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The International Comparative Legal Guide to:
Pharmaceutical Advertising 2011

A practical cross-border insight into pharmaceutical advertising

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Control of Advertising of Borderline Products: Medical Devices, Foods and Cosmetics

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Introduction

Increasingly, manufacturers of medical devices, foods and cosmetics wish to make claims about their products which bring them close to the borderline with medicinal products. It is therefore important to consider what constraints are imposed on the ways that such products can be advertised. This article will first consider briefly what determines whether a product will be treated as a medicinal product, a medical device, a food or a cosmetic, and will then review the control of advertising for each category of product in Europe, as well as examples from selected European countries (France, Germany, Italy, the Netherlands, Poland, Spain, Sweden and the UK) and the United States.

Determining the Status of Borderline Products

The regulation of products is based on a 'non cumulation' principle. This aims to exclude the possibility that a relevant product is regulated by multiple regulatory regimes. Instead, a given product can only be classified and regulated under one of the various frameworks. Defining a given product, and interpretation of the classification rules, is carried out by the competent authorities of the country where the product is on the market. We set out below the definitions of the product types in the legislation in Europe (although the precise definitions vary between Member States) and the US.

1. Medicinal products

The starting point is the definition of a medicinal product, which is defined in Directive 2001/83/EC [see Endnote 1] as:

"*(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 Commission has also provided a definition of pharmacological, immunological and metabolic action [see Endnote 2]:

'Pharmacological action' means:

"*interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect*".

'Immunological action' means:

"*action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction*".

'Metabolic action' means:

"*action which involves alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function . The fact that a product is metabolised by the human body does not necessarily mean that the substance contained in the product has a metabolic action upon the body*".

Paragraph (a) of the definition establishes the so-called 'presentational' criterion, while paragraph (b) establishes the 'functional' criterion: the case law from the Court of Justice of the European Union, the European Commission and guidance issued by the competent authorities in individual Member States refer to these two tests.

Directive 2001/83 states that in cases of doubt, where a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other legislation, the product will be classified as medicinal.

In the US, although each definition has been the subject of years of agency interpretation, legislation and litigation, the basic terms are found in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The term 'drug' means [see Endnote 3]:

(A) articles recognised in certain official pharmacopoeia and formularies; "*(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals*".

2. Medical devices

Medical devices are defined in Directive 93/42/EEC [see Endnote 4]:

"*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or*

compensation for an injury or handicap,

- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".

The Directive contains details about how combination products containing both medical devices and medicinal products (e.g., drug-coated stents), should be regulated. It also states that Directive 93/42 does not apply to medicinal products or cosmetic products, as defined under the relevant legislation. In deciding whether a product falls under the medical devices regime, particular account should be taken of the principal mode of action of the product. Typically, medical devices achieve their function through physical means (including mechanical actions, physical barriers, replacement of or support to organs or body functions). Medical devices can be assisted in this primary function by pharmacological, immunological or metabolic means, as long as the primary action is not achieved via these (medicinal) means.

In the US, the term 'device' generally is defined as including an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is [see Endnote 5]:

- "*recognized in the official National Formulary, or the US Pharmacopeia, or any supplement to them,*
- *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,*
- *or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes*".

The latter portion of the definition is a critical component of distinctions between drug and device products. For certain combination medical products, the distinction between products can be more subtle, with the primary mode of action generally deciding the regulatory approach.

3. Foods

Food is defined very broadly in the General Food Law Regulation 178/2002/EC [see Endnote 6] and includes:

"*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. [This] includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment*".

The definition also states that 'food' shall not include, among other things, medicinal products or cosmetics as defined in the relevant European legislation.

The EU also defines 'food supplement' and 'food additive'; these are categories of foods to which more detailed specific regulations apply. This article only discusses the more general requirements relating to all foods.

In the US, the term 'food' means [see Endnote 7]:

"*(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article*".

Although this does not include a requirement relating to the intended use of the food, as with other definitions in the US, the uses of conventional foods are typically limited to those associated with typical food uses - taste, aroma and nutritive value - including nutritive effects on the structure or function of the body.

4. Cosmetics

The definition of a cosmetic is set out in Directive 76/768/EEC [see Endnote 8] as:

"*any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition*".

Thus a cosmetic product may have a secondary preventative, but not curative, purpose.

The recitals to the Cosmetics Directive state that it relates "*only to cosmetic products and not to pharmaceutical specialities and medicinal products*" and that the "*delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use*". The recitals also clarify that the "*Directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease*", and that "*products containing substances or mixtures intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics*". The new Cosmetics Regulation contains similar provisions.

In the US the term 'cosmetic' is defined as [see Endnote 9]:

"*(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap*".

Classification of Borderline Products

Interpretation of these definitions is carried out by Member States on a case-by-case basis, taking into account all the characteristics of the product, including its composition, pharmacological properties, the way in which it is used and presented, the extent to which it is sold, its familiarity to the consumer, the risks which its use may entail and its presentation.

Each of the regulatory regimes states that it does not apply to other products, and the hierarchy clause in Directive 2001/83 confirms that in cases of doubt, the product should be classified as medicinal. This is based on a binary yes/no classification, although many products do not fit this type of assessment. European case law suggests that a given product, even if it falls within the definition of, in this particular case, a cosmetic product, must nevertheless be treated as a medicinal product if it is presented as possessing properties for the treatment or prevention of illness or disease. This reasoning was based on the aim of protecting public health, which is central to all of the regulatory regimes, "*since the legal rules applicable to proprietary medicinal products are more rigorous than those applicable to cosmetic products, in view of the particular dangers which the former may present to public health and cosmetic products generally do not*" [see Endnote 10]. The classification is therefore based on a risk-based approach, with a

greater level of control being placed by the authorities on those products which present the most risk to the public.

Case law [see Endnote 11] also determines that certain, again in this case cosmetics, 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, should not be considered as medicinal products. This means that a general capacity to restore, correct or modify physiological functions should not lead to a classification as a medicinal product, as confirmed more recently by the European Court [see Endnote 12]. Several substances contained in foods (such as garlic) have physiological effects, but the European Court has noted that it is not appropriate to treat all products having such effects at certain doses as medicinal, where the amount absorbed is no different from that which would be absorbed as part of a normal diet.

In the US, the status of a borderline product generally hinges on its 'intended use'. Such intent may be determined from the product label and labelling, as well as other materials that may accompany the product in various ways. For certain products, the circumstances in which the product is marketed may also be a factor. This intent determination can have an enormous impact on how a given product is regulated, including pre-clearance/approval requirements, manufacturing standards, and manner of dispensing and sale. With respect to advertising, the classification of a product can also determine the regulator - the Food and Drug Administration (FDA) or Federal Trade Commission (FTC) - and thus the standard applied to advertising claims.

Advertising

One of the more important consequences of the classification of a product is the way in which it can be advertised and the claims that can be made about it. Irrespective of the product classification, the over-arching aims of the regulatory controls are to balance the competing interests of the free movement of goods and the protection of public health and consumers. In relation to advertising, the key in all countries is that the labelling, advertising and presentation of products should be true, accurate and should not mislead consumers.

The focus of this article is 'advertising', which EU legislation defines as "*the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations*" [see Endnote 11]. These voluntary representations should be distinguished from mandatory labelling requirements and instructions for use contained in labelling or packaging, which are not dealt with here. In addition, this article does not discuss factual, scientific information that may be disseminated about a product, and which does not aim to promote its supply.

A number of EU-wide Directives and Regulations relate to advertising, such as Directive 2006/114/EC on misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices [see Endnote 14]. To the extent that a particular advertisement is not controlled by sector-specific legislation, these general rules apply. However, where European sector-specific legislation and guidance specifically cover advertising of a particular product, that specific legislation applies, and the general requirements are less likely to be relevant. Where sector-specific legislation does exist, the requirements relating to comparative and misleading advertising generally mirror the more general requirements.

Under the Directive, 'misleading advertising' means any advertising which deceives or is likely to deceive consumers or competitors, or which injures or is likely to injure a competitor. In order to determine whether advertising is misleading, the characteristics of the goods, the price and the conditions governing their supply, and the nature, attributes and rights of the advertiser should all be taken into account.

The US has a similar regulatory framework, as set out in the FFDCA and the Federal Trade Commission Act (FTCA), and in implementing regulations and guidance. The FTC and FDA operate under a Memorandum of Understanding, under which each agency assumes primary responsibility for certain aspects of product advertising. In general, the FDA takes primary responsibility for prescription drug and restricted device advertising. The FTC has a primary role in regulating the advertising of foods, dietary supplements, most non-prescription drugs, many medical devices, and cosmetics. States also maintain statutory and common law frameworks governing their advertising regulatory and enforcement activities.

The FTCA has a similar definition of false advertising as the EU Directive, and also lists factors to be taken into account when considering whether or not an advertisement is misleading, including representations made and the extent to which the advertisement reveals material facts about the product.

EU Directive 2005/29 on unfair commercial practices applies to all business-to-consumer transactions where the consumer is influenced by an unfair commercial practice that affects decisions on whether or not to purchase a product, and the freedom of choice in the event of purchase. The Directive sets out the general criteria for determining whether a commercial practice is unfair. It also incorporates provisions on the business-to-consumer transactions covered by the Directive on misleading advertising. Again, the FTCA contains similar provisions about unfair methods of competition.

Comparative advertising means any advertising which explicitly or implicitly identifies a competitor or goods offered by a competitor. Comparative advertisements are permitted in certain circumstances; when a comparison is not misleading, it can be a legitimate means of informing consumers of what is in their interest. Comparative advertising is permitted if, among other things, the advertisement is not misleading, compares goods meeting the same needs or intended for the same purpose, and objectively compares one or more material, relevant, verifiable and representative features of those goods, which may include price. In addition, it should not create confusion between the advertiser and a competitor, or discredit the trademarks of a competitor. Similarly, the FTCA generally permits comparative advertising, including the naming of, or even disparaging references to, competitors, but requires that such advertising be truthful and non-deceptive. In certain cases, comparative claims can result in governmental enforcement, as well as suits under the Federal Lanham Act and state consumer and business tort laws.

1. Advertising medicinal products

The position regarding the advertising of medicinal products is set out in detail elsewhere in this publication. In brief, all the countries considered in this article have specific legislation and codes of practice governing the advertising of medicinal products. The general requirements in the EU are set out in Titles VIII and VIIIa of Directive 2001/83: advertising is only allowed for products which have been granted a marketing authorisation, the advertising must comply with the approved Summary of Product Characteristics, and the advertising must be objective, not

exaggerated, and not misleading. The US has similar rules under the FFDCA.

In accordance with the legislation, in all the countries considered here, it is possible to advertise non-prescription medicines to the general public. However, various restrictions apply. None of the European countries permits advertising of prescription only medicines to the general public, with the exception that vaccination campaigns and, in France, medicines aimed at reduction of tobacco addiction, may be advertised to the public. In contrast, the US does permit advertising of most prescription-only medicines to the general public.

2. Advertising medical devices

In contrast with EU law on medicinal products, Directive 93/42 on medical devices does not expressly include provisions relating to control of advertising materials, nor does the Directive expressly prohibit advertising of medical devices direct to consumers. Instead, advertising of medical devices is governed by the general EU rules, and by national rules. Therefore, the general EU Directives on comparative advertising and unfair commercial practices apply.

The general principle under the EU Directive is that Member States should ensure that devices are placed on the market only if they comply with the requirements of the Directive when supplied and properly installed, maintained and used in accordance with their intended purpose. 'Intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials. Therefore, provided that the claims made in the promotional or advertising materials are consistent with the approved intended use of the device, such claims ought to be considered acceptable by the competent authorities in the Member States. In addition, the clinical data and scientific literature relating to the medical device can be used to substantiate any claims made. Where a medical device is assisted in its primary function by any pharmacological, immunological or metabolic action, promotional materials should not make claims about such action, and any such claims may lead to a classification as a medicinal product.

The European Medical Technology Industry Association (EUCOMED) has adopted a code of conduct in which member companies are required to ensure that all promotional materials, including claims and comparisons are accurate, balanced, fair, objective and unambiguous. Advertising and promotion should be justified by appropriate evidence, and statements should not mislead the intended audience.

Any promotion of a device should be limited to the intended purpose as assessed by or notified to the Notified Body. Generally speaking, a device should therefore not be promoted in the EU if it is not CE-marked. However, some commentators consider that if a device is not placed on the market it can be promoted, if it is made clear that it is not available in that territory. The Directive does allow devices to be 'shown' at trade fairs, exhibitions, demonstrations, etc. even when they do not conform to the Directive or have a CE-mark, provided that a visible sign clearly indicates that the device cannot be marketed or put into service until it does comply.

In the US, the FTC regulates the advertising of most consumer medical devices, and the overriding requirement relates to the prohibition of false or misleading advertising, and that claims must be substantiated.

Under the FFDCA, the FDA regulates the advertising of 'restricted' medical devices. The FFDCA states that a restricted device would be 'misbranded' if its advertising is false or misleading, or does not contain a brief statement of the device's intended use and relevant warnings, precautions, side-effects and contraindications [see Endnote 15].

EU Country requirements

The advertising of medical devices is largely controlled by legislation at a Member State level. In general, most Member States do not have specific requirements on the advertising of medical devices, but it is instead covered by general advertising laws, particularly in relation to misleading and comparative advertising. However, Italy and Spain both have specific regulations on medical devices. In Italy, there is an explicit requirement that only CE-marked devices may be advertised to the general public and healthcare professionals [see Endnote 16], and advertising of devices that are subject to a prescription or which must be used with the assistance of a medical practitioner is prohibited. Similarly in Spain, it is forbidden to make direct or indirect advertisements to the public of medical devices available on the national healthcare system [see Endnote 17].

3. Advertising foods

The main legislation in the EU relating to the advertising of foods which may be considered as borderline with medicinal products is Regulation 1924/2006/EC [see Endnote 18]. This sets out specific provisions relating to 'claims', including messages or representations which state, suggest or imply that a food has particular characteristics. The Regulation sets out general requirements that advertising must not be false, ambiguous or misleading. Claims are then divided into nutrition and health claims. Nutrition claims are claims which state that a food has particular beneficial nutritional properties due to the energy it does or does not provide, or the nutrients it does or does not contain. Such claims can only be used if they are specifically set out in the Annex to the Regulation, and are used in accordance with the conditions in the Annex.

Health claims are claims that state that a relationship exists between a food and health. Such claims can only be used if they have been approved and are contained on an EU-wide list of approved health claims. So-called 'reduction of disease risk claims', which means any health claim that states that the consumption of a food significantly reduces a risk factor in the development of a human disease, can also be used if they are specifically authorised. However, any product bearing such claim should also include a statement that the relevant disease has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Approved health claims are published in the Register after the European Food Safety Authority (EFSA) and the Commission have assessed the scientific data to support the claim. So far, this has been done in batches, the last batch being published on 19 October 2010. It is expected that all remaining opinions will be published in June 2011. On the whole, the majority of health claims have been rejected; industry is concerned that the level of scientific evidence required to support a health claim is too high, and they are in fact required to provide evidence more akin to what might be required to approve medicinal products.

In the US, health claims made in food labelling must be reviewed and evaluated by the FDA prior to use. The FTC assumes primary responsibility for regulating food advertising, and generally seeks to harmonise its advertising enforcement with the FDA's food labelling regulations, including permitted claims. Health claims characterise the relationship of food to a disease or health-related

condition. They are limited to claims about disease risk reduction, and cannot be made about the diagnosis, cure, mitigation, or treatment of disease. However, as a result of suits against the FDA challenging the constitutionality of restrictions on health claims as protected commercial speech under the First Amendment to the US Constitution, the FDA has also accepted certain 'qualified health claims' on food products.

A 'structure/function claim' made in the US describes the effect that a food substance has on the structure or function of the body, and does not make reference to a disease, similar to nutrition claims in the EU. Such claims must be truthful and not misleading, and are not required to be authorised by the FDA. In addition, dietary guidance statements, which refer to a specific food but not a disease or health-related condition, such as 'calcium is good for you', can be used if they are truthful and non-misleading.

Regulation 1924/2006 also contains specific provisions on comparative claims. The Guidance document states that "*comparative claims are nutrition claims*". Therefore, only comparative claims listed in the Annex to the Regulation can be used. A comparison should only be made "*between foods of the same category, taking into consideration a range of foods of that category*". The guidance states that products being compared should belong to a group of foods that are similar in terms of nutritional content, and in general, claims should be compared to a range of similar products on the market. Member States generally have quite similar requirements relating to comparative advertisements, which in turn have a close correlation to the EU provisions and Directive 2006/114 on comparative advertising.

Specific country requirements

In the EU, the Member States have generally ensured that the Regulation is incorporated into national law. Most countries also have a self-regulatory industry scheme that is in line with the Regulation and assists with its implementation. Similarly, in the US, certain self-regulatory schemes, such as the Council of Better Business Bureau (BBB), have adopted codes for food advertising, which focus on areas of public health or consumer protection.

The transitional provisions of Regulation 1924/2006 provide for a gradual implementation of the Regulation, to allow time for health claims in particular to be considered and authorised. During the transitional period, health claims relating to the role of a nutrient in growth, development and the functions of the body may be made until the adoption of the Register of approved claims, under the responsibility of the food business operator. However, they must also comply with the Regulation and existing applicable national provisions.

Where national provisions regarding health claims are in place, they generally relate to substantiation of the claims made. The US requirements also place emphasis on the substantiation of claims. The FTC assumes that consumers expect a 'reasonable basis' for advertising claims. What constitutes a reasonable basis depends on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.

In the EU Member States, certain claims, particularly relating to medicinal properties, are expressly prohibited. For example, France, Germany and the UK's national provisions all contain a specific prohibition whereby a food product must not claim that it prevents, treats or cures a disease (although Germany, for example, only prohibits the claim when made to the general public, rather than healthcare professionals). Italy and Poland also prohibit attributing certain therapeutic or disease prevention properties to a food. Sweden has an authorisation system for nutrition claims, known as Nyckelhålet, which is a collection of nutrition claims for fat, saturates, sugars, sodium and fibre.

4. Advertising cosmetics

At EU level, the advertising of cosmetic products is controlled by a combination of product specific and general legislative texts. Both the Cosmetics Directive currently in force and the new Cosmetic Products Regulation, which will replace the existing Cosmetics Directive and comes into force on 11 July 2013, contain provisions controlling certain aspects of the information and claims that may be made relating to cosmetic products, such as the prohibition of language or presentation that confuse cosmetics with foodstuffs, or the use of misleading claims concerning efficacy. For example, product labelling should not imply that products have characteristics which they do not have, and the manufacturer should keep information to substantiate any claims made with the safety information about the product (in the new Product Information File under the Cosmetics Regulation). The general EU Directives on unfair commercial practices and misleading and comparative advertising also apply to the advertising of cosmetics.

With respect to individual EU Member States, the majority have legislation and codes of practice which govern the advertising of cosmetics, although few of these are specific to cosmetic products but are more general advertising provisions. In Sweden, as in the UK, cosmetics may not be marketed with medicinal claims. Most countries in the EU also have a mechanism whereby if health-related claims are made about a cosmetic product, additional requirements will apply. For example, in France, there are no specific provisions applicable to the advertisement of cosmetics, but provisions can be applied to certain cosmetic products presented as having a favourable effect on human health. Similarly, in Poland, there are no specific provisions on advertising unless the product meets the criteria for a medicinal product. In the Netherlands, there are provisions on the labelling of cosmetics, but no specific rules on the advertising of cosmetics. However, the self-regulatory Code for the Advertising of Health Products [see Endnote 19] may be applicable in certain situations if a cosmetic product falls under the definition of health products.

In relation to the substantiation of claims made about cosmetic products, at an EU level, there are no specific provisions relating to the data necessary to support such claims. Under the new Cosmetic Products Regulation, the Commission, in cooperation with Member States, has undertaken the task of defining common criteria in relation to specific claims for cosmetic products. The Commission intends to adopt a list setting out the criteria for claims which may be used. Most EU countries do not have specific provisions relating to the evidence required to support claims made about cosmetics. However, the general provisions apply, whereby advertisements must not be false or misleading. As a matter of practice, this would usually require that any claims made are based on appropriate evidence. In Sweden, claims that are perceived to be borderline with medicinal products are subject to a strict reliability assessment, and evidence used to support such claims should be convincing and of a high scientific standard. Similarly in the Netherlands, health claims should be based on objective scientific data.

The authorities in some countries, such as France, also have the right to require data to ensure that claims made in advertising are justified. In other countries, such as Italy, this right only arises when proceedings are brought by the authorities in respect of the advertisement.

In the US, the FTC applies its general standards relating to deception and substantiation in evaluating cosmetic advertising. It is important to note that the definitions of cosmetics under the FFCDA has a physical limitation - articles applied to the body for particular limited (cleaning, altering appearance) purposes - and lacks a 'structure or function' component. Therefore, cosmetics may not be the subject of structure or function ('wrinkle remover') or disease claims [see Endnote 20].

Pre-approval of advertising

As a general principle, there is no prior approval required before advertising medicinal products. The exceptions are France and Italy, where prior approval is required, although in Italy it is not required when advertising only to health professionals. In the Netherlands and the UK, prior approval may be required in certain circumstances, as set out in the accompanying articles in this publication. In Sweden, prior approval is required for information relating to prescription-only drugs provided by pharmaceutical companies on a website.

In the US, pre-approval is generally required only with respect to certain categories of drug products, and particularly those presenting significant safety risks or gaps in proof of efficacy. However, prescription drug labelling and advertising must be submitted to the FDA on a regular basis.

Advertising of medical devices do not generally have to be pre-approved. However, in Italy and Spain, advertisements to the general public require prior approval. In the US, whereas copies of promotional materials for pharmaceutical products must be submitted to the FDA at the time of initial dissemination, this is not a requirement for medical devices [see Endnote 21].

Subject to the provisions set out above about authorisation of specific health claims, food advertisements do not generally have to be approved before publication. In fact in Sweden, prior review and approval of adverts would violate the Swedish Freedom of Press Act. The US does also not require any prior approval of food advertising. However, some countries have pre-approval provisions for certain media, for example pre-approval of television advertisements in France. Similarly, if a breach of the requirements is found in the UK, the authorities may require pre-approval of subsequent advertisements as part of the sanctions imposed on the marketer. In some countries, including the UK and the Netherlands, marketers can request pre-approval of advertisements to ensure compliance before publication.

In general, advertisements relating to cosmetic products do not have to be pre-approved before publication, and similar provisions as relate to foods apply. In France, there are some specific formalities if the cosmetic product is presented as having a favourable effect on human health: prior approval is required for advertisements directed at the general public, and those directed to healthcare professionals should be notified to the authorities within 8 days of publication [see Endnote 22].

Conclusion

The key to determining what requirements apply to a product is its classification and definition, carried out at a Member State level in the EU. The advertising and claims made about a product are taken into account when considering its classification. It is therefore essential that the claims made are carefully drafted with these definitions in mind.

The dividing line between what can be said about a particular product, and how that will affect its classification, can be quite thin. For example, with foods, as set out in the UK guidance, a claim that a food reduces a particular risk factor of a disease is allowed (subject to authorisation), but a claim that a food 'prevents or improves' the symptoms of a disease is likely to lead to that product being considered to be medicinal.

Claims made about medicinal products and medical devices do not generally have to be specifically authorised. However, in all countries, such products should only be advertised in accordance with the approved indication or intended use: medicinal products can only be advertised based on the approved Summary of Product Characteristics or Prescribing Information, and claims made about medical devices should be based on the data supporting the CE-marking in the EU, and should be substantiated in the US. When the authorities approve a product, they consider the evidence supporting the indication or intended use. By considering this evidence, the authorities are also considering how the product should be positioned on the market and advertised to intended recipients. While this does not specifically authorise the advertising or claims made, the approval has clear implication for the advertising allowed.

While foods themselves need not be authorised in the EU, health claims made about foods must be specifically authorised by the Commission, and nutrition claims can only be used if set out in the Regulation. In the US, the FDA evaluates health claims made on the labelling of foods, and the FTC seeks to harmonise its enforcement decisions with the FDA requirements. The key in all countries is that any claims made about the product can be substantiated by objective scientific evidence.

Claims made in relation to cosmetics do not have to be authorised: once the product can be lawfully placed on the market, claims can be made as long as they are accurate and not misleading. The safety file, and new Product Information File under the Cosmetics Regulation, that the manufacturer must keep to show that the product meets the requirements for it to be placed on the market in the EU, should also set out the evidence to support any claim made. Similarly, in the US, there are no specific requirements, but all claims must be substantiated.

In essence therefore, although the level of control and authorisation by the authorities varies between the different products to reflect the level of risk perceived to be associated with the particular product type, the advertising of all products in all countries should not be false, misleading or inaccurate. Where claims are made, there should be evidence to substantiate the claim in order to ensure that the product is positioned on the market, and used by patients and consumers, in accordance with the available objective evidence.

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Endnotes

1. Article 1(2), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
2. Guidelines Relating to the Application of the Council Directive 90/385/EEC on Active Implantable Medical Devices, the

Council Directive 93/42/EEC on Medical Devices, MEDDEV 2. 1/3 rev 3.

3. FFDCA Section 201(g).
4. Article 1(2)(a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
5. FFDCA Section 201(f)(h).
6. Article 2, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
7. FFDCA Section 201(f).
8. Article 1(1), Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC). The definition under the new cosmetics Regulation is substantially the same (Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products).
9. FFDCA Section 201(i).
10. Case C-369/88. Judgment of the Court of 21 March 1991 (extract from para 21).
11. Case C-112/89 Upjohn NV [1991].
12. Case C-140/07 Hecht-Pharma [2009] ECR 1-00000, paragraph 41.
13. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.
14. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Directives 84/450/EEC, 97/7/EC, 98/27/EC and 2002/65/EC and Regulation (EC) No 2006/2004.
15. Section 502(q) and 502(r) FFDCA.
16. Legislative Decree no. 46 of February 24 1997, art. 21 and Ministerial Decree of February 23 2006, on the advertising of medical devices; see question 8.1 of the Chapter on Italy.
17. Law 29/2006 and Royal Decree 1591/2009 of 16 October; see question 8.2 of the Chapter on Spain.
18. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
19. *Code voor de aanprijzing van gezondheidsproducten*.
20. FFDCA Section 201(f)(i).
21. 21 CFR section 202.1(j).
22. Article L. 5122-14 of the French Public Health Code.

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Representative Matters

Product liability where representation is in the public domain include multi-claimant cases for Wyeth (benzodiazepine tranquillisers); Searle (intrauterine device); DuPont (pesticide); SP Veterinary (sheep dip); Schering (oral contraceptives); St. Jude Medical (heart valves); and Sanofi-Pasteur (sodium valproate).

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