IRISH
MEDICINES
BOARD

GUIDE TO THE DEFINITION OF A MEDICINAL PRODUCT

Edition 1
May 1999

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

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1. INTRODUCTION

The manufacture, importation, distribution and supply of medicinal products for human use in Ireland is regulated by the Irish Medicines Board.

The Irish Medicines Board (IMB) is the licensing authority for medicinal products for human use in Ireland pursuant to the provisions of the Irish Medicines Board Act 1995.

IMB regulates the licensing and sale of medicinal products for human use in Ireland by means of the Medicinal Products (Licensing and Sale) Regulations (S.I. 142 of 1998) (Regulations) and relevant EC Directives.

These Regulations require that a medicinal product shall not be marketed without a Product Authorisation. The granting of such authorisation ensures that a product complies with 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 medicine is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications and the manner of marketing are consistent with the definition of the European Directives.

Article 1 (2) of European Council Directive 65/65/EEC defines a medicinal product as follows:

'*Any substance or combination of substances presented for treating or preventing disease in human beings or animals.*

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product'.

There are products, however, which could be said to occupy a "borderline" position between for example medicines and nutritional products, between medicines and cosmetic substances between medicines and medical devices and between medicines and so-called "lifestyle" products.

1. INTRODUCTION CONTINUED

These present guidelines are intended to describe IMB policy in categorisation of medicinal products for human use. They are intended as guidelines only and should not be assumed to be a definition of the law in this area. They should be read in conjunction with the various relevant Directives and Regulations, in particular the following:

Directive	65/65/EEC[4]	(Medicines)
Directive	76/768/EEC[5]	(Cosmetic Products)
Directive	89/398/EEC[6]	(Nutritional Products)
Directive	93/42/EEC[7]	Medical Devices
Directive	90/385/EEC	(Active Implantable Medical Devices)
S.I. No.	142 of 1998	(Medicines)
S.I. No.	87 of 1997	(Cosmetic Products)
S.I. No's	252 and 253 of 1994	(Medical Devices)
S.I. No.	333 of 1991	(Foods for particular uses)

2. THE IRISH MEDICINES BOARD

The powers and functions of the IMB are set out in the Irish Medicines Board Act 1995 referred to above. The IMB is the competent authority for the licensing and supervision of human and veterinary medicines in Ireland. The mission of the IMB is to protect and enhance public health and animal health through the regulation of human and veterinary medicinal products. The regulation of these products is founded on science and law to ensure their purity, potency, safety, efficacy and appropriate storage, transport and distribution. The IMB also participates in systems designed to ensure quality, safety and efficacy of medicines throughout the European Union. Under the terms of the Irish Medicines Board Act, 1995, anyone who contravenes a regulation made by the Minister under the Act, is liable to fines or to a prison term, as appropriate.

3. THE REQUIREMENTS OF A MEDICINAL PRODUCT

Before a medicinal product can be authorised for use, an application must be made for a product authorisation to the IMB, (or in the case of centrally licensed products to the European Agency for the Evaluation of Medicinal Products). Such applications should contain the data necessary to support the quality, safety and efficacy of the medicinal product. The application is reviewed and a conclusion reached based upon the likely balance of the benefits versus risks associated with the product. The IMB requires that the interests of consumers of medicines should be protected, notably in the following areas:

3.1. A medicine should be of adequate quality such that its contents and its pharmaceutical performance should conform to acceptable standards.

3.2. The risk of using a medicine 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.

3.3. There should be a demonstrable therapeutic benefit. If a medicinal claim is made the consumer is entitled, within reason, 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.

In addition there is a requirement that the holder of a product authorisation should keep the IMB informed of the discovery of any adverse effects or any events with potential safety consequences for his products.

4. WHAT IS A MEDICINAL PRODUCT ?

The definition of a medicinal product is given in Article 1 (2) of Directive 65/65/EEC. The definition is set out in two paragraphs, covering the presentation of the product and the purpose for which it is administered respectively.

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 for treating or preventing disease in human beings or animals'.

In reviewing a product in this context the IMB examines the "totality" of the product including:

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

While not intending to be exhaustive, the following list contains examples of these words or phrases:

'Cures, heals, treats, restores, prevents, clears, stops, protects, helps with, traditionally used for, strengthens the immune system, calms, helps maintain normal water balance'.

In addition the IMB has regard to judgements of the European Court of Justice (ECJ) in determining such claims. The ECJ has held that: *'A product which is recommended or described as having preventive or curative properties is a medicinal product within the meaning of the provisions of Article 1.. of Council Directive 65/65/EEC…even if it is generally considered as a foodstuff and even if it has no known therapeutic effect in the present state of scientific knowledge'.*[1]

4.1.2. 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 as medicinal products.

4. WHAT IS A MEDICINAL PRODUCT ? CONTINUED

4.1.3. Once a given product has been classified by the IMB as medicinal 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 65/65/EEC provides:

'Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product'.

Thus any product containing a substance with a known significant pharmacological effect, will usually be classified as a medicinal product by the IMB irrespective of the presence or absence of claims in the product packaging or literature.

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, 1996, the Poisons Regulations or the Misuse of Drugs Regulations is automatically deemed to be a medicinal product requiring an authorisation.

4.3. IMB Policy and Practice

(ECJ) judgements, the evolution of professional opinion, changes in marketing practices, and other changing circumstances have required corresponding changes to the way the IMB 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.

4. WHAT IS A MEDICINAL PRODUCT ? CONTINUED

In practice, the IMB 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" or publications, or in the product's actual name).

(b) The pharmacological 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, ointment etc.) and the way in which it is intended to be used.

(f) To whom the product or information about the product is directed, perhaps sections of the population with, or vulnerable to, a specific adverse condition.

(g) Whether there are similar authorised medicinal products on the market, fulfilling similar functions.

5. BORDERLINE PRODUCTS

The status of many products occupying the "borderline" area between medicines and, for example, nutritional or cosmetic substances can be difficult to determine. These guidelines have been drawn up to explain the IMB's policy and practice on borderline products like these, and the principles on which they are based.

These guidelines are not intended to provide detailed information on the borderline between medicinal products and medical devices, for which a separate EU guideline (MEDDEV.2.1/3 Rev. 5.1 - March 1998)[3] offers detailed advice.

5.1. Cosmetic Products

The Cosmetics Directive 76/768/EEC, as amended, defines cosmetic products and sets limits for certain ingredients. Where medicinal claims are made for cosmetic products, the determination of an individual product's status should be informed by reference to both the Cosmetic and Pharmaceutical Directives.

Under the European Communities (Cosmetic Products) Regulations, 1997 (S.I. No. 87 of 1997) the expression “cosmetic product” is defined as being -

‘any substance or preparation intended for placing 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 membrances 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’.

An illustrative list of the categories of preparations considered as cosmetic products is reproduced from the EEC Council Directive relating to Cosmetic (76/768/EEC) as Appendix 1 to this guide.

In general cosmetic products placed on the market in accordance with the European Communities (Cosmetic Products) Regulations, 1984 (as amended) are not considered to be medicinal products provided their labelling or their accompanying or associated literature does not make a medicinal claim.

5. BORDERLINE PRODUCTS CONTINUED

In general medicinal substances such as antibiotics, antifungal agents, hormones, chloroform, lignocaine or hexachlorophane and medicinal herbal substances are not permitted in cosmetic products. The prohibition and/or restrictions on such substances are set out in the schedules to the 1997 cosmetic products regulations. Accordingly, unless provided for in these regulations preparations containing any of these substances cannot be viewed as being cosmetic products. The presence of such substances in products therefore can only be justified on the basis that the products are medicinal and as such would require product authorisations.

Preparations intended to be ingested, inhaled, injected or implanted in the human body cannot be considered to be cosmetic products. Consequently preparations for oral use containing substances such as canthaxanthin or betacarotene are considered as medicinal products for which product authorisations must be held even though skin tanning may be their declared purpose. Similarly, preparations for use in the eye (e.g. eye brighteners) are considered as medicinal products, by virtue of their route of administration.

Again, an (ECJ) judgement[2] has held that: *'Any product satisfying either set of criteria laid down in Article 1(2) of Directive 65/65/EEC is a medicinal product. Such products are subject to the relevant legal rules relating to proprietary medicinal products, to the exclusion of the regulations governing cosmetic products, which might otherwise apply'.*

5.2. Foods

In general most foods are clearly not medicinal products. There are however certain manufactured preparations presented in a form, such as capsules, tablets or certain liquids, usually associated with medicines to which have been added various substances such as vitamins, minerals, amino acids and herbal ingredients. Such preparations may be classed as medicinal products even in circumstances where they may be described by the manufacturers concerned as "foods" or "food supplements". In these cases the use assigned by the purchasers and users of the products will be taken into account by IMB in establishing the classification of a product.

The following therefore is an outline of the position in regard to those products which are presented in a form usually associated with medicinal products :

5. BORDERLINE PRODUCTS CONTINUED

5.2.1. Products containing vitamins and/or mineral ingredients

These preparations are considered to be medicinal products when -

(a) their labelling or accompanying or associated literature makes any preventative, curative or remedial claim; or

(b) the recommended daily intake calculated with respect to any of the added vitamin or mineral constituents exceeds the maximum recommended daily dietary allowance for such constituents as published from time to time by the Minister for Health, or if their content is otherwise sufficient to exert pharmacological or toxicological effects.

The current Table of Maximum Recommended Daily Dietary allowances is set out in Appendix 2 to this guideline. In the case of preparations intended for a particular population category, e.g. children, the maximum recommended allowance for that category is applied.

It should also be noted that where there are no written particulars or directions as to dosage the vitamin or mineral preparation concerned is automatically classed as a medicinal product, thereby requiring a product authorisation under the Regulations, because of the risk of overdosing in the absence of such dosage instructions.

5.2.2. Products containing selected amino acids

These preparations are considered to be medicinal products when -

(a) the labelling or accompanying or associated literature makes any preventative, curative or remedial claim or

(b) any of the amino acid constituents are presented at an enhanced level greater than that ordinarily encountered in the course of a normal daily diet.

5. BORDERLINE PRODUCTS CONTINUED

It must be noted that amino acids are the constituent units of dietary protein and break down during digestion. For the most efficient use to be made of amino acids to the body a complete range must be supplied in the diet at the same time.

The taking of individual amino acids at levels greater than ordinarily encountered in the course of a normal diet cannot therefore be considered as being of dietary or nutritive value alone.

The use of amino acids in these circumstances is considered medicinal and accordingly such preparations are considered to be medicinal products for which product authorisations must be held under the Regulations.

It should also be noted that certain amino acids if used in non-dietary proportions may be hazardous to health. This has been recognised in the case of oral preparations of L-Tryptophan which under the Medicinal Products (Prescription and Control of Supply) Regulations, 1996, may only be sold on presentation of a medical prescription.

5.2.3. Products containing other ingredients (e.g. Fish Oils, Omega 3 Fatty Acids, Evening Primrose Oil and Caprilic Acid etc.)

In the case of fish oils such as cod liver oil to which no additives have been added the classification for product authorisation purposes will be considered on the basis of the recommended daily intake of the vitamin constituents as described in paragraph (5.2.1) above.

The position in regard to products containing other ingredients will be considered on their individual merits. In the case of Omega 3-fatty acids, evening primrose oil and caprilic acid (and its salts) it is clear from the promotional literature associated with those products available on the market that their use is medicinal and accordingly product authorisations are required.

5. BORDERLINE PRODUCTS CONTINUED

5.3. Herbals (Products containing medicinal herbal ingredients)

Herbal medicines (herbal remedies) are medicinal products containing active substances derived from plant material and/or vegetable substance preparations.

All such preparations are considered to be medicinal products, since by definition these plant substances have known pharmacological properties.

However, it should be noted that preparations consisting of dried, crushed or comminuted herb(s) labelled in a manner which specifies the herb(s) and the process of production only are excluded from the scope of the regulations provided no other name is given to the preparation and no recommendation as to use as a medicinal product is made (Article 10b of SI 142) 1998.

Examples of such exempted products would include senna leaves, cinnamon bark, ginger root and carrageen moss appropriately labelled.

Examples of herbal substances can be found in Appendix 3A to this guideline.

Certain herbal substances are known to have potent pharmacological action and many of these have therefore been restricted to tightly controlled sale or supply conditions. For example, the substances listed in Appendix 3B may be only supplied in Ireland on foot of a prescription from a registered medical practitioner. This list also includes certain potent plant substances where the active principle is well characterised and more usually presented as a purified substance.

5.4. Slimming Products

Preparations presented in a form, such as capsules, transdermal patches, tablets or other dose forms usually associated with medicines and which are intended for use with a view to weight loss or weight control are considered as medicinal products for which product authorisations are required under the Regulations.

Examples of products which fall into this category include appetite suppressants, bulk forming agents (e.g. methycellulose, sterculia) starch blockers, amino acids and “anti cellulite” preparations.

6. HOMOEOPATHIC MEDICINES

Homoeopathic and anthroposophic medicines represent special types of medicinal product for which particular rules may be applied by Member States recognising their tradition of homoeopathic practice, in accordance with the requirements of Directive 92/73/EEC[8]. This Directive is given effect in Irish legislation by the Regulations (S.I. 142 of 1998) made under the Irish Medicines Board Act, 1995. Under this legislation it is recognised that the principles of Directive 65/65/EEC apply to any homoeopathic 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 7 of Directive 92/73/EEC may also be applicable be those homoeopathic products marketed without medicinal claims as specified in Article 8 of the Regulations. In order to obtain the certificate of registration referred to above, an application should be made to the IMB setting out the documents specified in the Third Schedule to the Regulations.

7. DISINFECTANTS	Disinfectant preparations which are not intended for administration to human beings are not considered as medicinal products. A disinfectant preparation which is intended for administration to the skin as an antiseptic in wound treatment would be considered as a medicinal product requiring a product authorisation. Disinfectant products are in general regulated under EC Biocides Legislation.

8. MEDICAL DEVICES

The borderline between products regulated as medical devices, or as medicinal products is explained in the Guideline (MedDev 1998) referred to above. However, there are certain products which were formerly regulated as medicines and which are now regulated as Medical Devices under Directive 93/42/EC. These include:

- contact lens care products (not intended for administration into the eye),
- certain medicated dressings,
- concentrates for haemodialysis,
- certain irrigation fluids,
- bone cements containing antibiotics which are ancillary to the primary purpose of the cement,
- blood collection bags containing anticoagulant solutions,
- intrauterine contraceptive devices containing copper,
- absorbable sutures

For further information consult document MEDDEV.2.1/3 Rev 5.1 - March 1998.[3]

9. SUMMARY

9.1. The definition of a medicinal product used in Ireland and throughout the European Community is that contained in Article 1 of European Council Directive 65/65/EEC.

9.2. This definition is in two parts. The first refers to the presentation of the product and the second refers to its actions on the body.

9.3. A summary of the IMB's policy is as follows:

9.3.1. Products which claim to cure, alleviate or prevent disease are considered medicines. The IMB takes into account in its decision the words used, the presentation and the relationship to similar products.

9.3.2. Products which contain substances of a type and in amounts such as to exert a significant pharmacological effect, will also be considered as medicines.

9.3.3. Products presented as nutritional or cosmetic substances may be considered as medicinal products if medicinal claims are made or if they contain ingredients which have significant pharmacological effects.

9.4. Unless a specific exemption has been granted medicinal products may not be marketed without a current product authorisation, in accordance the 1998 regulations (S.I. 142 of 1998).

9.5. It is the responsibility of the person or organisation marketing such a product to ensure that the relevant legislation is complied with. Failure to comply with this legislation may result in prosecution with liability for fines or prison terms as specified in the Irish Medicines Board Act 1995.

9.6. This document is for guidance only and should not be considered to be a complete or definitive statement of the law. It may be subject to change in the light of new developments over time or as appropriate.

10. DEFINITIONS

Biocide:

A substance with antimicrobial and insecticidal properties. In particular a substance intended for use on inanimate objects as described in Council Directive 98/8/EEC.

Homoeopathic Medicinal Product:

"Homoeopathic medicinal product" means any medicinal product prepared from preparations, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described in the European Pharmacopoeia or, in the absence of a manufacturing procedure for homoeopathic medicinal products in that pharmacopoeia, in accordance with a homoeopathic manufacturing procedure in any pharmacopoeia in official use in a Member State of the European Communities.

Medicinal Herbal Substance:

A substance with medicinal activity derived exclusively from plant material or extracts. A herbal drug or a preparation thereof is regarded as one active substance in it entirety, whether or not the constituents with therapeutic activity are known.

Medical Devices:

Any instrument, apparatus, appliance, material or other article, whether used above or in combination .. intended to be used for diagnosis, prevention, monitoring or treatment of a disease, injury, handicap etc. (c/f Council Directive 93/42/EEC).[7]

Product Authorisation:

A licence to market a medicinal product granted by the Irish Medicines Board in accordance with Article 7 of the Medicinal Products (Licensing and Sale) Regulations, 1998.

11. REFERENCES

1. Official Journal of the European Communities, 1991, **C219**, 91.

2. Official Journal of the European Communities, 1989, **C112**, 89.

3. Guidelines relating to the demarcation between:

   - Directive 90/385/EEC on Active Implantable Medical Devices,
   - Directive 93/42/EEC on Medical Devices and
   - Directive 65/65/EEC relating to Medicinal Products and related Directives
   - (MED.DEV.2.1/3 Revision 1 - March 1998), Commission of the European Communities, 1998.

4. Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (O.J. L. No.22 of 9/2/65 Pg. 369).

5. Directive 76/768/EEC on the approximation of laws relating to cosmetic products.

6. Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (O.J. L186, 30/6/89, Pg. 27) as amended.

7. Directive 93/42/EEC concerning medical devices (O.J. L169, 12/7/93, Pg.1).

8. Council Directive 92/73/EEC of 22nd September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homoeopathic medicinal products (O.J. L297 of 13/10/92, Pg. 8).

APPENDIX 1 **llustrative List by Category of Cosmetic Products**

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc).
- Face masks (with the exception of peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc).
- Depilatories.
- Deodorants and anti-perspirants.
- Hair care products:
  - hair tints and bleaches,
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc).
- Products for making up and removing make-up from the face and eyes.
- Products intended for application to the lips.
- Products for care of the teeth and mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without the sun.
- Skin-whitening products.
- Anti-wrinkle products.

Appendix 2

RECOMMENDED DIETARY ALLOWANCES FOR USE BY HEALTH SERVICES REPUBLIC OF IRELAND – 1983

AS COMPILED BY THE FOOD ADVISORY COMMITTEE FOR THE MINISTER FOR HEALTH

	AGE RANGES (YEARS)	REFERENCE WEIGHT		REFERENCE HEIGHT		ENERGY		PROTEIN +	THIAMIN	RIBOFLAVIN	NIACIN	ASCORBIC ACID	B12	FOLATE	*PTRIDOXINE (B6)	VIT A	VIT D	*VIT E	*CALCIUM	IRON	*ZINC
		Kg	lb	cm	in	MJ	kcals	g	mg	mg	mg	mg	ug	ug	mg	ug	ug	mg	mg	mg	mg
INFANTS	LESS THAN 1 YEAR	9	20	71	28	.48-.4 x kg	115 – 100 x kg	2.8-2.5x kg	0.3	0.4	5	35	1.5	50	0.6	450	10	4	540	7	5
CHILDREN	1—3	13	29	90	35	5.6	1300	33	0.5	0.7	8	45	2.0	100	0.9	300	10	5	800	8	10
	4 - 6	20	44	112	44	7.0	1700	43	0.7	0.9	10	45	2.5	200	1.3	300	10	6	800	9	10
	7—10	28	62	132	52	8.5	2000	51	0.8	1.1	12	45	3.0	200	1.6	480	10	7	800	10	10
MALE ADOLESCENTS	11—14	45	99	157	62	11	2600	66	1.1	1.4	16	50	3.0	300	1.8	725	10	8	1200	13	15
	15 -18	66	145	176	69	12	2900	72	1.2	1.7	19	60	3.0	300	2.0	750	10	10	1200	14	15
FEMALE ADOLESCENTS	11 –14	46	101	157	62	9	2100	53	0.9	1.4	16	50	3.0	300	1.8	725	10	8	1200	14	15
	15—18	55	120	163	64	9	2100	53	0.9	1.7	19	60	3.0	300	2.0	750	10	8	1200	14	15
MEN																					
SEDENTARY		70	154	178	70	10.5	2500	63	1.0	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
MODERATELY ACTIVE	19 –34	70	154	178	70	12	2900	72	1.2	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
VERY ACTIVE		70	154	178	70	14	3300	84	1.3	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
SEDENTARY		70	154	178	70	10	2400	60	1.0	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
MODERATELY ACTIVE	35—64	70	154	178	70	11.5	2700	69	1.1	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
VERY ACTIVE		70	154	178	70	14	3300	84	1.3	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
	65 -74	70	154	178	70	10	2400	60	1.0	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
	75+	70	154	178	70	9	2100	54	0.9	1.6	18	60	3.0	300	2.2	750	7.5	10	800	10	15
WOMEN																					
MOST OCCUPATIONS	19—54	55	120	163	64	9	2100	54	0.9	1.3	15	60	3.0	300	2.0	750	7.5	8	800	14	15
VERY ACTIVE		55	120	163	64	10.5	2500	62	1.0	1.3	15	60	3.0	300	2.0	750	7.5	8	800	14	15
	55—74	55	120	163	64	8	1900	47	0.8	1.3	15	60	3.0	300	2.0	750	7.5	8	800	9	15
	75+	55	120	163	64	7	1700	42	0.7	1.3	15	60	3.0	300	2.0	750	7.5	8	800	9	15
PREGNANCY (Z) (SECOND HALF)		—	—	—	—	10	2400	60	1.0	1.6	18	80	4.0	500	2.6	750	10	10	1200	15	20
LACTATION (Z) (FIRST SIX MONTHS)		—	—	—	—	11.5	2700	69	1.1	1.8	21	80	4.0	400	2.5	1200	10	11	1200	15	25

+ Based on 75% biological utilization

* These figures are based on USA 1980 figures and refer, in the "infant" age range, to the 6—12 month age group.

(Z) Refers to women in "most occupations".

Maximum Recommended Daily Dietary Allowances.									1.3	1.8	21	80	4.0	400	2.5	1200	10	11	1200	15	25

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APPENDIX 3A

Examples of medicinal herbal substances found in herbal medicinal products.

Note: This list is by no means exhaustive and must only be considered as illustrative.

Achillea (Yarrow)	Fennel
Aconite (Monkshood)	Feverfew (Tanacetum)
Aesculin	Garlic (oil)
Angelica	Gelsemium
Anise	Germander (Teucruim)
Aristolochia	Ginger
Artemisia (Levant Wormseed)	Ginkgo Biloba (Maidenhair)
Baldo	Ginseng
Berberis	Hops
Betel	Houndstongue
Borage	Hypericum (St. Johns Wort)
Bryony	Hyoscyamus
Burdock	Kamala
Butterbur	Liquorice
Cajuput	Madder
Capsicum	Male Fern
Caraway	Meadowsweet
Cardamom	Melissa
Cassia	Mullein
Chamomile	Nux vomica
Chenopodium	Parsley Fruit
Cinnamon (oil)	Passiflora
Clove (oil)	Periwinkle (Vinca)
Coltsfoot	Plantain
Comfrey	Pulsatilla
Coriander	Ragwort
Croton	Rosemary
Dandelion	Rue
Digitalis	Sassafras
Dill (oil)	Savin
Elder	Scammony
Ergot of Rye	Tansy
Eucalyptus (oil)	Uvae Ursi
Exogonium	Valerian
	Wintergreen

APPENDIX 3B

Products Subject to Prescription Control

The following medicinal substances for human use of herbal origin are subject to prescription-only control in Ireland.

Aconite Belladonna (herb and root) Broom (Cytisus scoparius species) Confrey (Symphytum species) Conium leaf (Coniine) Croton oil Croton seed Curare Digitalis leaf (whether prepared or not) Ephedra (including Ma-Huang) Ergot (prepared) Ginkgo biloba Jaborandi	Mistletoe (Viscum album L) Nux vomica seed Papaveretum Podophyllum (including resin) Pokeroot (Phytolacca species) Poppy capsule Ragwort (Senecio jacobaea L) Rauwolfia serpentina Rauwolfia vomitoria Sabadilla Sassafras (bark and root) Sassafras oil Yohimbine hydrochloride