2011/245

Medicines Amendment Regulations 2011

Anand Satyanand, Governor-General

Order in Council

At Wellington this 11th day of July 2011

Present:
The Right Hon John Key presiding in Council

Pursuant to sections 62 and 105 of the Medicines Act 1981, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations or bodies appearing to the Minister to be representative of persons likely to be substantially affected, and acting on the advice and with the consent of the Executive Council, makes the following regulations.

Contents

Regulations

1 Title

These regulations are the Medicines Amendment Regulations 2011.

2 Commencement

(1) These regulations, except regulations 14, 15, and 18, come into force on 1 August 2011.

(2) Regulations 14, 15, and 18 come into force on 1 December 2011.

3 Principal regulations amended

These regulations amend the Medicines Regulations 1984.

4 Interpretation

(1) Regulation 2(1) is amended by revoking the definitions of **approved school**, **colouring substance**, and **Dispensary Assistant's Certificate**.

(2) Regulation 2(1) is amended by revoking the definition of **dispensary technician** and substituting the following definition:

"**dispensary technician** means a person who holds a certificate issued by the Pharmaceutical Society of New Zealand before 18 September 2004 that—

"(a) classifies the holder as a dispensary assistant; or

"(b) records that the person has completed the requirements of the Pharmacy Technicians Certificate".

(3) Regulation 2(1) is amended by inserting the following definition in its appropriate alphabetical order:

"**general sale medicine** has the meaning given to it by section 99(2) of the Act".

(4) Regulation 2(1) is amended by inserting the following definition in its appropriate alphabetical order:

"**Pharmacy Council** means the Pharmacy Council established by section 114(5) of the Health Practitioners Competence Assurance Act 2003".

(5) Regulation 2(1) is amended by revoking the definitions of **pharmacy graduate**, **pharmacy student**, and **pharmacy technician** and substituting the following definitions in their appropriate alphabetical order:

"**pharmacy graduate** means a person who is not a pharmacist, but who—

"(a) has 1 or more of the qualifications prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003 for registration as a pharmacist; and

"(b) is actively taking steps towards registration as a pharmacist

"**pharmacy student** means a person who is undertaking, but has not yet completed, the course and examinations leading to a qualification of a kind prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003

"**pharmacy technician** means any person who has a National Certificate in Pharmacy (Technician)".

5 Regulation 6 revoked

Regulation 6 is revoked.

6 New regulation 8 substituted

Regulation 8 is revoked and the following regulation substituted:

"**8 Advertisements for medicines**

"(1) Every advertisement for a prescription medicine must include—

"(a) the words 'Prescription medicine' or words of a similar meaning; and
"(b) the name of each active ingredient; and
"(c) the appropriate quantitative particulars of each active ingredient; and
"(d) a statement of the purpose for which the medicine is intended to be used; and
"(e) a statement that the medicine has risks and benefits; and
"(f) a statement about how to find further information on the risks and benefits of the medicine.

"(2) Every advertisement for a restricted medicine must include—
"(a) the following statements, or statements with a similar meaning:
"(i) 'Available only from your pharmacist.'; and
"(ii) 'If symptoms persist, see your doctor or health professional.'; and
"(iii) 'Use only as directed.'; and
"(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:
'Always read the label.'; and
"(c) a statement of the purpose for which the medicine is intended to be used; and
"(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(3) Every advertisement for a pharmacy-only medicine or a general sale medicine must include—
"(a) the following statements, or statements with a similar meaning:
"(i) 'If symptoms persist, see your doctor or health professional.'; and
"(ii) 'Use only as directed.'; and
"(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:
'Always read the label.'; and
"(c) a statement of the purpose for which the medicine is intended to be used; and
"(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(4) Every advertisement for a medicine to be supplied by mail order, direct marketing, or via the Internet must—

"(a) include the name of each active ingredient; and

"(b) include the appropriate quantitative particulars of each active ingredient; and

"(c) comply with the following, to the extent they are applicable:

"(i) subclause (1)(a), and (d) to (f):

"(ii) subclause (2)(a), (c), and (d):

"(iii) subclause (3)(a), (c), and (d).

"(5) A statement required by this regulation must be—

"(a) clearly printed; or

"(b) clearly spoken.

"(6) A statement that is required by this regulation may be both clearly printed and clearly spoken.

"(7) This regulation does not apply to—

"(a) an advertisement for a medicine that does not refer to a therapeutic purpose:

"(b) an advertisement (not being an advertisement of the kind described in subclause (4)) that is—

"(i) located at the point of sale; and

"(ii) positioned immediately above, below, or next to the medicine to which it relates:

"(c) labels:

"(d) price lists.

"(8) An advertisement for a prescription, restricted, pharmacy-only, or general sale medicine that is subsequently reclassified must be treated as compliant with this regulation if—

"(a) the advertisement was compliant with every applicable requirement in this regulation immediately before the medicine was reclassified; and

"(b) not more than 3 months have elapsed since the medicine was reclassified.

"(9) In any proceedings for an offence against section 57 of the Act, it is for the defendant to prove that subclause (8) applies."

7 Regulation 11 substituted

Regulation 11 is revoked and the following regulation substituted:

"**11 Advertisements intended for health professions**

"(1) This regulation applies—

"(a) to advertisements intended for members of the medical, dental, pharmaceutical, and related professions; and

"(b) in addition to the requirements in regulations 7, 9, and 10 (but not regulation 8).

"(2) Every advertisement for a medicine must—

"(a) include—

"(i) the classification of the medicine; and

"(ii) the name of each active ingredient; and

"(iii) the appropriate quantitative particulars of each active ingredient; and

"(iv) a statement of the purpose for which the medicine is intended to be used; and

"(v) a statement of the appropriate precautions to be taken in the use of the medicine; and

"(vi) information on the effectiveness and limitations of the medicine; and

"(vii) a statement of any restriction imposed on distribution; and

"(viii) the dosage regime and mode of administration, or method of use, of the medicine; and

"(ix) a statement of any contraindications to the use of the medicine; and

"(x) information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences; and

"(xi) a statement of the known or likely poisonous effects of, or adverse reactions to, the medicine; but

"(b) not include—

"(i) a statement (based on the citation of a report) relating to the effectiveness or safety of the medicine that omits relevant parts of the report, or quotes from the report in such a way that another meaning to that intended by the report is conveyed; or

"(ii) an unsubstantiated comparison with other medicines; or

"(iii) data, previously considered valid, but made obsolete or false by subsequent findings; or

"(iv) a statement of the use of the medicine, or the dosage of the medicine, that contravenes any condition of a consent given under section 20, 23, or 24 of the Act.

"(3) Nothing in subclause (2)(a)(iii) or (vi) to (xi) applies to an advertisement that—

"(a) is intended to provide a practitioner with details of—

"(i) a major therapeutic indication of a medicine; or

"(ii) the listing of a medicine in the pharmaceutical schedule (within the meaning of section 6(1) of the New Zealand Public Health and Disability Act 2000); or

"(iii) a new or changed strength of a medicine; and

"(b) does not enable the practitioner to reach a prescribing decision.

"(4) Every advertisement for a related product or medical device must include—

"(a) a statement of any restriction imposed on distribution; and

"(b) the dosage regime and mode of administration, or method of use, of the related product or medical device; and

"(c) information on the effectiveness and limitations of the related product or medical device."

8 New regulations 13 to 16 substituted

Regulations 13 to 16 are revoked and the following regulations substituted:

"**13 Labelling of medicines**

"(1) Every container of a medicine must, unless otherwise provided by these regulations, bear a label containing the following information:

"(a) the trade name of the medicine or, if there is no trade name, the appropriate designation of the medicine:

"(b) the name of each active ingredient:

"(c) the appropriate quantitative particulars of each active ingredient:

"(d) a description of the medicine, including dose form, or presentation, that indicates the true nature of the medicine:

"(e) a statement of the net weight or volume or number of the contents of the container, as the case may require:

"(f) in the case of a prescription medicine,—

"(i) the words 'PRESCRIPTION MEDICINE' or words of a similar meaning; or

"(ii) the words 'PRESCRIPTION-ONLY MEDICINE' or words of a similar meaning; or

"(iii) the acronym 'POM':

"(g) in the case of a restricted medicine,—

"(i) the words 'RESTRICTED MEDICINE'; or

"(ii) the words 'PHARMACIST-ONLY MEDICINE':

"(h) in the case of a pharmacy-only medicine,—

"(i) the words 'PHARMACY-ONLY MEDICINE' or words of a similar meaning; or

"(ii) the words 'PHARMACY MEDICINE' or words of a similar meaning:

"(i) any warning statement required by these regulations for the medicine:

"(j) in the case of a medicine other than a prescription medicine, a statement of the purpose for which the medicine is intended to be used:

"(k) in the case of a medicine sold, or intended for sale, for external use,—

"(i) a statement of directions for use and frequency of use; and

"(ii) the words 'Caution: not to be taken', or 'For external use only', or words of a similar meaning:

"(l) in the case of a medicine sold, or intended for sale, for internal use,—

"(i) the dose recommended; and

"(ii) the frequency of that dose:

"(m) the words 'Batch Number' or 'Lot Number', or the word 'Batch' or 'Lot', or the letter 'B' (either alone or inside

a circle) followed by the batch or lot number of the medicine:

"(n) the words 'Use by' or 'Use before', or words of a similar meaning, followed by the expiry date (being in no case later than 5 years after the date of manufacture of the medicine) appropriate to the stability of the medicine:

"(o) where appropriate, a statement of the recommended storage conditions:

"(p) the name and address of—

"(i) the manufacturer or seller of the medicine; or

"(ii) the owner of the rights of manufacture; or

"(iii) the agent of any person who comes within subparagraph (i) or (ii).

"(2) For the purposes of subclause (1)(p),—

"(a) an address at a post office is not sufficient:

"(b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the medicine is wholly manufactured and packed outside New Zealand:

"(c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.

"(3) In the case of a medicine intended for administration only in accordance with the directions of a practitioner, it is sufficient compliance with subclause (1)(l) to indicate the dose by a range if the container is accompanied by a more specific statement relating to each usage.

"(4) In the case of a prescription medicine, compliance with the requirements of subclause (1)(k) or (l) is required only at the time at which that medicine—

"(a) is sold by retail; or

"(b) is supplied in circumstances corresponding to retail sale; or

"(c) is supplied by way of gift or sample for the purpose of promoting a sale.

"(5) Subclause (1)(l) does not apply in the case of a medicine intended to be administered by or under the supervision of a practitioner, in circumstances where the dosage is to be dependent on concurrent skilled observation.

"(6) Every container of a medicine that is prepared for injection into the human body and that contains an antiseptic or preservative must be labelled with a statement of the nature and amount of the antiseptic or preservative.

"(7) Every container of a medicine that is a biochemical preparation must, in addition to the other requirements in this regulation, bear a label containing the following:

"(a) a statement of the potency of the preparation; and

"(b) a statement of the nature and amount of every antiseptic or preservative (if any) used in the medicine.

"(8) Where it is impractical to put all of the information required by this regulation on a label because the container is too small, it is sufficient compliance with this regulation to print the information required by subclause (1)(i), (j), and (o) on a separate information sheet, in the same manner as that information would be required by these regulations to be printed on a label, and to supply that sheet to the customer with the medicine.

"(9) This regulation is subject to regulations 15 and 23.

"**14 Labelling of related products**

"(1) Every container of a related product must, unless otherwise provided by these regulations, bear a label containing the following information:

"(a) the trade name of the related product or, if there is no trade name, the appropriate designation of the related product:

"(b) the name of each active ingredient:

"(c) the appropriate quantitative particulars of each active ingredient:

"(d) a description of the related product that indicates the true nature of the related product:

"(e) a statement of the net weight or volume or number of the contents of the container, as the case may require:

"(f) any warning statement required by these regulations for the related product:

"(g) in the case of a related product sold, or intended for sale, for external use,—

"(i) a statement of directions for use and frequency of use; and

"(ii) the words 'Caution: not to be taken', or 'For external use only', or words of a similar meaning:

"(h) in the case of a related product sold, or intended for sale, for internal use,—

"(i) the dose recommended; and

"(ii) the frequency of that dose:

"(i) the words 'Batch Number' or 'Lot Number', or the word 'Batch' or 'Lot', or the letter 'B' (either alone or inside a circle) followed by the batch or lot number of the related product:

"(j) where appropriate, an expiry date:

"(k) the name and address of—

"(i) the manufacturer or seller of the related product; or

"(ii) the owner of the rights of manufacture; or

"(iii) the agent of any person who comes within subparagraph (i) or (ii).

"(2) For the purposes of subclause (1)(k),—

"(a) an address at a post office is not sufficient:

"(b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the related product is wholly manufactured and packed outside New Zealand:

"(c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.

"**15 Exemptions from regulations 13 and 14**

"(1) Nothing in regulation 13 (except subclause (1)(a), (b), (c), (m), and (n)) and nothing in regulation 14 (except subclause (1)(a), (b), (c), (i), and (j)) applies to—

"(a) a container that—

"(i) contains a single dose of a medicine or related product; and

"(ii) is made of sheet material; and

"(iii) is not attached to another container; and

"(iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and

"(v) is not intended for sale other than in that package:

"(b) a container that—
"(i) contains a single dose of a medicine or related product; and
"(ii) is not made of sheet material; and
"(iii) has a volume of 20 millilitres or less; and
"(iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
"(v) is not intended for sale other than in that package:
"(c) a container (other than an aerosol container) that—
"(i) contains a medicine or related product that is a gas; and
"(ii) is of a kind commonly used for storing or transporting gases in compressed, liquefied, or dissolved form; and
"(iii) has a capacity not exceeding 250 litres water capacity:
"(d) a container of a remedy that is, or is described as, homeopathic.

"(2) Nothing in regulation 13 or 14 applies to a strip of containers that—
"(a) is made of sheet material; and
"(b) bears the information required by—
"(i) regulation 13(1)(m) and (n) or regulation 14(1)(i) and (j) (as the case requires) at least once on the strip; and
"(ii) regulation 13(1)(a), (b), and (c) or regulation 14(1)(a), (b), and (c) (as the case requires)—
"(A) at least once in relation to every 2 containers, if the containers are easily detached from the strip; and
"(B) at least once on the strip in any other case; and
"(c) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
"(d) is not intended for sale other than in that package.

"(3) In this regulation, **strip of containers** means a series of containers that each contain a single dose of a medicine or related product and that together form a strip.

"(4) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only medicine, held for sale by a manufacturer or wholesaler, for the period of 3 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the manufacturer or wholesaler.

"(5) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only medicine, held for sale by a retailer, for the period of 6 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the retailer.

"(6) For the purposes of subclauses (4) and (5), any goods purchased before the date on which a substance becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) for importation into New Zealand are deemed to be part of the purchaser's stock-in-trade in New Zealand.

"(7) In any proceedings for an offence against section 44 of the Act in respect of any container that does not comply with regulation 13(1)(f), (g), or (h), the onus is on the defendant to prove that the relevant paragraph does not apply by virtue of subclause (4) or (5) of this regulation.

"**16 Principal display panel**

"(1) The principal display panel of the label of a medicine must contain—

"(a) the information required by regulation 13(1)(a), (d), and (e); and

"(b) the information required by regulation 13(1)(b) and (c), but only if the medicine contains 3 or fewer active ingredients.

"(2) Subclause (1) is subject to regulation 23.

"(3) The principal display panel of the label of a related product must contain—

"(a) the information required by regulation 14(1)(a), (d), and (e); and

"(b) the information required by regulation 14(1)(b) and (c), but only if the related product contains 3 or fewer active ingredients.

"(4) Nothing in subclause (1) or (3) prevents the inclusion in the principal display panel of any other matters required by these regulations to appear on a label of any medicine or related product.

"(5) Subclause (4) is subject to regulation 19."

9 Labelling of prescription medicines, restricted medicines, and pharmacy-only medicines

Regulation 19 is amended by omitting "Subject to regulation 37(3) of these regulations, where" and substituting "Where".

10 Regulation 20 revoked

Regulation 20 is revoked.

11 New regulation 22 substituted

Regulation 22 is revoked and the following regulation substituted:

"**22 Warning statements for medicines and related products**

"(1) Every container of a medicine or related product must include on its label any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(2) A warning statement is additional to any other statement or information that is required by these regulations to be shown on a label.

"(3) Subclause (1) is subject to regulation 23."

12 Labels on containers of medicines sold by authorised prescribers or pharmacists

(1) Regulation 23 is amended by omitting "regulation 15(1)" and substituting "regulation 16(1)".

(2) Regulation 23 is amended by revoking paragraph (a) and substituting the following paragraph:

"(a) the name of, or a description of the nature of, the contents; and".

(3) Regulation 23 is amended by adding "; and" and also by adding the following paragraphs:

"(f) a unique identifying number or code for the prescription or record of supply; and

"(g) the date on which the medicine was packed, sold, or supplied."

13 Safety containers

Regulation 37(3) is revoked.

14 New regulation 39 substituted

Regulation 39 is revoked and the following regulation substituted:

"**39 Conditions under which authorised prescribers and veterinarians may prescribe prescription medicines**

"(1) An authorised prescriber (including a designated prescriber) may only prescribe a prescription medicine if the authorised prescriber—

"(a) is prescribing the prescription medicine—

"(i) for the treatment of a patient under the authorised prescriber's care; and

"(ii) within, and in accordance with all conditions (if any) stated in, the authorised prescriber's scope of practice, as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003 by the authority responsible for the registration of the authorised prescriber; and

"(b) is not prohibited by a notice under section 48(1) of the Act from prescribing that prescription medicine or any prescription medicines of a class or description that includes that prescription medicine.

"(2) An authorised prescriber who is a designated prescriber may only prescribe a prescription medicine if—

"(a) the prescription medicine is of a class or description that the designated prescriber is authorised to prescribe by regulations made under the Act; and

"(b) the requirements specified in or imposed under those regulations are satisfied.

"(3) A veterinarian may only prescribe a prescription medicine that is for the treatment of an animal under the veterinarian's care.

"(4) Subclause (1) does not apply to an authorised prescriber who is acting in the course of his or her employment by the Crown."

15 New regulation 39A inserted

The following regulation is inserted after regulation 39:

"**39A Limit on period of supply of prescription medicines**

"(1) An authorised prescriber may not on any occasion prescribe for any patient a quantity of any prescription medicine that exceeds—

"(a) 6 months' supply in the case of an oral contraceptive; or

"(b) 3 months' supply in any other case.

"(2) However, the Director-General may, at his or her discretion, authorise—

"(a) an authorised prescriber to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b):

"(b) a class of authorised prescribers to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b)."

16 Prescriptions to comply with regulations

Regulation 40(1) is amended by omitting "veterinary surgeon" and substituting "veterinarian".

17 Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing

Regulation 40A is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

18 Form of prescription

(1) Regulation 41 is amended by revoking paragraph (c) and substituting the following paragraph:

"(c) set out the following information in relation to the prescriber:

"(i) the prescriber's full name; and

"(ii) the full street address of the prescriber's place of work or, in the absence of the prescriber having a place of work, the postal address of the prescriber; and

"(iii) the prescriber's telephone number; and".

(2) Regulation 41(d) is amended by revoking subparagraph (i) and substituting the following subparagraph:

"(i) the surname, each given name, and the address of the person for whose use the prescription is given; and".

(3) Regulation 41 is amended by revoking paragraph (f) and substituting the following paragraph:

"(f) indicate the total amount of medicine that may be sold or dispensed, or the total period of supply; and".

(4) Regulation 41 is amended by revoking paragraph (i).

(5) Regulation 41(j) is amended by revoking subparagraph (i) and substituting the following subparagraph:

"(i) set out the surname, each given name, and the address of the owner of the animal; and".

19 Dispensing of prescription medicines

(1) Regulation 42 is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

(2) Regulation 42 is amended by revoking subclauses (3) and (4) and substituting the following subclauses:

"(3) Every person dispensing a prescription relating to a prescription medicine must comply with the following requirements:

"(a) if the prescription has been communicated orally under regulation 40A(1), the prescription must not be dispensed on more than 1 occasion before the pharmacist

has received the written confirmation of the prescription, as required by regulation 40A(2):

"(b) the following information must be recorded on the prescription:

"(i) the name and address of the proprietor of the business at which the prescription is dispensed; and

"(ii) the date on which the prescription is dispensed; and

"(iii) the quantity of medicine dispensed; and

"(iv) a unique identifying number or code for the prescription:

"(c) a prescription for a medicine other than an oral contraceptive must not be dispensed on any occasion after 6 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:

"(d) a prescription for a medicine that is an oral contraceptive must not be dispensed on any occasion after 9 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:

"(e) every prescription must be retained for a period of 3 years by the pharmacist on the premises on which it was dispensed or at a place approved by the Medical Officer of Health and must be kept in an orderly and consecutive manner so as to be readily available for inspection.

"(4) If an authorised prescriber or a veterinarian refers in a prescription to a medicine by its trade mark or trade name, or by reference to the name of its manufacturer, a pharmacist may supply an alternative brand of medicine, provided that—

"(a) the authorised prescriber or veterinarian has not marked the prescription 'No brand substitution permitted' or with words of similar meaning; and

"(b) the substituted brand contains the same active ingredient or active ingredients, and no other active ingredients; and

"(c) the substituted brand is in the same dose form and strength as the prescribed brand; and

"(d) there is no clinical reason why the substituted brand should not be supplied; and

"(e) the pharmacist records the brand substitution on the prescription; and

"(f) the pharmacist signs and dates the prescription; and

"(g) the pharmacist informs the patient of the brand substitution.

"(5) This regulation is subject to regulation 43."

20 New regulation 43 substituted

Regulation 43 is revoked and the following regulation substituted:

"**43 Director-General may waive certain requirements**

"(1) Despite the requirements in regulations 41 and 42, the Director-General may, at his or her discretion,—

"(a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and

"(b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.

"(2) A form of prescription that may be authorised under subclause (1)(a) includes, but is not limited to, an electronic form of prescription."

21 Prescriptions for prescription medicines not required in certain cases

(1) Regulation 44(f) is amended by omitting "veterinary surgeon" and substituting "veterinarian".

(2) Regulation 44 is amended by revoking paragraph (h) and substituting the following paragraph:

"(h) a patient under the care of an authorised prescriber, provided that—

"(i) the medicine is administered by a person who has been instructed by the authorised prescriber (either verbally or in writing) to do so; and

"(ii) the person administering the medicine records the administration in the patient's medical record; and

"(iii) the authorised prescriber records the instruction under subparagraph (i) in the patient's medical record; or".

(3) Regulation 44(m) is amended by omitting "(except a dentist)".

(4) Regulation 44(n) is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

22 New regulations 51 to 53 substituted

Regulations 51 to 54 are revoked and the following regulations substituted:

"**51 Interpretation**

In this Part, unless the context otherwise requires, **data sheet**, in relation to a medicine, means a document containing information relating to the safe and effective use of the medicine.

"**52 Approval of data sheets for new medicines**

"(1) A person who applies under section 20 or 23 of the Act for the consent of the Minister to the distribution of a prescription medicine or restricted medicine (an **applicant**) must include with his or her application a proposed data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health.

"(2) On receipt of the proposed data sheet, the Minister may—

"(a) approve the data sheet; or

"(b) require the data sheet to be resubmitted for approval after such changes have been made to it as the Minister considers appropriate.

"(3) Within 10 days after the Minister's consent to the distribution of a prescription medicine or restricted medicine has been notified in the *Gazette*, the applicant must send to the Director-General for publication an electronic copy of the approved data sheet for that medicine.

"**53 Approval of data sheets for changed medicines**

"(1) An importer or manufacturer who gives to the Director-General a notice under section 24(1) of the Act describing a material change to a prescription medicine or restricted medicine must include with the notice a proposed revised data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health if a revision of the data sheet is necessary or desirable because of the material change.

"(2) On receipt of the proposed revised data sheet, the Director-General may—

"(a) approve the revised data sheet; or

"(b) require the revised data sheet to be resubmitted for approval after such changes have been made to it as the Director-General considers appropriate.

"(3) After the Director-General has approved a revised data sheet, the Director-General must give written notice of the approval to the importer or manufacturer.

"(4) Within 10 days after receiving a notice of approval under subclause (3), the importer or manufacturer must send to the Director-General for publication an electronic copy of the approved revised data sheet."

23 New regulation 58A inserted

The following regulation is inserted above regulation 59:

"**58A Substances that are not medicines or related products for purposes of Act**

"(1) The following classes of substances are not medicines or related products for the purposes of the Act:

"(a) dentifrice products, provided that—

"(i) the dentifrice product does not contain a medicine specified in Schedule 1; and

"(ii) the dentifrice product is not claimed to be for use in relation to any therapeutic purpose other than 1 or both of the following:

"(A) preventing dental decay:

"(B) improving oral hygiene:

"(b) anti-dandruff hair products, provided that—

"(i) the hair product does not contain a medicine specified in Schedule 1; and

"(ii) the hair product is not claimed to be for use in relation to any therapeutic purpose except controlling dandruff; and

"(iii) the hair product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the scalp and not through any other process:

"(c) anti-acne skin care products, provided that—

"(i) the skin care product does not contain a medicine specified in Schedule 1; and

"(ii) the skin care product is not claimed to be for use in relation to any therapeutic purpose except preventing acne; and

"(iii) the skin care product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the skin and not through any other process:

"(d) barrier cream products, provided that—

"(i) the barrier cream product does not contain a medicine specified in Schedule 1; and

"(ii) the barrier cream product is not claimed to be for use in relation to any therapeutic purpose except preventing nappy rash; and

"(iii) the barrier cream product is claimed to be effective through providing a barrier to the transmission of moisture and not through any other process:

"(e) anti-bacterial skin products, provided that—

"(i) the product does not contain a medicine specified in Schedule 1; and

"(ii) the product is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium); and

"(iii) the product is not presented as being for use in connection with—

"(A) any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or

"(B) either of the procedures specified in subclause (2); and

"(iv) the product is not recommended for use in connection with the provision of health services (as defined in section 2 of the Health and Disability Commissioner Act 1994).

"(2) The procedures referred to in subclause (1)(e)(iii)(B) are—

"(a) piercing the skin or mucous membrane for any purpose; and

"(b) venipuncture, or the delivery of an injection."

24 New regulation 59 substituted

Regulation 59 is revoked and the following regulation substituted:

"**59 General sale medicines may be sold by vending machine**

"(1) The Director-General may, by notice in the *Gazette*,—

"(a) approve the sale of a general sale medicine by means of a vending machine:

"(b) specify any conditions to which an approval under paragraph (a) is subject:

"(c) withdraw an approval given under paragraph (a):

"(d) vary or revoke any conditions specified under paragraph (b), or specify additional conditions, to which an approval under paragraph (a) is subject.

"(2) A notice given under subclause (1) takes effect on the day after the date of notification."

25 Offences

(1) Regulation 64(1)(a) is amended by omitting "39(1), 39(2), 39(3), 39(4), 39(5), 39(7), 39(8)" and substituting "39, 39A(1)".

(2) Regulation 64(1)(c) is amended by omitting "52(1), 52(2), 52(5)" and substituting "52(3), 53(4)".

26 New regulation 65A inserted

The following regulation is inserted after regulation 65:

"**65A Transitional provision arising from enactment of Medicines Amendment Regulations 2011**

"(1) Until 1 February 2012, it is sufficient compliance with the advertising requirements of regulations 8 and 11 to comply with regulations 8 and 11 as in force immediately before 1 August 2011.

"(2) For medicines and related products manufactured or imported before 1 September 2012, it is sufficient compliance with the labelling requirements of regulations 13 to 16, 19, 22, 23, and 37 to comply with regulations 13 to 16, 19, 20, 22, 23, and 37 as in force immediately before 1 August 2011."

27 New Schedule 1 substituted

Schedule 1 is revoked and the Schedule 1 set out in the Schedule of these regulations substituted.

28 Form 1B of Schedule 2 amended

Form 1B of Schedule 2 is amended by omitting "section 2 of the Property Law Act 1952" and substituting "section 4 of the Property Law Act 2007".

29 Schedule 3 revoked

Schedule 3 is revoked.

30 Amendments to Misuse of Drugs Regulations 1977

(1) This regulation amends the Misuse of Drugs Regulations 1977.

(2) Regulation 25(3)(a)(i) is amended by omitting "regulations 13(1)(a) and 16(1)(ab)" and substituting "regulation 15(2)".

(3) Regulation 25(3)(b) is amended by revoking subparagraph (ii) and substituting the following subparagraph:

"(ii) the labelling of the safety container complies with the Medicines Regulations 1984."

Schedule

r 27

New Schedule 1 substituted

Schedule 1

r 3

Prescription, restricted, and pharmacy-only medicines

Every reference to a medicine in this schedule applies whether the medicine is synthetic in origin or is from biological or mineral sources.

Unless specific reference is made otherwise, every reference applies also to medicines that are—

- preparations and admixtures containing any proportion of any substance listed in this schedule:
- salts and esters of any substance listed in this schedule:
- preparations or extracts of biological materials listed in this schedule:
- salts or oxides of elements listed in this schedule.

Unless specific reference is made otherwise, every reference to a medicine in this schedule applies,—

- if the medicine is an injection or eye preparation, to any concentration of that medicine; and
- if the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram.

Where any reference is modified by a statement of the strength of the medicine, the strength is calculated using the free acid, base, alcohol, or element unless specifically stated otherwise.

Part 1
Prescription medicines

Amending or replacing this Part may affect designated prescriber regulations under section 105(1)(q) of the Act.

1 19-norandrostenedione

2 2,4-dinitrochlorobenzene

3 4-aminopyridine

4 4-chloromethandienone

5 4-chlorotestosterone

Schedule 1—*continued*
Part 1—*continued*

6 Abacavir
7 Abatacept
8 Abciximab
9 Abrus precatorius; at all strengths
10 Acamprosate
11 Acarbose
12 Acebutolol
13 Acepromazine
14 Acetanilides
15 Acetarsol
16 Acetazolamide
17 Acetohexamide
18 Acetylcarbromal
19 Acetylcholine; except in medicines containing 1 milligram or less per litre or per kilogram
20 Acetylcysteine; for injection or inhalation
21 Acetyldigitoxin
22 Acetylmethyldimethyloximidophenylhydrazine
23 Acetylstrophanthidin
24 Aciclovir; except for external use for the treatment of herpes labialis
25 Acipimox
26 Acitretin
27 Acokanthera ouabaio
28 Acokanthera schimperi
29 Aconitum spp.; except when specified elsewhere in this schedule
30 Acrivastine
31 Adalimumab
32 Adapalene
33 Adefovir
34 Adenosine; for injection

Schedule 1—*continued*
Part 1—*continued*

35 Adinazolam
36 Adiphenine
37 Adonis vernalis
38 Adrafinil
39 Adrenal extract; except for dermal use in medicines containing 0.02% or less of ketosteroids
40 Adrenaline; in medicines containing more than 1%
41 Adrenocortical hormones; except adrenal extract for dermal use containing 0.02% or less of ketosteroids
42 Agalsidase
43 Agomelatine
44 Alatrofloxacin
45 Albendazole
46 Albumin; except human albumin
47 Alclofenac
48 Alclometasone; except when specified elsewhere in this schedule
49 Alcohol; for injection in medicines containing more than 20%
50 Alcuronium
51 Aldesleukin
52 Aldosterone; except in medicines containing 10 micrograms or less per litre or per kilogram
53 Alefacept
54 Alemtuzumab
55 Alendronic acid
56 Alfacalcidol
57 Alfentanil
58 Alfuzosin
59 Alglucerase
60 Alglucosidase
61 Aliskiren
62 Alkyl sulfonals

Schedule 1—*continued*
Part 1—*continued*

63 Allergens
64 Allopurinol
65 Allylisopropylacetylurea; at all strengths
66 Allyloestrenol
67 Alosetron
68 $Alpha_1$-proteinase inhibitor
69 Alphadolone
70 Alphaxalone
71 Alprazolam
72 Alprenolol
73 Alprostadil
74 Alseroxylon
75 Alteplase
76 Altretamine
77 Amantadine
78 Ambenonium
79 Ambrisentan
80 Ambucetamide
81 Ambutonium
82 Amcinonide
83 Amethocaine; for internal use; for external use in medicines containing more than 10%; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
84 Amfebutamone
85 Amfepramone
86 Amidopyrine
87 Amifostine
88 Amikacin
89 Amiloride
90 Aminocaproic acid
91 Aminoglutethimide

Schedule 1—*continued*
Part 1—*continued*

92 Aminometradine
93 Aminophenazone; at all strengths
94 Aminophylline; except for oral use in liquid form in medicines containing 2% or less
95 Aminopterin
96 Aminorex
97 Aminosalicylic acid
98 Amiodarone
99 Amiphenazole
100 Amisometradine
101 Amisulpride
102 Amitriptyline
103 Amlodipine
104 Ammi visnaga
105 Ammonium bromide
106 Amobarbital
107 Amodiaquine
108 Amorolfine; except for external use
109 Amoxapine
110 Amoxycillin
111 Amphomycin
112 Amphotericin
113 Ampicillin
114 Amprenavir
115 Amrinone
116 Amsacrine
117 Amygdalin; at all strengths
118 Amyl nitrite; except when sold to a person who holds a controlled substances licence (issued under section 95B of the Hazardous Substances and New Organisms Act 1996) authorising the person to possess cyanide
119 Amylocaine

Schedule 1—*continued*
Part 1—*continued*

120 Anabolic steroids
121 Anagrelide
122 Anakinra
123 Anastrozole
124 Ancestim
125 Anchusa officinalis; at all strengths
126 Ancrod and its immunoglobulin antidote
127 Androgenic and anabolic steroidal agents
128 Androgens
129 Androisoxazole
130 Androstanolone
131 Androstenediol
132 Androstenedione
133 Anecortave
134 Angiotensinamide
135 Anidulafungin
136 Anistreplase
137 Antazoline; except for ophthalmic use
138 Antibiotic substances; except when specified elsewhere in this schedule
139 Antigens
140 Antihistamines; except when specified elsewhere in this schedule
141 Antimony; except in medicines containing 1 milligram or less per litre or per kilogram
142 Antisera; for injection
143 Apocynum spp.
144 Apomorphine; except in medicines containing 1 milligram or less per litre or per kilogram
145 Apraclonidine
146 Aprepitant
147 Apronal

Schedule 1—*continued*
Part 1—*continued*

148 Aprotinin
149 Arecoline
150 Aripiprazole
151 Aristolochia spp.; at all strengths
152 Aristolochic acid; at all strengths
153 Arsenic; except in medicines containing 1 milligram or less per litre or per kilogram
154 Artemether
155 Articaine
156 Asparaginase
157 Aspirin; for injection; when combined with caffeine, paracetamol, or salicylamide
158 Astemizole
159 Atamestane
160 Atazanavir
161 Atenolol
162 Atomoxetine
163 Atorvastatin
164 Atosiban
165 Atovaquone
166 Atracurium
167 Atropa belladonna; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less of total solanaceous alkaloids per litre or per kilogram
168 Atropine; except when specified elsewhere in this schedule; except when used as an antidote in a device designed for self-injection; except in medicines containing 300 micrograms or less per litre or per kilogram
169 Atropine methonitrate
170 Auranofin
171 Aurothiomalate sodium
172 Aviptadil
173 Azacitidine

Schedule 1—*continued*
Part 1—*continued*

174 Azacyclonol
175 Azapropazone
176 Azaribine
177 Azatadine; except when specified elsewhere in this schedule
178 Azathioprine
179 Azelaic acid; except for dermal use
180 Azelastine; except when specified elsewhere in this schedule
181 Azithromycin
182 Azlocillin
183 Aztreonam
184 Bacampicillin
185 Bacitracin
186 Baclofen
187 Balsalazide
188 Bambuterol
189 Bamethan
190 Bamipine
191 Barbital
192 Barbiturates
193 Basiliximab
194 Bazedoxifene
195 Becaplermin
196 Beclamide
197 Beclomethasone; except when specified elsewhere in this schedule
198 Bemegride
199 Benactyzine
200 Benazepril
201 Bendrofluazide
202 Benethamine penicillin
203 Benorylate
204 Benoxaprofen

Schedule 1—*continued*
Part 1—*continued*

205 Benperidol
206 Benserazide
207 Benzathine penicillin
208 Benzatropine
209 Benzhexol
210 Benzilonium
211 Benzocaine; except when specified elsewhere in this schedule; except in dermal preparations containing 2% or less of total anaesthetic substances; except in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit
212 Benzodiazepines
213 Benzoyl metronidazole
214 Benzoyl peroxide; except for external use in medicines containing 10% or less
215 Benzthiazide
216 Benzydamine; for internal use
217 Benzylpenicillin
218 Bepridil
219 Beractant
220 Beta carotene; in medicines containing more than 18 milligrams per recommended daily dose
221 Betahistine
222 Betamethasone
223 Betaxolol
224 Bethanechol
225 Bethanidine
226 Bevacizumab
227 Bevantolol
228 Bexarotene
229 Bezafibrate
230 Bicalutamide

Schedule 1—*continued*
Part 1—*continued*

231 Bifonazole; except for dermal use
232 Bimatoprost
233 Biperiden
234 Bismuth; except for external use in medicines containing 3% or less
235 Bisoprolol
236 Bithionol; at all strengths
237 Bivalirudin
238 Bleomycin
239 Bolandiol
240 Bolasterone
241 Bolazine
242 Boldenone
243 Bolenol
244 Bolmantalate
245 Boron including borax and boric acid; except for internal use in medicines containing 6 milligrams or less per recommended daily dose; except in dermal medicines for use other than paediatric use containing 0.35% or less; except when present as an excipient
246 Bortezomib
247 Bosentan
248 Botulinum toxins
249 Bretylium
250 Brimonidine
251 Brinzolamide
252 Bromazepam
253 Bromocriptine
254 Bromoform
255 Brompheniramine; except when specified elsewhere in this schedule
256 Bromvaletone

Schedule 1—*continued*
Part 1—*continued*

257 Brotizolam
258 Brugmansia spp.
259 Buclizine; except for oral use
260 Budesonide; except when specified elsewhere in this schedule
261 Bufexamac; except in suppositories or for dermal use in medicines containing 5% or less
262 Bumetanide
263 Buniodyl sodium; at all strengths
264 Buphenine
265 Bupivacaine
266 Buprenorphine
267 Bupropion
268 Buserelin
269 Buspirone
270 Busulphan
271 Butacaine
272 Butobarbital
273 Butoconazole; except for vaginal use
274 Butorphanol
275 Butyl aminobenzoate; except for dermal use in medicines containing 2% or less
276 Butyl nitrite
277 Butylchloral hydrate
278 Cabergoline
279 Cacalia spp.; at all strengths
280 Cadmium
281 Calcipotriol; except in medicines containing not more than 50 micrograms per gram or per millilitre and when sold in a pack of not more than 30 grams or 30 millilitres by a pharmacist to an adult with mild to moderate psoriasis previously diagnosed by a doctor
282 Calcitonin

Schedule 1—*continued*
Part 1—*continued*

283 Calcitriol
284 Calcium carbimide
285 Calcium polystyrene sulphonate
286 Calotropis gigantea
287 Calotropis procera
288 Calusterone
289 Camazepam
290 Camphorated oil
291 Camphotamide
292 Canakinumab
293 Candesartan
294 Candicidin
295 Cannabidiol
296 Capecitabine
297 Capreomycin
298 Captodiame
299 Captopril
300 Capuride
301 Caramiphen
302 Carbachol
303 Carbamazepine
304 Carbaryl; except for external use in medicines containing 2% or less
305 Carbazochrome
306 Carbenicillin
307 Carbenoxolone; for internal use
308 Carbetocin
309 Carbidopa
310 Carbimazole
311 Carbocromen
312 Carboplatin
313 Carboprost

Schedule 1—*continued*
Part 1—*continued*

314 Carbromal
315 Carbutamide
316 Carbuterol
317 Carindacillin
318 Carisoprodol
319 Carmustine
320 Carprofen
321 Carvedilol
322 Caspofungin
323 Cefacetrile
324 Cefaclor
325 Cefaloridine
326 Cefamandole
327 Cefapirin
328 Cefazolin
329 Cefepime
330 Cefetamet
331 Cefixime
332 Cefodizime
333 Cefonicid
334 Cefoperazone
335 Cefotaxime
336 Cefotetan
337 Cefotiam
338 Cefoxitin
339 Cefpirome
340 Cefpodoxime
341 Cefsulodin
342 Ceftazidime
343 Ceftibuten
344 Ceftriaxone
345 Cefuroxime

Schedule 1—*continued*
Part 1—*continued*

346 Celecoxib
347 Celiprolol
348 Cephaelis acuminata; except in medicines containing less than 0.2% of emetine
349 Cephaelis ipecacuanha; except in medicines containing less than 0.2% of emetine
350 Cephalexin
351 Cephalothin
352 Cephradine
353 Cerivastatin
354 Certolizumab pegol
355 Ceruletide
356 Cetirizine; except for oral use
357 Cetrorelix
358 Cetuximab
359 Chenodeoxycholic acid
360 Chloral hydrate; except for dermal use in medicines containing 2% or less
361 Chloralformamide
362 Chloralose
363 Chlorambucil
364 Chloramphenicol; except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except when specified elsewhere in this schedule
365 Chlorandrostenolone
366 Chlorazanil
367 Chlorcyclizine
368 Chlordiazepoxide
369 Chlormerodrin
370 Chlormethiazole
371 Chlormezanone

Schedule 1—*continued*
Part 1—*continued*

372 Chloroform; for anaesthesia; except when specified elsewhere in this schedule
373 Chloroquine
374 Chlorothiazide
375 Chlorotrianisene
376 Chloroxydienone
377 Chloroxymesterone
378 Chlorpheniramine; except when specified elsewhere in this schedule
379 Chlorphentermine
380 Chlorpromazine
381 Chlorpropamide
382 Chlorprothixene
383 Chlorquinaldol
384 Chlortetracycline
385 Chlorthalidone
386 Chlorzoxazone
387 Cholera vaccine
388 Choline salicylate; except in medicines containing 10% or less and in pack sizes of 15 grams or less
389 Chorionic gonadotrophin; except in pregnancy test kits
390 Chymopapain
391 Ciclacillin
392 Ciclesonide
393 Ciclopirox; except for external use
394 Cidofovir
395 Cilastatin
396 Cilazapril
397 Cilostazol
398 Cimetidine; except when specified elsewhere in this schedule
399 Cinacalcet

Schedule 1—*continued*
Part 1—*continued*

400 Cinchocaine; for injection; for ophthalmic use; for external use in medicines containing more than 0.5%
401 Cinchophen
402 Cinoxacin
403 Ciprofloxacin
404 Cisapride
405 Cisatracurium
406 Cisplatin
407 Citalopram
408 Cladribine
409 Clarithromycin
410 Clavulanic acid
411 Clemastine; except for oral use
412 Clemizole
413 Clenbuterol
414 Clevidipine
415 Clidinium
416 Clindamycin
417 Clioquinol; at all strengths
418 Clobazam
419 Clobetasol
420 Clobetasone; except when specified elsewhere in this schedule
421 Clocortolone
422 Clodronic acid
423 Clofarabine
424 Clofazimine
425 Clofenamide
426 Clofibrate
427 Clomiphene
428 Clomipramine
429 Clomocycline
430 Clonazepam

Schedule 1—*continued*
Part 1—*continued*

431 Clonidine
432 Clopamide
433 Clopidogrel
434 Clorexolone
435 Clorprenaline
436 Clostebol
437 Clotiazepam
438 Clotrimazole; except when specified elsewhere in this schedule
439 Cloxacillin
440 Cloxazolam
441 Clozapine
442 Cobalt
443 Cocaine; except when specified elsewhere in this schedule
444 Codeine; except when specified elsewhere in this schedule
445 Co-dergocrine
446 Colaspase
447 Colchicine
448 Colchicum
449 Colecalciferol; in medicines containing more than 25 micrograms per recommended daily dose except in parenteral nutrition replacement preparations
450 Colestipol
451 Colestyramine
452 Colfosceril
453 Colistin
454 Collagen; in injections or implants for tissue augmentation or cosmetic use
455 Conium maculatum; at all strengths
456 Convallaria keiski
457 Convallaria majales
458 Corifollitropin alfa

Schedule 1—*continued*
Part 1—*continued*

459 Coronilla spp.
460 Corticosterone
461 Corticotrophin
462 Cortisone and other steroidal hormones of the adrenal cortex; except when specified elsewhere in this schedule; except adrenal extract for dermal use in medicines containing 0.02% or less of ketosteroids
463 Cotarnine; at all strengths
464 Co-trimoxazole
465 Coumarin
466 Crotalaria spp.; at all strengths
467 Croton tiglium; except in medicines containing 1 milligram or less per litre or per kilogram
468 Crystal violet
469 Curare
470 Cyclandelate
471 Cyclizine; except for oral use
472 Cyclobenzaprine
473 Cyclofenil
474 Cycloheximide
475 Cyclopenthiazide
476 Cyclopentolate; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
477 Cyclophosphamide
478 Cyclopropane
479 Cycloserine
480 Cyclosporin
481 Cyclothiazide
482 Cycrimine
483 Cymarin
484 Cynoglossum spp.; at all strengths

Schedule 1—*continued*
Part 1—*continued*

485 Cyproheptadine; except for oral use
486 Cyproterone
487 Cysteamine
488 Cytarabine
489 Dabigatran
490 Dacarbazine
491 Daclizumab
492 Dactinomycin
493 Dalfopristin
494 Dalteparin
495 Danaparoid
496 Danazol
497 Danthron
498 Dantrolene
499 Dapoxetine
500 Dapsone
501 Daptomycin
502 Darbepoetin
503 Darifenacin
504 Darunavir
505 Dasatinib
506 Datura spp.; except for oral use when specified elsewhere in this schedule; except datura stramonium or datura tatula for smoking or burning
507 Daunorubicin
508 Deanol
509 Debrisoquine
510 Decamethonium
511 Deferasirox
512 Deferiprone
513 Deflazacort
514 Dehydrochloromethyltestosterone

Schedule 1—*continued*
Part 1—*continued*

515 Dehydrocorticosterone
516 Delavirdine
517 Delorazepam
518 Demecarium
519 Demeclocycline
520 Deoxycortone
521 Deoxyribonuclease; except for external use
522 Desferrioxamine
523 Desflurane
524 Desipramine
525 Desirudin
526 Deslanoside
527 Desloratadine; except for oral use
528 Deslorelin
529 Desmopressin
530 Desogestrel
531 Desonide
532 Desoximetasone
533 Desvenlafaxine
534 Dexamethasone
535 Dexamfetamine
536 Dexchlorpheniramine; except when specified elsewhere in this schedule
537 Dexfenfluramine
538 Dexmedetomidine
539 Dextromethorphan; except when specified elsewhere in this schedule
540 Dextromoramide
541 Dextropropoxyphene
542 Dextrorphan
543 Di-iodohydroxy quinoline; except for vaginal use
544 Di-isopropylamine dichloroacetate

Schedule 1—*continued*
Part 1—*continued*

545 Diazepam
546 Diazoxide
547 Dibenzepin
548 Dibotermin
549 Dibrompropamidine; except for ophthalmic use
550 Dichloralphenazone
551 Dichlorophen
552 Dichlorphenamide
553 Diclofenac; except when specified elsewhere in this schedule; except for external use
554 Dicloxacillin
555 Dicyclomine
556 Didanosine
557 Dienoestrol
558 Dienogest
559 Diethazine
560 Diethylcarbamazine
561 Diethylstilbestrol
562 Diflorasone
563 Diflucortolone
564 Diflunisal
565 Digitalis lanata
566 Digitalis purpurea
567 Digitoxin
568 Digoxin
569 Digoxin-specific antibody fragment
570 Dihydralazine
571 Dihydrocodeine
572 Dihydroergotoxine
573 Dihydrolone
574 Dihydrotachysterol
575 Diltiazem

Schedule 1—*continued*
Part 1—*continued*

576 Dimenhydrinate; except when specified elsewhere in this schedule
577 Dimercaprol
578 Dimethandrostanolone
579 Dimethazine
580 Dimethindene; except for oral use
581 Dimethothiazine
582 Dimethoxanate
583 Dimethyl sulphoxide
584 Dinitrocresols
585 Dinitronaphthols
586 Dinitrophenols
587 Dinitrothymols
588 Dinoprost
589 Dinoprostone
590 Diperodon
591 Diphemanil; except for dermal use
592 Diphenhydramine; except when specified elsewhere in this schedule
593 Diphenidol
594 Diphenoxylate; except when specified elsewhere in this schedule
595 Diphenylpyraline
596 Diphtheria toxoid
597 Diphtheria vaccine
598 Dipivefrin
599 Dipyridamole
600 Dirithromycin
601 Disopyramide
602 Distigmine
603 Disulfiram
604 Disulphamide

Schedule 1—*continued*
Part 1—*continued*

605 Ditiocarb
606 Dobutamine
607 Docetaxel
608 Dofetilide
609 Dolasetron
610 Domperidone
611 Donepezil
612 Dopamine
613 Dopexamine
614 Doripenem
615 Dornase
616 Dorzolamide
617 Dothiepin
618 Doxantrazole
619 Doxapram
620 Doxazosin
621 Doxepin
622 Doxorubicin
623 Doxycycline
624 Doxylamine; except when specified elsewhere in this schedule
625 Droperidol
626 Drospirenone
627 Drostanolone
628 Drotrecogin
629 Duboisia leichhardtii; except when specified elsewhere in this schedule
630 Duboisia myoporides; except when specified elsewhere in this schedule
631 Dulcin; at all strengths
632 Duloxetine
633 Dutasteride
634 Dydrogesterone

Schedule 1—*continued*
Part 1—*continued*

635 Econazole; except when specified elsewhere in this schedule
636 Ecothiopate
637 Ectylurea
638 Edetic acid; in medicines containing more than 0.25%; except in contact lens preparations; except dicobalt edetate for the treatment of cyanide poisoning
639 Edoxudine
640 Edrophonium
641 Efalizumab
642 Efavirenz
643 Eflornithine
644 Eletriptan
645 Eltrombopag olamine
646 Emepronium
647 Emetine; in medicines containing more than 0.2%
648 Emtricitabine
649 Enalapril
650 Enestebol
651 Enflurane
652 Enfuvirtide
653 Enoxacin
654 Enoxaparin
655 Enoximone
656 Enprostil
657 Entacapone
658 Entecavir
659 Ephedrine
660 Epicillin
661 Epinastine
662 Epirubicin
663 Epitiostanol
664 Eplerenone

Schedule 1—*continued*
Part 1—*continued*

665 Epoetins
666 Epoprostenol
667 Eprosartan
668 Eptifibatide
669 Ergocalciferol; in medicines containing more than 25 micrograms per recommended daily dose
670 Ergometrine
671 Ergot
672 Ergotamine
673 Ergotoxine
674 Erlotinib
675 Ertapenem
676 Erysimum spp.; except in medicines containing 1 milligram or less per litre or per kilogram
677 Erythromycin
678 Erythropoietin
679 Escitalopram
680 Esmolol
681 Esomeprazole
682 Estazolam
683 Estramustine
684 Estropipate
685 Etanercept
686 Ethacrynic acid
687 Ethambutol
688 Ethamivan
689 Ethanolamine; for injection
690 Ethchlorvynol
691 Ether; for anaesthesia
692 Ethinamate
693 Ethinyloestradiol
694 Ethionamide

Schedule 1—*continued*
Part 1—*continued*

695 Ethisterone
696 Ethoglucid
697 Ethoheptazine
698 Ethopropazine
699 Ethosuximide
700 Ethotoin
701 Ethoxzolamide
702 Ethyl chloride; for inhalation
703 Ethyl loflazepate
704 Ethyldienolone
705 Ethylhexanediol; at all strengths
706 Ethyloestrenol
707 Ethynodiol
708 Etidocaine
709 Etidronic acid; except in medicines for external use containing 1% or less
710 Etilefrine
711 Etodolac
712 Etofenamate; except for external use
713 Etonogestrel
714 Etoposide
715 Etoricoxib
716 Etravirine
717 Etretinate
718 Everolimus
719 Exemestane
720 Exenatide
721 Ezetimibe
722 Factor VIII inhibitor bypassing fraction
723 Famciclovir; except when specified elsewhere in this schedule
724 Famotidine; except when specified elsewhere in this schedule
725 Fampridine

Schedule 1—*continued*
Part 1—*continued*

726 Farfugium japonicum; at all strengths
727 Felbinac; except for external use
728 Felodipine
729 Felypressin; except when combined with a local anaesthetic and used in practice by a dental therapist registered with the Dental Council
730 Fenbufen
731 Fenclofenac
732 Fenfluramine
733 Fenofibrate
734 Fenoldopam
735 Fenoprofen
736 Fenoterol
737 Fenpipramide
738 Fenpiprane
739 Fentanyl
740 Fexofenadine; except for oral use
741 Fibrin
742 Fibrinolysin; except for external use
743 Filgrastim
744 Finasteride
745 Flecainide
746 Fleroxacin
747 Floctafenine
748 Fluanisone
749 Fluclorolone
750 Flucloxacillin
751 Fluconazole; except when specified elsewhere in this schedule
752 Flucytosine
753 Fludarabine
754 Fludiazepam
755 Fludrocortisone

Schedule 1—*continued*
Part 1—*continued*

756	Flufenamic acid
757	Flumazenil
758	Flumethasone
759	Flumethiazide
760	Flunisolide
761	Flunitrazepam
762	Fluocinolone
763	Fluocinonide
764	Fluocortin
765	Fluocortolone
766	Fluorescein; for injection
767	Fluorides; for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council
768	Fluorometholone
769	Fluorouracil
770	Fluoxetine
771	Fluoxymesterone
772	Flupenthixol
773	Fluphenazine
774	Flurandrenolone
775	Flurazepam dihydrochloride
776	Flurbiprofen; except in locally acting oromucosal preparations containing 10 milligrams or less per dosage unit
777	Fluroxene
778	Fluspirilene
779	Flutamide
780	Fluticasone; except when specified elsewhere in this schedule
781	Fluvastatin

Schedule 1—*continued*
Part 1—*continued*

782 Fluvoxamine
783 Folic acid; for injection except in parenteral nutrition replacement preparations
784 Folinic acid; for injection
785 Follicle-stimulating hormone; except in medicines containing 100 micrograms or less per litre or per kilogram
786 Follitropin
787 Fomivirsen
788 Fondaparinux
789 Formebolone
790 Formestane
791 Formoterol
792 Fosamprenavir
793 Fosaprepitant
794 Foscarnet
795 Fosfestrol
796 Fosinopril
797 Fosphenytoin
798 Fotemustine
799 Framycetin
800 Fulvestrant
801 Furaltadone
802 Furazabol
803 Furazolidone
804 Furosemide
805 Fusidic acid
806 Gabapentin
807 Galantamine
808 Galanthus spp.
809 Gallamine
810 Galsulfase
811 Ganciclovir

Schedule 1—*continued*
Part 1—*continued*

812 Ganirelix
813 Gatifloxacin
814 Gefitinib
815 Gemcitabine
816 Gemeprost
817 Gemfibrozil
818 Gemifloxacin
819 Gemtuzumab ozogamicin
820 Gentamicin
821 Gestodene
822 Gestonorone
823 Gestrinone
824 Gitalin
825 Glatiramer acetate
826 Glibenclamide
827 Glibornuride
828 Gliclazide
829 Glimepiride
830 Glipizide
831 Glisoxepide
832 Glutathione; for injection
833 Glyceryl trinitrate; for injection; for transdermal use; except in medicines containing 100 micrograms or less per litre or per kilogram
834 Glycopyrronium; for injection
835 Glymidine
836 Golimumab
837 Gonadorelin
838 Gonadotrophic hormones; except when specified elsewhere in this schedule
839 Goserelin
840 Gramicidin

Schedule 1—*continued*
Part 1—*continued*

841 Granisetron
842 Grepafloxacin
843 Griseofulvin
844 Guaiphenesin; for oral use in medicines containing more than 2% or 200 milligrams per dose form except when specified elsewhere in this schedule; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing not more than 5 days' supply approved by the Minister or the Director-General for distribution as a general sale medicine
845 Guanabenz
846 Guanethidine
847 Guanidine
848 Hachimycin
849 Haematin
850 Haemophilus influenzae vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
851 Halazepam
852 Halcinonide
853 Halofantrine
854 Halofenate
855 Haloperidol; except in medicines containing 1 milligram or less per litre or per kilogram
856 Halothane
857 Haloxazolam
858 Halquinol; for internal use
859 Heliotropium spp.; at all strengths
860 Hemerocallis
861 Heparins; for internal use; except when present as an excipient
862 Hepatitis A vaccine
863 Hepatitis B vaccine
864 Hetacillin
865 Hexachlorophane; in medicines containing more than 3%

Schedule 1—*continued*
Part 1—*continued*

866 Hexamethonium
867 Hexetidine; for internal use
868 Hexobendine
869 Hexocyclium
870 Hexoprenaline
871 Histamine; in medicines containing more than 0.5%
872 Homatropine
873 Human chorionic gonadotrophin; except in pregnancy test kits
874 Human papillomavirus vaccine
875 Human protein C
876 Hyaluronic acid; in injections or implants for tissue augmentation or cosmetic use
877 Hydralazine
878 Hydrargaphen
879 Hydrochlorothiazide
880 Hydrocortisone; except when specified elsewhere in this schedule
881 Hydrocyanic acid; except when specified elsewhere in this schedule; except in medicines containing 1 microgram or less per litre or per kilogram
882 Hydroflumethiazide
883 Hydromorphone
884 Hydroquinone; except in medicines for external use containing 2% or less
885 Hydroxychloroquine
886 Hydroxyephedrine
887 Hydroxyphenamate
888 Hydroxyprogesterone
889 Hydroxystenozol
890 Hydroxyurea
891 Hydroxyzine

Schedule 1—*continued*
Part 1—*continued*

892 Hylan polymer; in injections or implants for tissue augmentation or cosmetic use
893 Hyoscine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram
894 Hyoscine butylbromide; except when specified elsewhere in this schedule
895 Hyoscyamine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram
896 Hyoscyamus niger; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less of total solanaceous alkaloids per litre or per kilogram
897 Hypothalamic releasing factors
898 Hypromellose; for injection; except in intraocular viscoelastic products
899 Ibandronic acid
900 Ibogaine
901 Ibritumomab tiuxetan
902 Ibufenac
903 Ibuprofen; except when specified elsewhere in this schedule
904 Ibuterol
905 Ibutilide
906 Idarubicin
907 Idoxuridine; except for dermal use in medicines containing 0.5% or less
908 Idursulfase
909 Ifosfamide
910 Iloprost
911 Imatinib
912 Imiglucerase
913 Imipenem
914 Imipramine

Schedule 1—*continued*
Part 1—*continued*

915 Imiquimod
916 Immunoglobulins
917 Indapamide
918 Indinavir
919 Indomethacin; except for external use in medicines containing 1% or less; except in medicines containing 1 milligram or less per litre or per kilogram
920 Indoprofen
921 Indoramin
922 Infliximab
923 Influenza and coryza vaccines; for injection; for nasal use
924 Insulins
925 Interferons
926 Interleukins
927 Iodothiouracil
928 Ipecacuanha; except in medicines containing less than 0.2% of emetine
929 Ipratropium; except for nasal use
930 Ipriflavone
931 Iprindole
932 Iproniazid
933 Irbesartan
934 Irinotecan
935 Iron; for injection except in parenteral nutrition replacement preparations
936 Isoaminile
937 Isoamyl nitrite
938 Isobutyl nitrite
939 Isocarboxazid
940 Isoconazole; except when specified elsewhere in this schedule
941 Isoetarine
942 Isoflurane

Schedule 1—*continued*
Part 1—*continued*

943 Isometheptene
944 Isoniazid
945 Isoprenaline
946 Isoprinosine
947 Isopropamide; except for dermal use in preparations containing 2% or less
948 Isosorbide dinitrate
949 Isosorbide mononitrate
950 Isotretinoin
951 Isoxicam
952 Isoxsuprine
953 Isradipine
954 Itraconazole
955 Ivabradine
956 Ivermectin
957 Ixabepilone
958 Japanese encephalitis vaccine
959 Juniperus sabina; at all strengths
960 Kanamycin
961 Ketamine
962 Ketanserin
963 Ketazolam
964 Ketoconazole; except for dermal use
965 Ketoprofen; except when specified elsewhere in this schedule; except for dermal use
966 Ketorolac
967 Ketotifen; except for ophthalmic use in medicines containing 0.025% or less
968 Khellin
969 Labetalol
970 Lacidipine
971 Lacosamide

Schedule 1—*continued*
Part 1—*continued*

972 Lamivudine
973 Lamotrigine
974 Lanatosides
975 Lanreotide
976 Lansoprazole; except when specified elsewhere in this schedule
977 Lanthanum
978 Lapatinib
979 Laronidase-rch
980 Laropiprant
981 Latamoxef
982 Latanoprost
983 Laudexium
984 Lauromacrogols; for injection
985 Lead
986 Lefetamine
987 Leflunomide
988 Lenalidomide
989 Lenograstim
990 Lepirudin
991 Leptazol
992 Lercanidipine
993 Letrozole
994 Leucovorin; for injection
995 Leuprorelin
996 Levallorphan
997 Levamisole
998 Levetiracetam
999 Levobunolol
1000 Levobupivacaine
1001 Levocabastine; except for nasal or ophthalmic use
1002 Levocetirizine; except for oral use

Schedule 1—*continued*
Part 1—*continued*

1003 Levodopa

1004 Levomepromazine

1005 Levonorgestrel; except when specified elsewhere in this schedule; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

1006 Levosimendan

1007 Lidoflazine

1008 Lignocaine; for injection except when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or dental therapist registered with the Dental Council; for oral use except in throat lozenges containing 30 milligrams or less per dose form; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for external use in medicines containing more than 10%

1009 Ligularia dentata; at all strengths

1010 Lincomycin

1011 Lindane; except for external use in medicines containing 2% or less

1012 Linezolid

1013 Liothyronine

1014 Liraglutide

1015 Lisinopril

1016 Lisuride

1017 Lithium; except when specified elsewhere in this schedule; except when present as an excipient in dermal medicines containing 0.25% or less

1018 Lodoxamide; except in medicines for ophthalmic use

1019 Lofexidine

1020 Lomefloxacin

Schedule 1—*continued*
Part 1—*continued*

1021 Lomustine
1022 Loperamide; except when specified elsewhere in this schedule
1023 Lopinavir
1024 Loprazolam
1025 Loracarbef
1026 Loratadine; except for oral use
1027 Lorazepam
1028 Lormetazepam
1029 Losartan
1030 Loxapine
1031 Lumefantrine
1032 Lumiracoxib
1033 Luteinising hormone
1034 Lymecycline
1035 Mafenide
1036 Mannomustine
1037 Maprotiline
1038 Maraviroc
1039 Mazindol
1040 Measles vaccine
1041 Mebanazine
1042 Mebeverine
1043 Mebhydrolin
1044 Mebolazine
1045 Mebutamate
1046 Mecamylamine
1047 Mecasermin
1048 Mecillinam
1049 Meclocycline
1050 Meclofenamate
1051 Meclofenoxate
1052 Meclozine; except when specified elsewhere in this schedule

Schedule 1—*continued*
Part 1—*continued*

1053 Medazepam
1054 Medigoxin
1055 Medroxyprogesterone
1056 Medrysone
1057 Mefenamic acid; except when specified elsewhere in this schedule
1058 Mefloquine
1059 Mefruside
1060 Megestrol
1061 Melagatran
1062 Melatonin
1063 Melengestrol
1064 Melia azedarach; at all strengths
1065 Meloxicam
1066 Melphalan
1067 Memantine
1068 Meningococcal vaccine
1069 Menotrophin
1070 Mepacrine
1071 Mepenzolate
1072 Mephenesin
1073 Mephentermine
1074 Mepindolol
1075 Mepitiostane
1076 Mepivacaine
1077 Meprobamate
1078 Meptazinol
1079 Mepyramine; except when specified elsewhere in this schedule
1080 Mequitazine
1081 Mercaptomerin
1082 Mercaptopurine

Schedule 1—*continued*
Part 1—*continued*

1083 Mercury; except when specified elsewhere in this schedule; except in medicines containing 1 milligram or less per litre or per kilogram
1084 Meropenem
1085 Mersalyl
1086 Mesabolone
1087 Mesalazine
1088 Mesna
1089 Mestanolone
1090 Mesterolone
1091 Mestranol
1092 Metamfetamine
1093 Metandienone
1094 Metaraminol
1095 Metenolone
1096 Metergoline
1097 Metformin
1098 Methacholine
1099 Methacycline
1100 Methadone
1101 Methallenoestril
1102 Methandriol
1103 Methanthelinium
1104 Methazolamide
1105 Methdilazine; except for oral use
1106 Methicillin
1107 Methimazole
1108 Methisazone
1109 Methixene
1110 Methocarbamol
1111 Methohexitone
1112 Methoin

Schedule 1—*continued*
Part 1—*continued*

1113 Methotrexate
1114 Methoxamine; except for external use
1115 Methoxsalen
1116 Methoxyflurane
1117 Methsuximide
1118 Methyclothiazide
1119 Methyl aminolevulinate
1120 Methyl androstanolone
1121 Methyl clostebol
1122 Methyl mercury; except in medicines containing 300 micrograms or less per litre or per kilogram
1123 Methyl salicylate; for internal use except when present as an excipient in medicines containing 1.04% or less per dose form
1124 Methyl trienolone
1125 Methyldopa
1126 Methylene blue; for injection
1127 Methylergometrine
1128 Methylnaltrexone
1129 Methylpentynol
1130 Methylphenidate
1131 Methylphenobarbital
1132 Methylprednisolone
1133 Methyltestosterone
1134 Methylthiouracil
1135 Methyprylon
1136 Methysergide
1137 Metoclopramide; except when specified elsewhere in this schedule
1138 Metolazone
1139 Metoprolol
1140 Metribolone
1141 Metrifonate

Schedule 1—*continued*
Part 1—*continued*

1142 Metronidazole
1143 Metyrapone
1144 Mexiletine
1145 Mezlocillin
1146 Mianserin
1147 Mibefradil
1148 Mibolerone
1149 Miconazole; except when specified elsewhere in this schedule
1150 Midazolam
1151 Midodrine
1152 Mifepristone
1153 Miglitol
1154 Miglustat
1155 Milrinone
1156 Minocycline
1157 Minoxidil; except for dermal use in medicines containing 5% or less
1158 Mirtazapine
1159 Misoprostol
1160 Mitobronitol
1161 Mitomycin
1162 Mitoxantrone
1163 Mitragyna speciosa
1164 Mitragynine
1165 Mivacurium
1166 Moclobemide
1167 Modafinil
1168 Molgramostim
1169 Molindone
1170 Mometasone; except when specified elsewhere in this schedule
1171 Monobenzone

Schedule 1—*continued*
Part 1—*continued*

1172 Monoclonal antibodies; except in pregnancy test kits
1173 Montelukast
1174 Moperone
1175 Morazone
1176 Moricizine
1177 Morphine; except when specified elsewhere in this schedule
1178 Motrazepam
1179 Motretinide
1180 Moxifloxacin
1181 Mumps vaccine
1182 Mupirocin
1183 Muraglitazar
1184 Muromonab
1185 Mustine
1186 Mycophenolic acid
1187 Nabilone
1188 Nabumetone
1189 Nadolol
1190 Nadroparin
1191 Nafarelin
1192 Naftidrofuryl
1193 Nalbuphine
1194 Nalidixic acid
1195 Nalorphine
1196 Naloxone
1197 Naltrexone
1198 Nandrolone
1199 Naproxen; except when specified elsewhere in this schedule
1200 Naratriptan
1201 Natalizumab
1202 Natamycin
1203 Nateglinide

Schedule 1—*continued*
Part 1—*continued*

1204 Nebacumab
1205 Nebivolol
1206 Nedocromil
1207 Nefazodone
1208 Nefopam
1209 Nelfinavir
1210 Neomycin
1211 Neostigmine
1212 Nepafenac
1213 Nerium oleander
1214 Nesiritide
1215 Netilmicin
1216 Nevirapine
1217 Nialamide
1218 Nicardipine
1219 Nicergoline
1220 Nicofuranose
1221 Nicorandil
1222 Nicotine; for nasal use except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner; in medicines other than for smoking cessation
1223 Nicotinic acid except nicotinamide; in medicines containing more than 250 milligrams per dose form
1224 Nicoumalone
1225 Nifedipine
1226 Nifenazone
1227 Nikethamide
1228 Nilotinib
1229 Nilutamide
1230 Nimesulide
1231 Nimetazepam
1232 Nimodipine

Schedule 1—*continued*
Part 1—*continued*

1233 Nimorazole
1234 Niridazole
1235 Nisoldipine
1236 Nitrazepam
1237 Nitrendipine
1238 Nitric oxide
1239 Nitrofurantoin
1240 Nitrofurazone
1241 Nitrous oxide
1242 Nitroxoline
1243 Nizatidine; except when specified elsewhere in this schedule
1244 Nomifensine
1245 Noradrenaline
1246 Norandrostenolone
1247 Norbolethone
1248 Norclostebol
1249 Nordazepam
1250 Norelgestromin
1251 Norethandrolone
1252 Norethisterone
1253 Norfloxacin
1254 Norgestrel
1255 Noribogaine
1256 Normethandrone
1257 Nortriptyline
1258 Noxiptyline
1259 Nux vomica; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine
1260 Nystatin; except when specified elsewhere in this schedule
1261 Octamylamine
1262 Octatropine
1263 Octreotide

Schedule 1—*continued*
Part 1—*continued*

1264 Octyl nitrite
1265 Oestradiol; except in medicines containing 10 micrograms or less per litre or per kilogram
1266 Oestriol
1267 Oestrogens
1268 Oestrone; except in medicines containing 1 milligram or less per litre or per kilogram
1269 Ofloxacin
1270 Olanzapine
1271 Oleandomycin
1272 Oleandrin
1273 Olmesartan
1274 Olopatadine
1275 Olsalazine
1276 Omalizumab
1277 Omeprazole; except when specified elsewhere in this schedule
1278 Ondansetron
1279 Opipramol
1280 Opium; except when specified elsewhere in this schedule
1281 Orciprenaline
1282 Orlistat; except in medicines for weight control containing 120 milligrams or less per dose form
1283 Ornidazole
1284 Ornipressin
1285 Orphenadrine
1286 Orthopterin
1287 Oseltamivir; except when sold in a pharmacy between the months of April to November inclusive by a registered pharmacist who is satisfied that the medicine is for the treatment of a consumer who is resident in New Zealand, is 12 years of age or more, and currently has the symptoms of influenza
1288 Ouabain

Schedule 1—*continued*
Part 1—*continued*

1289 Ovandrotone
1290 Oxabolone
1291 Oxacillin
1292 Oxaliplatin
1293 Oxandrolone
1294 Oxaprozin
1295 Oxazepam
1296 Oxazolam
1297 Oxcarbazepine
1298 Oxedrine; in medicines containing more than 30 milligrams per recommended daily dose
1299 Oxetacaine; except for internal use
1300 Oxiconazole; except when specified elsewhere in this schedule
1301 Oxitropium
1302 Oxolamine
1303 Oxolinic acid
1304 Oxpentifylline
1305 Oxprenolol
1306 Oxybuprocaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
1307 Oxybutynin
1308 Oxycodone
1309 Oxymesterone
1310 Oxymetholone
1311 Oxyphenbutazone
1312 Oxyphencyclimine
1313 Oxyphenisatin; at all strengths
1314 Oxyphenonium
1315 Oxytetracycline
1316 Oxytocin; except in medicines containing 1 microgram or less per litre or per kilogram

Schedule 1—*continued*
Part 1—*continued*

1317 Paclitaxel
1318 Palifermin
1319 Paliperidone
1320 Palivizumab
1321 Palonosetron
1322 Pamaquin
1323 Pamidronic acid
1324 Pancreatic enzymes; in medicines containing more than 20 000 BP units of lipase activity
1325 Pancuronium
1326 Panitumumab
1327 Pantoprazole; except when specified elsewhere in this schedule
1328 Papaveretum
1329 Papaverine; for injection
1330 Paracetamol; except when specified elsewhere in this schedule
1331 Paraldehyde
1332 Paramethadione
1333 Paramethasone
1334 Parecoxib
1335 Paricalcitol
1336 Paromomycin
1337 Paroxetine
1338 Pazopanib
1339 Pecazine
1340 Pefloxacin
1341 Pegaptanib
1342 Pegfilgrastim
1343 Peginterferon
1344 Pegvisomant
1345 Pemetrexed
1346 Pemoline

Schedule 1—*continued*
Part 1—*continued*

1347 Pempidine
1348 Penbutolol
1349 Penciclovir; except for external use for the treatment of herpes labialis
1350 Penicillamine
1351 Pentaerythrityl tetranitrate
1352 Pentagastrin
1353 Pentamethonium
1354 Pentamidine
1355 Pentazocine
1356 Penthienate
1357 Pentolinium
1358 Pentosan polysulfate sodium
1359 Pentoxifylline
1360 Pergolide
1361 Perhexiline
1362 Pericyazine
1363 Perindopril
1364 Permethrin; in medicines containing more than 5%
1365 Perphenazine
1366 Pertussis antigen
1367 Pertussis (whooping cough) vaccine
1368 Pethidine
1369 Phenacemide
1370 Phenacetin; except when present as an excipient
1371 Phenaglycodol
1372 Phenazone; except for external use
1373 Phenazopyridine
1374 Phenelzine
1375 Pheneticillin
1376 Phenformin
1377 Phenglutarimide

Schedule 1—*continued*
Part 1—*continued*

1378 Phenindione
1379 Pheniramine; except when specified elsewhere in this schedule
1380 Phenisatin
1381 Phenobarbital
1382 Phenol; for injection
1383 Phenolphthalein
1384 Phenoperidine
1385 Phenoxybenzamine
1386 Phenoxymethylpenicillin
1387 Phensuximide
1388 Phentermine
1389 Phenthimentonium
1390 Phentolamine
1391 Phenylbutazone
1392 Phenylephrine; except when specified elsewhere in this schedule
1393 Phenylpropanolamine
1394 Phenyltoloxamine
1395 Phenytoin
1396 Pholcodine; except when specified elsewhere in this schedule
1397 Phosphodiesterase type 5 inhibitors; except when present as an unmodified, naturally occurring substance; except when specified elsewhere in this schedule
1398 Phthalylsulfathiazole
1399 Physostigmine
1400 Picric acid
1401 Picrotoxin
1402 Pilocarpine; except in medicines containing 0.025% or less
1403 Pimecrolimus
1404 Pimozide
1405 Pinacidil
1406 Pinazepam

Schedule 1—*continued*
Part 1—*continued*

1407 Pindolol
1408 Pioglitazone
1409 Pipecuronium
1410 Pipemidic acid
1411 Pipenzolate
1412 Piperacillin
1413 Piperidine
1414 Piperidolate
1415 Pipobroman
1416 Pipothiazine
1417 Pipradrol
1418 Piracetam
1419 Pirbuterol
1420 Pirenoxine
1421 Pirenzepine
1422 Piretanide
1423 Piroxicam; except for external use
1424 Pirprofen
1425 Pituitary hormones
1426 Pivampicillin
1427 Pizotifen
1428 Plicamycin
1429 Pneumococcal vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
1430 Podophyllotoxin; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 1%; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
1431 Podophyllum emodi; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 20% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

Schedule 1—*continued*
Part 1—*continued*

1432 Podophyllum peltatum; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 20% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
1433 Polidexide
1434 Poliomyelitis vaccine
1435 Polyacrylamide; in injections or implants for tissue augmentation or cosmetic use
1436 Polyestradiol
1437 Polylactic acid; in injections or implants for tissue augmentation or cosmetic use
1438 Polymyxin
1439 Polysulfated glycosaminoglycans; for injection except in intraocular viscoelastic products
1440 Polythiazide
1441 Poractant alfa
1442 Posaconazole
1443 Potassium bromide
1444 Potassium perchlorate
1445 Practolol
1446 Pralidoxime
1447 Pramipexole
1448 Pramocaine
1449 Prampine
1450 Prasterone
1451 Prasugrel
1452 Pravastatin
1453 Prazepam
1454 Praziquantel
1455 Prazosin
1456 Prednisolone
1457 Prednisone

Schedule 1—*continued*
Part 1—*continued*

1458 Pregabalin
1459 Pregnenolone
1460 Prenalterol
1461 Prenylamine
1462 Prilocaine; for injection except when used as a local anaesthetic in practice by a dental therapist registered with the Dental Council; except when specified elsewhere in this schedule
1463 Primaquine
1464 Primidone
1465 Probenecid
1466 Probucol
1467 Procainamide
1468 Procaine
1469 Procaine penicillin
1470 Procarbazine
1471 Prochlorperazine; except when specified elsewhere in this schedule; except when sold for the treatment of nausea associated with emergency contraception by pharmacists or nurses accredited to sell levonorgestrel for emergency contraception
1472 Procyclidine; except for dermal use in medicines containing 5% or less
1473 Progesterone; except in medicines containing 1 milligram or less per litre or per kilogram
1474 Progestogens
1475 Proglumide
1476 Proguanil
1477 Prolintane
1478 Promazine
1479 Promethazine; except when specified elsewhere in this schedule
1480 Promoxolane
1481 Propafenone
1482 Propamidine; except for ophthalmic use

Schedule 1—*continued*
Part 1—*continued*

1483 Propanidid
1484 Propantheline
1485 Propetandrol
1486 Propionibacterium acnes
1487 Propofol
1488 Propranolol; except in medicines containing 1 milligram or less per litre or per kilogram
1489 Propylthiouracil
1490 Propyphenazone
1491 Proquazone
1492 Proscillaridin
1493 Prostaglandins
1494 Protamine
1495 Prothionamide
1496 Prothipendyl
1497 Protirelin
1498 Protoveratrines
1499 Protriptyline
1500 Proxymetacaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
1501 Pseudoephedrine; except when specified elsewhere in this schedule
1502 Pulmonaria spp.; at all strengths
1503 Pyrazinamide
1504 Pyridinolcarbamate
1505 Pyridostigmine
1506 Pyridoxal; in medicines containing more than 200 milligrams per recommended daily dose
1507 Pyridoxamine; in medicines containing more than 200 milligrams per recommended daily dose
1508 Pyridoxine; in medicines containing more than 200 milligrams per recommended daily dose

Schedule 1—*continued*
Part 1—*continued*

1509 Pyrimethamine
1510 Pyrvinium
1511 Quazepam
1512 Quetiapine
1513 Quinagolide
1514 Quinapril
1515 Quinbolone
1516 Quinethazone
1517 Quinidine
1518 Quinine; except in medicines containing 50 milligrams or less per recommended daily dose
1519 Quinisocaine
1520 Quinupristin
1521 Rabeprazole
1522 Rabies vaccine
1523 Raloxifene
1524 Raltegravir
1525 Raltitrexed
1526 Ramipril
1527 Ranibizumab
1528 Ranitidine; except when specified elsewhere in this schedule; except in medicines containing 150 milligrams or less per dose unit that have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack containing not more than 7 days' supply
1529 Rapacuronium
1530 Rasagiline
1531 Rasburicase
1532 Rauwolfia serpentina
1533 Rauwolfia vomitoria
1534 Razoxane

Schedule 1—*continued*
Part 1—*continued*

1535 Reboxetine
1536 Remifentanil
1537 Remoxipride
1538 Repaglinide
1539 Reserpine
1540 Reteplase
1541 Ribavirin
1542 Rifabutin
1543 Rifampicin
1544 Rifamycin
1545 Rifapentine
1546 Riluzole
1547 Rimexolone
1548 Rimiterol
1549 Rimonabant
1550 Risedronic acid
1551 Risperidone
1552 Ritodrine
1553 Ritonavir
1554 Rituximab
1555 Rivaroxaban
1556 Rivastigmine
1557 Rizatriptan; except when specified elsewhere in this schedule
1558 Rocuronium
1559 Rofecoxib
1560 Roflumilast
1561 Rolitetracycline
1562 Romiplostim
1563 Ropinirole
1564 Ropivacaine
1565 Rosiglitazone
1566 Rosoxacin

Schedule 1—*continued*
Part 1—*continued*

1567 Rosuvastatin
1568 Rotavirus vaccine
1569 Rotigotine
1570 Roxibolone
1571 Roxithromycin
1572 Rubella vaccine
1573 Ruboxistaurin
1574 Sabadilla; except in preparations containing 10 milligrams or less of total alkaloids of Schoenocaulon officinale per litre or per kilogram
1575 Safrole; for internal use except in medicines containing 0.1% or less
1576 Salbutamol
1577 Salcatonin
1578 Salmeterol
1579 Saquinavir
1580 Saxagliptin
1581 Schoenocaulon officinale; except in preparations containing 10 milligrams or less of total alkaloids of Schoenocaulon officinale per litre or per kilogram
1582 Scopolia carniolica
1583 Secbutabarbital
1584 Secobarbital
1585 Selegiline
1586 Selenium; except when specified elsewhere in this schedule; except for oral use in medicines containing 150 micrograms or less per recommended daily dose; except for external use in medicines containing 3.5% or less of selenium sulphide
1587 Sermorelin
1588 Sertindole
1589 Sertraline
1590 Serum, dried human
1591 Sevelamer

Schedule 1—*continued*
Part 1—*continued*

1592 Sevoflurane
1593 Sex hormones and all substances having sex hormone activity
1594 Sialoepoetin
1595 Sibutramine
1596 Silandrone
1597 Sildenafil and its structural analogues
1598 Silicones; for injection
1599 Silver sulfadiazine; except for external use in packs containing 50 grams or less
1600 Simvastatin
1601 Sirolimus
1602 Sisomicin
1603 Sitagliptin
1604 Sitaxentan
1605 Sodium bromide
1606 Sodium cellulose phosphate; for internal use
1607 Sodium cromoglycate; except for nasal and ophthalmic use
1608 Sodium morrhuate; for injection
1609 Sodium nitroprusside
1610 Sodium phosphate; in oral laxative preparations
1611 Sodium polystyrene sulphonate
1612 Sodium tetradecyl sulphate; for injection
1613 Solasadine
1614 Solifenacin
1615 Somatostatin
1616 Somatropin
1617 Sontoquine
1618 Sorafenib
1619 Sotalol
1620 Sparfloxacin
1621 Sparteine
1622 Spectinomycin

Schedule 1—*continued*
Part 1—*continued*

1623 Spiramycin
1624 Spirapril
1625 Spironolactone
1626 Stanolone
1627 Stanozolol
1628 Staphylococcus aureus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
1629 Stavudine
1630 Stenbolone
1631 Steroid hormones
1632 Stilboestrol
1633 Stramonium; except for oral use where specified elsewhere in this schedule; except Datura stramonium or Datura tatula for smoking or burning
1634 Streptococcus beta-haemolyticus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
1635 Streptodornase
1636 Streptokinase
1637 Streptomycin
1638 Strontium ranelate
1639 Strophanthins
1640 Strophanthus spp.
1641 Strychnos spp.; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine
1642 Styramate
1643 Succimer
1644 Sufentanil
1645 Sugammadex
1646 Sulbactam
1647 Sulconazole; except for dermal use
1648 Sulfacetamide; except for ophthalmic use in medicines containing 10% or less

Schedule 1—*continued*
Part 1—*continued*

1649 Sulfadiazine; except silver sulfadiazine for external use in pack sizes of 50 grams or less
1650 Sulfadimethoxine
1651 Sulfadimidine
1652 Sulfadoxine
1653 Sulfafurazole
1654 Sulfaguanidine
1655 Sulfamerazine
1656 Sulfamethizole
1657 Sulfamethoxazole
1658 Sulfamethoxydiazine
1659 Sulfamethoxypyridazine
1660 Sulfametrole
1661 Sulfamonomethoxine
1662 Sulfamoxole
1663 Sulfaphenazole
1664 Sulfapyridine
1665 Sulfasalazine
1666 Sulfathiazole
1667 Sulfatroxazole
1668 Sulfinpyrazone
1669 Sulfomyxin
1670 Sulfonmethane
1671 Sulindac
1672 Sultamicillin
1673 Sulthiame
1674 Sumatriptan; except when specified elsewhere in this schedule
1675 Sunitinib
1676 Suprofen
1677 Sutilains
1678 Suxamethonium
1679 Suxethonium

Schedule 1—*continued*
Part 1—*continued*

1680 T cell receptor antibody
1681 Tacrine
1682 Tacrolimus
1683 Tadalafil and its structural analogues
1684 Tamoxifen
1685 Tamsulosin
1686 Tanacetum vulgare; in medicines containing more than 0.8% of oil of tansy
1687 Tapentadol
1688 Tasonermin
1689 Tazarotene
1690 Tazobactam
1691 Tegafur
1692 Tegaserod
1693 Teicoplanin
1694 Telbivudine
1695 Telithromycin
1696 Telmisartan
1697 Temazepam
1698 Temozolomide
1699 Temsirolimus
1700 Tenecteplase
1701 Teniposide
1702 Tenofovir
1703 Tenoxicam
1704 Terazosin
1705 Terbinafine; except when specified elsewhere in this schedule
1706 Terbutaline
1707 Terfenadine
1708 Teriparatide
1709 Terlipressin
1710 Terodiline

Schedule 1—*continued*
Part 1—*continued*

1711 Teropterin
1712 Testolactone
1713 Testosterone; except in medicines containing 1 milligram or less per litre or per kilogram
1714 Tetanus antitoxin
1715 Tetanus toxoid
1716 Tetanus vaccine
1717 Tetrabenazine
1718 Tetracosactrin
1719 Tetracycline
1720 Tetraethylammonium
1721 Tetrahydrocannabinol
1722 Tetrazepam
1723 Tetroxoprim
1724 Thalidomide
1725 Thenyldiamine
1726 Theophylline; except in liquid form for oral use in medicines containing 2% or less
1727 Thevetia peruviana
1728 Thevetin
1729 Thiambutosine
1730 Thiazosulfone
1731 Thiethylperazine
1732 Thioacetazone
1733 Thiocarlide
1734 Thioguanine
1735 Thiomesterone
1736 Thiopentone
1737 Thiopropazate
1738 Thioproperazine
1739 Thioridazine
1740 Thiotepa

Schedule 1—*continued*
Part 1—*continued*

1741 Thiothixene
1742 Thiouracil
1743 Thiourea; except in medicines containing 0.1% or less
1744 Thymoxamine
1745 Thyroid
1746 Thyrotrophin
1747 Thyrotrophin-releasing factor
1748 Thyroxine; except in medicines containing 10 micrograms or less per litre or per kilogram
1749 Tiagabine
1750 Tiaprofenic acid
1751 Tiaramide
1752 Tibolone
1753 Ticarcillin
1754 Ticlopidine
1755 Tiemonium
1756 Tienilic acid
1757 Tigecycline
1758 Tigloidine
1759 Tiletamine
1760 Tilidine
1761 Tiludronic acid
1762 Timolol
1763 Tinidazole
1764 Tinzaparin
1765 Tioconazole; except when specified elsewhere in this schedule
1766 Tiotropium
1767 Tipepidine
1768 Tiprinavir
1769 Tirilazad
1770 Tirofiban
1771 Tobramycin

Schedule 1—*continued*
Part 1—*continued*

1772 Tocainide
1773 Tocilizumab
1774 Tolazamide
1775 Tolazoline
1776 Tolbutamide
1777 Tolcapone
1778 Tolfenamic acid
1779 Tolmetin
1780 Tolonium
1781 Tolpropamine
1782 Tolrestat
1783 Tolterodine
1784 Topiramate
1785 Topotecan
1786 Torasemide
1787 Toremifene
1788 Toxoids; for injection
1789 Tramadol
1790 Trandolapril
1791 Tranexamic acid
1792 Tranylcypromine
1793 Trastuzumab
1794 Travoprost
1795 Trazodone
1796 Trenbolone
1797 Treosulphan
1798 Treprostinil
1799 Trestolone
1800 Tretamine
1801 Tretinoin
1802 Triacetyloleandomycin

Schedule 1—*continued*
Part 1—*continued*

1803 Triamcinolone; except when specified elsewhere in this schedule
1804 Triamterene
1805 Triaziquone
1806 Triazolam
1807 Trichlormethiazide
1808 Trichloroacetic acid; except for external use in medicines containing 12.5% or less for the treatment of warts other than anogenital warts
1809 Trichloroethylene
1810 Trichodesma africana; at all strengths
1811 Triclofos
1812 Tricyclamol
1813 Tridihexethyl
1814 Trifluoperazine
1815 Trifluperidol
1816 Triflupromazine
1817 Trimeprazine; except when specified elsewhere in this schedule
1818 Trimetaphan
1819 Trimethoprim
1820 Trimipramine
1821 Trimustine
1822 Trinitrophenol
1823 Trioxysalen
1824 Triparanol; at all strengths
1825 Triple antigen vaccine
1826 Triprolidine; except when specified elsewhere in this schedule
1827 Triptorelin
1828 Troglitazone
1829 Trometamol; for injection in medicines containing more than 3%

Schedule 1—*continued*
Part 1—*continued*

1830 Tropicamide; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
1831 Tropisetron
1832 Trovafloxacin
1833 Troxidone
1834 Tryptophan; in medicines containing more than 100 milligrams per recommended daily dose except in parenteral nutrition replacement preparations
1835 Tuberculosis vaccine
1836 Tubocurarine
1837 Tulobuterol
1838 Typhoid vaccine
1839 Unoprostone
1840 Uracil
1841 Urapidil
1842 Urethane
1843 Urofollitropin
1844 Urokinase
1845 Ursodeoxycholic acid
1846 Ustekinumab
1847 Vaccines; except when specified elsewhere in this schedule
1848 Vaccinia virus vaccine
1849 Valaciclovir
1850 Valdecoxib
1851 Valganciclovir
1852 Valnoctamide
1853 Valproic acid
1854 Valsartan
1855 Vancomycin
1856 Vardenafil and its structural analogues
1857 Varenicline

Schedule 1—*continued*
Part 1—*continued*

1858 Varicella (chickenpox) vaccine
1859 Vasopressin
1860 Vecuronium
1861 Venlafaxine
1862 Verapamil
1863 Veratrum spp.
1864 Vernakalant
1865 Verteporfin
1866 Vidarabine
1867 Vigabatrin
1868 Vildagliptin
1869 Viloxazine
1870 Vinblastine
1871 Vincamine
1872 Vincristine
1873 Vindesine
1874 Vinflunine
1875 Vinorelbine
1876 Vinyl ether
1877 Virginiamycin
1878 Visnadine
1879 Vitamin A; for internal use in medicines containing more than 3 milligrams of retinol equivalents per recommended daily dose except in parenteral nutrition replacement preparations; for external use in medicines containing more than 1%
1880 Vitamin D; for internal use in medicines containing more than 25 micrograms per recommended daily dose except in parenteral nutrition replacement preparations
1881 Voriconazole
1882 Warfarin
1883 Xamoterol
1884 Xanthinol nicotinate

Schedule 1—*continued*
Part 1—*continued*

1885 Ximelagatran
1886 Xipamide
1887 Yellow fever vaccine
1888 Yohimbine
1889 Zafirlukast
1890 Zalcitabine
1891 Zaleplon
1892 Zanamivir
1893 Zidovudine
1894 Zimeldine
1895 Zinc; for internal use in medicines containing more than 25 milligrams per recommended daily dose; except for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except in parenteral nutrition replacement preparations
1896 Ziprasidone
1897 Zoledronic acid
1898 Zolmitriptan; except when specified elsewhere in this schedule
1899 Zolpidem
1900 Zonisamide
1901 Zopiclone
1902 Zoxazolamine
1903 Zuclopenthixol

Part 2
Restricted medicines

1 Adrenaline; in medicines containing 1% or less and more than 0.02%

Schedule 1—*continued*
Part 2—*continued*

2 Alclometasone; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack

3 Aminophylline; for oral use in liquid form in medicines containing 2% or less

4 Amorolfine; for external use in medicines containing more than 0.25%

5 Aspirin; in slow-release forms; in enteric coated forms containing more than 300 milligrams per dose form; except when specified elsewhere in this schedule

6 Azatadine; for oral use in adults and children over 2 years of age

7 Azelastine; in medicines for ophthalmic use containing 0.05% or less

8 Brompheniramine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

9 Buclizine; for oral use

10 Butoconazole; for vaginal use

11 Chloramphenicol; for ophthalmic use; except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

12 Chlorbutol; in medicines containing more than 5%

13 Chlorpheniramine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

14 Ciclopirox; for external use in medicines containing more than 2%

15 Cimetidine; in medicines that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack containing not more than 14 days' supply

Schedule 1—*continued*
Part 2—*continued*

16 Clemastine; for oral use

17 Clobetasone; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack

18 Clotrimazole; for vaginal use

19 Codeine; in medicines for oral use containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, for use as an analgesic and when sold in a pack of not more than 5 days' supply, approved by the Minister or the Director-General for distribution as a restricted medicine

20 Cyclizine; for oral use

21 Cyproheptadine; for oral use

22 Dexchlorpheniramine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

23 Di-iodohydroxy quinoline; for vaginal use

24 Diclofenac; in solid dose form in medicines containing 25 milligrams or less and more than 12.5 milligrams per dose form in packs containing not more than 30 tablets or capsules

25 Dimenhydrinate; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

26 Dimethindene; for oral use

27 Diphenhydramine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

28 Dithranol

Schedule 1—*continued*
Part 2—*continued*

29 Doxylamine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

30 Econazole; for vaginal use

31 Erythrityl tetranitrate

32 Famciclovir; in tablets containing 500 milligrams or less when sold in a pack approved by the Minister or the Director-General for distribution as a restricted medicine

33 Flavoxate

34 Fluconazole; for oral use in medicines that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack containing 150 milligrams or less as a single dose for the treatment of vaginal candidiasis

35 Fluorides; for external use in liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as restricted medicines; for external use in non-liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram, except in medicines containing 1.5 grams or less and more than 1 gram per litre or per kilogram; except when supplied to a dental professional registered with the Dental Council

36 Glucagon; except in medicines containing 100 micrograms or less per litre or per kilogram

37 Glyceryl trinitrate; for oral or sublingual use; for rectal use

38 Glycopyrronium; except for injection

39 Guaiphenesin; for oral use in modified-release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing more than 5 days' supply but not more than 30 days' supply approved by the Minister or the Director-General for distribution as a restricted medicine

40 Haemophilus influenzae vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

Schedule 1—*continued*
Part 2—*continued*

41 Hydrocortisone and hydrocortisone acetate but no other esters of hyrocortisone; for dermal use in medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base with no other active ingredient except an antifungal and in a quantity of 30 grams or less or 30 millilitres or less per container; in rectal medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base and in combination with a local anaesthetic and in a quantity of 35 grams or less per container or up to 12 suppositories per pack

42 Hyoscine butylbromide; for oral use in medicines containing not more than 10 milligrams per dose form and in packs containing not more than 20 tablets or capsules

43 Ibuprofen; for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age

44 Inositol nicotinate

45 Isoconazole; for vaginal use

46 Ketoprofen; in solid dose form containing 25 milligrams or less per dose form in packs of not more than 30 capsules or tablets

47 Lansoprazole; in tablets or capsules containing 15 milligrams or less when sold in a pack approved by the Minister or the Director-General for distribution as a restricted medicine

48 Levonorgestrel; in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

49 Macrogols; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures

Schedule 1—*continued*
Part 2—*continued*

50 Malathion; for external use in medicines containing more than 2%

51 Mannityl hexanitrate

52 Mepyramine; for oral use in medicines for adults and children over 2 years of age

53 Methdilazine; for oral use

54 Metoclopramide; when compounded with paracetamol in packs of not more than 10 tablets or capsules for the treatment of nausea associated with migraine

55 Miconazole; for the treatment of oral candidiasis; for vaginal use

56 Nicotinic acid except nicotinamide; in medicines containing 250 milligrams or less but more than 100 milligrams per dose form

57 Nicotinyl alcohol; in medicines containing more than 100 milligrams per dose form

58 Nystatin; for the treatment of oral candidiasis; for vaginal use

59 Omeprazole; in tablets or capsules containing 20 milligrams or less when sold in a pack approved by the Minister or the Director-General for distribution as a restricted medicine

60 Orlistat; in medicines for weight control containing 120 milligrams or less per dose form

61 Oxiconazole; for vaginal use

62 Pantoprazole; in tablets or capsules containing 20 milligrams or less of pantoprazole when sold in a pack approved by the Minister or the Director-General for distribution as a restricted medicine

63 Pheniramine; for oral use in medicines for adults and children over 2 years of age

64 Pneumococcal vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

65 Podophyllotoxin; for external use for the treatment of warts other than anogenital warts in medicines containing 1% or less

Schedule 1—*continued*
Part 2—*continued*

and more than 0.5%; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

66 Podophyllum emodi; for external use for the treatment of warts other than anogenital warts in medicines containing 20% or less and more than 10% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

67 Podophyllum peltatum; for external use for the treatment of warts other than anogenital warts in medicines containing 20% or less and more than 10% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

68 Prochlorperazine; in packs containing not more than 10 tablets or capsules for the treatment of nausea associated with migraine

69 Promethazine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

70 Rizatriptan; for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms, when in wafers containing 5 milligrams or less per wafer and when sold in a pack containing not more than 2 wafers approved by the Minister or the Director-General for distribution as a restricted medicine

71 Salicylic acid; except in medicines for dermal use containing 40% or less

72 Santonin

73 Sodium phosphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures

74 Sodium picosulphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures

75 Staphyloccocus aureus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

Schedule 1—*continued*
Part 2—*continued*

76 Stramonium; for oral use in liquid form; in solid dose form in medicines containing more than 0.3 milligrams per dose or more than 1.2 milligrams per recommended daily dose

77 Streptococcus beta-haemolyticus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

78 Sulfacetamide; for ophthalmic use in medicines containing 10% or less

79 Sumatriptan; for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets that has received the consent of the Minister or the Director-General to its sale as a restricted medicine

80 Theophylline; in liquid form for oral use in medicines containing 2% or less

81 Tioconazole; for vaginal use

82 Triamcinolone; for buccal use in medicines containing 0.1% or less of triamcinolone acetonide and in pack sizes of 5 grams or less

83 Trimeprazine; for oral use in adults and children over 2 years of age; except when specified elsewhere in this schedule

84 Triprolidine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

85 Zolmitriptan; in a pre-filled nasal spray device containing not more than 5 milligrams of zolmitriptan, for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms and when sold in a pack of not more than 2 devices approved by the Minister or the Director-General for distribution as a restricted medicine

Schedule 1—*continued*

Part 3
Pharmacy-only medicines

1 8-hydroxyquinoline and its non-halogenated derivatives; in medicines containing more than 1% of such substances

2 Acetic acid and preparations containing more than 80% of acetic acid (CH_3COOH); excluding its salts and derivatives

3 Acetylcysteine; for oral use in medicines containing more than 1 gram per recommended daily dose

4 Aciclovir; for external use for the treatment of herpes labialis except in medicines containing 5% or less and in tubes containing 10 grams or less

5 Aconitum spp; for oral use in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids; for dermal use in concentrations of 0.02% or less and in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids

6 Aloes; for internal use; except when obtained solely from the mucilaginous gel of the leaf

7 Aloin

8 Aloxiprin

9 Amethocaine; for external use in medicines containing 10% or less and more than 2%

10 Amorolfine; for external use in medicines containing 0.25% or less except in medicines for tinea pedis only

11 Antazoline; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

12 Atropa belladonna; for external use in medicines containing 0.03% or less of the alkaloids of belladonna; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna

Schedule 1—*continued*
Part 3—*continued*

13 Atropine; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose; in medicines containing atropine sulphate for the treatment of organophosphorus poisoning either in packs of not more than 20 dose units containing 0.6 milligrams or less per dose unit or in injections in packs of not more than 5 vials containing 0.6 milligrams per millilitre; except when sold as an antidote in a device designed for self-injection from outlets licensed to sell organophosphorus poisons; except in medicines containing 300 micrograms or less per litre or per kilogram

14 Azelaic acid; for dermal use

15 Azelastine; for nasal use

16 Beclomethasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 400 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine

17 Benzocaine; in preparations for topical use, other than eye drops, containing 10% or less of total anaesthetic substances except in dermal preparations containing 2% or less of total anaesthetic substances; in divided preparations containing 200 milligrams or less of total anaesthetic substances per dosage unit except in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit

18 Benzoyl peroxide; for external use in medicines containing more than 5% and not more than 10%

19 Benzydamine; for external use except for dermal use

20 Bephenium

Schedule 1—*continued*
Part 3—*continued*

21 Bifonazole; for dermal use except in medicines for tinea pedis only or in shampoos containing 1% or less

22 Bisacodyl

23 Bromhexine

24 Brompheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing brompheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

25 Budesonide; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation and when the maximum recommended daily dose is no greater than 400 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine

26 Carbetapentane; in medicines containing more than 0.5%

27 Carbocisteine

28 Cetirizine; for oral use

29 Chlophedianol

30 Chlorbutol; in medicines containing 5% or less and more than 0.5%

31 Chloroform; in medicines other than for anaesthesia containing more than 0.5%

32 Chlorpheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing chlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

33 Ciclopirox; for external use in medicines containing 2% or less except in medicines for tinea pedis only

Schedule 1—*continued*
Part 3—*continued*

34 Cinchocaine; for external use in medicines containing 0.5% or less

35 Cinnamedrine

36 Clotrimazole; for external use except in medicines for tinea pedis only

37 Cocaine; in medicines for oral use, containing not more than 0.1% of cocaine when combined with 1 or more active ingredients, in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health and when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

38 Codeine; in medicines for oral use, containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, for the treatment of the symptoms of cough and cold and when sold in a pack of not more than 6 days' supply, approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

39 Colocynth

40 Creosote; in medicines containing more than 10%

41 Cresols; in medicines containing more than 3%

42 Datura spp.; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

43 Delphinium staphisagria; in medicines containing more than 0.2%

44 Desloratadine; for oral use

Schedule 1—*continued*
Part 3—*continued*

45 Dexchlorpheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing dexchlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

46 Dextromethorphan; in liquid form containing more than 0.25% or in solid dose form containing more than 15 milligrams per dose form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams; in medicines for the treatment of the symptoms of cough and cold in children aged 6–12 years

47 Dibrompropamidine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

48 Diclofenac; in solid dose form in medicines containing 12.5 milligrams or less per dose form in packs containing not more than 30 tablets or capsules and with a recommended daily dose of not more than 75 milligrams

49 Diphenoxylate; in liquid form containing in each millilitre not more than 0.5 milligrams of diphenoxylate calculated as base and not less than 5 micrograms of Atropine sulphate; in solid dose form containing not more than 2.5 milligrams of diphenoxylate calculated as base and not less than 5 micrograms of atropine sulphate

50 Dimenhydrinate; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults or children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft

51 Diphenhydramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing diphenhydramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a

Schedule 1—*continued*
Part 3—*continued*

sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft

52 Doxylamine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing doxylamine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

53 Duboisia leichhardtii; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

54 Duboisia myoporides; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

55 Econazole; for dermal use except in medicines for tinea pedis only

56 Etafedrine

57 Ether; in medicines containing more than 10%

58 Etofenamate; for external use

59 Famotidine; in medicines that have received the consent of the Minister or the Director-General to their distribution as pharmacy-only medicines and that are sold in the manufacturer's original pack containing not more than 14 days' supply

60 Felbinac; for external use

Schedule 1—*continued*
Part 3—*continued*

61 Fexofenadine; for oral use except when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride when sold in a pack approved by the Minister or the Director-General for distribution as a general sales medicine

62 Fluorides; for internal use in medicines containing 0.5 milligrams or less per dose unit; except in parenteral nutrition replacement preparations; for external use in liquid form in medicines containing 1 gram or less per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as pharmacy-only medicines except in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride; except when supplied to any dental professional registered with the Dental Council; except in medicines containing 15 milligrams or less per litre or per kilogram

63 Flurbiprofen; in locally acting oromucosal preparations containing 10 milligrams or less per dosage unit

64 Fluticasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 200 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine

65 Folic acid; for oral use in medicines containing more than 500 micrograms per recommended daily dose

66 Folinic acid; for oral use in medicines containing more than 500 micrograms per recommended daily dose

67 Formaldehyde; in medicines containing more than 5%

68 Gelsemium sempervirens; except in medicines containing 1 milligram or less per litre or per kilogram

69 Glutaraldehyde

Schedule 1—*continued*
Part 3—*continued*

70 Hexachlorophane; in medicines containing 3% or less but more than 0.75%

71 Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; for dermal use in medicines containing 0.5% or less by weight of hydrocortisone base with no other active ingredient except an antifungal and in a quantity of 30 grams or less or 30 millilitres or less per container; in rectal medicines containing 0.5% or less by weight of hydrocortisone base and in combination with a local anaesthetic and in a quantity of 35 grams or less per container or 12 suppositories or fewer per pack

72 Hydrocyanic acid; for oral use in packs containing 5 milligrams or less and more than 0.5 milligrams; except in medicines containing 1 microgram or less per litre or per kilogram

73 Hydroquinone; for external use in medicines containing 2% or less except in hair preparations containing 1% or less

74 Hyoscine; for transdermal use in medicines containing 2 milligrams or less of total solanaceous alkaloids per dose unit; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

75 Hyoscyamine; for external use in medicines containing 0.03% or less of total solanaceous alkaloids; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

76 Hyoscyamus niger; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose

Schedule 1—*continued*
Part 3—*continued*

and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose except in packs containing 30 micrograms or less of total solanaceous alkaloids

77 Ibuprofen; for oral use in liquid form in packs containing not more than 4 grams in medicines that have received the consent of the Minister or the Director-General to their distribution as pharmacy-only medicines and that are sold in the manufacturer's original pack; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams and in packs containing not more than 100 dose units and when in medicines that have received the consent of the Minister or the Director-General to their distribution as pharmacy-only medicines and that are sold in the manufacturer's original pack; except in packs containing 200 milligrams or less per oral solid dose form and not more than 25 dose units per pack in medicines that have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack

78 Indanazoline

79 Indomethacin; for external use in medicines containing 1% or less; except in medicines containing 1 milligram or less per litre or per kilogram

80 Iodine; for external use in medicines containing more than 2.5%; for internal use in medicines containing 300 micrograms or more per recommended daily dose

81 Ipecacuanha; in medicines containing 0.2% or less of emetine and 40 micrograms or more of ipecacuanha alkaloids per recommended dose for the treatment of the symptoms of cough and cold in children aged 6–12 years

82 Ipomoea

83 Ipratropium; for nasal use

Schedule 1—*continued*
Part 3—*continued*

84 Iron; for oral use either in medicines containing more than 24 milligrams per recommended daily dose or in medicines containing more than 5 milligrams per dose unit and more than 750 milligrams of iron per pack; except in parenteral nutrition replacement preparations

85 Isoconazole; for dermal use

86 Isopropamide; for dermal use in preparations containing 2% or less

87 Jalap resin

88 Ketoconazole; for dermal use except in medicines for tinea pedis only or in medicines for treatment of the scalp containing 1% or less

89 Ketotifen; for ophthalmic use in medicines containing 0.025% or less except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

90 Leucovorin; in medicines containing more than 500 micrograms per recommended daily dose

91 Levocabastine; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

92 Levocetirizine; for oral use

93 Lignocaine; for urethral use; for external use in medicines containing 10% or less and more than 2%

94 Lindane; for external use in medicines containing 2% or less

95 Lithium; for dermal use in medicines containing 1% or less but more than 0.01%; except when present as an excipient in dermal medicines containing 0.25% or less

96 Lobelia inflata; except in medicines for smoking or burning

97 Lobeline; except when in medicines for smoking or burning

98 Lodoxamide; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

99 Loperamide; in packs containing not more than 20 tablets or capsules; except in divided solid dosage forms for oral use

Schedule 1—*continued*
Part 3—*continued*

containing 2 milligrams or less of loperamide per dosage form when sold in a pack containing not more than 8 dosage forms approved by the Minister or the Director-General for distribution as a general sales medicine for the symptomatic treatment of acute non-specific diarrhoea

100 Loratadine; for oral use

101 Mebendazole

102 Meclozine; in a sealed container of not more than 12 tablets or capsules for the prevention or treatment of travel sickness except when sold at a transport terminal or aboard a ship or aircraft

103 Mefenamic acid; in solid dose form in packs containing not more than 30 tablets or capsules for the treatment of dysmenorrhoea

104 Mepyramine; for dermal use

105 Mercuric oxide; for ophthalmic use

106 Mercury; for external use in medicines containing 0.5% or less

107 Methoxamine; for external use in medicines containing more than 1%

108 Methoxyphenamine

109 Methylephedrine

110 Miconazole; for external use except in medicines for tinea pedis only

111 Minoxidil; for dermal use in medicines containing 5% or less

112 Mometasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation and when the maximum recommended daily dose is no greater than 200 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine

113 Morphine; in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered

Schedule 1—*continued*
Part 3—*continued*

by readily applicable means or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

114 Naphazoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

115 Naproxen; in solid dose form containing 250 milligrams or less per dose form in packs of not more than 30 tablets or capsules

116 Niclosamide

117 Nicotine; for inhalation except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner, nurse, pharmacist, or psychologist

118 Nizatidine; in medicines that have received the consent of the Minister or the Director-General to their distribution as pharmacy-only medicines and that are sold in the manufacturer's original pack containing not more than 14 days' supply

119 Noscapine

120 Nystatin; for dermal use

121 Omeprazole; in divided solid dosage forms for oral use containing 20 milligrams or less, with a maximum daily dose of 20 milligrams in a pack size of up to 14 dosage units, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

122 Opium; in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

123 Oxetacaine; for internal use

Schedule 1—*continued*
Part 3—*continued*

124 Oxiconazole; for dermal use except in medicines for tinea pedis only

125 Oxymetazoline; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

126 Papaverine; except for injection

127 Paracetamol; in liquid form; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack

128 Paraformaldehyde; in medicines containing more than 5%

129 Penciclovir; for external use for the treatment of herpes labialis

130 Phedrazine

131 Phenazone; for external use

132 Pheniramine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing pheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

133 Phenol; in medicines other than for injection containing more than 3%

134 Phenylephrine; for nasal use in medicines containing more than 1%; for ophthalmic use in medicines containing 5% or less and more than 1%; for oral use in medicines containing more than 50 milligrams per recommended daily dose or in packs containing more than 250 milligrams of phenylephrine per pack; in medicines for the treatment of the symptoms of cough and cold in children aged 6–12 years

Schedule 1—*continued*
Part 3—*continued*

135 Pholcodine; in medicines for oral use containing not more than 15 milligrams of pholcodine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of pholcodine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

136 Piperazine

137 Podophyllotoxin; for external use for the treatment of warts other than anogenital warts in medicines containing 0.5% or less; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

138 Podophyllum emodi; for external use for the treatment of warts other than anogenital warts in medicines containing 10% or less of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

139 Podophyllum peltatum; for external use for the treatment of warts other than anogenital warts in medicines containing 10% or less of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram

140 Potassium; for internal use: in slow-release or enteric coated forms; in medicines containing more than 100 milligrams per recommended dose except in medicines for oral rehydration therapy, parenteral nutrition replacement, or dialysis; except in glucosamine sulphate complexed products containing 600 milligrams or less of potassium chloride per recommended dose

141 Potassium chlorate; except in medicines containing 10% or less

142 Prilocaine; for dermal use in medicines containing 10% or less of local anaesthetic substances

143 Procyclidine; for dermal use in medicines containing 5% or less

Schedule 1—*continued*
Part 3—*continued*

144 Promethazine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing promethazine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft

145 Propamidine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

146 Pseudoephedrine; in medicines for oral use containing not more than 60 milligrams of pseudoephedrine per solid dosage unit or per dose of liquid, and containing either a single ingredient or when combined with 1 or more active ingredients, when sold in a pack containing not more than 1.8 grams of pseudoephedrine, approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

147 Pyrantel

148 Pyrethrins; in medicines containing more than 10%

149 Pyrithione zinc; except in medicines for treatment of the scalp containing 2% or less

150 Ranitidine; in medicines that have received the consent of the Minister or the Director-General to their distribution as pharmacy-only medicines and that are sold in the manufacturer's original pack containing not more than 14 days' supply; except in medicines containing 150 milligrams or less per dose unit that have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack containing not more than 7 days' supply

151 Salicylamide

Schedule 1—*continued*
Part 3—*continued*

152 Selenium; for oral use in medicines containing 300 micrograms or less and more than 150 micrograms per recommended daily dose; for external use except in medicines containing 3.5% or less of selenium sulphide

153 Sennosides

154 Silver; except in oral solutions containing 0.3% or less or other medicines containing 1% or less

155 Silver sulfadiazine; for external use in pack sizes of 50 grams or less

156 Sodium cromoglycate; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

157 Sodium nitrite; except for use as an excipient

158 Sodium picosulphate; in oral laxative preparations

159 Squill; in medicines containing more than 1%

160 Stramonium; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids

161 Sulconazole; for dermal use

162 Sulfadiazine, silver; for external use in pack sizes of 50 grams or less

163 Terbinafine; for dermal use except in medicines for tinea pedis only

164 Tetrachloroethylene

165 Tetrahydrozoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

166 Thiabendazole

167 Tioconazole; for dermal use except in medicines for tinea pedis only

Schedule 1—*continued*
Part 3—*continued*

168 Tramazoline

169 Triamcinolone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age and when in aqueous nasal sprays delivering up to 55 micrograms per actuation when the maximum recommended daily dose is no greater than 220 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine

170 Trimeprazine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing trimeprazine or when at least 1 of the other therapeutically active ingredients is a sympathomimetic decongestant

171 Triprolidine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing triprolidine or when at least 1 of the other active ingredients is a sympathomimetic decongestant

172 Tuaminoheptane

173 Tymazoline

174 Xylenols; in medicines containing more than 3%

175 Xylometazoline; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

176 Zinc chloride; for dermal use in medicines containing more than 5%

Rebecca Kitteridge,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which are made under the Medicines Act 1981, amend the Medicines Regulations 1984 (the **principal regulations**). The majority of the regulations come into force on 1 August 2011, with the remainder coming into force on 1 December 2011.

The most significant amendments to the principal regulations relate to the following:

- advertising and labelling requirements for medicines:
- prescribing rights and requirements:
- dispensing requirements:
- data sheets:
- products that are not medicines or related products:
- the sale of medicines by vending machine.

The regulations also substitute a *new Schedule 1* of the principal regulations, which lists all classified medicines.

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