 in letters to the food law stakeholders platform[3] and to the Federation of the Netherlands' food industry.[4] The reasoning of the Ministry of Health goes as follows. Every product bearing a medicinal claim by definition comes within the ambit of medicinal law. Food products by definition cannot bear medicinal claims because every product with a medicinal claim is a medicinal product and a medicinal product is not a food. Imagine, for example, a business placing a package of butter on the market with the claim 'helps to prevent cancer' or a carton of fruit juice bearing the claim 'beneficial against flue'. It is clear, according to the Ministry, that butter and fruit juice *in fact* are foods. Nevertheless, as a consequence of the way these products are placed in the market *in a legal sense* they have to be qualified as medicinal products. The producer or trader, who chooses to use such a claim on such a product, is responsible for the legal consequences. The ban on medicinal claims in food law is superfluous and confusing because it already follows from medicinal law. For this reason, the Ministry considers it desirable that the prohibition of medicinal claims will be removed from food law. This requires an adjustment first of EU law and then of national law. The Ministry announced (in 2009) that it would discuss the issue in Brussels in the context of the negotiations on the regulation to replace the General Food Labelling Directive 2000/13 (i.e. the current FIC).

As far as I have been able to assess, the Ministry has not actually brought this point to the negotiations.[5] In any case, the Ministry's interpretation clearly has not been embraced by the EU legislature as the prohibition of medicinal claims has been kept in the FIC (in Article 7(3) quoted above).

Nevertheless, the Ministry of Health continues to implement its interpretation in its enforcement policy. The Dutch food and consumer product safety authority (NVWA[6]) provides some information regarding this enforcement policy on its website. Under the heading 'prohibition of medicinal claims'[7] businesses are informed that they may not use medicinal claims for foods; not in information to consumers or businesses nor in information to health care professionals. The use of medicinal claims will in many instances result in the product to be classified as a medicinal product. Under the heading 'How to avoid (prohibited) medicinal claims', it is further stated that in assessing medicinal claims on food products, the NVWA first checks if the product must be classified as a medicinal product. If a claim is not allowed, it is quite likely that using it for a food turns this food into a medicinal product.[8]

Products bearing claims that the Ministry deems to be beyond the limits of what is allowed under the Regulation on Nutrition and Health Claims[9] are deemed to be medicinal products. Businesses plac-

1 The Food Information Regulation in recital 20 uses the expression 'medicinal properties'.

2 Volksgezondheid, Welzijn en Sport.

3 Regulier Overleg Warenwet (ROW).

4 Federatie Nederlandse Levensmiddelenindustrie (FLNI).

5 I have been informed that no report of any meeting of a Commission working group, Standing Committee or the like shows any indication that this point has been raised. Thank you for this information Christine Grit (FLNI) and Joost van Hilten (Waar&Wet). I have tried to acquire further information under Regulation (EC) 1049/2001 from the European Commission and under the Dutch Freedom of Information Act (Wet openbaarheid van bestuur) from the Ministry of Health. By letter of 10th of March 2015 (reference SANCO/E4/AtR/mm purs(2015)1064497 – RefGestDem No 2015/1087), the European Commission informed me that no documents conforming to my request had been found. By letter dated 23rd of March 2015, the Ministry informed me that in the negotiations in Brussels the Netherlands had had other priorities and that the issue was not raised.

6 Nederlandse Voedsel- en Warenautoriteit.

7 See (in Dutch): <https://www.nvwa.nl/onderwerpen/claims-levensmiddelen/verbod-op-medische-claims>.

8 See (in Dutch): <http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/claims-levensmiddelen/verbod-op-medische-claims/hoe-verboden-medische-claims-te-vermijden>.

9 Regulation (EC) 1924/2006.

ing these products on the market are sanctioned on the basis of medicinal law instead of food law. A motivating factor for this policy may well be that fact that in the Netherlands administrative fines under food law were low and 100 times higher under medicinal law. Extreme examples of this policy include frying oil,[10] food supplements providing vitamin D,[11] food supplements providing magnesium[12] and margarine.[13]

This state of affairs brings us to the central question of this article: Is the prohibition of medicinal claims on foods indeed redundant for the reason that a product bearing a medicinal claim by definition cannot be a food?

IV. Medicinal Product by Virtue of Its Presentation

According to Article 1(2) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (hereinafter: the Medicines code) a medicinal product is:

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

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

The two criteria relate to what a product actually does (b – medicinal product by virtue of its function) and what a product promises to do (a – medicinal product by virtue of its presentation).

V. Functions

Both the prohibition of medicinal claims and the presentation criterion for medicinal products relate to communication. They serve, however, very distinct functions.

The presentation criterion serves to *classify products*. On this classification depends which *legal framework applies*: medicinal law or another legal framework – in the context of this article that other framework would be food law. The prohibition of medicinal claims, by contrast, provides a *behavioural norm*. In case food law applies, the consequence is that it is not allowed to make a medicinal claim.

This is notwithstanding the fact that, next to a behavioural function, within food law the prohibition of medicinal claims also has a certain structural function. Some parts of the Regulation on Nutrition and Health Claims have been positioned as exceptions to this prohibition.

10 A ruling by the district court (Rechtbank) of The Hague of 14 November 2012 (ECLI:NL:RBSGR:2012:BY5486) concerns, among other things, a claim on coco-oil. An information sheet found in a shop under the heading 'what is the best oil for frying' held the information that saturated fats generally have a bad reputation. Coco-oil, however, is an exception. It contains natural ingredients that promote health. They also have anti-microbial properties that may have a beneficial effect in the context of combatting harmful bacteria, viruses and fungi in the body. With regard to pirella oil the claim was made that it is rich in polyunsaturated fats. These are transformed into prostaglandins. These have anti-inflammatory properties. Krill-oil holds an anti-oxidant that protects against free radicals that may damage tissue and are suspected of causing chronic diseases. Because of these claims, the NVWA classified these oils as medicinal products and the court agreed. Also, the district court in Rotterdam considered krill oil a medicinal product in relation to the claim that it reduces infiltration of inflammation cells into the joints (ruling of 6 March 2014 ECLI:NL:RBROT:2014:1615).

11 In the ruling of the district court in Rotterdam, mentioned in the previous footnote, several vitamin-D supplements were also considered medicinal products because of a webpage on 'supplements in the media'. This page indicated that vitamin D retards inflammation. For this reason, vitamin D supplements are beneficial for patients who suffer from chronic inflammatory diseases such as asthma and arthritis if they are deficient in vitamin D.

12 The ruling of the district court in Rotterdam, mentioned in the previous two footnotes, went on to consider magnesium supplements as medicinal products because the webpage on 'supplements in the media' mentioned scientific research that showed that magnesium reduces the risk of stroke. For this research see the American Journal of Clinical Nutrition: <http://ajcn.nutrition.org/content/early/2011/12/26/ajcn.111.022376>.

13 The district court in Rotterdam ruled on the 23rd of January 2014 in two cases regarding margarine (ECLI:NL:RBROT:2014:277 and ECLI:NL:RBROT:2014:278). The court considered margarine with added plant sterols a medicinal product because in the presentation on a website a connection was made between lowering blood cholesterol and prevention of cardiovascular diseases. The court concluded the same with regard to the claim that reduction of sodium is beneficial for blood pressure. The fact that plant sterols enjoy an Article-14 claim regarding cholesterol did not change the court's mind because the additional information required by the Claims Regulation was missing and the claim that was actually made went beyond the scope of the approved health claim. According to the court, also the following statement fulfilled the presentation criterion: "The product has been fortified with vitamins B6, B12 and folic acid. These vitamins ensure that levels of homocysteine do not become too high. This is important because a high level of homocysteine probably has a negative impact on cardiovascular health."

Article 14(1) of Regulation (EC) 1924/2006 on nutrition and health claims made on foods, reads:

> Notwithstanding Article 7(3) of Regulation (EU) 1169/2011,[14] reduction of disease risk claims and claims referring to children's development and health may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation for inclusion in a Community[15] list of such permitted claims together with all the necessary conditions for the use of these claims.

Apparently, the EU legislature considers children's development claims and disease risk reduction claims to be within the scope of the prohibition of medicinal claims. This stands to reason given the broad wording of this prohibition.[16] However, they are explicitly exempted from the prohibition in so far as they have been authorised and all other requirements are complied with. For other nutrition and health claims this exemption has not been put in place. Nevertheless, the EU legislature considers them as allowed when all requirements are fulfilled. Apparently, the EU legislature considers these claims to be outside the scope of the prohibition of medicinal claims.

In summary, fulfilment of the presentation criterion is a *condition* for the applicability of medicinal law. Applicability of the prohibition of medicinal claims is a *consequence* of the applicability of food law. Or, to phrase it differently, the presentation criterion is an input criterion, the prohibition of medicinal claims is an output criterion.

VI. Medicinal Law Takes Priority over Food Law

Generally speaking, medicinal law takes precedence over other areas of law. To this end Article 2(2) of the Medicines code states: "In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply."

In relation to EU food law, this provision is meaningless. Medicinal products within the meaning of the Medicines code are as a category excluded from the definition of food. Therefore the situation in which a product falls both within the definition of a medicinal product and within the definition of food legally cannot occur.[17] Article 2(2) of the Medicines code does not apply, or at the very least does not seem to apply, to the situation where it is uncertain whether a product is within the definition.

Article 2 of Regulation (EC) 178/2002 (hereinafter: the General Food Law, and GFL) defines a food as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. (...)."

In the remainder of the provision, the scope of this definition is expanded and limited. The limitation that concerns us here is the following:

"'Food' shall not include:(...)(d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;[18](...)."

Thus, a product *cannot* at the same time be a food and a medicinal product. If on the basis of its presentation a product becomes a medicinal product, by definition it stops being a food. This leaves no room for a doubt that is based on the applicability of both definitions simultaneously. Neither can Article 2 of the Medicines code be applicable. This makes it all the more crucial to determine when the presentation criterion applies, and when it does not.

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14 Actually, the text says: "Article 2(1)(b) of Directive 2000/13/EC" According to Article 53(2) FIC references to Directive 2000/13/EC "shall be construed as references to" the FIC. In this case "Article 2(1)(b) of Directive 2000/13/EC" must, therefore, be read as "Article 7(3) of Regulation (EU) 1169/2011". When will such shamelessly sloppy legislation be a thing of the past? EU legislation is complicated enough as it is, without expecting stakeholders to figure out for themselves when and how texts should be "construed" to say something different from their actual text. Proper legislation requires amendment of the text itself.

15 Does it follow implicitly from Article 1 of the Treaty on European Union that the word 'Community' shall be construed as 'Union'?

16 In the Dutch language version, the last words of Article 7(3) FIR "nor refer to such properties" are phrased in a way that is best translated into English as "nor make allusions to such properties". While the English 'refer' may have this meaning, it is usually understood in a more restricted sense. The German text is somewhere in between these two: "make the impression of such properties appear" (which should probably be read as "imply such properties"). The Italian version also can be understood either way. The Polish and Spanish versions are like the English one.

17 Such would at least be my interpretation. In the Netherlands, both in literature and in case law the opinion is advocated that Article 2 of the Medicines code is crucial and even that a product can be both a food and a medicinal product at the same time. District court (Rechtbank) of Rotterdam, 23 January 2014, ECLI:NL:RBROT:2014:278; Christine Fontaine, Levensmiddel of geneesmiddel? Is het onderscheid nu echt zo lastig of gaat het om de financiën? Waar&Wet July 2014, pp. 2-4.

18 According to Article 128 of the Medicines code "[r]eferences to the repealed Directives shall be construed as references to this Directive". The observation regarding shamelessly sloppy legislation made in footnote 14 needs to be repeated here.

VII. Case Law

In the case law of the Court in Luxembourg (hereinafter: the Court or CJEU[19]) the classification of a product as a medicinal product has been at issue several times. The ruling in *Upjohn/Farzoo*[20] shows that the purpose of the presentation criterion is to protect consumers not only from medicinal products that are harmful or toxic as such, but also from products that are used instead of adequate medicinal products. According to the Court, a product can be a medicinal product if it is presented as such without actually having the property to prevent or cure. The Court further elaborates in the *Ter Voort* case (at 26):[21]

> The conduct, action and approaches of the manufacturer or the seller which disclose his intention to make the product he markets appear to be a medicinal product in the eyes of an averagely well-informed consumer may therefore be conclusive for the purposes of deciding whether a product should be regarded as a medicinal product by virtue of its presentation.

On 15 November 2007, the Court gave its ruling in case C-319/05, also known as the 'garlic-case'. The ruling was given in an infringement procedure against the Federal Republic of Germany. The question at issue is whether a garlic preparation offered for sale in the form of capsules constitutes a medicinal product by function or by presentation. Germany had prohibited the import of this product, which was legally marketed as food supplement in other EU Member States because it has curative properties (that were, however, not claimed). According to Germany it thus qualifies as a medicinal product and cannot be admitted to the market without authorisation. The Court addresses both elements of the definition: function and presentation. Regarding both elements, the Court recognises a threshold that must be exceeded before classification as a medicinal product is justified.[22] Regarding function the Court acknowledges that certain foods have curative properties, but not to a sufficient degree so as to classify them as medicinal products.[23]

The core considerations regarding presentation, considerations 44, 46 and 47, deserve to be quoted in full:

> 44 In that context, a product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83 when it is *expressly 'indicated' or 'recommended' as such*, possibly by means of labels, leaflets or oral representation (see, to that effect, van Bennekom, paragraph 18, and Monteil and Samanni, paragraph 23).
> (...)
> 46 A product is also 'presented for treating or preventing disease' whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question (see, to that effect, van Bennekom, paragraph 18, and Monteil and Samanni, paragraph 23).
> 47 In that regard, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the 'form' must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product (see, to that effect, van Bennekom, paragraph 19, and Monteil and Samanni, paragraph 24).

From these considerations, two things follow: first, a connection between function and presentation and, second, a distinction between two aspects of presentation.

The function criterion protects consumers from products that possess certain properties. The presentation criterion protects consumers from products they are led to believe are medicinal products. Logic dictates that the presentation must relate to proper-

19 For simplicity sake, this abbreviation is also applied to cases litigated before the Lisbon Treaty.

20 Case C-112/89.

21 CJEU 28 October 1992, case C-219/91 (*Ter Voort*).

22 In doing so, the Court overruled a position taken by Germany in the proceedings. Germany had explicitly denied the existence of a 'materiality threshold'. See consideration 25.

23 CJEU 15 November 2007, case C-319/05 (*Commission v. Germany 'Garlic'*) at 65: "As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83."

ties that, if present, would fulfil the function criterion. In other words, the impression created is one of medicinal product by function. In this regard, see also the *Van Bennekom* case (at 17):[24]

> [I]t should be observed that the directive, by basing itself, in the first Community definition of a medicinal product, on the criterion of the product's "presentation", is designed to cover not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of their presentation. The directive thereby seeks to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. For that reason, the concept of the "presentation" of a product must be broadly construed.

In case the effect claimed would, if present, not be sufficient to classify a product as a medicinal product by function, there would be little reason to classify it as a medicinal product by presentation. What is claimed simply does not suffice.

The second connection is derived from the wording in consideration 44, "expressly 'indicated' or 'recommended' as such," and in consideration 46, "whenever any averagely well-informed consumer gains the impression."

Apparently, the presentation criterion encompasses two alternative aspects. The first aspect relates to the *action* of the manufacturers or the sellers (that shows their intent). The second is the *reaction* of the consumers (their impression to be dealing with a genuine medicinal product). On the intention of the business, see further the cases *Delattre* and *Van Bennekom*.

Delattre (C-369/88 at 38)

> As has already been pointed out by the Court in its judgment in Van Bennekom, (...), to which, moreover, the national court refers, although the external form given to a product may serve as strong evidence of the seller's or manufacturer's intention to market the product as a medicinal product, it cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered.

Van Bennekom (C-227/82)

> 18 It is therefore necessary to take the view that a product is 'presented for treating or preventing disease' within the meaning of directive 65/65 not only when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the community definition.
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> 19 In particular, the external form given to the product in question - such as that of a tablet, pill or capsule - may in this connection serve as strong evidence of *the seller's or manufacturer' s intention* to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered.

The first aspect is about the business laying claim to the status of medicinal product (i.e. that it has therapeutic or prophylactic properties). The second aspect shifts emphasis from the action of the business to the effect on the consumer. Key in the Court's thinking is protection of the consumer who is led to believe that a product is a medicinal product. In consideration 65 of the *garlic case*, the Court juxtaposes this belief with "products generally recognised as foodstuffs".[25] In my view, the conclusion must be that the presentation criterion is not about an isolated communication but about the total (and definite) pic-

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24 CJEU 30 November 1982 case 227/82 (*Van Bennekom*).

25 In the *Orthica* case (CJEU 9 June 2005, *HLH Warenvertrieb and Orthica v. Germany*; joined cases C-211/03, C-299/03, C-316/03 and C-318/03), the CJEU stated that the evaluation of a product by function should be conducted "having regard to all of their characteristics, in particular their composition, their pharmacological properties – to the extent to which they can be established in the present state of scientific knowledge – the manner in which they are used, the extent of their distribution, their familiarity to consumers and the risks which their use may entail". On this topic see also Malgorzata Korzycka-Iwanow and Monika Zboralska, Never-ending Debate on Food Supplements: Harmonisation or Disharmonisation? EFFL 3|2010, pp. 124-135. The Court repeated this reference to *familiarity to consumers* in its ruling CJEU 6 September 2012 *Chemische Fabrik Kreussler&Co. GmbH*. v. *Sunstar Deutschland GmbH*, Case C-308/11. If familiarity to consumers has to be taken into account in classifying a product by function, should this not be even more the case in classifying it by presentation?

ture that "any averagely well-informed consumer" gains, or at least that the business attempts to make this consumer gain. If the presentation of the product taken in its totality conveys to these consumers the definite impression that they are dealing with a medicinal product with all its implications, then this presentation classifies the product as a medicinal product. If, however, the product at issue is "generally recognised as a foodstuff", an isolated communication that suggests otherwise must be dealt with under food law – as an infringement on the prohibition of medicinal claims – as long as it is insufficient to convince an averagely well-informed consumer that the product in fact is not/no longer a food but rather a medicinal product, or if the business acts on the intention to achieve this effect.

The Court approaches 'presentation' as the total definite picture that emerges for the averagely well-informed consumer from all elements taken together, including shape of the product, packaging, labelling and recommendations. This totality must either show the business' intention to make the averagely well-informed consumer believe that the product is a medicinal product or it must have the effect with this consumer that the definite impression is gained (regardless if this was the business' intention).

If one would narrow-down the concept of 'presentation' to a single communication in isolation from its context and in isolation from its likely effect on the averagely well-informed consumer, the risk occurs against which the Advocate General Geelhoed warns in his opinion in the *Orthica* case[26] (at 36):

> In my opinion, there are three objections to too broad an interpretation and application of the definition of medicinal product. First of all, the concept of 'medicinal product' would cease to have any differentiating effect if it were to include products whose properties and action did not justify their being classified as such. This would harm rather than serve the interests of human health. Secondly, it could result in the specific Community regulations for certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory object. I am thinking, inter alia, of Regulation No 258/97 concerning novel foods and novel food ingredients and Directive 2002/46 on food supplements. Thirdly, a 'stealthy' extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods.

From the case law quoted above, it follows that the ratio of the presentation criterion is to protect the consumer from being made to believe that a product has certain curative properties while in reality it does not. It is, in other words, about protection against quackery. The situations to which the Dutch Ministry of Health applies this criterion are far outside the scope of this ratio. They include situations where scientific evidence shows that the product actually does have the properties claimed, but according to the Ministry, it is not or not in the form chosen allowed to inform the consumer of this scientifically proven fact.

VIII. Consumer

The Court applies as a yardstick 'the averagely well-informed consumer'. In French, the Court's working language, this is 'un consommateur moyennement avisé'. One of the first cases where this formula was introduced was the *Van Bennekom* case (1983). This case was litigated in Dutch language. The Dutch expression is 'een met gemiddeld onderscheidingsvermogen begiftigde consument', that is a consumer who has been gifted with an average capacity to distinguish. In these different renderings, we seem to find, on the one hand, more emphasis on the information available to the consumer and, on the other hand, on the capacity of the consumer to make sense of the information.

The consumer in this case law is not an empirical reality but a legal model. Therefore, the impression this consumer gains does not vary from person to person. In assessing the impression this consumer gains, the courts can reach an unambiguous classification of a product. It is a medicinal product if to the model consumer it definitely appears to be a medicinal product; if not it is not. The classification does not differ from consumer to consumer.[27]

In my understanding, the averagely well-informed consumer is intelligent, attentive, aware of and takes an interest in the communication at issue, has a de-

26 CJEU 9 June 2005, *HLH Warenvertrieb and Orthica v. Germany*; joined cases C-211/03, C-299/03, C-316/03 and C-318/03.

27 Logically, it should not differ either from business to business. It seems, however, that the presentation criterion is upheld only against the business wrongfully creating the impression that a product is a medicinal product.

cent general education but no expert knowledge.[28] This consumer does not believe that Red Bull actually gives a person wings, but does take the underlying message seriously that the product provides energy.

The nagging question now is whether or under which circumstances this model consumer can distinguish a medicinal product from a food with a claim.

IX. Continuous Classification?

Two objections can be raised against the interpretation of the Dutch Ministry of Health that the prohibition of medicinal claims coincides with the presentation criterion.

The first objection is that this interpretation disregards that *communication* is the regulatory object (to speak with Geelhoed) of the prohibition of medicinal claims, while the regulatory object of the presentation criterion is the *product*. The presentation criterion is about classifying the product in light of the communication. The key question is how a consumer perceives the product. A simple communication *can* cause a product to be perceived in a certain way (see also *Ter Voor*t at 20), but that is not necessarily the case. Also, other factors and prior knowledge may influence how the averagely well-informed consumer perceives the product.

The second – related – objection is that the Ministry's interpretation focusses solely on the criterion for classification. It disregards the question when classification is due; the question, in other words, in which situation this criterion must be applied. The Ministry's interpretation implies that classification is a continuous process that can occur at any communication. A product can be a food in the morning and a medicinal product in the afternoon depending on the eructation of a marketing department. From a point of view of delineation of areas of law,[29] such state of affairs would be highly problematic. The same product would be subject to food law requirements and food inspection one moment and medicinal law requirements and medicinal inspections the next, just because some advertisement has been published.[30]

In my view, classification is due when it has not (yet) taken place (e.g., a product appears on the market after product development or import), if a serious difference of opinion regarding the nature of the product exists or if there is reason to doubt the (continued) validity of prior classification. These situations have in common that in all fairness the averagely well-informed consumer can wonder 'what kind of product is this?'.

This is not the place for a systematic analysis of all cases of the CJEU where classification has played a role. If we limit ourselves to the cases that have been mentioned above, we find the following.

The *Upjohn* case[31] resulted from a conflict between two competitors. Both marketed a product intended to counteract alopecia androgenetica, or natural baldness, containing 'minoxidil' as an active ingredient. The one business marketed it as a proprietary medicinal product, the other as a cosmetic product.

The *Ter Voort* case concerns criminal prosecution for marketing a botanical (herbal tea) whether or not having medicinal properties.

The *garlic* case is about the refusal to grant an import licence for capsules containing a concentrate of the active substances in garlic (with an allicin content between 0.95% and 1.05%).[32]

The *Van Bennekom* case,[33] again, results from criminal prosecution. The product a quo is a vitamin preparation. Among other things, the Court considers "that it is impossible in the present state of scientific knowledge to state whether the criterion of concentration alone is always sufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product".

Another case, *Monteil and Samanni*,[34] is about prosecution for marketing of eosin of a strength of 2% and modified alcohol of a strength of 70%. The ruling shows that Member States differ on the question whether or not these are medicinal products. It is undisputed that they have antiseptic and antimicrobial properties, but so does soap.

Discussion in the *Delattre* case[35] is, among other things, about slimming products, an anti-itching

28 See also CJEU case C-210/96 (*Gut Springenheide*) and CJEU case C-470/93 (*Mars*).

29 In this case – the delineation of food law from medicinal law.

30 The Netherlands has indeed drawn the consequence of its interpretation by granting the food safety authority the competence not only to inspect compliance with food law but also with medicinal law.

31 C-112/89 (*Upjohn/Farzoo*).

32 CJEU 15 November 2007, case C-319/05 (*Commission v. Germany 'Garlic'*).

33 CJEU 30 November 1982, case 227/82 (*Van Bennekom*).

34 CJEU 21 March 1991, case C-60/89 (*Monteil and Samanni*).

35 Case C-369/88 (*Delattre*).

product and a method for stopping smoking. The *Ortica* case,[36] finally, concerns the import of probiotics.

All these cases have in common that the question whether we are dealing with a medicinal product is an earnest question. We do not find any trace here of the distinction that the Dutch Ministry of Health makes between a food *in fact* but a medicinal product *in law*. There is no example of a "product generally recognised as foodstuff" that becomes classified as a medicinal product because of an isolated communication about a genuine property of the product.

The closest to this situation is the *Ter Voort* case. The Court explicitly considers (at 21) "that a product recommended or indicated as having prophylactic or therapeutic properties is a medicinal product (...) even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect". We should bear in mind, however, that the Court focusses on the business' *intention*, not on the consumers' definite impression. See, for example, at consideration 25 stating that "the provisions of Directive 65/65 are designed among other things to avoid products being placed on the market which do not have therapeutic effects but, for a commercial purpose, are presented as medicinal products by the manufacturer or the seller," and at consideration 26, which reads as follows:

> The conduct, action and approaches of the manufacturer or the seller which disclose his intention to make the product he markets appear to be a medicinal product in the eyes of an averagely well-informed consumer may therefore be conclusive for the purposes of deciding whether a product should be regarded as a medicinal product by virtue of its presentation.

Apparently, "products generally recognised as foodstuffs" can be classified when a business seriously – even if unsuccessfully – attempts to convince the consumer that the product is a medicinal product. This is still rather remote from the situation where a business supplies information that, even though it is genuine, should not have been supplied.

X. Interpretation by the Legislature

The fact that medicinal law takes priority over food law does not imply that what the legislature does in the area of food is totally irrelevant to the interpretation of medicinal law.

EU law has built a system that allows nutrition and health claims to be made, including children's development claims and disease risk reduction claims. The legislature also sees room to claim health relevance for mineral water[37] and for foods for special purposes. The EU legislature apparently believes that it is possible to make such claims for foods. This, however, is only the case if the product remains a food when such a claim is made. In its turn, a product only remains a food if the legislature is convinced that from a claim of this category 'the averagely well-informed consumer' does not gain the impression that the product has therapeutic or prophylactic properties.

Thus, the legislature gives an interpretation 'which, is definite, though it results from implication' of the presentation criterion. Because the cue in the presentation criterion is the consumer's definite impression not the legal status of the claim, in my view this interpretation applies equally with regard to claims that have not been authorised but are of a type that could be authorised (if only sufficient scientific evidence would be presented to EFSA). In the latter situation, obviously, making the claim is an infringement. This infringement, however, is of a food law nature.

The same line of argument applies to the prohibition of medicinal claims. The mere fact that the legislator prohibits such claims implies that in the view of the legislature such claims can be made. If the Dutch Ministry of Health has put its point forward

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36 CJEU 9 June 2005, *HLH Warenvertrieb and Orthica v. Germany*; joined cases C-211/03, C-299/03, C-316/03 and C-318/03.

37 This room, however, should not be overrated. Article 9(2) of Directive 2009/54/EC on the exploitation and marketing of natural mineral waters, reads:"All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited.
However, the indications listed in Annex III shall be authorised if they meet the relevant criteria laid down in that Annex or, in the absence thereof, criteria laid down in national provisions and provided that they have been drawn up on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognised scientific methods, in accordance with Annex I, Section I, point 2.
Member States may authorise the indications 'stimulates digestion', 'may facilitate the hepato-biliary functions' or similar indications. They may also authorise the inclusion of other indications, provided that the latter do not conflict with the principles provided for in the first subparagraph and are compatible with those provided for in the second subparagraph."
Annex III of these directives mainly relates to content claims rather than medicinal claims. Nothing comes closer than the allowed claim: 'Suitable for a low-sodium diet'.

in Brussels as it intended to do, then this means that the legislature's choice to reinstate the prohibition of medicinal claims was made in the awareness of the Dutch interpretation that it is redundant and that the majority rejects this interpretation. If the Netherlands has refrained from making its point as it seems the country has, it is all the more committed to the prevailing interpretation. It must be the EU legislature's opinion that the prohibition of medicinal claims is meaningful because trespassing it is possible and also exceptions for mineral waters, special foods, children's development claims and disease risk reduction claims are meaningful and can apply to foods.

All this shows that the EU legislature requires more than trifles before it considers the presentation criterion fulfilled. In the view of the legislature, 'the averagely well-informed consumer' has no problems distinguishing a food with a claim from a medicinal product. If the legislature works on the basis of the assumption that the averagely well-informed consumer's capacity to distinguish is well developed, in my view administrative and judicial authorities in the Member States cannot deny the same consumer this capacity.[38]

XI. Interpretation in other Member States

So how do other EU Member States approach this issue?[39]

During the Food Science Dialogue in Hamburg (15 – 20 September 2014), I asked the participants if they were aware of similar interpretations in their home countries. Only the Dutch participants responded affirmatively. Participants included, among others, experts with knowledge regarding food law in Germany, Italy, Spain and the UK. Earlier on, the Dutch interpretation had been discussed in FoodDrinkEurope. Again, participants from other countries reported that the Dutch approach did not exist in their home countries.[40]

Further inquiry within my network of food law experts reinforced this picture. In the countries on which I acquired information, the question whether a product should be classified as a medicinal product by virtue of its presentation and the question whether a claim made for a food infringes on the prohibition on medicinal claims are separate questions. These questions are answered on a case-by-case basis, in most cases by separate authorities.

Table 1 (see Appendix) shows the countries to which this applies and also indicates the experts who were so kind to provide information.

It has to be admitted that my inquiry did not cover *all* 28 EU Member States, let alone the entire EEA, but, as far as I can see, the Netherlands does not enjoy much (if any) support for its position. Even within the Netherlands, the Advertisement Code Commission (Reclame Code Commissie) – a self-regulatory board on proper advertisement practices – does not follow the lead of the Ministry of Health but repeatedly considered that a product is a food and therefore is not allowed to bear a medicinal claim.[41]

XII. Conclusion

From a systematic perspective, it must be accepted that the presentation criterion leaves ample room for communications that infringe upon the prohibition of medicinal claims, i.e. for foods with medicinal claims.

In my view it is important to distinguish two legal moments: 1) the classification of a product that leads to the applicability of a set of rules (i.e. medicinal law or food law); and, 2) legal consequences that occur through the application of the rules. In a legal-systematic sense, the former has to come before the latter.

The presentation criterion is about the classification of *products*. It serves to designate the applicable law. By its very nature, classification is structural. Once it has occurred it remains in place until something crucial changes. Classification is due when it can seriously be asked what kind of a product one is dealing with. This is particularly the case at market introduction (which includes the discovery on the

38 And if they insist to differ, at the very least a preliminary ruling should be asked from the CJEU.

39 In my view it is important to invest more in horizontal comparison of EU food law. By this I mean, investigating how EU food legal concepts are understood in the different EU Member States. In a previous publication I called upon you – my colleagues – to join forces with me. See: Bernd van der Meulen, Durchsetzung des EU-Lebenmittelrechts in den Mitgliedstaaten: die Beispiele „Medizinische Claims" und „Pferdefleischskandal" als Aufforderung zur Schaffung eines horizontal vergleichenden EU-Lebensmittelrecht, in: Ines Härtel (ed.) Wege der Ernährungswirtschaft – global, regional, europäisch, Nomos 2017, p. 73-89.

40 Thank you for this information Christine Grit and Joost van Hilten.

41 See, for example, Waar&Wet 2014/1, pp. 24-25 and Waar&Wet 2014/5, pp. 76-77.

market of a product that authorities were not previously aware of). Classification is only structural if it is accepted that a certain threshold applies that must be surpassed before re-classification can take place.

The prohibition of medicinal claims is a behavioural norm. In that sense, it is not structural but incidental. By all kinds of communication, infringements can take place which can easily be terminated by changing the communication.

The presentation criterion regards the averagely well-informed consumer's definite impression of a product regarding its curative or prophylactic properties. It encompasses two elements: the business' intention to create this impression, and the impression that the consumer actually gains. These elements are alternative. If one of the two is fulfilled, the product qualifies as a medicinal product. If the threshold is not passed, neither with regard to the intention of the business nor with regard to the impression the averagely well-informed consumer gains from the presentation, the product does not qualify as a medicinal product.[42]

The averagely well-informed consumer is not an empirical consumer but a legal construct. In assessing which impression this consumer gains, account must be taken of the interpretations the EU legislature holds as appears from the legislation.

In case the product is a food, the admissibility of communications must be assessed on the basis of food law. If these communications go beyond authorised claims, food law enforcement is due.

In this whole constellation, the prohibition of medicinal claims holds its own independent position. I do not share the opinion that it is redundant.

XIII. Discussion: Time for Phood?

With the conclusion that the prohibition of medicinal claims is not redundant, nothing has yet been said about the question whether it is desirable to have such a prohibition.

The delineation of food law from medicinal law is far from simple. Neither the function criterion nor the presentation criterion is unambiguous. The bipolar separation of food and medicinal product does not do justice to reality[43] where curative and prophylactic properties are a matter of degree and of dose.[44] Even the CJEU explicitly recognises the existence of medicinal properties in foods.[45]

The prohibition of medicinal claims has been framed within the context of the prohibition to mislead the consumer. One has to wonder, however, if this remedy is not worse than the disease in situations where it leads to the consequence that consumers may not be informed of a truth that has been established scientifically.

In my view, it is high time for a reassessment of the delineation of food law and medicinal law. Elements in this reassessment could be the recognition that the realities to which these legal domains relate, overlap; an application of the presentation criterion only to those situations where its ratio applies (i.e. protecting the consumer from products that are not the medicinal products the consumer is led to believe) and limitation of the scope of the prohibition of medicinal claims to situations where it is likely that consumers may be misled. If there are really foods that can prevent or cure disease, that is a truth that must be told – or at least allowed to be told. It can be regulated to protect the consumer, but not suppressed altogether. Increasingly the term 'phood' is used to designate innovations in which the food and pharmaceutical sectors join forces. In foresight studies performed at the request of the European Commission, this is one of the likely scenarios for the coming decades.[46]

The averagely well-informed consumer is expected to be able to distinguish good politics from bad politics when voting, to be able to decide when to

42 Explicitly to this effect: CJEU 30 November 1982 case 227/82 (*Van Bennekom*) at 23: "a product which is covered by neither the first nor the second part of the Community definition of a medicinal product may not be regarded as a medicinal product".

43 The EU approach does not represent the only possibility. In the USA, food and drugs are regulated under one legal framework, the Federal Food, Drug and Cosmetic Act administered by the Food and Drug Administration, instead of under two strictly separated legal frameworks. A product can come within both legal frameworks without this seeming to cause many problems. See Lisa Heinzerling, U.S. Food Law: Cases and Materials, Georgetown University Law Center, second edition 2015, Chapter 2.

44 Sebastián Romero Melchor and Liesbeth Timmermans, "It's the Dosage, stupid": The ECJ clarifies the Border between Medicines and Botanical Food Supplements, EFFL 3|2009, pp. 185-191.

45 CJEU 15 November 2007, case C-319/05 (*Commission v. Germany 'Garlic'*) at 65: "As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes."

46 See Delivering on EU Food Safety and Nutrition in 2050 - Future challenges and policy preparedness <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/delivering-eu-food-safety-and-nutrition-2050-future-challenges-and-policy-preparedness>.

self-treat with over-the-counter medicinal products and when to consult a physician. Why may this very same consumer not be informed that adjustment of the diet may be beneficial in view of a disease? The CJEU acknowledges that it is a scientifically established fact that garlic can help to cure me if I suffer from arteriosclerosis.[47] Does it serve any reasonable interest that, due to the prohibition of medicinal claims, it is not allowed to inform averagely well-informed consumers like me of this fact?

47 CJEU 15 November 2007, case C-319/05 (*Commission v. Germany 'Garlic'*).