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No. S 000

PATENTS ACT
(CHAPTER 221)

PATENTS (MEDICINAL HEALTH PRODUCTS) RULES 2012

ARRANGEMENT OF RULES

Rule

1. Citation and commencement
2. Definitions
3. Medicinal health product
 The Schedule

In exercise of the powers conferred by section 115 of the Patents Act, the Minister for Law, after consulting with the Intellectual Property Office of Singapore, hereby makes the following Rules:

Citation and commencement

1. These Rules may be cited as the Patents (Medicinal Health Products) Rules 2012 and shall come into operation on 2012.

Definitions

2. In these Rules, unless the context otherwise requires —
 “health product” and “therapeutic product” have the same meanings as in the Health Products Act (Cap. 122D);
 “medicinal purpose” means any one or more of the following purposes:
 - (a) treating or preventing disease;

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- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- (c) contraception;
- (d) inducing anaesthesia;
- (e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Medicinal health product

3.—(1) For the purposes of the definition of “medicinal health product” in section 2(1) of the Act, a health product is prescribed as a medicinal health product, if the health product satisfies all of the following requirements:

- (a) it is a therapeutic product;
- (b) it is a substance or an article which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:
 - (i) use by being administered to one or more human beings or animals for a medicinal purpose;
 - (ii) use as an ingredient in the preparation of a substance or an article which is to be administered to one or more human beings or animals for a medicinal purpose; and
- (c) it is not any thing excluded under paragraph (2).

(2) For the purposes of paragraph (1)(c), the following things are excluded:

- (a) any instrument, apparatus or appliance;
- (b) any substance or article —

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- (i) which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, and is to be administered to them —
 - (A) in the course of the business of the manufacturer, or on behalf of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person;
 - (B) solely by way of a test for ascertaining what effects it has when so administered; and
 - (C) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous in relation to, those animals, as the case may be; and
 - (ii) which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in sub-paragraph (i)(A), (B) and (C);
 - (c) any substance used in dental surgery for filling dental cavities;
 - (d) any bandage or other surgical dressing, except any medicated dressing where the medication has a palliative or curative function which is not limited to sterilising the dressing; or
 - (e) any substance or article of such other description or class as is specified in the Schedule.
- (3) Where, in accordance with this rule, any health product is prescribed as a medicinal health product immediately after it has been manufactured, imported or exported as mentioned in paragraph (1), or immediately after the first occasion on which it has been sold or supplied as mentioned in that paragraph, then it

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shall not cease to be prescribed as a medicinal health product by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in any way that is not specified in that paragraph.

THE SCHEDULE

Rule 3(2)(e)

SPECIFIED SUBSTANCES AND ARTICLES

1. Phisoderm (oily and normal formulations)
2. Any anti-wrinkle or rejuvenation substance which does not contain any ingredient specified in the Poisons Act (Cap 234)
3. Any substance used for the treatment of freckles and age-spots, being a substance which does not contain any ingredient specified in the Poisons Act (Cap 234)
4. Any sunscreen substance which does not contain any ingredient specified in the Poisons Act (Cap 234)
5. Any face cleanser which helps to prevent pimples or acne (not being any face cleanser for the treatment of pimples or acne) and which does not contain any ingredient specified in the Poisons Act (Cap 234)
6. Any substance used for the treatment of nappy rash or prickly heat, being a substance which does not contain any ingredient specified in the Poisons Act (Cap 234)
7. Ginseng tea
8. Garlic pills
9. Any high protein preparation or substance used for slimming
10. Any oyster, yeast or mushroom extract
11. Herbal tea drinks
12. Any anti-dandruff preparation which does not contain any ingredient specified in the Poisons Act (Cap 234)
13. Health foods with vague or general medicinal claims
14. Sweets for relieving cough or throat irritation

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15. Staminade powder
16. Mouthwashes or gargles for bad breath or for general oral hygiene
17. Any substance used for bleaching or to reduce pigmentation, being a substance which does not contain any ingredient specified in the Poisons Act (Cap 234)

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