

قرار رقم (٩) لسنة ٢٠١٦
بشأن تصنيف المستحضرات الصيدلانية
وتحديد الأغذية الصحية

رئيس المجلس الأعلى للصحة

الهيئة الوطنية لتنظيم المهن والخدمات الصحية:

بعد الاطلاع على القانون رقم (٣) لسنة ١٩٧٥ بشأن الصحة العامة وتعديلاته،
وعلى المرسوم بقانون رقم (١٨) لسنة ١٩٩٧ بشأن تنظيم مهنة الصيدلة والمراكز
الصيدلانية والمعدل بالمرسوم بقانون رقم (٢٠) لسنة ٢٠١٥،
وعلى القانون رقم (٣٨) لسنة ٢٠٠٩ بإنشاء الهيئة الوطنية لتنظيم المهن والخدمات
الصحية المعدل بالمرسوم بقانون رقم (٣٢) لسنة ٢٠١٥،
وعلى المرسوم رقم (٥) لسنة ٢٠١٣ بإنشاء المجلس الأعلى للصحة وتعديلاته،
وعلى القرار رقم (١٠) لسنة ٢٠١٣ بشأن تحديد الأغذية الصحية وتنظيم تراخيصها،
وعلى القرار رقم (١) لسنة ٢٠١٤ بشأن تشكيل لجنة تراخيص الأغذية الصحية ونظام عملها،
وبعد موافقة المجلس الأعلى للصحة في اجتماعه رقم (٢) لسنة ٢٠١٥ بتاريخ ٥ نوفمبر
٢٠١٥،

وبناءً على ما عرضه الرئيس التنفيذي للهيئة الوطنية لتنظيم المهن والخدمات الصحية،

قرّر الآتي:

المادة الأولى

يُعمد الدليل الإرشادي (المرجعي) المرفق بهذا القرار في شأن تصنيف المستحضرات
الصيدلانية وتحديد الأغذية الصحية بناءً على نسب محتوياتها، وتنظيم أماكن بيعها، ويطبق
في شأنها أحكام المرسوم بقانون رقم (١٨) لسنة ١٩٩٧ بشأن تنظيم مهنة الصيدلة والمراكز
الصيدلانية.

المادة الثانية

تتولى الهيئة الوطنية لتنظيم المهن والخدمات الصحية إثبات ما يقع من مخالفات تتعلق
بتنفيذ أحكام هذا القرار وذلك على النحو الآتي:

١- تلقي الإخطارات الواردة إليها من المختصين بوزارة الصحة أثناء قيامهم بالتمتيش والرقابة
على المحال المرخص لها ببيع الأغذية الصحية المشار إليها بالمادة السابقة وفقاً لأحكام
قانون الصحة العامة.

٢- التقارير المعدة بمعرفة مفتشي الهيئة أثناء التفتيش على المراكز الصيدلانية وفقاً لأحكام قانون تنظيم مهنة الصيدلة والمراكز الصيدلانية.

المادة الثالثة

يُلغى القرار رقم (١٠) لسنة ٢٠١٣ بشأن تحديد الأغذية الصحية وتنظيم تراخيصها ، والقرار رقم (١) لسنة ٢٠١٤ بشأن تشكيل لجنة تراخيص الأغذية الصحية ونظام عملها ، كما يلغى كل حكم يتعارض مع هذا القرار.

المادة الرابعة

على الرئيس التنفيذي للهيئة الوطنية لتنظيم المهن والخدمات الصحية تنفيذ هذا القرار، ويُعمل به من اليوم التالي لتاريخ نشره في الجريدة الرسمية

رئيس المجلس الأعلى للصحة
الفريق طبيب/محمد بن عبدالله آل خليفة

صدر بتاريخ: ٢٧ رجب ١٤٣٧هـ
الموافق: ٤ مايو ٢٠١٦م

nhra
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الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Pharmaceutical Product Classification Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

23th May 2013

Version 1.0

Chief of Pharmaceutical Product Regulation:

Dr / Roaya Al Abbasi

Date:

NHRA CEO Approval:

Dr / Bahaa Eldin Fateha

Date:

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1.0	2/3/2013	Pharmaceutical Product Regulation Department	Draft
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1. Introduction

Guideline documents are meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. Guideline documents also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent and effective.

The purpose of this guideline is to provide clear definitions of the products for which the Pharmaceutical Products Regulation Department of the NHRA has responsibility and to provide an understanding of the factors that guide classification decisions by NHRA in relation to any pharmaceutical products for human use.

Before a pharmaceutical product can be placed on the market in the Kingdom of Bahrain, an application must be made for a licence to the NHRA. Such applications should contain the data necessary to support the quality, safety and efficacy for the product. These data are reviewed by the NHRA and a conclusion reached based upon the likely balance of the benefits versus risks associated with the product.

As indicated above, the licence must be granted prior to the product being placed on the market. The NHRA requires that the interests of consumers and users of pharmaceutical products should be protected, notably in the following areas:

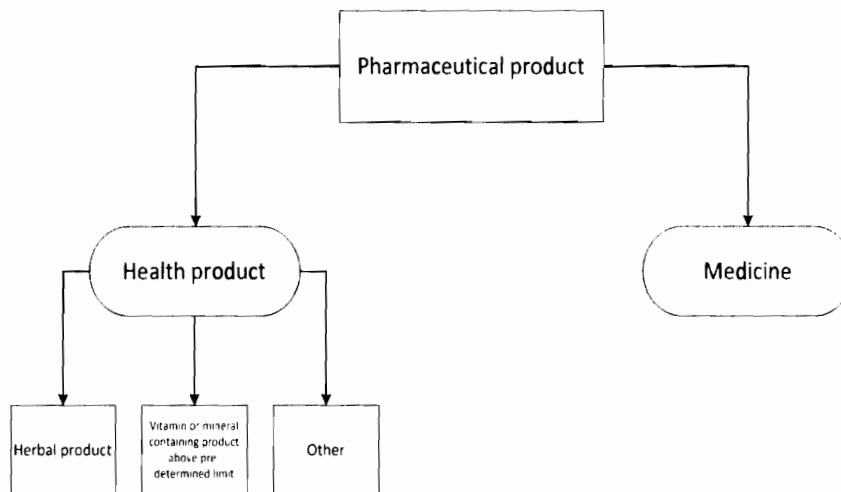
- A pharmaceutical product should be of appropriate quality such that its contents and its pharmaceutical performance should conform to acceptable standards,
- The risk of using the product should be acceptable and reasonable, taking into account that the use of any medicine carries a risk, which should be considered in the light of the likely benefit,
- There should be a demonstrable benefit for pharmaceutical products. If a medicinal claim is made, the consumer is entitled to expect a benefit.

This document should be read in conjunction with other applicable guideline documents.

2. Scope

This guideline defines those pharmaceutical products which are subject to NHRA control and outlines the procedure for classification of such products.

The following flow chart shows the classification categories:



Flow chart 1: NHRA Classification Categories

A product for which the NHRA has responsibility will therefore fall into one of the following definitions:

2.1 Medicine

A medicine is defined as follows:

- 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.

Where a substance is defined as any matter irrespective of origin which may be:

- human, e.g. human blood and human blood products;

- animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
- vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;
- chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

2.2 Health product

A health product cannot have any of the following characteristics:

- be sterile,
- be administered by injection,
- be subject to a medical prescription,
- necessitate the intervention of a licensed healthcare professional.

As such, products with these characteristics are considered to be medicines as per the definition in 2.1 above.

Taking due consideration of the above prohibited characteristics, a health product is a product falling within one of the 4 sub-definitions as follows:

2.2.1 Herbal product

Herbal products are health products containing as active substances herbal substances or herbal preparations, alone or in combination.

A herbal substance is whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually 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 binomial system (genus, species, variety and author).

A herbal preparation is obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Herbal products should not carry medicinal indications or make medical claims that are unsuitable for self-diagnosis and self-treatment i.e. without the intervention of a licensed healthcare professional. Any claims made in association with herbal products should be consistent with available evidence regarding the safety and traditional use of those products e.g. European Herbal Substances Community List, European Herbal Substances Community Monographs, ESCOP Monographs or published peer-reviewed scientific literature and/or other recognised herbal medicine text books.

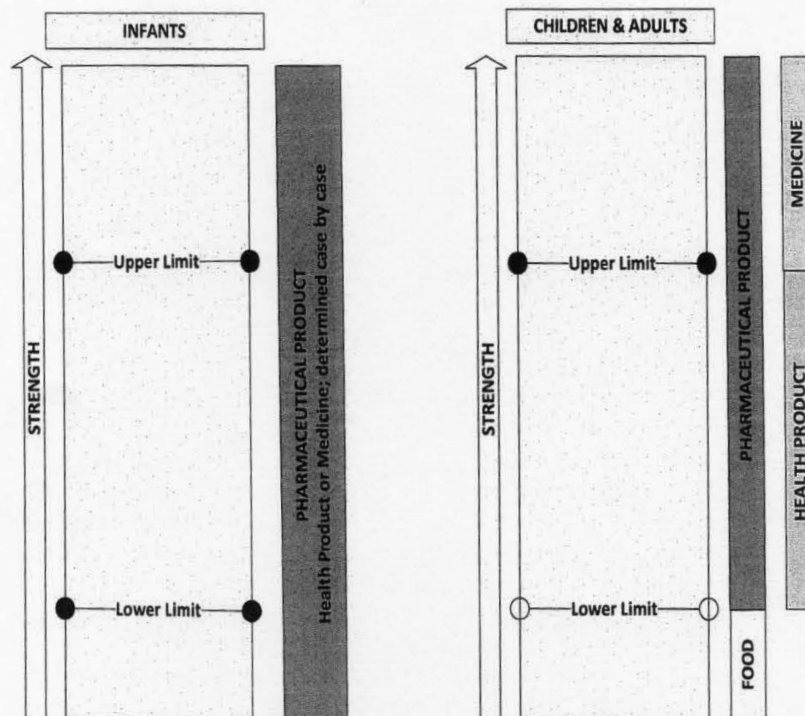
Products containing more than five herbal substances and/or preparations are not permitted in the Kingdom of Bahrain.

Finally there are certain herbal substances/preparations that are unsuitable for inclusion in health products because of concerns regarding their safety. A list of such herbal substances/preparations is provided in Annex I.

2.2.2 Vitamin/mineral-containing product

Whether vitamin and/or mineral-containing products are considered to fall within the scope of pharmaceutical products, i.e. are health products or medicines, depends on the amount of the vitamin and/or mineral in question in the given product.

The following is a diagrammatic representation of when such products are considered to be health products and when such products are considered to be medicines:



As such, products containing vitamins and/or minerals above the lower limit and below the upper limits (UL) included in Annex II to this guideline are considered to be health products. Products containing vitamins and/or minerals above the upper limits (UL) included in Annex II are considered to be medicines. In addition, all vitamin/mineral-containing products specifically recommended or formulated

for infants (between 0 and 12 months) are considered to be pharmaceutical products and a decision on their classification as health products or medicines will be taken on a case-by-case basis.

Note, the inclusion of medical claims in association with any vitamin/mineral-containing product will automatically raise the classification of the product to a medicine in accordance with section 3 of this guideline.

2.2.3 Other

'Other' health products are defined according to their contents. The following is a non-exhaustive list of substances which when contained in a product render that product a health product:

- Amino acids
- Charcoal
- Choline salts
- Lipids, including an essential fatty acid or phospholipids e.g. omega 3
- A substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
- Natural enzyme products
- Crude or refined coal tars
- Certain antiseptics (see section 4.1 below)

Additional products, not otherwise defined in this guideline will be reviewed by the NHRA on an ongoing basis through its internal procedure for classification taking due consideration of the factors outlined in section 3. below.

2.3 Prohibited substances

There are certain substances that are not permitted by the NHRA to be included in medicines or health products because they are considered to be unsuitable for use.

In the Kingdom of Bahrain, extracts of or any part of swine (pig) is not allowed to be used in a medicine or health product.

The NHRA will publish a list of such substances in accordance with an appropriate Board order.

3. Classification

For the purposes of classification, a pharmaceutical product can be considered to be comprised of two key features or characteristics, the presentation of the product and the purpose for which it is administered.

3.1 Presentation

In considering a product for classification, the NHRA examines the 'totality' of the product as discussed in the following sections:

3.1.1 Claims

Products for which (explicitly or implicitly) claims to cure, alleviate or prevent disease are made are considered as medicines. Any particular words or phrases which imply such a claim will be taken into account. While not intending to be exhaustive, Annex III contains examples of such words or phrases that are considered to be medicinal/medical.

Of note, health products may only carry medical claims consistent with the restrictions as outlined in Section 1.2.2 above.

3.1.2 Mechanism of action

Products for which the principle intended action is pharmacological, metabolic or immunological are regulated as medicines or health products; whereas where the principle intended action is physical or mechanical then the product is regulated as a medical device.

3.1.3 Product information & advertising

Products which are presented in a way that 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 are considered to medicines or health products. The contents and proposed medicinal usage will determine which of the two categories apply.

Health products and/or medicines containing vitamins and minerals are not permitted to be presented in a form considered to be a food or a sweet, e.g. gummy bear-shaped vitamins for children, as this is considered to inappropriately encourage the patient population not to think of such products as pharmaceutical products.

3.1.4 Other similar products

Once a given product has been classified by the NHRA as a medicine or health 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.

3.2 Purpose

Any product containing a substance with a known pharmacological effect will be classified as a medicine by the NHRA irrespective of the presence or absence of claims in the product packaging or literature.

In the case of herbal products, a pharmacological effect should be consistent with the known use of the product and available evidence to support such use.

It should be further noted that any product containing a substance which is confined to supply on a medical prescription is automatically deemed to be a medicine.

3.3 Combination products

For combination products i.e. products containing two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity the general rule is that the product is regulated in accordance with the strictest regulations e.g. a product containing a steroid and a herbal substance would be regulated as a medicine and not a health product.

4. Additional clarification on specific products

Certain products, depending on their content and/or medical claims made may be considered to be either a health product or a medicine. This section provides details on those products and defines the borderline between health product and medicine for each specific product type.

4.1 Antiseptics

4.1.1 Antiseptic products for human use containing any of the following active substances are classified as health products:

Proper name(s)	Common name(s)	Quantity
Ethanol	Ethanol	60-80%
Ethyl alcohol	Ethyl alcohol	
Anhydrous alcohol	Anhydrous alcohol	
Isopropanol	Isopropanol	60-70%
Isopropyl alcohol	Isopropyl alcohol	
2-propanol		
Povidone-iodine	Povidone-iodine	0.5-10.0%

4.1.2 Antiseptic products for human use containing any of the following ingredients are classified as medicines:

Common name	Quantity
Benzalkonium chloride	0.1 - 0.15%
Benzethonium chloride	0.05 - 0.5%
Chlorhexidine gluconate	2.0 - 4.0%
Chloroxlenol	0.5 - 3.0%
Methylbenzethonium chloride	0.05 - 0.5%
Triclocarban	1.5% only
Triclosan	0.1 - 1.0 %

4.2 Topical products

Topical products or products that fall in the borderline area between cosmetics and pharmaceutical products need special consideration, particularly in the context of the existing GCC Standards Organisation guidance GSO 1943/2009.

In accordance with that guidance the following classifications apply:

- 4.2.1 Topical products containing substances listed in or in forms prohibited by Table 1 of GSO 1943/2009 may be considered to be pharmaceutical products and will be evaluated in accordance with the classification procedure in section 3 of this guideline.
- 4.2.2 Topical products containing substances listed in Table 2 of GSO 1943/2009 where the cosmetic requirements, as per that guide are not met may be considered to be pharmaceutical products and will be evaluated in accordance with the classification procedure in section 3 of this guideline.

Whether such products are considered to be medicines or health products will be determined according to the definitions and classification processes outlined in this document.

5. Classification queries

Where a stakeholder wishes to place a product on the market in the Kingdom of Bahrain but is uncertain regarding the classification of that product i.e. whether the product is considered to be a pharmaceutical product or not, he can submit a classification query to the NHRA using the Pharmaceutical product classification application form published with this guideline.

Each application for classification should include all the information requested in the Product Classification Form-PPR0018, together with the fee of 10 Bahraini Dinar per product.

Annex I

Herbal substances and preparations considered unsuitable for inclusion in health products:

Name	Synonyms	Comment
<i>Aconitum napellus</i> L.	Aconite Monkshood Wolfsbane	
<i>Acorus calamus</i> L.	Calamus <i>Calamus aromaticus</i> Sweet flag Sweet sedge	
<i>Actea</i> species	White baneberry Red baneberry	
<i>Adonis vernalis</i> L.	<i>Adonis autumnalis</i> L. False Hellebore Red chamomile Yellow pheasants eye	
<i>Aesculus hippocastanum</i> L.	<i>Hippocastanum vulgare</i> L. Horse chestnut	
<i>Aletris farinosa</i> L.	Aloe root grass Argue root Black root Blazing star Colic root Crow corn Devil's bit Star root Stargrass Starwort True unicorn root	Root
<i>Alkanna tinctoria</i> (Tausch)	Alkanet Dyer's bugloss	Contains pyrrolizidine alkaloids
<i>Anamirta cocculus</i> (L.) Wight & Arn.	<i>Cocculus indicus</i> Fishberries	Contains a poisonous alkaloid
<i>Anchusa arvensis</i> (L.) M. Bieb	Small bugloss	Contains pyrrolizidine alkaloids
<i>Anchusa italica</i> Retz.	<i>Anchusa azurea</i> Italian bugloss	Contains pyrrolizidine alkaloids
<i>Anchusa officinalis</i> L.	Common bugloss	Contains pyrrolizidine alkaloids
<i>Angelica officinalis</i> L.	<i>Angelica archangelica</i> L.	Root

	Angelica root European Angelica	
<i>Angelica sinensis</i> (Oliv.) Diels	<i>Angelica polymorpha</i> Dong Quai Tang Kuei	Root
<i>Apocynum androsaemifolium</i> L.	Dogbane Spreading dogbane	
<i>Arctostaphylos uva-ursi</i> (L.) Spreng.	Bearberry Uva-ursi	
<i>Areca catechu</i> L.	Areca nut Betel nut	
<i>Aristolochia</i> species	Fangji Mu Tong Pipe vines	Contains pyrrolizidine alkaloids
<i>Arnica montana</i> L.	Arnica European arnica Leopard's bane Wolf's bane	
<i>Asclepias tuberosa</i> L.	Butterfly weed Canada root Flux root Milkweed Orange swallow-wort Pleurisy root Tuber root White root Wind root	Root
<i>Atropa belladonna</i> L.	Belladonna Black cherry Deadly nightshade Devils cherries Devils herb Divale Dwale Dwayberry Great morel Naughty man's cherries	Herb & root
<i>Berberis aristata</i>	<i>Darlahad</i> Nepal barberry Ophthalmic barberry	
<i>Berberis vulgaris</i> L.	Berberis cortex <i>Berberis dumetorum</i> Barberry Common barberry European barberry Pipperidge bush	
<i>Borago officinalis</i> L.	Borage	Contains

	Starflower	pyrrolizidine alkaloids
<i>Brachyglottis</i> species		Contains pyrrolizidine alkaloids
<i>Bryonia alba</i> L.	<i>Bryonia dioica</i> Jacq. Wild Bryony White vane	
<i>Calotropis procera</i> Ait.	<i>Asclepias procera</i> Mudar bark Mudar yercum	Bark
<i>Cannabis sativa</i> L.	Cannabis Hemp	
<i>Caulophyllum thalictroides</i> (L.) Mich.	Blue cohosh Papoose root Squaw root	
<i>Centella asiatica</i> L.	Fo Ti Tieng Gotu kola Hydrocotyle <i>Hydrocotyle asiatica</i> L. Indian pennywort Marsh penny White rot	Extract
<i>Chamaelirium luteum</i> (L.) Gray	Blazing star root False unicorn root Helonias root	Root
<i>Chelidonium majus</i> L.	Common celandine Greater celandine	
<i>Cinnamomum camphora</i> L.	Camphor	Oil
<i>Cinnamomum micranthum</i> L.	Micranthum	Oil
<i>Cimicifuga racemosa</i>	<i>Actaeae racemosa</i> Black cohosh Black snakeroot Bugbane <i>Macrotys actaeae</i> Rattleweed	
<i>Claviceps purpurea</i> Fr. Tul.	Ergot of rye Cockspur rye Hornseed Mother of rye Rye ergot Smut rye Spurred rye	
<i>Clematis</i> species		Contains aristolochic acid
<i>Colchicum autumnale</i> L.	Colchicum Autumn crocus	

	Meadow saffron Naked lady	
<i>Conium maculatum</i> L.	Hemlock Mother die Poison hemlock	
<i>Convallaria majalis</i> L.	Convallaria Lily of the valley May lily Muguet	
<i>Cyclamen europaeum</i>	Cyclamen Groundbread Sowbread Swinebread	
<i>Cytisus scoparium</i> L. Link	Broom Broom tops <i>Genista scoparius</i> (L.) Lam. Irish broom Scotch broom <i>Sarothamnus scoparius</i> (L.) K. Koch <i>Spartium scoparium</i> L.	
<i>Cynoglossum officinale</i> L.	Hound's tongue	Contains pyrrolizidine alkaloids
<i>Daphne</i> species	Daphne Dwarf bay Mezereon Spurge laurel Spurge olive	
<i>Datura stramonium</i> L.	Jamestown weed Jimson weed Stramonium Thornapple	
<i>Digitalis</i> species	Foxglove Purple foxglove Wooly foxglove	Leaves
<i>Dipteryx odorata</i> (Aubl.) Willd.	<i>Coumarouna odorata</i> Aubl. <i>Dipteryx oppositifolia</i> Tonka bean Tonquin bean	
<i>Drimia maritima</i> (L.) Steam.	Scilla Indian squill Maritime squill Red/White squill Sea onion Squill <i>Urginea maritima</i>	
<i>Dryopteris filix-mas</i> L.	<i>Aspidium filix-mas</i> L.	

	American aspidium <i>Dryopteris abbreviata</i> L. Male fern Marginal fern	
<i>Dysphania ambrosioides</i> (L.) Mosyakin & Clemants	American wormseed <i>Chenopodium ambroides</i> L. Wormseed	
<i>Ephedra</i> species	Ma Huang	
<i>Erechtites hieracifolia</i> (L.) Raf. Ex de Cand	Fireweed	Contains pyrrolizidine alkaloids
<i>Eupatorium</i> species		Contain pyrrolizidine alkaloids
<i>Euphorbia</i> species	Spurges	
<i>Fritillaria</i> species	Pei Mu Zhe Bei Mu	
<i>Gaultheria procumbens</i> L.	Aromatic wintergreen Boxberry Deerberry Mountain tea Teaberry The du Canada Wintergreen	Allowed as a flavour
<i>Gelsemium nitidum</i> L.	<i>Begonia semprevirans</i> L. Gelsemium <i>Gelsemium semprevirans</i> (L.) J. St.-Hil Wild jasmine/jessamine Wild woodbine Yellow jasmine/jessamine	
<i>Ginkgo biloba</i> L.	Ginkgo Kew tree Maidenhair tree	Fruit & seeds
<i>Gloriosa superb</i> L.	Flame lily	Contains colchicine
<i>Hedeoma pulegiodes</i> (L.) Pers.	American pennyroyal False pennyroyal	
<i>Heliotropium</i> species	Heliotrope (Garden, Peruvian, European & Indian)	Contains pyrrolizidine alkaloids
<i>Hydrastis canadensis</i> L.	Goldenseal Hydrastis Orange or yellow root	
<i>Hyoscyamus niger</i> L.	Common henbane Henbane Hog's bean Jupiter's bean Stinking nightshade	

<i>Juniperus communis</i> L.	Common juniper Genevrier Ginepro Juniper	Berries
<i>Kalmia latifolia</i> L.	Broad-leaved laurel Calico bush <i>Kalmia angustifolia</i> L. Lambkill Sheepkill Spoonwood	
<i>Lantana camera</i> L.	Lava Red, yellow or wild sage Spanish flag West Indian lantana	
<i>Larrea tridentata</i> (DC.) Coville	Chaparral Creosote bush <i>Larrea divaricate</i> Cav. Greasewood	
<i>Lithospermum officinalis</i> L.	Common gromwell	Contains pyrrolizidine alkaloids
<i>Lobelia inflata</i> L.	Indian tobacco Lobelia Pukeweed	
<i>Magnolia officinalis</i> Rehder & Wilson	Magnolia	
<i>Mahonia aquifolium</i> (Pursh) Nutt.	<i>Mahonia nervosa</i> Mountain grape root Oregon grape	
<i>Mandragora officinarum</i> L.	European mandrake <i>Mandragora autumnalis</i> Bertol. Satan's apple	
<i>Maranta arundinaceae</i> L.	<i>Maranta malaccensis</i> Burm.f. Spanish arrowroot Bermuda arrowroot	
<i>Mentha pulegium</i> L.	European pennyroyal Pulegium Pudding grass	
<i>Myrica cerifera</i> L.	Bayberry Candleberry Wax berry Wax myrtle	
<i>Narcissus pseudonarcissus</i> L.	Chinese sacred lily Daffodil Lent lily <i>Narcissus tazetta</i> Porillon	
<i>Paeonia officinalis</i> L.	Paeony	

	Peony	
<i>Papaver species</i>	Opium poppy Scarlet poppy	
<i>Pausinystalia yohimba</i> (K. Schum) Pierre ex Beille	<i>Corynanthe yohimbe</i> Yohmibe Yohimbine bark	
<i>Petasites species</i>	<i>Butterbur</i>	Contains pyrrolizidine alkaloids
<i>Petroselinum crispum</i> (Mill.)	<i>Apium petroselinum</i> L. Parsley Persele Persely <i>Petroselinum lativum</i> <i>Petroselinum sativum</i>	Oil
<i>Phorandendron tomentosum</i> (DC.) Engelm.	American mistletoe Birdlime False mistletoe Golden bough <i>Phorandendron flavescens</i> <i>Phorandendron serotinum</i>	
<i>Physostigma venenosum</i> Balf.	Calabar bean Chopnut Ordeal bean	
<i>Phytolacca species</i>	Pigeonberry Pocan Pokeberry Pokeweed Poke root Red plant Red pokeweed	
<i>Piper methyticum</i> G. Forst.	Kava Kava kava Kawa Kew Tonga	
<i>Platycodon grandiflorus</i> (Jacq.) A.DC.	Balloon flower Chinese bellflower	
<i>Podophyllum species</i>	American mandrake Apples of the fool Duck's foot Hog apple May apple Racoonberry Wild lemon Wild mandrake	
<i>Prunus serotina</i>	Black cherry	

	Mountain black cherry Rum cherry Wild black cherry	
<i>Prunus virginiana</i>	Bitter berry Black chokecherry Chokecherry Virginian prune	
<i>Rauwolfia</i> species	African snakeroot Devil's pepper Indian snakeroot	
<i>Ricinus communis</i> L.	Castor bean Castor oil plant Palma christi Wonder tree	
<i>Ruta graveolens</i> L.	Herb of grace Herby grass Galena Garden/German rue Rue	
<i>Sabina vulgaris</i> A.	<i>Juniperus sabina</i> L. Savin Savin tops	Oil
<i>Salvia officinalis</i> L.	Sage (Garden, Spanish or Red)	Oil
<i>Sanguinaria canadensis</i> L.	Blood root Red Indian paint	
<i>Sassafras</i> species	Ague tree Cinnamon wood Saloop Sassafrax	Oil, root & bark
<i>Schoenocaulon officinale</i> (Schlect & Cham) A. Gray	Cevadilla Sabadilla <i>Veratrum sabadilla</i>	
<i>Senecio</i> species	Common ragwort Common groundsel Golden ragwort Golden senecio Life root Ragwort Silver ragwort Squaw weed Wood ragwort	Contains pyrrolizidine alkaloids
<i>Solanum</i> species	Bittersweet Bittersweet nightshade Black nightshade Fellonwood Fellonwort Woody nightshade	

<i>Stephania rotunda</i> Lour.		
<i>Stephania tetrandia</i> S. Moore	Han Fang Ji	
<i>Strophanthus</i> species	Kombe	
<i>Strychnos ignatii</i> Berg.		Contains strychnine
<i>Strychnos nux vomica</i> L.		Contains strychnine
<i>Symphytum</i> species	Blackwort Comfrey (Common, Prickly, Russian, Tuberos) Consolida Knitbone Nipbone <i>Symphytum uplandicum</i>	Contains pyrrolizidine alkaloids
<i>Tanacetum vulgare</i> L.	Buttons <i>Chrysanthemum vulgare</i> (L.) Bernh Tanacetum Tansey	Oil
<i>Thuja occidentalis</i> L.	Arborvitae American cedar Thuja Tree of life White cedar Yellow cedar	
<i>Tussilago farfara</i> L.	Coltsfoot Coughwort Bull's foot Foal's foot Horsehoof	Contains pyrrolizidine alkaloids
<i>Veratrum album</i> L.	European hellebore	
<i>Veratrum viride</i> Ait.	America hellebore	
<i>Viburnum opulus</i>	Cramp bark Cranberry Guelder rose Snowball	Berries
<i>Viscum album</i> L.	Birdlime mistletoe European mistletoe Herbe de la croix Mistletoe	
<i>Zamia integrifolia</i> L.f.	Coonties Florida arrowroot	Seeds

Annex II

Table for Lower and Upper Concentrations Limits for Vitamins and Minerals

Life Stage Group		Vitamin A (μg AE/day)		Vitamin C (mg/day)		Vitamin D (μg /day)		Vitamin E (mg/day)		Vitamin K1 & K2 (μg /day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	300	600	15	400	15	25	6	179	30	30
	4-8 y	400	900	25	650	15	25	7	179	55	55
Adolescents	9-13 y	600	1700	45	1200	15	25	11	179	60	60
	14-18 y	700	2800	65	1800	15	25	15	179	75	75
Adults	≥ 19 y	700	3000	75	2000	15	25	15	179	90	120

Life Stage Group		Thiamine (mg/day)		Riboflavin (mg/day)		Niacin or Niacinamide (mg/day)		Vitamin B6 (mg/day)		Folate (μg /day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	0.5	100	0.5	100	6	10	0.5	30	150	300
	4-8 y	0.6	100	0.6	100	8	15	0.6	40	200	400
Adolescents	9-13 y	0.9	100	0.9	100	12	20	1.0	60	300	600
	14-18 y	1.0	100	1.0	100	14	30	1.2	80	400	800
Adults	≥ 19 y	1.1	100	1.1	100	14	500	1.3	100	400	1000

Life Stage Group		Vitamin B12 (μg /day)		Pantothenic acid (mg/day)		Biotin (μg /day)		Choline (mg/day)		Calcium (mg/day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	0.9	1000	2	500	8	500	200	1000	700	1500
	4-8 y	1.2	1000	3	500	12	500	250	1000	1000	1500
Adolescents	9-13 y	1.8	1000	4	500	20	500	375	1000	1300	1500
	14-18 y	2.4	1000	5	500	25	500	400	1000	1300	1500
Adults	≥ 19 y	2.4	1000	5	500	30	500	425	1000	1000	1500

Life Stage Group		Chromium (µg/day)		Flouride (mg/day)		Iodine (µg/day)		Iron (mg/day)		Magnesium (mg/day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	11	-	0.7	0.7	90	133	7	40	80	65
	4-8 y	15	-	1	1	90	200	10	40	110	110
Adolescents	9-13 y	21	-	2	2	120	400	8	40	240	350
	14-18 y	24	-	3	3	150	800	11	45	350	350
Adults	≥ 19 y	20	500	4	4	150	800	8	45	310	500

Life Stage Group		Manganese (mg/day)		Molybdenum (µg/day)		Phosphorus (mg/day)		Selenium (µg/day)		Zinc (mg/day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	1.2	2	17	300	460	2000	2.0	90	3	7
	4-8 y	1.5	3	22	600	500	2000	3.0	150	5	12
Adolescents	9-13 y	1.6	6	34	1100	1250	2000	4.0	280	8	23
	14-18 y	1.6	9	43	1700	1250	2000	5.5	400	9	34
Adults	≥ 19 y	1.8	9	45	2000	700	2000	5.5	400	8	50

Life Stage Group		Potassium (mg/day)		Sodium (g/day)		Chloride (g/day)		Boron (µg/day)		Copper (µg/day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	3.0	-	1	1	1.5	1.5	-	-	340	700
	4-8 y	3.8	-	1.2	1.2	1.9	1.9	-	-	440	2500
Adolescents	9-13 y	4.5	-	1.5	2.3	2.3	2.3	-	-	700	4000
	14-18 y	4.7	-	1.5	2.3	2.3	2.3	-	-	890	6500
Adults	≥ 19 y	4.7	100	1.3	2.3	2.0	2.3	-	700	900	8000

Life Stage Group		Nickel (µg/day)		Vanadium (µg/day)		Lutein (mg/day)		Beta-carotene (µg/day)		L-Methionine (mg/day)	
		LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
Children	1-3 y	-	-	-	-	-	-	60	1200	-	1000
	4-8 y	-	-	-	-	-	-	60	1800	-	1000
Adolescents	9-13 y	-	-	-	-	-	-	60	3400	-	1000
	14-18 y	-	-	-	-	-	-	130	5600	-	1000
Adults	≥ 19 y	-	350	-	182	-	10	130	6000	-	1000

Life Stage Group		Inositol (mg/day)		Cobalt (µg/day)	
		LL	UL	LL	UL
Children	1-3 y	-	650	0.004	44
	4-8 y	-	650	0.004	44
Adolescents	9-13 y	-	650	0.004	44
	14-18 y	-	650	0.006	44
Adults	≥ 19 y	-	650	0.006	44

Annex III

Examples of words or phrases that in context may suggest or imply a medical claim about a product:

Alleviates ...
Avoids ...
Boosts ... e.g. immune system
Burns fat
Calms ...
Can benefit those who suffer from ...
Clears ...
Clinical trials evidence suggests ...
Clinical trials suggest ...
Clinically proven to ...
Combats ...
Controls ...
Counteracts ...
Cures ...
Eliminates ...
Fights ...
Maintains a normal ... e.g. water balance, mood etc.
Helps ...
Helps with ...
Increases metabolic rate
Is said to help ...
Is said to help with ...
Medical research suggests ...
Lowers cholesterol
Prevents ...
Protects against ...
Removes ...
Repairs ...
Restores ...
Stimulates ... e.g. the nervous system
Stops ...
Strengthens the immune system
Strips of pre-cancerous sun-damaged cells
Traditionally used for ...
Treats ...

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