

# Are e-cigarettes medicines?

A briefing by Clive Bates

Version 3

Updated 28 March 2013

This document discusses whether e-cigarettes should be classed as medicines or consumer products, focussing on legal and regulatory views of this issue.

## Contents

Introduction - characteristics of e-cigarettes.....	2
An expert view and user view .....	3
Formal definition of medicine in EU law.....	3
UK regulatory committee challenges medicines classification.....	4
Legal interpretations in the European Union member states .....	5
1. Netherlands.....	5
2. Cologne, Germany.....	5
3. Sachsen-Anhalt, Germany.....	6
4. Estonia.....	7
Relevant European Court of Justice case law .....	7
1. Germany - the garlic case.....	7
2. Germany - the fermented red rice case.....	8
Legal principle in the European Union.....	8
The principle of proportionality.....	8
The principle of non-discrimination.....	9
International legal provisions .....	9
WTO - Technical Barriers to Trade.....	9
What is the right approach to take? .....	10
Appendix: The garlic case - extract from ECJ judgement paragraphs 59-71 .....	12

## Introduction - characteristics of e-cigarettes

If enacted, the proposed [EU Tobacco Products Directive](#) would mean that that the vast majority of e-cigarettes would be [regulated as medicines](#). I have written at length about the danger of this:

- [Medicines Regulation for e-cigarettes: when caution can kill](#)
- [Reduce harm or protect the cigarette industry?](#)

But can e-cigarettes be lawfully classified as medicines? Should they? Some points to consider:

- **Positioning.** E-cigarettes are marketed as consumer products, not medicines. They are a modern technology for delivery of a legal widely used recreational drug, nicotine, that has been historically sold in tobacco form, most commonly for smoking.
- **Comparator is cigarettes.** These products are sold as superior hi-tech alternatives to cigarettes, not as smoking cessation aids or as a form of NRT.
- **Consumer product characteristics.** E-cigarettes have important consumer product characteristics - such as [dozens of \(sometimes frivolous\) flavours](#). These increase the appeal relative to cigarettes but are not commonly found in medicines, and would likely be prevented by medicines regulation.
- **Claims.** They make no claims for quitting, and they satisfy rather than treat nicotine addiction. They are likely to have the effect of reducing disease, but they are not treatments for disease. Many consumer products have health benefits, but are not considered medicines.
- **Type of risks.** Most of the risk associated with e-cigarettes relate to electrical and heating element safety and to the containment of e-liquids, rather than adverse physiological reactions or overdose by users.
- **Health risk.** Given what is already known of the product characteristics, the difference in risk between smoking tobacco cigarettes and e-cigarettes is likely to be at least two orders of magnitude. Given the relative risks, regulation of e-cigarettes should be proportionate and non-discriminatory, when compared to the regulation of cigarettes.
- **Normal concerns.** Safety and quality concerns are common to a vast number of consumer products and there is already adequate consumer protection legislation to cover these. These risks are better managed under the [General Product Safety Directive](#) and [framework of consumer protection policy](#). The EU's [RAPEX system](#) captures reports of defective products and enables them to be removed from the market.
- **Consumer choice not regulatory decision.** Whether they are 'effective' alternatives to cigarettes is not a question for regulators, but a matter for consumer preference and there is no objective 'right answer' to this. As long as the products are acceptably safe,

(ie far safer than cigarettes), work as designed and are described appropriately, they should not face further barriers to competing with cigarettes.

## An expert view and user view

**The expert.** The late [Professor Michael Russell](#), a pioneer in the understanding of nicotine and behaviour, captured the distinction more than twenty years ago. Writing in the [British Journal of Addiction](#) in 1991 he recognised the potential for a different type of nicotine delivery product:

*It is argued here that it is not so much the efficacy of new nicotine delivery systems as temporary aids to cessation, but their potential as long-term alternatives to tobacco that makes the virtual elimination of tobacco a realistic future target. [...] A case is advanced for selected nicotine replacement products to be made as palatable and acceptable as possible and actively promoted on the open market to enable them to compete with tobacco products.*

**The user.** In response to a February 2013 article in the New Scientist [E-cigarettes may soon be sold as life-saving medicine](#), a user 'Graham' left the following online comment, and it is typical of many of the [testimonials of e-cigarette users](#).

*I cannot offer a scientific analysis, just a personal one. I stopped by my local convenience store a few weeks ago, preparing for a night in front of the TV watching Euro football. As I purchased my 20 smokes with my beer, the cashier suggested I try an eCig. So I bought one. £4.99 for a metal tube that supposedly replicates 20 cigarettes. I got home, put on the footie, cracked a beer, and sucked on this metal tube thing for the first time ever. I haven't smoked a 'real' cigarette since. The pack of 20 real cigs remains in a drawer, next to the TV remote. It says on the pack - if you don't already smoke, don't try this product. But I did smoke, and now I can say I don't smoke cigarettes. If you recognise yourself in my story - please try them. They work.*

This person does not appear to regard himself as in treatment or taking a medicine - I hope that is obvious. It is important to listen carefully to what users say and how they use the products. The common thread is that they are using these as alternatives to cigarettes, not as medicines, exactly as envisaged by Michael Russell all those years ago.

## Formal definition of medicine in EU law

This is the definition of a medical product in the medicines directive ([2001/83/EC](#)).

### **Article 1. Definitions**

#### **2. Medicinal product:**

*(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 UK medicines regulator, the Medicines and Healthcare Products Regulatory Authority believes this definition gives adequate legal cover to regulate e-cigarette as medicines (see this [MHRA Q&A](#) - question 2). But that doesn't mean they have to be regulated in this way.

**Definition under part a.** Some argue that part (a) in the definition above might apply - that e-cigarettes are used for quitting smoking and preventing disease, and therefore have an *implicit* therapeutic claim. They argue therefore that the tests of 'efficacy' are required to prove that these products work as smoking cessation aids. They may well be used in this way, but the manufacturers don't make that claim any more than *Tropicana* claims its orange juice wards off colds and flu. Just because something has beneficial health effects doesn't make it *de facto* or *de jure* a medicine. The real purpose of the first part of the definition of a medicine is to allow regulators is to test 'therapeutic claims'... ie. claims by the maker that it will help you quit smoking, reduce cancer risk, cure addiction or similar. But the vendors of these products do not make therapeutic claims, they simply argue that these are alternatives to cigarettes with largely self-evident superior characteristics. Note NRT products come under this definition because the makers seek an '[indication](#)' that is a regulator-approved claim that the products have certain beneficial [therapeutic effects](#).

**Definition under part b.** Some argue that part (b) in the definition might apply. This definition could cover things like pain killers or insulin, an agent that modifies physiological functions by exerting a pharmacological action. To the extent that e-cigarettes deliver a psychoactive drug effect this might apply - this argument is used by MHRA in its [Q&A](#). But this idea isn't always applied - alcoholic drinks and caffeinated drinks like Red Bull could also fit this definition but come under food regulation, cigarettes deliver nicotine and come under tobacco regulation - in these cases an appropriate regulatory framework has been defined. In reality, e-cigarettes are a cleaner delivery system for a legal recreational drug, rather than a medicine.

The following discussion outlines legal and regulatory scepticism about the classification of e-cigarettes as medicines.

## UK regulatory committee challenges medicines classification

The special purpose [Regulatory Policy Committee](#) (RPC) provides independent scrutiny of regulatory proposals for the UK government. It dismissed the case for medical regulation in its [opinion](#) of June 2010 on the MHRA's consultation and impact assessment (IA):

*The RPC is of the opinion that the IA and consultation letter do not provide sufficient evidence to suggest that there is a significant risk to public health from currently unlicensed NCPs which would justify the future regulation of these products. MHRA should have made clearer what evidence is available to suggest there are safety and public health concerns about these products and considered a wider range of policy options before consulting on the introduction of a mandatory licensing requirement for all NCPs. In addition, the data and assumptions used in the IA for estimating the costs and benefits of the new regulations do not appear to be robust.*

On 18 February 2013, a UK official confirmed that further regulatory scrutiny would be required (personal communication):

*Ultimately any change to regulation in this area would (as with all regulatory changes affecting business) require collective Ministerial agreement and sign off by the Reducing Regulation Cabinet Sub-Committee. Prior to putting such proposals to the RRC - departments are required to send the associated Impact Assessment to the Regulatory Policy Committee.*

## Legal interpretations in the European Union member states

There have been four cases where the courts have examined the interpretation of e-cigarettes as medicines under national laws which are implementations of the EU law in this area.

Here are some examples (my thanks to [ECITA](#) for their assistance):

### 1. Netherlands

United Tobacco Vapor Group Inc. versus the State of the Netherlands (the Ministry of Health, Welfare and Sport and the Ministry of Finance), in the Netherlands Court of the Hague, [2012], [Case number 414117](#)

The s-Gravenhage Court in the Netherlands concluded in its ruling of 13 March 2012 that:

*“the state will be required to provide evidence that upon the use of an e-cigarette the pharmacological properties are, for that purpose, stronger than those observed when the original product (cut tobacco leaves) is used. The state has failed to supply any scientific evidence to prove its allegations”*

*"The State has argued that it is not the State who has the burden to scientifically demonstrate that the e-cigarette produces pharmacological effects under the Medicines Directive. The judge considers this view untenable. It is the minister who has decided to classify e-cigarette products as medicinal brands. It is for the Minister to provide adequate justification. This case rests under Article 150 of the Code of Civil Procedure meaning the State has the burden of proof in law of the propositions which he wishes to see. On this basis, the court considers that the final decision of the Minister to classify the e-cigarette as medicinal brands is in violation of the law and the general principles of good governance, particularly the justification principle and the principle of legal certainty."*

**Interpretation.** This is interesting because it takes cigarettes as a reference point, and argues that the nicotine delivery would need to be somehow more potent than for cigarettes. Given that smokers and vapers generally control their own exposure to obtain their desired dose, this view suggests that a regulator would struggle to prove that e-cigarettes gave a nicotine exposure more than from cigarette smoking.

### 2. Cologne, Germany

The ruling of Administrative Court of Köln [Case No. 7K3169/11](#): 20 March 2012 that

*“the obligation to prove pharmacological properties lies with the defending party (i.e. the respective competent state authority), as it has alleged that we’re dealing with a functional medicinal product [see clauses 111-113 jj of the ruling]. We need confirmation that the use of an e-cigarette would not just only wean smokers from their smoking habit, but also treat nicotine addiction [see clause 130 of the referred ruling]. There is no scientific evidence to show whether this specific product is suitable for the treatment of nicotine addiction. Above all, the Court has found that we’re not speaking of nicotine addiction, as long as nicotine is obtained from electronic cigarette instead of a tobacco cigarette. The nicotine addiction will then prevail. Nicotine addiction is satisfied, not treated” [see clause 132 of the ruling].*

The Administrative Court of Köln ruled that:

*“when observing the products that serve as the object of the dispute, we can’t ignore the fact that the definition of a functional medicinal product usually covers authentic medicinal products and therefore, products that serve a therapeutic or prophylactic purpose. We have to distinguish products that have a different primary objective, for example, nourishment or getting a satisfaction” (see clause 171 of the ruling).*

**Interpretation:** this recognises that the purpose of an e-cigarette is not primarily as a therapeutic device to overcome addiction or quit smoking, but to provide ‘satisfaction’ in a different way to smoking.

### **3. Sachsen-Anhalt, Germany**

The Supreme Court of Sachsen-Anhalt State of Germany stated in its [ruling of 5 June 2012](#):

*“We must not ignore the main function of a substance considered as a potential functional medicinal product. Regardless of pharmacological properties, a product is not considered as a functional medicinal product solely because it contains some substance – nicotine, in given case – that is accompanied by health risks when used, as a definition of a functional medicinal product includes fighting against diseases or undesirable physical conditions of reaching a medical diagnosis as a function of the medicinal product.” /.../ “Pure physiological effect of nicotine is not sufficient to classify something as a functional medicinal product. Usually, only products that have either therapeutic or prophylactic purpose can be therefore functional medicinal product. The Medicinal Products Act does not cover products with different main objectives, for example, being used for nourishment or as substances for pleasure and gratification.” /.../ “The Medicinal Products Act can only be applied if it’s definitely known, as a product is manufactured, that it’s future purpose will be, without exception, medicinal function in human body – even where combined effect with some other substance will be needed for that purposes. As for the object of dispute – a liquid that contains nicotine – this can’t be assumed. Weaning from the use of tobacco cigarettes or alleviation of nicotine addiction do not take the front stage”.*

In the final part of the ruling the Supreme Court of Sachsen-Anhalt State of Germany also explained:

*“This would mean, above all, that the regulation applicable under the Medicinal Products Act can only be implemented if the suitability of a product as a medicinal product has been identified.*

*Otherwise, the stricter rules, arising from the Medicinal Products Act, would be applicable also to other circumstances and this would prohibit the free movement of products in the European Union without the situation being sufficiently justified by health protection requirements”.*

**Interpretation:** this makes an argument that the application of more restrictive medicines regulation inhibits free movement of goods in the EU without showing any health benefits. It asserts that the simple presence of psychoactive substance (nicotine) is insufficient to classify the product as a medicine.

#### 4. Estonia

Tartu Administrative Court on behalf of the Republic of Estonia found in favour of the complainant, Zandera Ltd (an e-cigarette company) and against the respondent, the Estonia State Agency of Medicines, when the latter tried to classify e-cigarettes as medicines. In its ruling in [Case 3-12-2345 on 7 March 2013](#), the court said:

*The respondent [...] has not explained why the electronic cigarette is to be classified as a medicinal product, while the normal cigarettes which also contain nicotine and its consumption goal is the same, have never been defined as medicine products. It is not clear why the pharmacological effects of the manufactured liquid nicotine on the body are different from the effect of the nicotine in a normal cigarette or whether any pharmacological effect manifests itself in a normal cigarette. In the contested decisions, there is no answer to the claim raised by the complainant that there is no science based evidence and examples of why particularly E-Lites products or their properties negatively affect public health and influence human physiology more than do conventional cigarettes.*

[...]

*If the effects produced by E-Lites cigarettes are unique to medicinal products only, then the question arises as to why the normal cigarettes do not have the same effect unique to a medicinal product. In this case, the desired nicotine is received from an e-cigarette instead of a tobacco cigarette; nicotine addiction is satisfied, not cured.*

[...]

*Nicotine is received from an e-cigarette instead of a tobacco cigarette. Also, people who have given up smoking tobacco cigarettes in favor of e-cigarettes for health reasons do not use nicotine as a medicinal product, but as a drug which is less detrimental to the health instead of a more hazardous cigarette.*

**Interpretation.** The court does not find that the mere fact of a physiological effect is sufficient to regard something as a medicine. Throughout the judgement, the court compares e-cigarettes with cigarettes, not NRT or other pharmacological treatments for nicotine withdrawal.

## Relevant European Court of Justice case law

### 1. Germany - the garlic case

The European Commission has also challenged member states when they have over-zealously classified non-medicinal products as medicines. In the ‘garlic capsule’ case of 2007 the European Commission challenged a member state classification of these products as a

medicine by the regulators in the Federal Republic of Germany, on the grounds that they are not medicines and that the regulatory burdens of medicines regulation created disproportionate obstacles to trade in the EU internal market. For e-cigarettes, the case ([C-319/05](#) - 15 November 2007) drew highly relevant conclusions in paragraphs 59-71 of the [judgement](#). These are reproduced in full at the [Appendix](#) below, with commentary. Some critical extracts:

*61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.*

*[...]*

*64 In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease. [emphasis added]*

*[...]*

*71. ... the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.*

**Interpretation:** this judgement stresses the balance to be struck between the efficient operation of the internal market and the protection of public health through appropriate regulation. In pursuit of this aim, the ECJ has tightly circumscribed what can be lawfully classed as medicines. The judgement limits medicines to products that are '*genuinely designed*' to '*modify physiological functions*' strictly with the '*function of treating or preventing disease*'. That clearly rules out e-cigarettes, which are not designed to do this at all, but to supply an alternative source of recreational nicotine.

## 2. Germany - the fermented red rice case

In [Case C140-07](#) (Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg), the ECJ lays down some important case law. This case was about classification of a novel food as a medicine. The ruling states

*Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.*

**Interpretation.** This means that it is not just the pharmacological and physiological properties of nicotine that matter in defining a medicine by function (definition [above](#)) it is also how it is traded and used by consumers.

## Legal principle in the European Union

### The principle of proportionality

Behind these judgements, is the idea that burdens should be proportionate to the objectives that measures are intended to achieve. The principle of proportionality is laid down in Article 5 of the [Treaty on European Union](#).

*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.*

The criteria for applying it is set out in the [Protocol \(No 2\)](#) on the application of the principles of subsidiarity and proportionality annexed to the Treaty.

*...Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.*

**Interpretation:** there is an obligation on the Commission to seek the least burdensome way of protecting health. This means it cannot just declare that the medicines regulatory framework embodied in directive 2001/83/EC can meet the health protection objectives. It has to show that the much less burdensome consumer protection framework *cannot* meet the health protection objectives. It has not shown this or attempted to show it, nor has it consulted on this option.

## The principle of non-discrimination

The principle of non-discrimination or equal treatment is widely applied by the European Court of Justice. The following extract from an ECJ ruling is one concise expression of the idea: ([Case 304/01 Sept 2004](#) para 31)

*... the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.*

**Interpretation.** If e-cigarettes are alternatives to smoking cigarettes, rather than to NRT, then any excessive regulatory burdens that are placed on e-cigarettes and not on cigarettes would be discriminatory if not justified on health ground, which they cannot be. Conversely, restrictions placed on cigarettes but not on e-cigarettes, can be justified as non-discriminatory because of the pronounced difference in risk. The comparison with NRT is not valid, for the reasons described in the introduction above, but also because NRTs are licensed with a therapeutic claim (ie. they are medicines by virtue of part a of the definition of a medicine in EU law, whereas, e-cigarettes could only be justified under part b).

## International legal provisions

### WTO - Technical Barriers to Trade

The [Agreement on Technical Barriers to Trade](#) is part of the World Trade Organisation agreements. It is conceivable that a complaint could be brought by a WTO member

government under this agreement if it believes its manufacturers are unfairly disadvantaged by the regulations. It has the following purpose in overview:

*Technical regulations and product standards may vary from country to country. Having many different regulations and standards makes life difficult for producers and exporters. If regulations are set arbitrarily, they could be used as an excuse for protectionism. The Agreement on Technical Barriers to Trade tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles, while also providing members with the right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or the environment.*

The TBT has similar provisions to the EU Treaties – protecting trade from regulatory measures that exceed that needed to achieve the health objective:

*When is a technical regulation an unnecessary obstacle to trade? Unnecessary obstacles to trade can result when (i) a regulation is more restrictive than necessary to achieve a given policy objective, or (ii) when it does not fulfil a legitimate objective. A regulation is more restrictive than necessary when the objective pursued can be achieved through alternative measures which have less trade-restricting effects, taking account of the risks non-fulfilment of the objective would create.*

The TBT aims to reduce the degree of prescription in regulation to the minimum necessary – favouring regulation based on performance standards (ie. toxicity thresholds), rather than specification of process or product design (ie. specifying manufacturing process):

[Article 2.8](#) *Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.*

**Interpretation.** A TBT challenge should be regarded as a future vulnerability as the category grows and member governments seek fair treatment for their industries. The question is whether a high level of health protection can be attained without recourse to medicines regulation, which tends to be prescriptive about process, as well as product characteristics. The existing supply chain to Europe is currently dominated by Chinese manufacturers.

## **What is the right approach to take?**

Regulation should go with the grain of reality. The [proposed revision to the Tobacco Products Directive](#) creates the opportunity to provide a genuine light touch regulatory framework for these products, working alongside standard consumer protection legislation that applies to all products. The overall change required to the proposal is that these products should be regulated as recreational consumer products with cigarettes as their main comparator, not as medicines for 'treatment' of smoking with NRT as the main comparator.

To do this, the TPD should be revised do six things differently with respect to NCPs:

- 1 Drop the requirement for mandatory medicine regulation, and allow this to become an opt-in for manufacturers who want to make a therapeutic claim or see commercial advantages in a medicines license;
- 2 Remove the arbitrary and poorly specified threshold in TPD Article 18.1 - it is not necessary to have a threshold, or alternatively set this at a level that captures only very high strength mixing liquids (>75 mg/ml nicotine density) at which point they would be classed as poisons (in the UK);
- 3 Re-assert the basic framework of European consumer protection applies, and refer to or restate these. Member states all have legislation and institutional capacity to address this need.
- 4 As necessary, create a basis for a future light touch non-medicines regulatory regime, for example, based on consumer protection regulation through a CE marking, Commission Decision or new regulation or directive specific to NCPs (following the approach used for cosmetics, for example) - the consumer protection tools exist outside medicines regulation;
- 5 Add a meaningful mandatory label proportionate to the risk and encouraging smokers to switch;
- 6 Design a proper transitional arrangement that will not destroy or drive away incumbents with no guarantee of adequate new entrants. The EU should not overburden small businesses with regulation where this is not necessary.

**Or design a new regulatory approach.** Alternatively, remove provisions relating to 'Nicotine Containing Products' (Article 18) of the Tobacco Products Directive and give the European Commission a mandate to design a regulatory approach that is: proportionate and fit for purpose, aligned with the real-world characteristics of e-cigarettes, does not excessively burden relative to cigarettes and open to consultation so that those affected could have a proper opportunity to contribute to the design of a credible regulatory regime.

**Disclaimer: this document is provided for information and orientation and should not be treated as formal legal advice.**

**Clive Bates  
London, UK**

## Appendix: The garlic case - extract from ECJ judgement paragraphs 59-71

This is from the [judgement](#) in case [C-319/05](#) November 2007. My commentary is included between paragraphs.

*59 The pharmacological properties of a product are the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (HLH Warenvertrieb and Orthica, paragraph 52).*

59 highlights the relevance of the second part of the definition of a medicine - see [above](#)

*60 Although, as the Advocate General observed in point 58<sup>1</sup> of her [Opinion](#), that definition is broad enough to include products which, although they are capable of having an effect on bodily functions have in fact another purpose, that criterion must not lead to the classification as a medicinal product by function of substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (Upjohn, paragraph 22).*

60 states that products that have an effect on the body but do not significantly affect the metabolism and affect the way the body function - the 'significantly' is arguable for e-cigarettes, certainly by reference to other recreational drugs. You would certainly consider a drug like morphine as having a significant effect, but nicotine would be better compared with caffeine.

*61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.*

*62 Such an interpretation is in accordance with the aims of Directive 2001/83 which, as is clear from the second to the fifth recitals in the preamble, seeks to reconcile the aim of protection of public health with the principle of free movement of goods.*

61 states that there must be a purpose ('genuinely designed') to the modification of physiological functions and 62 notes that the importance of trade-offs between public health and free movement of goods]

*63 Furthermore, although only the provisions of Community law specific to medicinal products apply to a product which satisfies the conditions for classification a medicinal product, even if it comes within the scope of other, less stringent Community rules (see, to that effect, [Delattre](#), paragraph 22, [Monteil and Samanni](#),*

---

<sup>1</sup> [Advocate General opinion](#) (emphasis added) 58. As Advocate General Tesauro rightly stated in [Delattre](#), (34) the wording 'restoring, correcting or modifying physiological functions' contained in the second subparagraph of Article 1(2) of Directive 2001/83 is formulated in broad terms in order to extend to those products which, although without doubt inherently able to affect physiological functions, have an essentially nutritional purpose. I have already argued elsewhere that such an interpretation ultimately promotes neither the protection of health nor the free movement of goods. (35) Nor can that be the intention of the Community legislature. Concurring with the proposals made by Advocate Generals Geelhoed (36) and Tesauro, (37) I therefore take the view that the concept of a medicinal product by function must be interpreted restrictively. (38) Accordingly, the definition should cover only products with scientifically identifiable pharmacological properties. It should not be sufficient for the product merely to have physiological and nutritional effects. Rather, I consider that it must either be intended to prevent or treat disease, have relevant health risks or secondary effects which are detrimental to health, or have an excessive effect on physical functions." (39)

paragraph 17, *Ter Voort*, paragraph 19, and *HLH Warenvertrieb and Orthica*, paragraph 43 ), it must be stated, as is shown by a reading of Article 1(2) of Directive 2001/83 in conjunction with Article 2 of Directive 2002/46, that the physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements.

63 shows that not all products with physiological effect have to be classed as medicines

64 *In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease. [emphasis added]*

64 is critical as it completes the reasoning that to be a medicines a product that has physiological effect must be designed to treat or prevent disease

65 *That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. 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.*

65 shows that simply being beneficial to health is not sufficient reason to class as a medicine

66 *In this case, the Federal Republic of Germany does not dispute that the physiological effects that it relies on, essentially with respect to the prevention of arteriosclerosis, may also be obtained by ingesting 7.4 g of garlic as a foodstuff. It is significant in that regard that the fact that the studies on which the Federal Republic of Germany bases its arguments relate both to the potential effects of ingesting garlic preparations in the form of capsules, powders or solutions, and to the potential effects of consuming garlic in its natural state.*

67 *It is also common ground that the disputed product does not have any additional effects as compared to those which derive from the consumption of garlic in its natural state and, as the Advocate General observed in point 62 of her Opinion, those effects should not be regarded as any greater than, or different from, those of other vegetable or animal products which are taken as part of the daily diet.*

68 *In those circumstances, it must be held that the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a products capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.*

66-68 are relevant by virtue of comparison to the commonplace version of the product - in this case bulbs of garlic, in the case of e-cigarettes, the comparison would be drawn with cigarettes.

69 *Finally, and contrary to the Federal Republic of Germany's submissions, the fact that ingesting the product concerned could give rise to risks to health is not an indication that it is pharmacologically effective. It is clear from the case-law that the risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (*HLH Warenvertrieb and Orthica*, paragraph 53).*

69 clarifies that the risk of an adverse health impact is not in itself sufficient to justify medicines regulation.

*70 The assessment of the potential risks related to the use of the product concerned must be undertaken in the context of Directive 2001/83 and in the light of the principles of Community law in general.*

*71 As the Commission has observed, the Community provisions relating to medicinal products must ensure, in addition to the protection of human health, the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general, and the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.*

71 reiterates the importance of proportionate regulation and general idea of the free movement of goods. In other words, the restrictions placed on e-cigarettes must not be beyond those necessary to protect health. Given they are alternatives to cigarettes this is a low bar.