HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Definition of a Human Medicine

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

The guidance in this document applies to the classification of medicinal products for human use.

2 INTRODUCTION

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for medicinal products for human and veterinary use and for medical devices, pursuant to the provisions of the Irish Medicines Board Act 1995 and 2006. It is also the competent authority for cosmetics.

The HPRA regulates the licensing and sale of medicinal products for human use in Ireland in accordance with the requirements of the Medicinal Products (Control of Placing on the Market) Regulations (S.I. No. 540 of 2007) as amended, and relevant EC Directives, in particular Directive 2001/83/EC as amended by Directive 2004/27/EC and Directive 2004/24/EC.

These regulations require that a medicinal product shall not be marketed without a marketing authorisation, a certificate of registration or a certificate of traditional-use registration (depending on the type of medicinal product). The granting of such an authorisation/certificate indicates that the product complies with the required standards of quality, safety and efficacy. It is the responsibility of those marketing medicinal products to comply with the relevant legislation and to ensure that such products are only marketed in accordance with this legislation.

In most cases the classification of a product as a medicinal product is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications, its presentation and the manner of marketing are consistent with the definition of the Directives regarding medicinal products.

The definition of a medicinal product in Article 1 of Directive 2001/83/EC was amended by Directive 2004/27/EC. The revised definition states that a medicinal product is:

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

(ii) 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.

A new provision has been added as Article 2(2) of Directive 2001/83/EC which now states that:

'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'.

Recital 7 to Directive 2004/27/EC explains that the definition was amended to take account of the growing number of borderline products between the medicinal products sector and other sectors, such as foodstuffs and cosmetics. This recital goes on to explain:

'…Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive [i.e. medicinal products] should not apply'.

Taken together, these provisions are intended to address that where doubt exists over the classification of a product the stricter medicinal products regulatory regime should apply. The aim is to ensure that products that are on the borderline area, e.g. medicinal product/medical device, medicinal product/food supplement, medicinal product/cosmetic, etc., are brought under the appropriate regulatory control and ultimately protect the user of the product.

However, if a product can be clearly regulated more appropriately under another category then the regulatory control for that category should take precedence. Consequently, in order to provide the best protection to the public, the HPRA works together with other regulatory authorities in Ireland in its classification activities according to the principles of risk management.

The impact of the changes in legislation described above on conventional medicinal products and medical devices is not intended to cause confusion (where it is clear that a product falls within the scope of the medicinal products or medical devices legislation); these changes are intended to help clarify the procedure when the appropriate regulatory framework is not clear.

In addition, Directive 2004/24/EC brought in specific provisions to regulate herbal medicinal products and updated the special provisions for homeopathic medicinal products. Thus homeopathic medicinal products may be registered by a simplified registration procedure in accordance with Article 14 of Directive 2001/83/EC. Ireland has a national rules scheme in accordance with Article 16.2 of the Directive. However, in cases where products do not meet the requirements for the simplified registration procedure, then a marketing authorisation must be obtained, in order to place the product on the market in Ireland.

In the case of herbal medicinal products, Directive 2004/24/EC makes special provision to regulate traditional herbal medicinal products which meet the criteria specified in Article 16a of Directive 2001/83/EC. In summary, such products, provided that they have indications appropriate to traditional herbal usage and are intended and designed to be suitable for self-medication, can be marketed under a certificate of traditional-use registration.

It should be noted however that both traditional herbal and homeopathic products are still medicinal products. Consequently, those traditional herbal or homeopathic medicinal products which do not meet the criteria appropriate for registration for traditional herbal usage or for the simplified homeopathic registration procedure, respectively, require a marketing authorisation before being placed on the market.

3 REQUIREMENTS IN RELATION TO MEDICINAL PRODUCTS

Before a medicinal product can be placed on the market in Ireland, an application must be made to the HPRA for an authorisation or registration (or, in the case of centrally authorised products, to the European Medicines Agency). Such applications should contain the data necessary to support the quality, safety and – for conventional and traditional herbal medicinal products – efficacy or traditional use, respectively. These data are reviewed by the HPRA and a conclusion reached based upon the likely balance of the benefits versus risks associated with the product. As indicated above, the authorisation or registration must be granted prior to the product being placed on the market. The HPRA requires that the interests of consumers of medicines should be protected, notably in the following areas:

- A medicinal product should be of adequate quality such that its contents and its pharmaceutical performance should conform to acceptable standards.

- The risk of using a medicinal product should be acceptable and reasonable, taking into account that the use of any medicine carries a risk, which should be considered in the light of the likely benefit. The HPRA must be kept informed of any new safety data which emerge, and which might affect the benefit/risk balance.

- There should be a demonstrable therapeutic benefit for medicinal products with the exception that for certain product categories the demonstration of efficacy may not be required (e.g. homeopathic products – see below). If a medicinal claim is made, the consumer is entitled to expect a benefit and the review process should protect the consumer, so far as possible, from products which do not offer a potential for such benefit.

4 DEFINITION OF A MEDICINAL PRODUCT

The definition of a medicinal product is given in Article 1 of Directive 2001/83/EC, by 2004/27/EC as described above. The definition is set out in two paragraphs, covering the presentation of the product and the purpose for which it is administered respectively (i.e. its function).

4.1 Presentation

The first paragraph refers to the 'presentation' of the product and for convenience is repeated below:

'Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.'

In reviewing a product in this context the HPRA examines the 'totality' of the product as discussed in the following sections.

4.1.1 Products for which (explicitly or implicitly) claims to cure, alleviate or prevent disease are made are considered as medicinal products. Any particular words or phrases which imply such a claim will be taken into account in determining the intent behind the presentation.

While not intending to be exhaustive, the following list contains examples of such words or phrases which present a medicinal intent: *…cures; heals; treats; restores; prevents; clears; stops; protects against disease; helps control the symptoms of; traditionally used for treatment of; strengthens the immune system; calms; helps maintain normal water balance….*

In addition the HPRA has regard to judgments of the European Court of Justice (ECJ) in determining such claims, for example Case C – 227/82 *van Bennekom,* Case C- 60/89 *Monteil & Samanni*.

4.1.2 Products which are presented in a way that the composition, the labelling, the packaging, the pharmaceutical form, the promotional material or the intended audience (for example specific promotion to a group of people with a specific medical condition), implies a medicinal usage may be considered as medicinal products.

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 Case C-227/82 *van Bennekom,* para. 18, Case C-60/89 *Monteil & Samanni*, para. 23).

However, it must be recalled that, according to case law, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered (see Case C-227/82 *van Bennekom*, para 19, Case C-369/88 *Delattre*, para. 38).

4.1.3 Once a given product has been classified by the HPRA as a medicinal product it logically follows that closely related products will be similarly classified. Such a relationship could relate to the content, labelling, intended use, or presentation of the product.

4.2 The purpose for which a product is administered

The second paragraph of Article 1(2) of Directive 2001/83/EC as amended by Directive 2004/27/EC provides:

'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'.

Thus any product containing a substance with a known pharmacological effect at that dose level, or in the case of traditional herbal medicinal products a pharmacological effect that is plausible based on long-standing use and experience, will usually be classified as a medicinal product by the HPRA irrespective of the presence or absence of claims or medical purpose in the product packaging or literature.

Where the principal intended action of the product is pharmacological, metabolic or immunological, the product is regulated as a medicinal product, whereas where the principal intended action is physical or mechanical, the product is regulated as a medical device.

It should be further noted that any product containing a substance which is confined to supply on a medical prescription by virtue of the Medicinal Products (Prescription and Control of Supply) Regulations, the Poisons Regulations, or the Misuse of Drugs Regulations is generally deemed to be a medicinal product requiring an authorisation since it would normally be expected to exhibit a clear pharmacological, metabolic or immunological effect at that dose level.

It should also be stressed that a product administered with a view to making a medical diagnosis is likely to result in its classification as a medicinal product.

4.3 HPRA policy and practice

ECJ judgments, the evolution of professional opinion, changes in marketing practices, and other changing circumstances have required corresponding changes to the way the HPRA assesses products. In particular, it takes full account of the ECJ view that competent authorities of Member States should consider all the characteristics of the individual products, and are obliged to consider what impression of the product 'an averagely-well-informed consumer' would be likely to gain.

In practice, the HPRA considers each individual product on its merits and any information which may have a bearing on the product's status, such as:

a) the claims made for the product, implicit as well as explicit, (including any claims made on linked 'help-lines', websites or publications, or in the product's actual name)
b) the pharmacological, metabolic or immunological properties of the ingredient(s) and any significant effect(s) they have on human beings
c) the labelling, and the packaging literature, including any pictorial descriptions
d) the promotional literature (including testimonials and any literature issued by a third party on behalf of the manufacturer or producer) and advertisements
e) the product form (e.g. tablet, capsule, lozenge, ointment, etc.) and the way in which it is intended to be used (Any form intended for usage of a generally medicinal nature, including certain topical preparations, throat sprays, transdermal devices renders the product a medicinal product or in some circumstances a medical device.)
f) to whom the product or information about the product is directed, perhaps sections of the population with, or vulnerable to, a specific condition
g) similar authorised medicinal products on the market, fulfilling similar functions

5 CLASSIFICATION OF MEDICINAL PRODUCTS

As stated above Article 2(2) of Directive 2001/83/EC as amended by Directive 2004/27/EC, makes it clear that for products at the borderline between medicinal and other categories such as foods or cosmetics, then the classification of the product becomes very important since the users need to be aware of the legal restrictions on marketing of medicinal products and the fact that the more stringent legislation takes precedence.

Any company or individual who attempts to market a product in a given category may discover that the product is controlled under medicines legislation for which prior authorisation or registration is required as appropriate. It is for this reason that the HPRA has set up a classification procedure whereby applicants can request an opinion on the categorisation of a given product intended for administration to humans prior to placing it on the market. In this way applicants can obtain an authoritative opinion and avoid the risk of inadvertently breaking the law by placing a medicinal product on the market without the necessary authorisation. The classification service is operated by a clearly defined procedure following application to the HPRA using the standard form which can be downloaded from the 'Publications and Forms'

section of www.hpra.ie. Details of the fees applicable can be found on the website and applications should be made to the Scientific Affairs Administrator at the HPRA.

To assist in this process the HPRA has set up an internal multidisciplinary committee which meets approximately once ~~a month~~every one to two months to consider such applications and to provide a written opinion to the enquirer within a reasonably short timeframe. Parallel processes exist for medical device and veterinary medicinal product classification queries, using similar approaches and principles.

In arriving at any decision in regard to classification the HPRA must always be provided with sufficient information about the product and its intended usage including all promotional material. This includes not only labels, leaflets and all advertising materials but also any websites linked to such literature.

Should an applicant disagree with a decision of the Borderline Products Committee, they are free to appeal the decision to the HPRA ~~Management Committee~~Leadership Team, which may request the advice of the Advisory Committee on Human Medicines (ACHM) set~~ -~~ up under the Irish Medicines Board Act, 1995. The request for the appeal should be directed to the Scientific Affairs Administrator together with all supporting information. The data package forming the basis of the appeal will then be scheduled for consideration at the next available meeting of the ~~Management Committee~~HPRA Leadership Team which meets approximately every ~~two weeks~~month. The decision of the ~~Management Committee~~HPRA Leadership Team is final.

6 EXAMPLES OF PRODUCT CATEGORIES

The following examples of different product categories are provided to illustrate and explain the HPRA thinking in regard to categorisation of products as medicinal or otherwise. This list is by no means exhaustive and will be subject to regular update as new decisions are made, new product categories emerge, or other external factors (such as legislation or case law) change.

6.1 Herbal medicines (products containing plant-based medicinal ingredients)

Herbal medicinal products are medicinal products containing as active ingredients one or more herbal substances, one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

Herbal substances are defined as mainly whole, fragmented or cut plants, parts of plants, algae, fungi, lichen in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binominal system (genus, species, variety and author). Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These

substances include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

In 2004, a European procedure for the registration of 'traditional herbal medicinal products' was established by Directive 2004/24/EC. This recognises that while all such products remain medicinal products, they have specific characteristics that can make them eligible for a simplified registration procedure on the grounds of traditional usage for appropriate indications suitable for self-medication, where the requirement for demonstration of therapeutic efficacy is reduced. The HPRA has a procedure for the registration of such products and further information is available on the HPRA website.

Herbal medicinal products which are not eligible for the simplified registration scheme by virtue of, for example, their composition, route of administration or indications which are not compatible with the requirements of Directive 2004/24/EC must still be authorised as for any other medicinal product, prior to being placed on the market.

6.2 Homeopathic medicinal products

Homeopathic medicines represent special types of medicinal product for which particular rules may be applied by Member States recognising their tradition of homeopathic practice, in accordance with the requirements of Directive 2004/27/EC. This Directive is given effect in Irish legislation by the Medicinal Products (Control of Placing on the Market) Regulations (S.I. 540 of 2007) made under the Irish Medicines Board Acts, 1995 and 2006. Under this legislation it is recognised that the requirements for authorisation apply to any homeopathic medicinal product being placed on the market with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic benefit. However, a simplified registration procedure in accordance with Article 14 of Directive 2001/83/EC as amended by Directive 2004/27/EC, may be applicable to those homeopathic products marketed without medicinal claims as provided for in Regulation 6 of these regulations (S.I. 540 of 2007). In order to obtain the certificate of registration referred to above, an application should be made to the HPRA setting out the documents specified in Regulation 9 of these regulations. A national rules scheme for authorisation of homeopathic medicinal products with limited indications has also been provided for in Irish legislation, in accordance with Article 16.2 of the Directive.

6.3 Slimming products

Many products intended for assistance in weight loss programmes are properly marketed as foods particularly where such products are intended as food replacements. Such products are regulated by the Food Safety Authority of Ireland (FSAI) and must meet appropriate food standards and comply with food labelling regulations.
Some slimming products, however, contain agents with clear pharmacological or metabolic activity and may or may not make medicinal claims. Such products are clearly medicinal products as outlined in Section 3 above and require authorisation prior to marketing. Examples of such products include appetite suppressants, starch blockers, and certain bulk forming agents

containing, for example, methylcellulose which have other medicinal uses. Oral anti-cellulite products have also been regarded as medicinal products as well as products which claim to increase blood supply or have 'thermogenic' activity (so-called fat burners).

6.4 Hair loss products

Products claiming to treat or prevent baldness (male or female pattern) or alopecia, or to stop, slow down or reverse hair loss are all categorised as medicinal products. Products presented for promoting or strengthening existing hair growth and thereby reducing hair loss or to nourish thinning hair would not be considered to be making medicinal claims and therefore would not be regarded as medicinal products provided they did not contain ingredients with specific medicinal (pharmacological) activity. The latter group of products would therefore not be subject to authorisation as medicinal products but would be more properly regulated as foods or cosmetics depending upon whether they were taken by mouth or administered topically respectively.

6.5 Head lice products

Products intended for treatment or prevention of head lice infestation are always categorised as medicinal products requiring authorisation, irrespective of their composition. The only exception to this rule are products which act by a purely physical or mechanical means, e.g. solutions which are used with a medical device to facilitate the physical removal of lice or their eggs from the scalp. Such products are usually oils or shampoos acting as lubricants to assist in the removal of the lice by a medical device such as a comb. Such products are considered to be medical devices and are regulated by the European Communities (Medical Devices) Regulations 1994 (S.I. 252 of 1994) and are required to carry the CE mark.

6.6 Products for use in the eye

The HPRA considers that any product intended for administration to the eye must be regulated as either a medicinal product or a medical device depending upon whether the mode of action is by pharmacological, metabolic or immunological means in the former case or by physical or mechanical means in the latter.

Thus, in keeping with European guidelines on classification of medical devices, products intended for use as irrigation solutions for washing the eye are medical devices. Similarly, products intended for use with contact lenses such as disinfecting, cleaning and rinsing agents and solutions which aid insertion or wearing of contact lenses, even without a therapeutic claim, are considered to be medical devices. In general other products intended to be placed in the eye are medicinal products requiring authorisation.

6.7 Products for use in the ear or nose

As is the case for the eye, products presented for administration into the ear or nose are not compatible with cosmetic or food legislation. Consequently, the HPRA considers that any product intended for administration to the ear or nose must be regulated as either a medicinal product or medical device depending upon whether the mode of action is by pharmacological, metabolic or immunological means in the former case or by physical or mechanical means in the latter.

6.8 Medicated swabs

Medicated swabs have traditionally been considered as medicinal products requiring authorisation before being placed on the market in Ireland. These products typically contain antiseptics such as chlorhexidine or iodine used either as pre-injection swabs or wound cleansers. These products are categorised as medicinal products because they exert an antimicrobial activity on skin.

In contrast, medicated swabs containing alcohol intended as pre-injection swabs and used entirely for the sanitisation of unbroken skin prior to injection are often regulated as medical devices on the basis of a physical action and require the CE mark before being marketed in the EU. Bearing in mind that there are some differences in the way different Member States classify these products, the HPRA is prepared to accept a certain crossover of these two categories but insists that all such products bear either the CE mark or a marketing authorisation in order to be placed on the market legitimately in Ireland.

6.9 Topical products

Products intended for application to the skin (cutaneous application) may be categorised as medicinal products, cosmetics or even medical devices depending upon their composition, claims and functions. The definition of a cosmetic product is given in Directive 76/768/EEC, which is given effect in Irish law by the European Communities (Cosmetic Products) Regulations 2004 (S.I. 870 of 2004). These amendments include S.I. No. 440 of 2010, which made the HPRA the competent authority for cosmetics with effect from 1 October 2010. Directive 76/768/EEC has been recast as Regulation (EC) No. 1223/2009, which for the most part, applied from 11 July 2013.

The legislation defines a cosmetic product as any substance or mixture 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, protecting them, keeping them in good condition or correcting body odours.
This definition is quite specific and is clearly not intended to encompass application of products to skin, hair etc. with a view to delivering some component beneath the epidermis, into the

circulation or other parts of the body for intended action at some remote location from the point of application. Such activities are more in keeping with medicinal product intent.

Cosmetics may only make claims in accordance with the definition given above and functions such as 'anti-inflammatory', 'anti-itching', 'pain relief', 'burn relief', etc., are not compatible with cosmetic actions.

Products that claim to treat nappy rash are generally regarded as medicinal products. However, products designed to prevent nappy rash by presenting a physical barrier to prevent fluids and excretions from direct contact with the skin by a physical mechanism may alternatively be regarded as medical devices.

Claims referring to treatment or prevention of skin conditions such as acne, chapped skin, infections and chronic skin conditions such as eczema, psoriasis and dermatitis are medicinal claims which would render such products to be considered as medicinal products or medical devices depending upon their mode of action. Claims made in relation to moisturising dry or very dry skin must be within the definition of a cosmetic product. Cosmetic products must not make claims that would inappropriately lead the consumer to not seek treatment for an underlying medical condition that may be causing skin dryness, itchiness or irritation. Statements such as 'suitable for people who may be prone to eczema/dermatitis' should not be given undue prominence on the labelling and it must be clear that the product is not treating the eczema but simply moisturising the skin. All claims and statements made for cosmetic products must be supported and justified in the product information file.

Further information and guidance in relation to cosmetics is available on the HPRA website (www.hpra.ie).

6.10 Mouth hygiene products

Products for oral hygiene such as toothpastes and mouthwashes in general terms are intended to function as cosmetics. Such products meet the definition of cosmetics in terms of protecting, cleaning and maintaining the condition of the teeth and the oral cavity and in general the claims made on such products are in line with the definition of a cosmetic. Such claims could include cleaning, freshening, preventing bad breath, removing plaque, etc.

However, claims for prevention of caries or cavity formation or repairing tooth enamel are medicinal claims and are not consistent with the definition given in the cosmetics legislation. Similarly, mouthwashes aimed at plaque reduction are cosmetics but antiseptic mouthwashes intended to treat infections, sore gums and so on are considered to be making medicinal claims. The Court of Justice has ruled (Case C – 308/11, *Chemische Fabrik Kreussler*) that for a substance to be regarded as exerting a 'pharmacological action' within the meaning of Article 1(2)(b) of Directive 2001/83/EC, it is not necessary for there to be an interaction between the molecules of which it consists and a cellular constituent of the user's body, since an interaction between the

substance and any cellular constituent present within the user's body (such as bacteria, viruses or parasites) may be sufficient to be considered a pharmacological action.

Typical constituents of mouthwashes and toothpastes are permitted by cosmetic legislation. However, certain ingredients may not always be permitted and enquirers should check with the acceptability of components in cosmetics as laid down in the applicable legislation. (See Directive 76/768/EEC until the date of its repeal, and from then, Regulation (EC) No. 1223/2009 – for detail on the date(s) of repeal and transitional measures see Articles 38 to 40 of Regulation (EC) No. 1223/2009.)

A good example is the presence of fluoride salts which are permitted in cosmetics up to a maximum of 1,500 parts per million ('ppm') (0.15%) of fluorine (as fluorine). Products containing levels of fluoride above this limit are generally categorised as medicinal products on safety grounds. However, it should be noted that products with less than 1,500 ppm fluorine may still be regarded as medicinal products or medical devices depending upon claims made and the mechanism of action. There are also varnishes containing fluoride salts but whose mechanism of action would be as a physical barrier to protect the teeth and these would be primarily regarded as medical devices.

6.11 Intradermal fillers

Any wrinkle fillers presented as injections for intradermal administration to humans despite the name 'cosmetic' are not cosmetics and are considered to be medical devices (since they exert their proposed activity by a physical/mechanical method) or as medicinal products. According to the Medicinal Product (Prescription and Control of Supply) Regulations, 2007 to 2014, any product administered by injection is regarded as a prescription only medicinal product, and therefore this route of administration is not compatible with cosmetics.

6.12 Electronic cigarettes

Electronic cigarettes are battery powered devices designed to be used in the same way as real cigarettes. They contain either a refill chamber, tank or a disposable cartridge chamber designed to hold a nicotine-containing liquid. The liquid feeds to an atomiser and a sensor activates a heating element within the atomiser causing the nicotine to be vaporised so that it is available for inhalation via a mouthpiece.

The HPRA, in common with other EU countries, considers that such products are nicotine delivery systems and where such nicotine-containing liquids or prefilled cartridges are claimed to be used in or assist in smoking cessation, they are regarded as medicinal products and subject to medicines legislation. In this regard they are considered to be the same as other nicotine replacement therapies (NRT) and therefore require a marketing authorisation before being placed on the market in Ireland. This position is reinforced by a statement issued by the European Commission dated 22 May 2008. Where the delivery device (e.g. container/tank, mouthpiece or battery) itself is intended to be reusable and marketed separately from pre-filled

cartridges or nicotine-containing liquid, the medical device legislation will apply if smoking cessation claims are made.

In many cases electronic cigarettes are not promoted for smoking cessation but as alternatives to cigarettes where smoking is not permitted (for example in the workplace, during travel, etc.) and in such cases they are subject to tobacco legislation. The tobacco legislation has undergone review at EU level and Directive 2014/40/EU, which includes provisions relating to electronic cigarettes, has been transposed into national legislation by the European Union (Manufacture Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016). Where no medicinal claims are made for electronic cigarettes, S.I. No. 271 of 2016 will apply. The Health Service Executive (HSE) is responsible for implementing and enforcing the provisions relating to electronic cigarettes for which no medicinal claims are made under part 5 of those Regulations and further information can be obtained on their website.

6.13 Vitamin and mineral supplements

These products are considered to be medicinal products when their labelling or accompanying or associated literature make preventative, curative or remedial claims. In the past the HPRA has classified as medicinal products any product containing vitamins and/or mineral ingredients where the recommended intake calculated with respect to any of the added vitamin or mineral constituents exceeded the maximum recommended daily dietary allowance for such constituents as published by the Minister for Health. However, with the implementation of the European Communities (Food Supplements) Regulations of 2003 (S.I. 539 of 2003) a legislative framework for control of such products has been provided. This legislation has since been superseded by the European Communities (Food Supplements) Regulations 2007 (S.I. 506 of 2007) which is implemented by the FSAI.

The schedules to the regulations set out those vitamins and minerals which may be used in the manufacture of food supplements in the form in which they can be added to food supplements. Under this legislation, the FSAI is named as the official authority responsible for the supervision of this legislation. It is intended to introduce maximum safe upper limits of the vitamin and mineral supplements listed in the schedules to these regulations and recommendations in this area are provided by the European Food Safety Authority (EFSA). Once this has been achieved, then products containing vitamin and mineral supplements at levels up to these upper safe limits can be legitimately marketed under food legislation. Products that exceed the upper safe limit will not be permitted as food supplements and where such products fall under the definition of medicinal products, as above, then they will of course require authorisation in accordance with the medicinal products legislation.

It should be also noted that in some cases there are certain vitamins listed in the Medicinal Products (Prescription and Control of Supply) Regulations 2003, which have been developed on safety grounds. Companies intending to market products containing vitamins as food supplements should have regard to this legislation. Medicinal products which are restricted

under this legislation can only be supplied on foot of a medical prescription from a registered pharmacy and of course medicinal products require HPRA authorisation before being marketed.

In conclusion, vitamin and mineral supplements that meet the provisions of the Food Supplements Regulations may be marketed as food supplements and must comply with food safety law including labelling restrictions. Products that make a medicinal claim require a marketing authorisation issued by the HPRA before being placed on the market in Ireland.

6.14 Tissue salts/cell salts

Tissue salts/cell salts are considered to be medicinal products if they fall within the definitions of a 'medicinal product' or a 'homeopathic medicinal product' as listed in Directive 2001/83/EC.

They are also considered to be medicinal products if any of the following appear in the product information or in promotional material:

- the terms 'homeopathic remedy', 'homeopathy' or 'homeopathically prepared'
- a numerical value for the potency, e.g. 6X and/or the word 'potency' itself
- indications for use in a medical condition or a medicinal claim

All cases will be reviewed on a case-by-case basis.

7 CONCLUSION

The codification of legislation and the revision of the definition of a medicinal product provided by Directive 2004/27/EC is a welcome development. Taken in conjunction with developments in the regulation of other categories such as medical devices, food supplements and cosmetics, the status of borderline products and the mechanism of their regulation should become clearer for the benefit of public health. The HPRA classification process can aid in the clarification of the medicinal status and enquiries can be made to HPRA as described above. The HPRA collaborates with its regulatory partners in safeguarding public health for the population of Ireland, in accordance with the terms of its mission statement.

APPENDIX REFERENCES TO LEGISLATION

European

1 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 (Official Journal ('OJ') L 311, 28/11/2001, p. 67-128)

2 Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30/4/2004, p. 85-90)

3 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30/4/2004, p. 34-57)

4 Directive 93/42/EEC of the Council of the European Communities of 12 July 1993 concerning medical devices (OJ L 169, 12/7/2003, p. 1-43)

5 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002, on the approximation of the laws of the Member States relating to food supplements (OJ L 193, 2002, p. 51)

6 Directive 76/768/EEC of the European Council of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27/9/1976, p. 169)

7 Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22/12/2009, p. 59-140)

National

1 Medicinal Products (Control of Placing on the Market) Regulations, 2007 (S.I. 540 of 2007)

2 Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (S.I. 540 of 2003)

3 European Communities (Food Supplements) Regulations, 2007 (S.I. 506 of 2007)

4 European Communities (Cosmetic Products) Regulations, 2004 (S.I. 870 of 2004)

5 European Communities (Medical Devices) Regulations, 1994 (S.I. 252 of 1994)