Medicines Regulations 1984  
(SR 1984/143)

David Beattie, Governor-General

Order in Council

At the Government House at Wellington this 5th day of June 1984

Present:  
His Excellency the Governor-General in Council

Pursuant to section 105 of the Medicines Act 1981, and, in the case of Part 3 of the regulations, to section 62 of that Act, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representatives of persons likely to be substantially affected, and by and with the advice and consent of the Executive Council, hereby makes the following regulations.

Contents

|   | Title and commencement | 5 |

Note

Changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in this reprint.

A general outline of these changes is set out in the notes at the end of this reprint, together with other explanatory material about this reprint.

These regulations are administered by the Ministry of Health.
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Interpretation</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td><strong>Part 1</strong> Interpretation of medicines</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Classification of medicines</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td><strong>Part 2</strong> Standards of medicines, related products, medical devices, cosmetics, and surgical dressings</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Standards for medicines, related products, medical devices, cosmetics, and surgical dressings</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Pharmacist may dilute medicine in particular case</td>
<td>12</td>
</tr>
<tr>
<td>6</td>
<td>Colouring substances <em>[Revoked]</em></td>
<td>12</td>
</tr>
<tr>
<td></td>
<td><strong>Part 3</strong> Advertisements</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Advertisements not to claim official approval</td>
<td>12</td>
</tr>
<tr>
<td>8</td>
<td>Advertisements for medicines</td>
<td>13</td>
</tr>
<tr>
<td>9</td>
<td>Advertisements for related products</td>
<td>15</td>
</tr>
<tr>
<td>10</td>
<td>Advertisements for medical devices</td>
<td>15</td>
</tr>
<tr>
<td>11</td>
<td>Advertisements intended for health professions</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td><strong>Part 4</strong> Labelling</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Medicines, related products, and medical devices not to be sold unless properly labelled</td>
<td>17</td>
</tr>
<tr>
<td>13</td>
<td>Labelling of medicines</td>
<td>18</td>
</tr>
<tr>
<td>14</td>
<td>Labelling of related products</td>
<td>21</td>
</tr>
<tr>
<td>15</td>
<td>Exemptions from regulations 13 and 14</td>
<td>22</td>
</tr>
<tr>
<td>16</td>
<td>Principal display panel</td>
<td>24</td>
</tr>
<tr>
<td>17</td>
<td>Form and manner of labelling</td>
<td>25</td>
</tr>
<tr>
<td>18</td>
<td>Size of letters</td>
<td>26</td>
</tr>
<tr>
<td>19</td>
<td>Labelling of prescription medicines, restricted medicines, and pharmacy-only medicines</td>
<td>27</td>
</tr>
<tr>
<td>20</td>
<td>Consumer information panel <em>[Revoked]</em></td>
<td>27</td>
</tr>
<tr>
<td>21</td>
<td>Labels on containers of medicines or related products containing vitamins</td>
<td>27</td>
</tr>
<tr>
<td>22</td>
<td>Warning statements for medicines and related products</td>
<td>27</td>
</tr>
<tr>
<td>23</td>
<td>Labels on containers of medicines sold by authorised prescribers or pharmacists</td>
<td>28</td>
</tr>
<tr>
<td>24</td>
<td>Labels on containers of hair dyes</td>
<td>29</td>
</tr>
<tr>
<td>25</td>
<td>Misleading statements</td>
<td>29</td>
</tr>
</tbody>
</table>
Part 5
Manufacture, packing, storage, and handling

26 Persons handling medicines, related products, and cosmetics
27 Infected persons
28 Persons in contact with infected persons
29 Places of manufacture, storage, and sale
30 Dwellinghouses prohibited for manufacture and packing
31 Powers of Medical Officer of Health in respect of premises
32 Storage of medicines, etc
33 Construction and use of containers, etc
34 Exposure to toxic substances prohibited
35 Containers for medicines, related products, and cosmetics
36 Storage to be separate
37 Safety containers

Part 6
Importation and transport

38 Containers

Part 7
Prescriptions

39 Conditions under which authorised prescribers and veterinary surgeons may prescribe prescription medicines
40 Prescriptions to comply with regulations
40A Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing
41 Form of prescription
42 Dispensing of prescription medicines
43 Director-General may waive certain requirements
44 Prescriptions for prescription medicines not required in certain cases
44A Administration of vaccines in approved immunisation programmes
44B Duty to supply information

Part 7A
Export of prescription medicines

44C No export of prescription medicines for retail sale without New Zealand prescription
<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>44D</td>
<td>Supply of restricted medicine and pharmacy-only medicine</td>
</tr>
<tr>
<td>45</td>
<td>Application for licence to manufacture, hawk, sell, or pack medicine</td>
</tr>
<tr>
<td>45A</td>
<td>Application for licence to operate pharmacy</td>
</tr>
<tr>
<td>46</td>
<td>Form and conditions of licence</td>
</tr>
<tr>
<td>47</td>
<td>Licence to manufacture medicines</td>
</tr>
<tr>
<td>48</td>
<td>Licence to hawk certain medicines</td>
</tr>
<tr>
<td>48A</td>
<td>Licensing authority to be advised of change in particulars relating to operating pharmacy</td>
</tr>
<tr>
<td>49</td>
<td>Surrender of licence</td>
</tr>
<tr>
<td>50</td>
<td>Withdrawal of medicines, etc</td>
</tr>
<tr>
<td>51</td>
<td>Interpretation</td>
</tr>
<tr>
<td>52</td>
<td>Approval of data sheets for new medicines</td>
</tr>
<tr>
<td>53</td>
<td>Approval of data sheets for changed medicines</td>
</tr>
<tr>
<td>54</td>
<td>Particulars in data sheets [Revoked]</td>
</tr>
<tr>
<td>54A</td>
<td>Sale of Medicines Registers</td>
</tr>
<tr>
<td>55</td>
<td>Records of sales by retail or wholesale</td>
</tr>
<tr>
<td>56</td>
<td>Record of hawker’s sales</td>
</tr>
<tr>
<td>57</td>
<td>Record of supplies pursuant to prescriptions</td>
</tr>
<tr>
<td>58</td>
<td>Records to be kept</td>
</tr>
<tr>
<td>58A</td>
<td>Substances that are not medicines or related products for purposes of Act</td>
</tr>
<tr>
<td>59</td>
<td>General sale medicines may be sold by vending machine</td>
</tr>
<tr>
<td>60</td>
<td>Certificate of analyst</td>
</tr>
<tr>
<td>61</td>
<td>Fees</td>
</tr>
</tbody>
</table>
61A Waiver and refund of fees 65
61B Fees inclusive of goods and services tax 66
62 Medical devices 66
63 Restriction on, and supervision of, compounding medicine 66
64 Offences 67
65 Appeals to District Court 67
65A Transitional provision arising from enactment of Medicines Amendment Regulations 2011 68
66 Revocations 68

Schedule 1 69
Prescription, restricted, and pharmacy-only medicines

Schedule 2 159
Schedule 3 185

Loose sheet data sheet requirements [Revoked]

Schedule 4 185
Hawker’s Medicines book

Schedule 5 186
Analyst’s certificate under the Medicines Act 1981

Schedule 5A 187
Licence fees

Schedule 6 188
Regulations revoked

Regulations

1 Title and commencement
(1) These regulations may be cited as the Medicines Regulations 1984.
(2) These regulations shall come into force on 1 August 1984.

2 Interpretation
(1) In these regulations, unless the context otherwise requires,—
Act means the Medicines Act 1981
appropriate designation, in relation to a medicine, or an ingredient of a medicine, or a related product, or an active ingre-
dient of a related product, has the following meaning in each of the cases specified:

(a) where the medicine, related product, or ingredient is named or described in a monograph contained in the current edition of a specified publication, the term means the name or one of the synonyms used in that specified publication for that medicine, related product, or ingredient:

(b) where the medicine, related product, or ingredient—

(i) is not named or described in a monograph contained in the current edition of any specified publication but was named or described in a monograph contained in an earlier edition; and

(ii) is not sold under any name or description except the name or one of the synonyms used in that earlier edition for that medicine, related product, or ingredient,—

the term means the name or one of the synonyms so used in that earlier edition followed immediately by a reference to that earlier edition:

(c) where neither paragraph (a) nor paragraph (b) applies, the term means—

(i) the international non-proprietary name of the medicine, related product, or ingredient; or

(ii) if it has no international non-proprietary name, the name appearing in a list published in the United Kingdom on the recommendation of the Medicines Commission pursuant to section 100 of the Medicines Act 1968 (UK); or

(iii) if the medicine, related product, or ingredient has neither an international non-proprietary name nor a name appearing in a list referred to in subparagraph (ii), its accepted scientific name or some other name descriptive of the true nature of the medicine, related product, or ingredient

appropriate quantitative particulars, in relation to any active ingredients of a medicine or of a related product,—

(a) where the medicine or related product consists of or comprises tablets, capsules, or other separate portions,
means the quantity (expressed by weight or volume) of each of the ingredients contained in each portion; or
(b) in any other case, means the percentage of each of those ingredients contained in the medicine or related product, or the quantity of each of those ingredients contained in a stated quantity of the medicine or related product

**approved immunisation programme** means a vaccination programme—
(a) pursuant to the National Immunisation Schedule of the Ministry of Health; or
(b) approved by the Director-General or a Medical Officer of Health

**biochemical preparation** includes—
(a) an antigen; and
(b) an antitoxin; and
(c) a toxin; and
(d) a blood fractionation preparation; and
(e) an insulin; and
(f) a preparation from a mammalian gland; and
(g) a serum; and
(h) a vaccine; and
(i) any other substance or preparation that is similar in nature to any of those specified in paragraphs (a) to (h),— whether natural or synthetic, that is intended for diagnostic, prophylactic, or therapeutic purposes

**consent to distribute**, in relation to any medicine or related product, means a consent to the distribution of that medicine or related product given by the Minister under section 20 of the Act; and includes a provisional consent given under section 23 of the Act

**controlled drug** has the same meaning as in the Misuse of Drugs Act 1975

**described**, in relation to any medicine, related product, or medical device, means represented or held out (whether in writing or otherwise) by the manufacturer, seller, or supplier of the medicine, related product, or medical device
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

for external use, in relation to any medicine or related product, means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat, or vagina, where local action only is required and where extensive systemic absorption will not occur; but nothing in these regulations relating to medicines or related products intended for external use shall apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays, or throat tablets

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

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

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)

pharmacy technician student means a person who is undertaking, but who has not yet completed, training and examin-
ations leading to a National Certificate in Pharmacy (Technician)

**poison bottle** means a container that is made of glass, plastic, or other like material, and that either—

(a) has embossed on at least one-third of its outer surface narrow flutings, ribs, nettings, or points, or other similar surface impressions readily recognisable by touch; or

(b) has clearly embossed on 2 opposite sides of the shoulder of the container the word “POISON” in capital letters, the height of the letters being not less than half the width of that shoulder

**principal display panel** means the part of a label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and, if such likelihood is equal in respect of 2 or more panels, means every such panel

**printed** includes written, typewritten, engraved, lithographed, or otherwise traced or copied

**registered midwife** means a health practitioner who is, or is deemed to be, registered with the Midwifery Council established by section 114(3) of the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of midwifery

**safety container** means a container, whether or not part of a strip of containers, that—

(a) encloses a single tablet or other single item of a medicine that is a solid or a class of medicines that are solids (including a medicine or class of medicines in powder form); and

(b) is made of aluminium foil or laminated plastic, or such other material as may be approved by the Director-General in relation to the packaging of any solid medicine to which regulation 37 applies, either by notice in the *Gazette* or in writing addressed to a particular manufacturer, packer, importer, or seller of medicines; and

(c) is reasonably resistant to attempts by young children to open it
specified publication means a publication named in section 108(1) of the Act

student means a pharmacy student or a pharmacy technician student.

(2) In these regulations, unless the context otherwise requires, all references to proportions in a medicine (whether as percentages, parts per million, or otherwise) shall be references to—
   (a) proportions by weight, where the medicine is a solid; or
   (b) proportions by volume, where the medicine is a liquid at ambient temperatures.


Regulation 2(1) approved immunisation programme: amended, on 1 July 1993, pursuant to section 38(3) of the Health Amendment Act 1993 (1993 No 24).

Regulation 2(1) approved school: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) colouring substance: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).


Regulation 2(1) Dispensary Assistant’s Certificate: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) dispensary technician: substituted, on 1 August 2011, by regulation 4(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) general sale medicine: inserted, on 1 August 2011, by regulation 4(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) Pharmacy Council: inserted, on 1 August 2011, by regulation 4(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) pharmacy graduate: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) pharmacy student: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) pharmacy technician: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) pharmacy technician student: inserted, on 19 December 2002, by regulation 3(3) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

Regulation 2(1) registered midwife: substituted, on 18 September 2004, by section 175(3) of the Health Practitioners Competence Assurance Act 2003 (2003 No 48).
Regulation 2(1) **safety container** paragraph (b): amended, on 1 January 1995, by regulation 2 of the Medicines Regulations 1984, Amendment No 6 (SR 1994/299).

Regulation 2(1) **student**: added, on 19 December 2002, by regulation 3(4) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

### Part 1

**Classification of medicines**

3 **Classification of medicines**

(1) All medicines and classes of medicines specified in Part 1 of Schedule 1 are hereby declared to be prescription medicines.

(1A) *[Revoked]*

(1B) *[Revoked]*

(2) All medicines and classes of medicines specified in Part 2 of Schedule 1 are hereby declared to be restricted medicines.

(3) Subject to subclause (4), all medicines and classes of medicines specified in Part 3 of Schedule 1 are hereby declared to be pharmacy-only medicines.

(4) Nothing in subclause (3) shall apply to a remedy that is, and is described as, homoeopathic.


### Part 2

**Standards**

4 **Standards for medicines, related products, medical devices, cosmetics, and surgical dressings**

(1) Any medicine or related product, other than a medicine or related product for which a standard is otherwise prescribed in these regulations, shall, where it is described as conforming to a monograph in a specified publication, conform to the description and tests set out in that publication for that medicine or related product.
(2) Every medicine, related product, or cosmetic used or represented as suitable for application into the eye shall conform to the tests for sterility set out in a specified publication.

(3) Every medicine, related product, or cosmetic that is a dusting powder for use on the skin of a baby, or on any inflamed, abraded, or broken skin, shall be free of pathogenic organisms.

(4) No medicine, related product, cosmetic, or dentifrice intended for sale shall contain or have attached to it or enclosed with it any extraneous thing that is harmful, dangerous, or offensive.

(5) A surgical dressing that is described as conforming to a monograph in a specified publication shall conform to the description and tests set out in that publication for that surgical dressing.

(6) A medical device that is described as conforming to a particular description shall conform to that description.

5 Pharmacist may dilute medicine in particular case
Where any liquid medicine in respect of which a standard is prescribed by any of the provisions of these regulations is to be supplied by a pharmacist pursuant to a prescription issued for a particular patient, the pharmacist may add a compatible diluent to the medicine if he is satisfied that—
(a) such dilution is necessary to adjust the dose to a quantity easily measurable by the patient or by any other person on behalf of the patient; and
(b) the addition of that diluent will not affect injuriously the composition of the medicine.

6 Colouring substances
[Revoked]
Regulation 6: revoked, on 1 August 2011, by regulation 5 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Part 3
Advertisements

7 Advertisements not to claim official approval
No advertisement relating to any medicine, related product, or medical device shall contain a statement to the effect that an
advisory or technical committee established under section 8 of the Act, or any member of such a committee, or any officer in the service of the Government, has approved, or has refrained from disapproving, the advertisement or any of the claims or statements made in it.

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.

Regulation 8: substituted, on 1 August 2011, by regulation 6 of the Medicines Amendment Regulations 2011 (SR 2011/245).

9 Advertisements for related products
(1) Every advertisement for a related product, other than a label or a price list, shall include a statement of the uses of the related product.

(2) Every advertisement that refers to an active ingredient of a related product by name shall state the appropriate designation of the ingredient.

10 Advertisements for medical devices
Every advertisement for a medical device, other than a label or a price list, shall include, where appropriate, the following:
(a) an accurate description of the medical device:
(b) a statement of the uses of the medical device:
(c) a statement of the appropriate precautions to be taken in the use of the medical device:
(d) a statement of any contraindications to the use of the medical device.

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.

Regulation 11: substituted, on 1 August 2011, by regulation 7 of the Medicines Amendment Regulations 2011 (SR 2011/245).

**Part 4
Labelling**

**12 Medicines, related products, and medical devices not to be sold unless properly labelled**

(1) No person shall sell any medicine or related product in a container if the container—

(a) does not bear a label containing all the particulars required by these regulations to be on a label relating to such a container; or

(b) bears a label containing anything that is prohibited by these regulations from appearing on a label relating to such a container; or

(c) bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to such a container.

(2) No person shall sell a package containing a single container of any medicine or related product unless that package is labelled in a manner similar to that in which the container is labelled.
(3) No person shall sell any medicine in a poison bottle bearing any label that obscures any flutings, ribs, nettings, points, embossed words, or similar markings on the bottle.

(4) No person shall sell any medical device that does not bear the name of the manufacturer of the medical device or the name of the manufacturer’s distributor in New Zealand.

(5) Notwithstanding anything in the foregoing provisions of this regulation, the Director-General may, by notice in writing to the manufacturer or importer of any medicine, exempt from the labelling requirements of these regulations the sale of that medicine in a container of a specified type.

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

Regulation 13: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).
(iii) the agent of any person who comes within sub-paragraph (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.

Regulation 14: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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
Part 4 r 16

Medicines Regulations 1984

Reprinted as at 1 August 2011

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.

Regulation 15: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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.
Reprinted as at 1 August 2011
Medicines Regulations 1984 Part 4 r 17

Regulation 16: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

17 Form and manner of labelling
(1) Subject to subclause (4), every label that is required by these regulations to be borne on a container shall—
   (a) be conspicuously written in English and, for each statement separately required, be in a colour or colours contrasting strongly with the statement’s background; and
   (b) be legibly and durably marked either on the material of the container or on material firmly and securely attached to the container; and
   (c) be of such nature and material that it will not fade to the extent of becoming illegible, or become detached, by the influence of—
      (i) light; or
      (ii) atmospheric humidity or dryness; or
      (iii) normal atmospheric temperatures; or
      (iv) recommended storage temperatures; or
      (v) the contents of the container; and
   (d) be of such a nature and in such a position that it will not readily be defaced in the course of normal handling and use; and
   (e) be in such a position that it is not damaged, defaced, destroyed, or removed when the container is opened; and
   (f) not be obscured by any other label, folder, or pamphlet; and
   (g) [Revoked]

(2) The lettering of the words required by these regulations shall be clear, distinct, and legible, with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

(3) Every label that is required by these regulations to appear on a container shall, if the medicine or related product is sold otherwise than in a container, appear on the medicine or related product.
(4) It shall be sufficient compliance with subclause (1) if the particulars required by paragraphs (d) and (e) of regulation 13(1) are embossed conspicuously on the container of the medicine.


Regulation 17(1)(g): revoked, on 30 November 2000, by regulation 7(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

18 Size of letters

(1) A minimum size of lettering used on labels that is prescribed by these regulations refers to the height of capital letters, or lower case letters with an ascender or descender, in the typeface used.

(2) [Revoked]

(3) [Revoked]

(4) [Revoked]

(5) Subject to subclause (6) and except as otherwise expressly permitted by any of the provisions of these regulations, the lettering of words required by these regulations to appear on labels shall be not less than 1.5 millimetres in height.

(6) Where words are required by these regulations to appear on labels in letters of a specified size, and the container to be labelled is so small as to prevent the use of letters of that size, letters of a smaller size may be used if they are of the largest size practicable in the circumstances and are in any event no smaller than 0.75 millimetres.

(7) [Revoked]


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

Where a label on a container is required by these regulations to bear—

(a) the words “PRESCRIPTION MEDICINE” or words of a similar meaning; or
(b) the words “PRESCRIPTION ONLY MEDICINE” or words of a similar meaning; or
(c) the acronym “POM”; or
(d) the words “RESTRICTED MEDICINE”; or
(e) the words “PHARMACIST ONLY MEDICINE”; or
(f) the words “PHARMACY-ONLY MEDICINE” or words of a similar meaning; or
(g) the words “PHARMACY MEDICINE” or words of a similar meaning,—

the words or acronym, as the case may require, shall be placed prominently and legibly on the label.


20 Consumer information panel

[Revoked]

Regulation 20: revoked, on 1 August 2011, by regulation 10 of the Medicines Amendment Regulations 2011 (SR 2011/245).

21 Labels on containers of medicines or related products containing vitamins

The quantitative declaration of every vitamin in any medicine or related product shall be expressed in milligrams or micrograms.

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.
Part 4 r 23 Medicines Regulations 1984

Reprinted as at 1 August 2011

(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.


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

It shall not be necessary to comply with the requirements of regulation 13 or regulation 16(1) or regulation 22 in respect of any label on a container of a medicine that is packed, supplied, or sold by an authorised prescriber or a pharmacist with reference to the needs of a particular patient or (as the case may be) a particular customer, if the label contains the following:

(a) the name of, or a description of the nature of, the contents; and
(b) the name of the patient; and
(c) the name and address of the seller; and
(d) in the case of a medicine for internal use, the dose and frequency of dose; and
(e) in the case of a medicine for external use, a statement of the directions for use and frequency of use, and one or other of the following statements, or words of similar meaning:
   “Caution: Not To Be Taken”, or “For External Use Only”; and
(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.


Regulation 23(a): substituted, on 1 August 2011, by regulation 12(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(e): amended, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(f): added, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(g): added, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

24 Labels on containers of hair dyes

(1) This regulation applies to labels on containers of related products and cosmetics that are intended for dyeing hair and consist of or contain—

(a) phenylenediamine, or its salts; or
(b) toluenediamine, or its salts; or
(c) other aromatic amines intended for dyeing hair, or their salts; or
(d) any derivative of any substance to which paragraph (a) or paragraph (b) or paragraph (c) applies.

(2) Every label to which this regulation applies shall include the following:

(a) the name or description of the dye substance;
(b) the name and address of the manufacturer or (as the case may be) the packer or seller of the related product or cosmetic;
(c) directions for the use of the related product or cosmetic;
(d) one or other of the following statements, or words of similar meaning:
   “Not To Be Taken”, or “For External Use Only”;
(e) the following statement, or words of similar meaning:
   “May cause serious inflammation of the skin. Do not use on eyelashes”.

25 Misleading statements

(1) No written, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any medicine or medical device shall include any comment on, reference to, or explanation of any statement or label required by these regulations to be borne on any medicine or medical device if that
comment, reference, or explanation either directly or by implication contradicts, qualifies, or modifies that statement or the contents of that label.

(2) No written, pictorial, or other descriptive matter supplied or displayed with any medicine or medical device shall include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the medicine or medical device or any ingredients of the medicine or components of the medical device.

Part 5
Manufacture, packing, storage, and handling

26 Persons handling medicines, related products, and cosmetics

(1) Every person who—
   (a) is engaged or employed in the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale; and
   (b) in the course of his engagement or employment in that activity comes into direct contact with—
       (i) any medicine, related product, or cosmetic; or
       (ii) the interior part of any container containing any medicine, related product, or cosmetic; or
       (iii) a wrapper for any medicine, related product, or cosmetic—
shall, at all times while so engaged or employed, maintain his clothing and his person in a state of cleanliness.

(2) No person who is engaged or employed in the sale of any medicine, related product, or cosmetic, or in the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale, shall do any act or make any default or omission whereby that medicine, related product, or cosmetic becomes or is liable to become contaminated, polluted, or tainted.
27 **Infected persons**

No person who is suffering from a communicable disease (within the meaning of the Health Act 1956), or is a carrier (within the meaning of that Act), or is suffering from a condition causing a discharge of pus or exudate, shall engage or be employed in the sale, or the manufacture, packing, labelling, storage, or supply, for sale, of—

(a) any medicine, related product, or cosmetic; or

(b) any material or article used or likely to be used as a wrapper or container for any medicine, related product, or cosmetic.

28 **Persons in contact with infected persons**

(1) The Medical Officer of Health may, by notice in writing served on a person who has been in recent contact with any person to whom regulation 27 applies, prohibit the person so served from engaging or being employed in the sale of any medicine, related product, or cosmetic, or the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale.

(2) Where, in the opinion of the Medical Officer of Health, there is no longer any risk of any medicine, related product, or cosmetic becoming infected by a person on whom any such notice has been served, the Medical Officer of Health shall revoke the notice, and shall notify the person in writing of the revocation.

(3) No person shall—

(a) engage or undertake employment in any activity in contravention of a notice served on him under this regulation; or

(b) knowingly employ any other person in contravention of a notice served on that other person under this regulation.

29 **Places of manufacture, storage, and sale**

No person shall use any place or permit any place to be used for or in connection with the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, unless the place complies with the following requirements:
(a) the place shall be kept adequately lighted by daylight or artificial light, as the circumstances require, at all times when any work is being carried out there:

(b) the place shall be kept appropriately ventilated at all times while any medicine, related product, or cosmetic, or any container or material for the packing of any medicine, related product, or cosmetic, is present there:

(c) if a waste liquid is produced there, the place shall be provided with a means of drainage that is sufficient for the removal of the waste liquid, and that is kept in good, clean, working order and condition:

(d) the place shall be kept, so far as is practicable, clean and free from foul odours and free from dust and creatures likely to contaminate the medicine, related product, or cosmetic:

(e) the walls, floors, ceilings, and roofs shall be properly constructed and kept in good repair, and shall be easy to clean:

(f) the place shall not be used for any purpose (other than the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale) that might affect the quality of the medicine, related product, or cosmetic:

(g) the place shall be provided with sinks and other sanitary fittings reasonably necessary for cleansing appliances used there, and all such sinks and other sanitary fittings shall be maintained in good, clean working order and condition:

(h) the place shall be provided with an adequate supply of hot and cold water, and soap or other detergent:

(i) the place shall be provided adequately with wash basins and toilets for the use of persons engaged or employed in or about the premises, and all such wash basins and toilets shall be maintained in good, clean working order and condition, and shall be provided with an adequate supply of hot and cold water, soap or other detergent, nail brushes, and towels or other drying equipment.
30 Dwellinghouses prohibited for manufacture and packing
No person shall use any dwellinghouse, or permit any dwellinghouse to be used, for or in connection with the manufacture or packing of any medicine, related product, or cosmetic for sale if the use of the dwellinghouse is likely to result in the contamination of the medicine, related product, or cosmetic, or to affect injuriously its cleanliness.

31 Powers of Medical Officer of Health in respect of premises
(1) This regulation shall apply to premises that are, in the opinion of the Medical Officer of Health, by reason of their construction or disrepair, or by reason of the use or character of any neighbouring premises, in such a condition that any medicine, related product, or cosmetic in the first premises may be exposed to contamination or taint, or may deteriorate or become dirty.

(2) Subject to subclause (6), the Medical Officer of Health may serve a notice in writing on any owner or occupier of any premises to which this regulation applies, prohibiting the use of the premises for or in connection with the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale.

(3) Every such notice shall—
(a) specify the premises to which it relates:
(b) state the reason for the prohibition:
(c) specify a date on which the prohibition is to come into force.

(4) Subject to subclause (6), where in the opinion of the Medical Officer of Health the reason for which any such notice was served has ceased to exist, he shall revoke the notice, and shall notify in writing the owner or occupier of the premises concerned, and every other person on whom a copy of the notice has been served, of the revocation.

(5) While any such notice remains in force,—
(a) no person on whom it has been served shall use or permit the use of the premises specified in the notice for or in connection with the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale; and
(b) no person on whom a copy of the notice has been served or who knows the contents of the notice shall use those premises for any such purpose.

(6) No notice shall be served by a Medical Officer of Health pursuant to subclause (2) or subclause (4) unless approval to serve the notice has first been obtained from the Director-General.

32 Storage of medicines, etc

(1) Every person in possession of or control of any medicine, related product, or cosmetic for sale, or of any container or appliance used for or in connection with the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, shall at all times—

(a) keep the medicine, related product, cosmetic, container, or appliance clean and free from contamination by moisture, foul odours, or dust; and

(b) protect the medicine, related product, cosmetic, container, or appliance from access by creatures likely to contaminate it.

(2) Every person in possession of any medicine, related product, or cosmetic for sale shall at all times store and keep it packed in such manner as to minimise its deterioration, and shall comply with all requirements for storage stated on the label or contained in a specified publication in respect of that medicine, related product, or cosmetic.

33 Construction and use of containers, etc

(1) No person shall use, or permit to be used, any container, appliance, or vehicle for or in connection with the manufacture, storage, packing, or supply of any medicine, related product, or cosmetic for sale unless that container, appliance, or vehicle is constructed of such material and in such manner as to allow for easy cleaning, and is kept clean.

(2) No person shall use, or permit to be used, in the supply of any medicine, related product, or cosmetic for sale any container, appliance, or vehicle that is also used for the carriage of any matter that endangers or could endanger the cleanliness
or freedom from contamination of the medicine, related product, or cosmetic.

(3) No person shall use, or permit to be used, for the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, any container that has been used for any purpose that may contaminate or taint the medicine, related product, or cosmetic, unless the container has been thoroughly cleaned.

34 Exposure to toxic substances prohibited
Except as otherwise provided in these regulations, no person shall, in the course of the manufacture, storage, packing, or supply of any medicine, related product, or cosmetic for sale, keep, carry, spread, or use, or permit to be kept, carried, spread, or used, any toxic or noxious substance so as to expose the medicine, related product, or cosmetic to the risk of contamination by that substance at any time.

35 Containers for medicines, related products, and cosmetics
(1) A person must not pack, store, or sell a prescription medicine, restricted medicine, or pharmacy-only medicine in a container made of paper; but nothing in this subclause prevents the person from packing, storing, or selling the medicine in a container made of cardboard.

(2) [Revoked]

(3) No person shall use, or permit to be used, in the storage, packing, or supply of any medicine, related product, or cosmetic for sale, a container that yields, or could yield, to its contents a toxic, injurious, or tainting substance.

(4) Every container used in the packing of a medicine and made of glass or plastic shall comply with the tests for that type of container (if any) specified in the United States Pharmacopeia.

(5) Every container used in the packing of a medicine and made of metal shall be impermeable to moisture.

(6) Every container used in the packing of a medicine and made of metal or plastic shall be made of a material that will not adversely react with the contents of the container.

(7) Except as provided in subclause (8), no person shall store, pack, or sell in a container of a capacity of not less than 15
millilitres and not more than 2.5 litres any medicine, related product, or cosmetic that—
(a) is in liquid form; and
(b) is intended for external use; and
(c) has poisonous properties,—
unless the container is a poison bottle.

(8) It shall not be necessary to pack in a poison bottle any medicine, related product, or cosmetic to which subclause (7) applies if that medicine, related product, or cosmetic is—
(a) supplied to or held for use in educational establishments, or in scientific or industrial laboratories; or
(b) supplied to or held by analysts, pharmacists, authorised prescribers, or veterinary surgeons; or
(c) supplied to or held by persons engaged as suppliers to any of the establishments, laboratories, or classes of persons mentioned in paragraphs (a) and (b); or
(d) a hair dye to which regulation 24 applies.

(9) No person shall have in his possession or charge (whether for the purposes of sale or otherwise) in an open container, any medicine, related product, or cosmetic that has poisonous properties, except while the container is being filled or the medicine, related product, or cosmetic in the container is being used.

(10) No person in possession or charge of any medicine, related product, or cosmetic shall keep it, whether temporarily or permanently, in any bottle, jar, can, tinplate container, culinary utensil, or other container of a type that—
(a) bears any brand, mark, statement, or picture that indicates the presence in the container of any food, drink, or condiment; or
(b) is of a distinctive type in which any food, drink, or condiment, has been commonly or is being currently sold, whether or not the container bears any brand, mark, statement, or picture.


36 **Storage to be separate**

No person shall store or keep for ready use any medicine, related product, or cosmetic in such manner that a food or drink may be contaminated by the escape or leakage of the medicine, related product, or cosmetic, or by the release of vapours from the medicine, related product, or cosmetic.

37 **Safety containers**

(1) No person shall sell any tablet, or other single item in solid form that is intended to be taken orally, being or comprising a medicine or belonging to a class of medicines to which this regulation applies, unless the tablet or item is enclosed in a safety container.

(2) Subclause (1) shall not apply—

(a) where an authorised prescriber directs, either on the prescription or otherwise,—

(i) that a medicine is not to be sold enclosed in a safety container; or

(ii) that he or she does not wish the name of the medicine to appear on the label; or

(b) where a pharmacist is of the opinion that, because of the age or infirmity of a particular person, a medicine to be used by that person should not be enclosed in a safety container; or

(c) in the case of capsules, pills, powder, or other solid dose forms, prepared in a pharmacy with reference to the particular needs of a patient.

(3) [Revoked]

(4) This regulation applies to the following medicines: aspirin, and its salts; and medicines containing aspirin or its salts:

iron, in medicines for human use containing more than 24 milligrams of elemental iron per dose:

paracetamol; and medicines containing paracetamol.

(5) This regulation applies to the following classes of medicines: barbiturates:
phenothiazine, and derivatives of phenothiazine and their salts, except dimethothiazine, methdilazine, promethazine, and trimeprazine, and their salts and molecular compounds: tricyclic, tetracyclic, and analogous antidepressants.


Part 6
Importation and transport

38 Containers
(1) Every medicine imported into, or packed or consigned for transport in, New Zealand shall be securely packed in a container that is sufficiently strong to withstand, and to protect the contents from damage arising in, the ordinary course of transport.

(2) No person shall import into, or transport or cause to be transported in, New Zealand any medicine that is not packed in compliance with subclause (1).

(3) Every related product packed or consigned for transport in New Zealand shall be securely packed in a container that is sufficiently strong to withstand, and to protect the contents from damage arising in, the ordinary course of transport.

(4) No person shall transport or cause to be transported in New Zealand any related product that is not packed in compliance with subclause (3).

Part 7
Prescriptions

39 Conditions under which authorised prescribers and veterinary surgeons may prescribe prescription medicines
(1) No medical practitioner shall prescribe any prescription medicine otherwise than for the treatment of a patient under his care, unless the medical practitioner is acting in the course of his employment in the service of the Crown.
(2) No medical practitioner shall prescribe for any patient a quantity of any prescription medicine that exceeds,—
   (a) in the case of an oral contraceptive, 6 months’ supply; or
   (b) in any other case, 3 months’ supply.

(3) No dentist shall prescribe any prescription medicine otherwise than for the dental treatment of a patient under his care.

(4) No dentist shall prescribe for any patient a quantity of any prescription medicine exceeding 5 days’ supply, or, if the prescription provides for a repeat for consecutive days, exceeding 10 days’ supply in the aggregate.

(5) No veterinary surgeon shall prescribe any prescription medicine otherwise than in the practice of his profession for the treatment of an animal under his care.

(6) No registered midwife shall—
   (a) prescribe for any patient a quantity of any prescription medicine that exceeds 3 months’ supply; or
   (b) prescribe any prescription medicine otherwise than for antenatal, intrapartum, and postnatal care.

(7) No nurse authorised to prescribe a prescription medicine by regulations made under the Act may—
   (a) prescribe any prescription medicine if the nurse is for the time being 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:
   (ab) prescribe any prescription medicine otherwise than for use within, and in accordance with all conditions (if any) stated in, his or her scope of practice, as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003 by the Nursing Council of New Zealand:
   (b) prescribe any prescription medicine otherwise than for the treatment of a patient who is under the nurse’s care:
   (c) prescribe for a patient any quantity of any prescription medicine that exceeds,—
       (i) in the case of an oral contraceptive, 6 months’ supply; or
       (ii) in any other case, 3 months’ supply.
(8) No optometrist authorised to prescribe a prescription medicine by regulations made under the Act may—
(a) prescribe any prescription medicine if the optometrist is 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; or
(b) prescribe any prescription medicine otherwise than for the treatment of a patient who is under the optometrist’s care; or
(c) prescribe for a patient a quantity of a prescription medicine that exceeds 3 months’ supply:


40 Prescriptions to comply with regulations

(1) Except as provided in regulation 40A, every authorised prescriber or veterinarian who issues a prescription to a person must comply with regulation 41.

(2) Subclause (1) applies to a prescription for any medicine (whether a prescription medicine or not).

(3) Subclause (2) does not prevent the sale by retail, or the supply in circumstances corresponding to retail sale, or the dispensing, of a medicine (other than a prescription medicine) without a prescription.


40A Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing

(1) Where an authorised prescriber or veterinarian finds it necessary to do so, he or she may communicate orally to a pharmacist to whom he or she is known personally (whether in the pharmacist’s presence or by speaking to the pharmacist on the telephone) a prescription relating to a prescription medicine that the authorised prescriber or veterinarian requires urgently.

(2) Within 7 days after a communication made by an authorised prescriber or veterinarian to a pharmacist under subclause (1), the authorised prescriber or veterinarian must forward to the pharmacist a written prescription confirming the oral communication.


41 Form of prescription

Every prescription given under these regulations shall—

(a) be legibly and indelibly printed; and
(b) be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp), and dated; and
(c) set out the address of the prescriber; and
(d) set out—
(i) the title, surname, initial of each given name, and address of the person for whose use the prescription is given; and
(ii) in the case of a child under the age of 13 years, the date of birth of the child; and
(e) indicate by name the medicine and, where appropriate, the strength that is required to be dispensed; and
(f) indicate the total amount of the medicine that may be sold or dispensed on the one occasion, or on each of the several occasions, authorised by that prescription; and
(g) if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of dose; and
(h) if the medicine is for application externally, indicate the method and frequency of use; and
(i) if it is the intention of the prescriber that the medicine should be supplied on more than 1 occasion, bear an indication of—
   (i) the number of occasions on which it may be supplied; or
   (ii) the interval to elapse between each date of supply; or
   (iii) the period of treatment during which the medicine is intended to be used; and
(j) in the case of a prescription relating to the treatment of an animal,—
   (i) set out the title, surname, initial of each given name, and the address of the owner of the animal; and
   (ii) contain the following statement, or words of similar meaning:
      “Not for human use”.

42 Dispensing of prescription medicines
(1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinarian, pharmacist, pharmacy graduate, a pharmacy technician, a student, or dispensary technician may dispense a prescription medicine.
(1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:
   (a) dispensary technicians:
   (b) pharmacy graduates:
   (c) pharmacy technicians:
   (d) students.

(2) An agent or employee of a veterinarian may, in any particular case, dispense any prescription medicine at the direction of the veterinarian for use in the treatment of any animal under the care of the veterinarian.

(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:
Part 7 r 42

(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.


Regulation 42(1A): inserted, on 19 December 2002, by regulation 4(2) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).


Regulation 42(3): substituted, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 42(4): substituted, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).
Regulation 42(5): added, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

### 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.

Regulation 43: substituted, on 1 August 2011, by regulation 20 of the Medicines Amendment Regulations 2011 (SR 2011/245).

### 44 Prescriptions for prescription medicines not required in certain cases

A prescription medicine may be sold or dispensed otherwise than under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber if it is sold to or dispensed for—

(a) a person licensed to sell the prescription medicine by wholesale; or

(b) a person obtaining the prescription medicine for use in any process of manufacture or trade not involving the resale of the medicine; or

(c) an analyst under the Act, or a person approved by the Director-General and in charge of a laboratory maintained for the purposes of research, study, or analysis; or

(d) a hospital care operator within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or
(e) a pharmacist in control of any pharmacy, or any dispensary in a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or

(f) an authorised prescriber or veterinarian; or

(fa) [Revoked]

(fb) [Revoked]

(g) a patient under his or her care by an authorised prescriber; or

(ga) [Revoked]

(gb) [Revoked]

(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

(ha) [Revoked]

(hb) [Revoked]

(i) the master of a New Zealand ship within the meaning of the Maritime Transport Act 1994,—

  (i) if the medicine is prescribed by rules under section 36(1)(e) of that Act; or

  (ii) at a time before the commencement of the first rules made under section 36(1)(e) of that Act, if the medicine is authorised or required by scales issued under section 138 or section 239 of the Shipping and Seamen Act 1952; or

(ia) the master of a foreign ship within the meaning of the Maritime Transport Act 1994, if the law of the State whose flag the ship is entitled to fly requires the master to carry the medicine; or

(j) a person for inclusion in an emergency medical kit kept or to be kept for use in any vessel to which paragraph (i)
does not apply, and is so sold or dispensed pursuant to an order signed by a Medical Officer of Health; or

(k) the person in charge of an aircraft if the medicine is required to be carried on the aircraft as a condition of the issue of a certificate of airworthiness; or

(l) a person for inclusion in an emergency medical kit pursuant to an order signed by a Medical Officer of Health for use in a place of a class approved by the Director-General; or

(m) a person who has previously been supplied with the medicine on the prescription of an authorised prescriber for a particular condition, and is so sold or dispensed—

(i) by a pharmacist who is satisfied that the person requires an emergency supply of the medicine for that condition; and

(ii) in an amount not exceeding the quantity reasonably required by that person for a period of 72 hours, or a minimum pack of a special container from which it is not practicable to dispense a lesser amount; or

(n) any person by a veterinarian for the treatment of an animal under the care of the veterinarian; or

(o) a person or body authorised to distribute, or a person authorised to administer, the prescription medicine in an approved immunisation programme.


Regulation 44(e): substituted, on 1 October 2002, by section 58(3) of the Health and Disability Services (Safety) Act 2001 (2001 No 93).


Regulation 44(f): amended, on 1 August 2011, by regulation 21(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).


Regulation 44(g): substituted, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).


Regulation 44(h): substituted, on 1 August 2011, by regulation 21(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).


Regulation 44(ia): substituted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(ia): inserted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(ia): substituted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(ia): inserted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(m): amended, on 1 August 2011, by regulation 21(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).


Regulation 44(n): amended, on 1 August 2011, by regulation 21(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).


44A Administration of vaccines in approved immunisation programmes

(1) Any medical practitioner or other person who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.

(2) The Director-General or a Medical Officer of Health may authorise any person to administer a vaccine for the purposes of an approved immunisation programme if that person, following written application, provides documentary evidence satisfying the Director-General or the Medical Officer of Health, as the case may be, that that person—
(a) can carry out basic emergency techniques including resuscitation and the treatment of anaphylaxis; and
(b) has knowledge of the safe and effective handling of immunisation products and equipment; and
(c) can demonstrate clinical interpersonal skills; and
(d) has knowledge of the relevant diseases and vaccines in order to be able to explain the vaccination to the patient, or to the parent or guardian of the patient who is to consent to the vaccination on behalf of the patient, to ensure that the patient or the parent or guardian of the patient can give informed consent to the vaccination.

(3) Subject to subclause (4), any authorisation given by the Director-General or a Medical Officer of Health under subclause (2) shall be valid for a period of 2 years and shall be subject to such conditions as the Director-General or the Medical Officer of Health, as the case may be, thinks fit.

(4) An authorisation given to any person under subclause (2) may be withdrawn at any time before its expiry if the Director-General or a Medical Officer of Health is satisfied that the authorised person has failed to comply with any condition specified by the Director-General or the Medical Officer of Health under subclause (3).


44B Duty to supply information

(1) The Medical Officer of Health may require any authorised prescriber to supply information relating to the prescribing, administering, or supplying of any prescription medicines if the Medical Officer of Health has reason to suspect that prescription medicines may have been improperly prescribed, administered, or supplied by the authorised prescriber.

(2) Every requirement to supply information must be in writing, stating the reasons for the Medical Officer of Health’s suspicion.

49
(3) The information that must be supplied is information justifying the prescription, administering, or supply of the prescription medicines as follows:
   (a) the age of the patient:
   (b) the diagnosis of the patient’s condition:
   (c) the prognosis of the patient’s condition:
   (d) details of any specialist referral:
   (e) any alternative treatments considered or tried.

(4) An authorised prescriber to whom any such notice is sent must supply the required information in writing to the Medical Officer of Health within 30 days.


Part 7A
Export of prescription medicines


44C No export of prescription medicines for retail sale without New Zealand prescription

(1) No person may export a prescription medicine in the course or for the purpose of retail sale, otherwise than under a prescription given by a practitioner, a registered midwife, or a designated prescriber.

(2) The meaning of retail sale in subclause (1) must be determined by reference to section 5(2) of the Act.

(3) Subclause (1) is intended to limit the sale and supply of prescription medicines pursuant to section 33(b) of the Act.

Part 7B
Supply of restricted medicine and pharmacy-only medicine


44D Supply of restricted medicine and pharmacy-only medicine

(1) A person may, in the course of any business carried on by that person, supply a restricted medicine or pharmacy-only medicine if he or she—
   (a) is authorised to supply the medicine in accordance with a standing order; and
   (b) supplies that medicine in accordance with that standing order.

(2) The circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under subclause (1) are in addition to the circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under section 18(1)(b) or (c) of the Medicines Act 1981.


Part 8
Licences

45 Application for licence to manufacture, hawk, sell, or pack medicine

(1) Every application for a licence to manufacture, hawk, sell, or pack medicine must—
   (a) be made in form 1 of Schedule 2:
   (b) be accompanied by the appropriate fee:
   (c) specify—
       (i) the premises the applicant intends to use for the activity to which the application relates; or
       (ii) in the case of an application for a licence to hawk medicines, the area in which the applicant intends to operate:
(d) specify the medicines, or the descriptions or classes of medicines, that the applicant proposes to manufacture, hawk, sell, or pack:

(e) specify—
   
   (i) the applicant’s qualifications; or
   
   (ii) if the applicant is a body corporate, the qualifications of every person who will, if the application is successful, be a responsible person for the purposes of the licence to which the application relates:

(f) in the case of an application for a licence to sell any medicine by retail or to hawk any medicine, be accompanied by a certificate of character that states that the applicant—

   (i) is well known to the person giving the certificate; and
   
   (ii) is of good character; and
   
   (iii) is considered by the person giving the certificate to be a fit and proper person to be licensed to sell or hawk medicine.

(2) A licence to undertake an activity referred to in subclause (1) may only be granted in respect of 1 place of business.

(3) Despite subclause (2), the licensing authority may grant a licence that allows for the manufacture of medicine, or a description or class of medicines, at more than 1 place of business if—

   (a) the application to which the licence relates is made by a body corporate; and
   
   (b) the licensing authority is satisfied that the body corporate has taken steps to ensure appropriate supervision of the manufacture of the product at each of the places of business.

(4) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:

   (a) further information:

   (b) an opportunity to inspect the applicant’s premises and equipment.
(5) The licensing authority may, in order to determine if a person to whom section 51(1)(d) of the Act applies has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines to which a licence to manufacture, hawk, sell, or pack medicine relates, require that person to undertake and pass any oral, written, or practical tests that the licensing authority considers reasonably necessary in the particular case.


45A Application for licence to operate pharmacy

(1) Every application for a licence to operate a pharmacy must—

(a) be made,—

(i) in the case of a company, in form 1A of Schedule 2; and

(ii) in the case of a person (including a body corporate that is not a company), in form 1B of Schedule 2; and

(b) be accompanied by—

(i) the appropriate fee prescribed in Schedule 5A; and

(ii) a completed statutory declaration (as set out in the relevant form).

(2) A licence to operate a pharmacy may only be granted in respect of 1 place of business.

(3) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:

(a) further information:

(b) an opportunity to inspect the applicant’s premises and equipment.

(4) The licensing authority may, in order to determine if a person to whom section 51(1)(d) of the Act applies has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines to which a licence to operate a pharmacy relates, require that person to undertake and pass any oral, written, or practical tests that the licensing authority considers reasonably necessary in the particular case.
46 **Form and conditions of licence**

(1) The following licences must be in the following forms:

(a) a licence to manufacture medicines must be in form 2 of Schedule 2:

(b) a licence to hawk medicines must be in form 3 of Schedule 2:

(c) a licence to sell medicines by wholesale must be in form 4 of Schedule 2:

(d) a licence to sell medicines by retail must be in form 5 of Schedule 2:

(e) a licence to pack medicines must be in form 6 of Schedule 2:

(f) a licence to operate a pharmacy must be in form 7 of Schedule 2.

(2) On granting a licence under the Act, the licensing authority may impose such conditions as he thinks fit.


47 **Licence to manufacture medicines**

(1) Every application for a licence to manufacture any medicine shall specify which of the following descriptions or classes the medicine comes within or belongs to:

(a) antibiotics and preparations of antibiotics;

(b) vaccines and sera;

(c) sterile preparations;

(d) hormones and steroid preparations;

(e) preparations, other than vitamins, that have a dose of 5 milligrams or less per unit dose;

(f) antineoplastic agents and immunosuppressant agents, other than steroid preparations;

(g) other medicines.

(2) Where an application to manufacture medicines applies to 1 or more medicines or descriptions or classes of medicines, the
licensing authority may grant a licence for all the medicines or descriptions or classes of medicines to which the application relates, or for such of the medicines or descriptions or classes of medicines to which the application relates as the licensing authority is satisfied the applicant is qualified to manufacture and capable of manufacturing.

48 Licence to hawk certain medicines

(1) Subject to subclause (2), and without affecting the generality of regulation 46(2), every licence to hawk any prescription medicine, restricted medicine, or pharmacy-only medicine shall be granted subject to the following conditions:
(a) the licence shall apply only to those medicines or descriptions or classes of medicine specified in the licence:
(b) the licensee shall keep the stocks of medicines in a place approved by the licensing authority:
(c) where the licensing authority imposes a limit on the quantity of medicines that may be carried by the licensee when hawking, the licensee shall not carry medicines in excess of that quantity:
(d) the licensee shall hawk medicines only to those persons or classes of persons specified in the licence.

(2) No person shall be granted a licence to hawk any prescription medicines, restricted medicines, or pharmacy-only medicines by retail.

48A Licensing authority to be advised of change in particulars relating to operating pharmacy

(1) A company or person who is granted a licence to operate a pharmacy must advise the licensing authority as soon as practicable of any change in the details that relate to the application for that licence (including, without limitation, changes in the details of any additional information required by the licensing authority).

(2) A company that is granted a licence to operate a pharmacy under section 55D(2)(a) of the Act must immediately advise the licensing authority if there is a change or are changes in the ownership of the share capital of the company that means
that more than 50% of the share capital is no longer owned by a pharmacist or pharmacists.

(3) The requirement imposed by subclause (2) is in addition to the requirement imposed by subclause (1).


49 **Surrender of licence**

(1) Subclause (1A) applies if a licensee ceases to—
(a) manufacture, hawk, sell, or pack any medicine; or
(b) operate a pharmacy.

(1A) If this subclause applies, the licensee must, within 7 days of ceasing to undertake the activity to which the licence relates, surrender that licence to the licensing authority.

(2) The licensing authority, on receiving a licence pursuant to subclause (1A), shall retain the licence for the remainder of the current licence period.

(3) Nothing in this regulation shall prevent a licensee who has surrendered his licence pursuant to subclause (1A) from applying to the licensing authority for restoration of the licence to the licensee at any time during the current licence period.

(4) In any such case, but subject to subclause (5), the licensing authority, on being satisfied that the licensee complies with the requirements of the Act and these regulations relating to the granting of licences, shall restore the licence to the licensee.

(5) Notwithstanding anything in these regulations, it shall not be necessary for any licensee who surrenders his licence to pay a further licence fee on application for restoration of that licence.


Regulation 49(1A): inserted, on 18 September 2004, by regulation 7(1) of the Medicines Amendment Regulations 2004 (SR 2004/300).


Part 9
Withdrawal of medicines, etc

50 Withdrawal of medicines, etc

(1) The Director-General may issue to any importer, manufacturer, or seller of any medicine, related product, or medical device an order—

(a) directing the withdrawal from sale of any medicine, related product, or medical device in respect of which there is in force a notice given by the Minister under section 35 or section 37 of the Act, or of any portion of the produced quantity of any such medicine, related product, or medical device, if the Director-General believes on reasonable grounds that such withdrawal is necessary to protect the public; or

(b) directing the withdrawal from sale of any medicine, related product, or medical device, or any portion of the produced quantity of any medicine, related product, or medical device, that does not conform to the specifications claimed for that medicine, related product, or medical device; or

(c) requiring the disposal of any medicine or related product, or any specific quantity of a medicine or related product, that has been directed to be withdrawn under paragraph (a) or paragraph (b); or

(d) requiring the disposal or destruction of any medical device, or any specific quantity of any medical device, that has been directed to be withdrawn under paragraph (a) or paragraph (b).

(2) The importer, manufacturer, or seller shall, on receipt of an order made under subclause (1), advise the Director-General of the manner and time in which he proposes to comply with the order, and shall give written notice to the Director-General when the order has been complied with.

(3) Notwithstanding anything in subclause (2), the Director-General may issue directions to the recipient of an order made under subclause (1) as to the manner and time in which the order is to be complied with.
Part 10
Data sheets

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.

Regulation 51: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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.

Regulation 52: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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.

Regulation 53: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

54 Particulars in data sheets
[Revoked]

Regulation 54: revoked, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Part 11
Records

54A Sale of Medicines Registers

(1) This regulation applies to the sale of a medicine if it is—
   (a) a restricted medicine sold by retail otherwise than under a prescription; or
   (b) a prescription medicine, restricted medicine, or pharmacy-only medicine, sold by wholesale.

(2) A person who makes sales to which subclause (1) applies must—
   (a) maintain a Sale of Medicines Register for recording and keeping the information stated in subclause (4); and
   (b) ensure that the information kept in it is arranged in such a way that the information about each particular sale can be conveniently inspected, or retrieved and inspected.

(3) The register must be in 1 or more of the following forms:
(a) a system for recording and keeping the information electronically;
(b) a book for recording and keeping the information in writing;
(c) some other system for recording and keeping the information, approved by the Director-General (either generally or in any particular case) for the purposes of this regulation.

(4) The information to be recorded and kept in relation to each sale is—
(a) the date of the sale:
(b) the buyer’s name:
(c) the address of the buyer’s place of business or residence:
(d) the name of the medicine sold:
(e) the quantity of the medicine sold:
(f) the name of the person making the sale.


55 Records of sales by retail or wholesale
(1) Before giving to the buyer a medicine to whose sale regulation 54A(1) applies, the person making the sale must record in the Sale of Medicines Register maintained under regulation 54A(2) the information stated in regulation 54A(4).
(2) It is not necessary to comply with subclause (1) in relation to a sale by wholesale if the information stated in regulation 54A(4) can be discovered from the seller’s books and records.


56 Record of hawker’s sales
(1) Every person who hawks any prescription medicine, restricted medicine, or pharmacy-only medicine shall keep and maintain a “Hawker’s Medicines” book that records the medicines that he hawks or has in his possession.
(2) Each page of the Hawker’s Medicines book shall—
(a) be in the form set out in Schedule 4:
(b) relate to only 1 form and 1 strength of 1 medicine.
(3) The particulars in the Hawker’s Medicines book shall be legibly and indelibly entered not later than the ordinary business day next following the day on which the medicine concerned was sold.

(4) Every person to whom subclause (1) applies shall—
   (a) satisfy himself that the purchaser is entitled to the medicine; and
   (b) before selling the medicine to the purchaser, obtain from the purchaser a printed request for the medicine, signed and dated by the purchaser, that contains the following particulars:
      (i) the date of each transaction:
      (ii) the name of the purchaser:
      (iii) the address of the place of business or residence of the purchaser:
      (iv) the name of the medicine sold:
      (v) the quantity of the medicine sold.

57 Record of supplies pursuant to prescriptions

(1) Every person who dispenses or supplies any prescription medicine or restricted medicine pursuant to a prescription shall, not later than the ordinary business day next following the day on which the medicine was dispensed or supplied, record that dispensing or supply of the medicine in a “Prescriptions” register, or in such other form, or within such other period of time, as the Director-General may from time to time approve.
   (a) the date of each transaction:
   (b) the name of the patient or (as the case may require) the owner of the animal:
   (c) the address of the patient or (as the case may require) the owner of the animal:
   (d) the name of the medicine supplied:
   (e) the quantity of the medicine supplied:
   (f) the name of the prescriber:
   (g) in the case of a prescription medicine, the unique identifying number or code of the prescription.
58 Records to be kept
(1) The person responsible for a record to which this Part applies must keep it for at least 3 years after it was made (or, if it is kept together with other records, for at least 3 years after the most recent of them was made).

(2) The person must keep the record—
(a) in a secure place at his or her place of business; or
(b) in some other place authorised by the licensing authority.


Part 12
Miscellaneous

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 one 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.
Part 12 r 59 Medicines Regulations 1984 Reprinted as at 1 August 2011

Regulation 58A: inserted, on 1 August 2011, by regulation 23 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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.

Regulation 59: substituted, on 1 August 2011, by regulation 24 of the Medicines Amendment Regulations 2011 (SR 2011/245).

60 Certificate of analyst
The certificate of an analyst given for the purposes of section 70 of the Act shall be in the form set out in Schedule 5.

61 Fees
(1) The licence fees set out in Schedule 5A are payable for the licences to which they relate.

(2) The amount to be deposited with the Medicines Review Committee pursuant to section 13(2) of the Act shall be $9,000.

(3) The fee to accompany an application made under section 21 of the Act for the Minister’s consent under section 20 of the Act shall be $122,625 where any active ingredient of the medicine that is the subject of the application is not generally available as at the date of that application.

(4) The fee to accompany any other application made under section 21 of the Act for the Minister’s consent under section 20 of the Act shall be $43,875.

(5) The fee to accompany an application made under section 21 of the Act (as applied by section 96(1) of the Act) for the Minister’s consent under section 20 of the Act in relation to a related product shall be $5,500.
(6) The fee to accompany an application made under section 23 of the Act for the Minister’s provisional consent shall be $8,437.

(7) The fee to accompany a notice deposited with the Director-General under section 24 of the Act shall be $3,200.

(8) The fee to accompany an application made under section 30 of the Act for the approval of a clinical trial, and of the persons (in that section called investigators) who will conduct that trial, shall be $9,843.

(9) For the purposes of section 70(4) of the Act, the fee for a copy of a certificate of an analyst, or (as the case may be) a copy of a report made by an analyst in respect of a sample, shall be $60.

(10) For the purposes of section 97(1) of the Act, the fee for procuring a sample of any medicine and submitting it for analysis shall be $600.

(11) For the purposes of subclause (3), not generally available means not legally available other than pursuant to an exemption granted under any or all of sections 25, 26, 27, 28, 29, 30, 31, 32, 32A, or 33 of the Act.


61A Waiver and refund of fees

(1) The Director-General may, in a particular case or class of cases, waive or refund, in whole or in part, any fee otherwise payable under regulation 61.

(2) In exercising his or her powers under subclause (1), the Director-General shall have regard to—
(a) the time reasonably required to consider any application made or notice given under the Act:
(b) the degree of complexity involved in considering any such application or notice:
(c) the interests of public health in New Zealand.


**61B Fees inclusive of goods and services tax**

The fees fixed by these regulations are inclusive of goods and services tax under the Goods and Services Tax Act 1985.


**62 Medical devices**

No person shall sell any medical device that is claimed to operate by inducing, concentrating, directing, or producing, or counteracting, screening, or giving protection from, any magnetic, galvanic, electric, electronic, radiation, or vibratory forces or effects unless—

(a) such properties are, before or at the time of sale, quantitatively described to the purchaser in writing in terms that can be measured by scientific physical means; and
(b) the medical device demonstrably has the properties claimed and described.

**63 Restriction on, and supervision of, compounding medicine**

(1) A dispensary technician must not undertake any process of compounding a medicine.

(2) The following persons may compound a medicine, but only if under the direct personal supervision of a pharmacist:

(a) pharmacy graduates:
(b) pharmacy technicians:
(c) students:
(d) despite subclause (1), dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939.

64 Offences

(1) Every person commits an offence against these regulations who—

(a) contravenes or fails to comply with any of the provisions of regulations 26(1), 26(2), 27, 28(3), 29, 30, 31(5), 32(1), 32(2), 33(1), 33(2), 33(3), 34, 35(1), 35(3), 35(7), 35(9), 35(10), 36, 37(1), 39, 39A(1), 40(1), 40A(2), 42(1), 42(3), 42(4), 44B(4), and 49(1); or

(b) fails to comply with any order made by the Director-General under regulation 50(1); or

(c) contravenes or fails to comply with any of the provisions of regulations 50(2), 52(3), 53(4), 55(1), 56(1), 56(3), 56(4), 57(1), 58, 62, and 63.

(2) Every person who commits an offence against these regulations is liable on summary conviction to a fine not exceeding $500.

Regulation 64(1)(a): amended, on 1 August 2011, by regulation 25(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).


Regulation 64(1)(c): amended, on 1 August 2011, by regulation 25(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

65 Appeals to District Court

(1) Any occupier of premises in respect of which any decision has been made under regulation 31 by a Medical Officer of Health, may appeal against that decision to a District Court within 14 days after being notified in writing of the decision.

(2) An appeal under this regulation shall be made by way of originating application in accordance with the District Courts Rules 2009, and shall be filed in the office of the court nearest to the place of business or employment of the appellant.

(3) On hearing an appeal brought under this regulation, the court may confirm, reverse, or modify the decision made by the Medical Officer of Health, and the decision of the court on the appeal shall be final.

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.

Regulation 65A: inserted, on 1 August 2011, by regulation 26 of the Medicines Amendment Regulations 2011 (SR 2011/245).

66 Revocations

(1) The regulations specified in Schedule 6 are hereby revoked.

(2) Amendment(s) incorporated in the Drug Tariff 1981 (SR 1981/171).
Schedule 1

Prescription, restricted, and pharmacy-only medicines

Schedule 1: substituted, on 1 August 2011, by regulation 27 of the Medicines Amendment Regulations 2011 (SR 2011/245).

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
6 Abacavir
Part 1—continued

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 Acetylcarnitine
19 Acetylcarnitine; except in medicines containing 1 milligram or less per litre or per kilogram
20 Acetylcarnitine; for injection or inhalation
21 Acetyldigitoxin
22 Acetylthiocholine; for injection or inhalation
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
35 Adinazolam
36 Adiphenine
Part 1—continued

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
63  Allergens
64  Allopurinol
65  Allylisopropylacetlyurea; at all strengths
Part 1—continued

66  Allyloestrenol
67  Alosetron
68  Alpha,-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
92  Aminometradine
93  Aminophenazone; at all strengths
94  Aminophylline; except for oral use in liquid form in medicines containing 2% or less
Part 1—continued

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 Amphotericin
112 Ampicillin
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
120 Anabolic steroids
121 Anagrelide
122 Anakinra
123 Anastrozole
124 Ancestim
Part 1—continued

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
148 Aprotinin
149 Arecoline
150 Aripiprazole
151 Aristolochia spp.; at all strengths
152 Aristolochic acid; at all strengths
Part 1—continued

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
174 Azacyclonol
175 Azapropazone
176 Azaridine
177 Azatadine; except when specified elsewhere in this schedule
178 Azathioprine
Part 1—continued

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
205  Benperidol
206  Benserazide
207  Benzathine penicillin
208  Benzatropine
209  Benzhexol
210  Benzilonium
Part 1—continued

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

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
Part 1—continued

237  Bivalirudin
238  Bleomycin
239  Bolandiol
240  Bolasterone
241  Bolazine
242  Boldenone
243  Bolonol
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
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
Part 1—continued

264 Buphenine
265 Bupivacaine
266 Buprenorphine
267 Bupropion
268 Buserelin
269 Buspirone
270 Busulphan
271 Butacaïne
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
283 Calcitriol
284 Calcium carbimide
285 Calcium polystyrene sulphonate
286 Calotropis gigantea
287 Calotropis procera
288 Calusterone
289 Camazepam
290 Camphorated oil
291 Camphotamide
Part 1—continued

292  Canakinumab
293  Can desartan
294  Candicidin
295  Cannabidiol
296  Cape citabine
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
314  Carbromal
315  Carbutamide
316  Carbuterol
317  Carindacillin
318  Carisoprodol
319  Carmustine
320  Carprofen
321  Carvedilol
322  Caspofungin
323  Cefacetrile
Part 1—continued

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
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
Part 1—continued

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  Chloromethiazole
371  Chloromezanone
372  Chloroform; for anaesthesia; except when specified elsewhere in this schedule
373  Chloroquine
374  Chlorothiazide
375  Chlorotrianiene
376  Chloroxydienone
377  Chloroxymesterone
378  Chlorpheniramine; except when specified elsewhere in this schedule
379  Chlorphentermine
380  Chlorpromazine
381  Chlorpropamide
Part 1—continued

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
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
Part 1—continued

413  Clenbuterol
414  Clevidipine
415  Clidinium
416  Clindamycin
417  Cloquinarol; 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  Clofamamide
426  Clofibrate
427  Clomiphene
428  Clomipramine
429  Clomocycline
430  Clonazepam
431  Clonidine
432  Clopamide
433  Clopidogrel
434  Cloreoxolone
435  Cloprenaline
436  Clostebol
437  Clofiazipem
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

84
Reprinted as at 1 August 2011

Medicines Regulations 1984

Schedule 1

Part 1—continued

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 keiskei
457  Convallaria majales
458  Corifollitropin alfa
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
Part 1—continued

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
485 Cyproheptadine; except for oral use
486 Cyproterone
487 Cysteamine
488 Cytarabine
489 Dabigatran
490 Dacarbazine
491 Daclizumab
492 Dactinomycin
493 Dallopristin
494 Dalteparin
495 Danaparoid
496 Danazol
497 Danthron
498 Dantrolene
499 Dapoxetine
500 Dapsone
501 Daptomycin
Part 1—continued

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
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
### Schedule 1

**Medicines Regulations 1984**

Reprinted as at 1st August 2011

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>533</td>
<td>Desvenlafaxine</td>
</tr>
<tr>
<td>534</td>
<td>Dexamethasone</td>
</tr>
<tr>
<td>535</td>
<td>Dexamfetamine</td>
</tr>
<tr>
<td>536</td>
<td>Dexchlorpheniramine; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>537</td>
<td>Dextropropoxyphene; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>538</td>
<td>Dextromethorphan; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>539</td>
<td>Dextrorphan</td>
</tr>
<tr>
<td>540</td>
<td>Di-iodohydroxy quinoline; except for vaginal use</td>
</tr>
<tr>
<td>541</td>
<td>Di-isopropylamine dichloroacetate</td>
</tr>
<tr>
<td>542</td>
<td>Diazepam</td>
</tr>
<tr>
<td>543</td>
<td>Dibenzepin</td>
</tr>
<tr>
<td>544</td>
<td>Diethylamine</td>
</tr>
<tr>
<td>545</td>
<td>Diboterm</td>
</tr>
<tr>
<td>546</td>
<td>Dibrompropamidine; except for ophthalmic use</td>
</tr>
<tr>
<td>547</td>
<td>Dichloralphenzone</td>
</tr>
<tr>
<td>548</td>
<td>Dichlorophenol</td>
</tr>
<tr>
<td>549</td>
<td>Dichloropropamide</td>
</tr>
<tr>
<td>550</td>
<td>Dichlofenac; except when specified elsewhere in this schedule; except for external use</td>
</tr>
<tr>
<td>551</td>
<td>Dicloxacillin</td>
</tr>
<tr>
<td>552</td>
<td>Dicyclomine</td>
</tr>
<tr>
<td>553</td>
<td>Didanosine</td>
</tr>
<tr>
<td>554</td>
<td>Dienoestrol</td>
</tr>
<tr>
<td>555</td>
<td>Dienogest</td>
</tr>
<tr>
<td>556</td>
<td>Diethazine</td>
</tr>
<tr>
<td>557</td>
<td>Diethylcarbamazine</td>
</tr>
<tr>
<td>558</td>
<td>Diethyldestrol</td>
</tr>
<tr>
<td>559</td>
<td>Diethylstilbestrol</td>
</tr>
<tr>
<td>560</td>
<td>Diflorasone</td>
</tr>
</tbody>
</table>
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
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  Dinitrocreols
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
Part 1—continued

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
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

90
<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>626</td>
<td>Drospirenone</td>
</tr>
<tr>
<td>627</td>
<td>Drostanolone</td>
</tr>
<tr>
<td>628</td>
<td>Drotrecogin</td>
</tr>
<tr>
<td>629</td>
<td>Duboisia leichhardtii; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>630</td>
<td>Duboisia myoporides; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>631</td>
<td>Dulcin; at all strengths</td>
</tr>
<tr>
<td>632</td>
<td>Duloxetine</td>
</tr>
<tr>
<td>633</td>
<td>Dutasteride</td>
</tr>
<tr>
<td>634</td>
<td>Dydrogesterone</td>
</tr>
<tr>
<td>635</td>
<td>Econazole; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>636</td>
<td>Ectylurea</td>
</tr>
<tr>
<td>637</td>
<td>Edetic acid; in medicines containing more than 0.25%; except in contact lens preparations; except dicobalt edetate for the treatment of cyanide poisoning</td>
</tr>
<tr>
<td>639</td>
<td>Edoxudine</td>
</tr>
<tr>
<td>640</td>
<td>Edrophonium</td>
</tr>
<tr>
<td>641</td>
<td>Efalizumab</td>
</tr>
<tr>
<td>642</td>
<td>Efavirenz</td>
</tr>
<tr>
<td>643</td>
<td>Eflornithine</td>
</tr>
<tr>
<td>644</td>
<td>Eletriptan</td>
</tr>
<tr>
<td>645</td>
<td>Eltrombopag olamine</td>
</tr>
<tr>
<td>646</td>
<td>Emepronium</td>
</tr>
<tr>
<td>647</td>
<td>Emetine; in medicines containing more than 0.2%</td>
</tr>
<tr>
<td>648</td>
<td>Emtricitabine</td>
</tr>
<tr>
<td>649</td>
<td>Enalapril</td>
</tr>
<tr>
<td>650</td>
<td>Enestebol</td>
</tr>
<tr>
<td>651</td>
<td>Enflurane</td>
</tr>
<tr>
<td>652</td>
<td>Enfuvirtide</td>
</tr>
<tr>
<td>653</td>
<td>Enoxacin</td>
</tr>
<tr>
<td>654</td>
<td>Enoxaparin</td>
</tr>
</tbody>
</table>
Part 1—continued

655  Enoximone
656  Enprostil
657  Entacapone
658  Entecavir
659  Ephedrine
660  Epicillin
661  Epinastine
662  Epirubicin
663  Epitiostanol
664  Eplerenone
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
Part 1—continued

686 Ethacrynic acid
687 Ethambutol
688 Ethamivan
689 Ethanolamine; for injection
690 Ethchlorvynol
691 Ether; for anaesthesia
692 Ethinamate
693 Ethinyloestradiol
694 Ethionamide
695 Ethisterone
696 Ethoglucid
697 Ethoheptazine
698 Ethopropazine
699 Ethosuximide
700 Ethotoximide
701 Ethoxzolamide
702 Ethyl chloride; for inhalation
703 Ethyl loflazepate
704 Ethylidenolone
705 Ethylhexanediol; at all strengths
706 Ethylestrenol
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
Part 1—continued

718  Everolimus
719  Exemestane
720  Exenatide
721  Ezetimibe
722  Factor VIII inhibitor bypassing fraction
723  Famiclovir; except when specified elsewhere in this schedule
724  Famotidine; except when specified elsewhere in this schedule
725  Fampridine
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  Fenclorfenac
732  Fenfluramine
733  Fenofibrate
734  Fenoldopam
735  Fenoprofen
736  Fenoterol
737  Fenpipramid
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
Part 1—continued

749  Fluclorolone
750  Flucloxacillin
751  Fluconazole; except when specified elsewhere in this schedule
752  Flucytosine
753  Fludarabine
754  Fludiazepam
755  Fludrocortisone
756  Flufenamic acid
757  Flumazenil
758  Flumethasone
759  Flumethiazide
760  Flunixisole
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
Part 1—continued

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 Fluvasstatin
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 Fotelmustine
799 Framycetin
800 Fulvestrant
801 Furaltadone
802 Furazabol
803 Furazolidone
804 Furosemide
805 Fusidic acid

96
Part 1—continued

806 Gabapentin
807 Galantamine
808 Galanthus spp.
809 Gallamine
810 Galsulfase
811 Ganciclovir
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
841 Granisetron
842 Grepafloxacin
843 Griseofulvin
844 Guaiaphenesin; 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
Part 1—continued

862 Hepatitis A vaccine
863 Hepatitis B vaccine
864 Hetacillin
865 Hexachlorophane; in medicines containing more than 3%
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
Part 1—continued

890 Hydroxyurea
891 Hydroxyzine
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
<table>
<thead>
<tr>
<th>Part 1—continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>914</td>
</tr>
<tr>
<td>915</td>
</tr>
<tr>
<td>916</td>
</tr>
<tr>
<td>917</td>
</tr>
<tr>
<td>918</td>
</tr>
<tr>
<td>919</td>
</tr>
<tr>
<td>920</td>
</tr>
<tr>
<td>921</td>
</tr>
<tr>
<td>922</td>
</tr>
<tr>
<td>923</td>
</tr>
<tr>
<td>924</td>
</tr>
<tr>
<td>925</td>
</tr>
<tr>
<td>926</td>
</tr>
<tr>
<td>927</td>
</tr>
<tr>
<td>928</td>
</tr>
<tr>
<td>929</td>
</tr>
<tr>
<td>930</td>
</tr>
<tr>
<td>931</td>
</tr>
<tr>
<td>932</td>
</tr>
<tr>
<td>933</td>
</tr>
<tr>
<td>934</td>
</tr>
<tr>
<td>935</td>
</tr>
<tr>
<td>936</td>
</tr>
<tr>
<td>937</td>
</tr>
<tr>
<td>938</td>
</tr>
<tr>
<td>939</td>
</tr>
<tr>
<td>940</td>
</tr>
<tr>
<td>941</td>
</tr>
<tr>
<td>942</td>
</tr>
</tbody>
</table>
### Schedule 1

**Medicines Regulations 1984**

Reprinted as at 1 August 2011

---

**Part 1—continued**

<table>
<thead>
<tr>
<th>No.</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>943</td>
<td>Isometheptene</td>
</tr>
<tr>
<td>944</td>
<td>Isoniazid</td>
</tr>
<tr>
<td>945</td>
<td>Isoprenaline</td>
</tr>
<tr>
<td>946</td>
<td>Isoprinosine</td>
</tr>
<tr>
<td>947</td>
<td>Isopropamide; except for dermal use in preparations containing 2% or less</td>
</tr>
<tr>
<td>948</td>
<td>Isosorbide dinitrate</td>
</tr>
<tr>
<td>949</td>
<td>Isosorbide mononitrate</td>
</tr>
<tr>
<td>950</td>
<td>Isotretinoin</td>
</tr>
<tr>
<td>951</td>
<td>Isoxicam</td>
</tr>
<tr>
<td>952</td>
<td>Isoxsuprine</td>
</tr>
<tr>
<td>953</td>
<td>Isradipine</td>
</tr>
<tr>
<td>954</td>
<td>Itraconazole</td>
</tr>
<tr>
<td>955</td>
<td>Ivabradine</td>
</tr>
<tr>
<td>956</td>
<td>Ivermectin</td>
</tr>
<tr>
<td>957</td>
<td>Ixabepilone</td>
</tr>
<tr>
<td>958</td>
<td>Japanese encephalitis vaccine</td>
</tr>
<tr>
<td>959</td>
<td>Juniperus sabina; at all strengths</td>
</tr>
<tr>
<td>960</td>
<td>Kanamycin</td>
</tr>
<tr>
<td>961</td>
<td>Ketamine</td>
</tr>
<tr>
<td>962</td>
<td>Ketanserin</td>
</tr>
<tr>
<td>963</td>
<td>Ketazolam</td>
</tr>
<tr>
<td>964</td>
<td>Ketoconazole; except for dermal use</td>
</tr>
<tr>
<td>965</td>
<td>Ketoprofen; except when specified elsewhere in this schedule; except for dermal use</td>
</tr>
<tr>
<td>966</td>
<td>Ketorolac</td>
</tr>
<tr>
<td>967</td>
<td>Ketotifen; except for ophthalmic use in medicines containing 0.025% or less</td>
</tr>
<tr>
<td>968</td>
<td>Khellin</td>
</tr>
<tr>
<td>969</td>
<td>Labetalol</td>
</tr>
<tr>
<td>970</td>
<td>Lacidipine</td>
</tr>
<tr>
<td>971</td>
<td>Lacosamide</td>
</tr>
<tr>
<td>972</td>
<td>Lamivudine</td>
</tr>
</tbody>
</table>

---
Part 1—continued

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 Leuprolarin
996 Levallorphan
997 Levamisole
998 Levetiracetam
999 Levobunolol
1000 Levobupivacaine
1001 Levocabastine; except for nasal or ophthalmic use
1002 Levocetirizine; except for oral use
1003 Levodopa
1004 Levomepromazine
Part 1—continued

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

1021 Lomustine

1022 Loperamide; except when specified elsewhere in this schedule

1023 Lopinavir
Part 1—continued

1024 Loprazolam
1025 Loracarbef
1026 Loratadine; except for oral use
1027 Lorazepam
1028 Lorimetazepam
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 Mebbutamate
1046 Mecamylamine
1047 Mecasermin
1048 Mecillinam
1049 Meclocycline
1050 Meclofenamate
1051 Meclofenoxate
1052 Meclozine; except when specified elsewhere in this schedule
1053 Medazepam
1054 Medigoxin
1055 Medroxyprogesterone
1056 Medrysone
Part 1—continued

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 Mephenetermine
1074 Mepindolol
1075 Mepitostane
1076 Mepivacaine
1077 Meprobamate
1078 Meptazinol
1079 Mepyramine; except when specified elsewhere in this schedule
1080 Mequitazine
1081 Mercaptopmerin
1082 Mercaptopurine
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
Part 1—continued

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
1113  Methotrexate
1114  Methoxamine; except for external use
1115  Methoxsalen
1116  Methoxyflurane
1117  Methsuximide
1118  Methyclothiazide
Part 1—continued

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  Methypentynol
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
1142  Metronidazole
1143  Metryapone
1144  Mexiletine
1145  Mezlocillin
1146  Mianserin
1147  Mibefradil
1148  Mibolerone
Part 1—continued

1149 Miconazole; except when specified elsewhere in this schedule
1150 Midazolam
1151 Midodrine
1152 Mifepristone
1153 Miglitol
1154 Miglulstat
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
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
**Part 1—continued**

<table>
<thead>
<tr>
<th>Code</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1180</td>
<td>Moxifloxacin</td>
</tr>
<tr>
<td>1181</td>
<td>Mumps vaccine</td>
</tr>
<tr>
<td>1182</td>
<td>Mupirocin</td>
</tr>
<tr>
<td>1183</td>
<td>Muraglitazar</td>
</tr>
<tr>
<td>1184</td>
<td>Muromonab</td>
</tr>
<tr>
<td>1185</td>
<td>Mustine</td>
</tr>
<tr>
<td>1186</td>
<td>Mycophenolic acid</td>
</tr>
<tr>
<td>1187</td>
<td>Nabilone</td>
</tr>
<tr>
<td>1188</td>
<td>Nabumetone</td>
</tr>
<tr>
<td>1189</td>
<td>Nadolol</td>
</tr>
<tr>
<td>1190</td>
<td>Nadroparin</td>
</tr>
<tr>
<td>1191</td>
<td>Nafarelin</td>
</tr>
<tr>
<td>1192</td>
<td>Naftidrofuryl</td>
</tr>
<tr>
<td>1193</td>
<td>Nalbuphine</td>
</tr>
<tr>
<td>1194</td>
<td>Nalidixic acid</td>
</tr>
<tr>
<td>1195</td>
<td>Nalorphine</td>
</tr>
<tr>
<td>1196</td>
<td>Naloxone</td>
</tr>
<tr>
<td>1197</td>
<td>Naltrexone</td>
</tr>
<tr>
<td>1198</td>
<td>Nandrolone</td>
</tr>
<tr>
<td>1199</td>
<td>Naproxen; except when specified elsewhere in this schedule</td>
</tr>
<tr>
<td>1200</td>
<td>Naratriptan</td>
</tr>
<tr>
<td>1201</td>
<td>Natalizumab</td>
</tr>
<tr>
<td>1202</td>
<td>Natamycin</td>
</tr>
<tr>
<td>1203</td>
<td>Nateglinide</td>
</tr>
<tr>
<td>1204</td>
<td>Nebacumab</td>
</tr>
<tr>
<td>1205</td>
<td>Nebivolol</td>
</tr>
<tr>
<td>1206</td>
<td>Nedocromil</td>
</tr>
<tr>
<td>1207</td>
<td>Nefazodone</td>
</tr>
<tr>
<td>1208</td>
<td>Nefopam</td>
</tr>
<tr>
<td>1209</td>
<td>Nelfinavir</td>
</tr>
<tr>
<td>1210</td>
<td>Neomycin</td>
</tr>
<tr>
<td>1211</td>
<td>Neostigmine</td>
</tr>
<tr>
<td>1212</td>
<td>Nepafenac</td>
</tr>
<tr>
<td>110</td>
<td></td>
</tr>
</tbody>
</table>
Part 1—continued

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1213</td>
<td>Nerium oleander</td>
<td></td>
</tr>
<tr>
<td>1214</td>
<td>Nesiritide</td>
<td></td>
</tr>
<tr>
<td>1215</td>
<td>Netilmicin</td>
<td></td>
</tr>
<tr>
<td>1216</td>
<td>Nevirapine</td>
<td></td>
</tr>
<tr>
<td>1217</td>
<td>Nialamide</td>
<td></td>
</tr>
<tr>
<td>1218</td>
<td>Nicardipine</td>
<td></td>
</tr>
<tr>
<td>1219</td>
<td>Nicergoline</td>
<td></td>
</tr>
<tr>
<td>1220</td>
<td>Nicofuranose</td>
<td></td>
</tr>
<tr>
<td>1221</td>
<td>Nicorandil</td>
<td></td>
</tr>
<tr>
<td>1222</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>1223</td>
<td>Nicotinic acid except nicotinamide; in medicines containing more than 250 milligrams per dose form</td>
<td></td>
</tr>
<tr>
<td>1224</td>
<td>Nicoumalone</td>
<td></td>
</tr>
<tr>
<td>1225</td>
<td>Nifedipine</td>
<td></td>
</tr>
<tr>
<td>1226</td>
<td>Nifenazone</td>
<td></td>
</tr>
<tr>
<td>1227</td>
<td>Nikethamide</td>
<td></td>
</tr>
<tr>
<td>1228</td>
<td>Nilotinib</td>
<td></td>
</tr>
<tr>
<td>1229</td>
<td>Nilutamide</td>
<td></td>
</tr>
<tr>
<td>1230</td>
<td>Nimesulide</td>
<td></td>
</tr>
<tr>
<td>1231</td>
<td>Nimetazepam</td>
<td></td>
</tr>
<tr>
<td>1232</td>
<td>Nimodipine</td>
<td></td>
</tr>
<tr>
<td>1233</td>
<td>Nimorazole</td>
<td></td>
</tr>
<tr>
<td>1234</td>
<td>Niridazole</td>
<td></td>
</tr>
<tr>
<td>1235</td>
<td>Nisoldipine</td>
<td></td>
</tr>
<tr>
<td>1236</td>
<td>Nitrazepam</td>
<td></td>
</tr>
<tr>
<td>1237</td>
<td>Nitrendipine</td>
<td></td>
</tr>
<tr>
<td>1238</td>
<td>Nitric oxide</td>
<td></td>
</tr>
<tr>
<td>1239</td>
<td>Nitrofurantoin</td>
<td></td>
</tr>
<tr>
<td>1240</td>
<td>Nitrofurazone</td>
<td></td>
</tr>
<tr>
<td>1241</td>
<td>Nitrous oxide</td>
<td></td>
</tr>
<tr>
<td>1242</td>
<td>Nitroxoline</td>
<td></td>
</tr>
</tbody>
</table>
Part 1—continued

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
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
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 Oxrenolol
1306 Oxybuprocairne; 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
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
Part 1—continued

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 Pencilazine
1347 Pencilazine
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
Part 1—continued

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  Phenticillin
1376  Phenformin
1377  Phenglutarimide
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  Phenoxyethylpenicillin
1387  Phensuximide
1388  Phentermine
1389  Phenthimentonium
1390  Phentolamine
Part 1—continued

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
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
Part 1—continued

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
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  Polycrylamide; 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
Part 1—continued

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
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 Probufol
1467 Procainamide
1468 Procaine
1469 Procaine penicillin
1470 Procarbazine
Part 1—continued

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
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
Part 1—continued

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
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
Part 1—continued

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  Razoxxane
1535  Reboxetine
1536  Remifentanil
1537  Remoxifentanil
1538  Repaglinide
1539  Reserpine
1540  Reteplosa
1541  Ribavirin
1542  Rifabutin
1543  Rifampicin
1544  Rifamycin
1545  Rifapentine
1546  Riluzole
1547  Rimexolone
1548  Rimiterol
1549  Rimonabant
1550  Risedronic acid
Part 1—continued

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
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 Salecatonin
1578 Salmeterol
1579 Saquinavir
1580 Saxagliptin
Part 1—continued

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
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
Part 1—continued

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
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
Part 1—continued

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
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 Sulfoxazole
1663 Sulfaphenazole
1664 Sulfaazidine
1665 Sulfasalazine
1666 Sulfathiazole
Part 1—continued

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
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
Part 1—continued

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
1711 Teroperin
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
Part 1—continued

1730  Thiazosulfone
1731  Thiethylperazine
1732  Thioacetazone
1733  Thioacridine
1734  Thioguanine
1735  Thiomesterone
1736  Thiopentone
1737  Thiopropazate
1738  Thiopropazine
1739  Thioridazine
1740  Thiotepa
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
Part 1—continued

1762  Timolol
1763  Tinidazole
1764  Tinzaparin
1765  Ticlonazole; except when specified elsewhere in this schedule
1766  Tiotropium
1767  Tipepine
1768  Tiprinavir
1769  Tirilazad
1770  Tirofiban
1771  Tobramycin
1772  Tocainide
1773  Tocilizumab
1774  Tolazamide
1775  Tolazoline
1776  Tolbutamide
1777  Tolcapone
1778  Tolfenamic acid
1779  Tolmetin
1780  Tolonium
1781  Tolpropanime
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
Part 1—continued

1795 Trazodone
1796 Trenbolone
1797 Treosulphan
1798 Treprostinil
1799 Trestolone
1800 Tretamine
1801 Tretinoin
1802 Triacytyloleandomycin
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 Trifuoperazine
1815 Trifluperidol
1816 Triflupromazine
1817 Trimeprazine; except when specified elsewhere in this schedule
1818 Trimetaphan
1819 Trimethoprim
1820 Trimiptyline
1821 Trimustine
1822 Trinitrophenol
1823 Trioxysalen
Part 1—continued

1824  Triparanol; at all strengths
1825  Triple antigen vaccine
1826  Triploidine; except when specified elsewhere in this schedule
1827  Triptorelin
1828  Troglitazone
1829  Trometamol; for injection in medicines containing more than 3%
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
Part 1—continued

1852 Valnoctamide
1853 Valproic acid
1854 Valsartan
1855 Vancomycin
1856 Vardenafil and its structural analogues
1857 Varenicline
1858 Varicella (chickenpox) vaccine
1859 Vasopressin
1860 Vecuronium
1861 Venlafaxine
1862 Verapamil
1863 Veratrum spp.
1864 Vernakalant
1865 Verteporfin
1866 Vidaclabine
1867 Vigabatrin
1868 Vildagliptin
1869 Vloxazine
1870 Vinblastine
1871 Vincamine
1872 Vincristine
1873 Vinodesine
1874 Vinflunine
1875 Vinoelbline
1876 Vinyl ether
1877 Virginiaimycin
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%
Part 1—continued

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
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
Part 1—continued

1903 Zuclopenthixol

Part 2
Restricted medicines

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

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
Part 2—continued

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.

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.
Part 2—continued

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

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
Part 2—continued

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

41 Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; 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
Part 2—continued

49 Macrogols; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures
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
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 Staphylococcus aureus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds
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

Part 3

Pharmacy-only medicines

1 8-hydroxyquinoline and its non-halogenated derivatives; in medicines containing more than 1% of such substances
Part 3—continued

2  Acetic acid and preparations containing more than 80% of acetic acid (CH₃COOH); 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 andDispensing 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
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 Beclometasone; 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 ac-
tuation 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 dis-
tribution 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
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 con-
tainer 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 Chlphedianol
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
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
Part 3—continued

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

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
Part 3—continued

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 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
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

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

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

Etadefedrine

Ether; in medicines containing more than 10%

Etofenamate; for external use

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

Felbinac; for external use

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

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 ex-
Part 3—continued

cept 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% of hydrocortisone base

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

69 Glutaraldehyde

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 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 Min-
Part 3—continued

ister 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
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
Part 3—continued

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 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
Part 3—continued

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 Methylene
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 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
Part 3—continued

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
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
Part 3—continued

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

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
Part 3—continued

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

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
Part 3—continued

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

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 con-
Part 3—continued

taining 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solana-
ceous 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
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 sympatho-
omicetic decongestant
172 Tuaminoheptane
Part 3—continued

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%
Schedule 2

Form 1
Application for licence to manufacture, hawk, sell, or pack medicine

[Before completing this form you should make yourself familiar with the provisions of the Medicines Act 1981 and the Medicines Regulations 1984, especially those parts that deal with licences.

This form may be used to apply for licences to manufacture, pack, sell, or hawk medicines. It is divided into 7 parts. Every applicant must complete either Part 1 or Part 2, and must also complete at least one of Parts 3, 4, 5, 6, and 7.

Every application must be accompanied by the prescribed fee for each licence applied for (viz, regulation 61, Medicines Regulations 1984).]

The form must be completed in type, or in block capitals.

Part 1

[To be completed where the applicant is an individual applying for a licence on his own behalf.]

Name of applicant: [surname] [first names]
I am a New Zealand resident: Yes/No
Date of birth: [day/month/year]
Address (home):
Name of business:
Street address of business premises:

Postal address:
General nature of business:
Position of applicant (for example, “owner”, “manager” etc):

Have you previously held a licence to manufacture, pack, sell, or hawk medicines? Yes/No
Form 1—continued

If yes give details:

Have you ever been declined, or had revoked, a licence to manufacture, pack, sell, or hawk medicines? Yes/No
If yes give details:

Part 2
[To be completed where the applicant is an officer of a body corporate applying for a licence on behalf of the body corporate.]
Name of body corporate:
The body corporate is incorporated in New Zealand Yes/No
Street address of body corporate:

Postal address:
General nature of business of body corporate:

Name of person completing this form: [surname] [first names]

Position in body corporate of person completing form:

Details of persons nominated to be responsible persons under the Medicines Act 1981:
Form 1—continued

<table>
<thead>
<tr>
<th>Name</th>
<th>Date of birth</th>
<th>Position in body corporate</th>
</tr>
</thead>
</table>

Have any of the above nominees ever been declined, or had revoked, a licence to manufacture, pack, sell, or hawk medicines? **Yes/No**

If **yes** give details:

Have any of the above nominees ever been a licensee or responsible person under the Restricted Drugs Act 1960 or the Medicines Act 1981? **Yes/No**

If **yes** give details:

### Part 3

**Application to manufacture medicines**

I hereby make application for a licence to manufacture the medicines listed below (attach extra list if insufficient space provided here). Indicate (by reference to one of the following paragraphs) which of the following classes the medicines come within:

- **(a)** antibiotics, or preparations of antibiotics:
- **(b)** vaccines and sera:
- **(c)** sterile preparations:
- **(d)** hormones and steroid preparations:
- **(e)** preparations, other than vitamins, having a dose of 5 milligrams or less per unit dose:
- **(f)** antineoplastic agents and immunosuppressant agents other than steroid preparations:
- **(g)** other medicines not included in paragraphs (a) to (f), above.
Form 1—continued

Appropriate designation  Trade name of medicine  Class

Premises where manufacture (including packing and labelling) of the medicines will be carried out:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):
Date:

Part 4
Application to pack medicines
I hereby make application for a licence to pack the medicines listed below (attach extra list if insufficient space provided here). Indicate in the third column whether the medicine is a prescription medicine, restricted medicine, or pharmacy-only medicine.

Appropriate designation  Trade name of medicine  Class
Form 1—continued

Premises where packing and labelling will be carried out:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):
Date:

Part 5
Application to sell medicines by wholesale
I hereby make application to sell by wholesale the following medicines (attach extra list if insufficient space provided here):

Premises from where medicines are to be sold:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):
Date:
Form 1—continued

Part 6
Application to sell medicines by retail
I hereby make application to sell by retail the following medicines (attach extra list if insufficient space provided here):

Premises from where medicines are to be sold:

I declare the above premises are more than 10 kilometres by road from the nearest pharmacy.
The reasons for this application are:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):
Date:

Part 7
Application to hawk medicines
I hereby make application for a licence to hawk medicines.
Premises where stock of medicines will be kept:
Place where records of sale of medicines will be kept:

Geographical area in which it is proposed to hawk medicines:

Persons or classes of persons to whom it is proposed to hawk medicines:

Name and maximum quantity of medicines intended to be transported when hawking:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:


Form 1A r 45A(1)(a)(i)
Application for licence to operate pharmacy
made (by employee or agent) on behalf of
company

Important information
Before filling out this application please note the following important information:

• this form may be used by an employee or agent who is making
an application on behalf of a company:

• you must make yourself familiar with the provisions of the
Medicines Act 1981 and the Medicines Regulations 1984, in
particular those provisions relating to licensing and operating
pharmacies:

• the following must accompany this application:
  • the prescribed fee:
  • a completed statutory declaration:

• it is an offence to make a false statutory declaration:

• the licensing authority may require you to supply additional
information at a later date (see section 55B of the Medicines
Act 1981). If you do not supply that information within 30
days of the request, this application will lapse.

Please complete the following:

Applicant and company

I, [full name of employee or agent of company], [position in company], make this application for a licence to operate a pharmacy on behalf of [name of company], which—

(a) was incorporated in New Zealand on [date of incorporation];
and

(b) has the following board members:

[full names of all board members].

The address of the company is [address].
The following persons are nominated to be responsible persons for the purposes of the licence under the Medicines Act 1981:

[full names, dates of birth, and positions held].
Street address and description of pharmacy

The street address of the pharmacy to which this application relates is [street address].

The pharmacy will comprise the following part or parts of that street address: [specify the part or parts of the street address that are to be a pharmacy or attach a line drawing showing the part or parts].

Interests held in pharmacy

Note: Before filling out this part of the form please read section 5A of the Medicines Act 1981, which sets out the meaning of holding an interest in a pharmacy.

The following person(s) or company (or companies) hold an interest in the pharmacy (as defined in section 5A of the Medicines Act 1981) to which this application relates: [name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or “none” if applicable)].

The following person(s) who hold an interest in the pharmacy to which this application relates is a (or are) practitioner(s) (or registered midwife (midwives)) (or designated prescriber(s)): [name of the interest holder(s) and his or her relevant position (or “none” if applicable)].

Eligibility to hold licence

*The share capital of the company is more than 50% owned by [full name of pharmacist] who is a pharmacist† (or [full names of pharmacists] who are pharmacists) and effective control of the company is vested in the above-named pharmacist (or pharmacists).
†In this context, a pharmacist—

(a) means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy; and

(b) includes an administrator of the estate of a deceased pharmacist, and an assignee within the meaning of the Insolvency Act 1967 of the estate of a pharmacist, until—

(i) the expiry of the period of 1 year after the date of the death of the deceased pharmacist, or the date on which the pharmacist was adjudicated bankrupt; or

or

(ii) subject to any conditions that the licensing authority proposes, the extended period or periods permitted by the licensing authority.

or

*The pharmacy to which this application relates is in a hospital owned or operated by the company. [Specify details.]

or

*[Specify other ground in section 55D(2) of the Medicines Act 1981 that makes the company eligible to hold a licence.]

*Delete if inapplicable.

Practices and procedures for pharmacists working in pharmacy

The following practices and procedures will be in place to ensure that any pharmacist* who is employed or engaged in duties in the pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice: [specify relevant practices and procedures].

*In this context, a pharmacist means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy.
Other pharmacies
The company operates the following pharmacy (or pharmacies):
[name(s) and address(es) of pharmacy (or pharmacies) (or "none" if applicable)].
[Specify number, or “none” if applicable] of those pharmacies are (or is) currently for sale.

*Mortgagee in possession
The company is a mortgagee in possession† of the pharmacy to which this application relates.

*Delete if inapplicable.

†For the purposes of this application a mortgagee in possession has the same meaning as in section 4 of the Property Law Act 2007.

Signature of applicant:

Declaration
I, [full name of agent or employee of the company], of [place], [occupation], solemnly and sincerely declare that the statements made in the above application are true and correct.
I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Declared at [place, date] before me:

[Signature]
Justice of the Peace
(or other person authorised to take a statutory declaration)

Schedule 2 form 1A inserted, on 18 September 2004, by regulation 10 of the Medicines Amendment Regulations 2004 (SR 2004/300).
Form 1A—continued

Form 1B  
 Application for licence to operate pharmacy  
 made by person who is individual (or employee  
 or agent of body corporate that is not company)

**Important information**

Before filling out this application please note the following important information:

- this form may be used by—
  - an individual who is applying for a licence to operate a pharmacy; or
  - an employee or agent of a body corporate (other than a company) who is applying for a licence to operate a pharmacy on behalf of that body corporate (for example, an application made on behalf of a partnership or friendly society):

- you must make yourself familiar with the provisions of the Medicines Act 1981 and the Medicines Regulations 1984, in particular those provisions relating to licensing and operating pharmacies:

- the following **must** accompany this application:
  - the prescribed fee:
  - a completed statutory declaration:

- it is an offence to make a false statutory declaration:

- the licensing authority may require you to supply additional information at a later date (see section 55B of the Medicines Act 1981). If you do not supply that information within 30 days of the request, this application will lapse.

Please complete the following:

**Application (and body corporate)**

I, [full name], of [address], being a resident of New Zealand, apply for a licence to operate a pharmacy on—

*my own behalf.

*on behalf of the body corporate called [name of body corporate],

which—

(a) is not a company, but is a [specify the type of body corporate]; and
Form 1B—continued

(b) was incorporated in New Zealand on [date]; and
(c) has the following board members (or trustees) (or partners):
   [full names of board members (or trustees) (or partners)].

*Delete if inapplicable.

My address (or The address of the body corporate) is [address].
*I was born on [date].
or
*I hold the office of [specify office held] within the above-named body corporate. The following persons are nominated to be responsible persons under the Medicines Act 1981:
   [full names, dates of birth, and positions held].

*Delete if inapplicable.

Street address and description of pharmacy
The street address of the pharmacy to which this application relates is [street address].
The pharmacy will comprise the following part or parts of that street address: [specify the part or parts of the street address that are to be a pharmacy or attach a line drawing showing the part or parts].

Interests held in pharmacy
Note: Before filling out this part of the form please read section 5A of the Medicines Act 1981, which sets out the meaning of holding an interest in a pharmacy.
The following person(s) or company (or companies) hold an interest in the pharmacy (as defined in section 5A of the Medicines Act 1981) to which this application relates: [name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or “none” if applicable)].
The following person(s) who hold an interest in the pharmacy to which this application relates is a (or are) practioner(s) (or registered midwife (midwives)) (or designated prescriber(s)): [name of the interest holder(s) and his or her relevant position (or “none” if applicable)].
Form 1B—continued

Eligibility to hold licence

*I am (or [Name of person in body corporate who has the majority interest] is) a pharmacist for the purposes of this application because I am (or he or she is) a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy.

or

*I am (or The body corporate is) a pharmacist because [specify part of the definition of pharmacist in section 55E(3) of the Medicines Act 1981] applies.

or

*The pharmacy I am (or The body corporate is) applying to operate is in a hospital owned or operated by me (or the body corporate). [Specify details.]

or

*I am (or The body corporate is) eligible to operate a pharmacy because [specify other ground in section 55E(1) of the Medicines Act 1981 that makes person or body corporate eligible to hold a licence].

*Delete if inapplicable.

Practices and procedure for pharmacists working in pharmacy

The following practices and procedures will be in place to ensure that any pharmacist* who is employed or engaged in duties in the pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice: [specify practices and procedures].

*In this context, a pharmacist means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy.
Form 1B—continued

Other pharmacies
I operate (or have a majority interest in) (or The body corporate operates) the following pharmacy (or pharmacies): [name(s) and address(es) of the pharmacy (or pharmacies) (or “none” if applicable).]
[Specify number; or “none” if applicable] of those pharmacies are (or is) currently for sale.

*Mortgagee in possession
I am (or The body corporate is) the mortgagee in possession† of the pharmacy to which this application relates.

*Delete if inapplicable.

†For the purposes of this application a mortgagee in possession has the same meaning as in section 4 of the Property Law Act 2007.

Signature of applicant:

Declaration
I [full name of applicant], of [place], [occupation], solemnly and sincerely declare that the statements made in the above application are true and correct.
I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.
Declared at [place, date] before me:

[Signature]
Justice of the Peace
(or other person authorised to take a statutory declaration)

Schedule 2 form 1B: inserted, on 18 September 2004, by regulation 10 of the Medicines Amendment Regulations 2004 (SR 2004/300).
Schedule 2 form 1B: amended, on 1 August 2011, by regulation 28 of the Medicines Amendment Regulations 2011 (SR 2011/245).
Form 2

Licence to manufacture medicines
(Issued pursuant to the Medicines Act 1981)

Licence No:
Name of licensee:
Address of licensee:
Name of responsible persons:

The *licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to manufacture, pack, label, and sell by wholesale the following medicines or classes of medicines:

*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:
(1) The manufacture, packing, labelling, or sale of the medicines shall be carried out in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
(2) [Further conditions imposed by the licensing authority]:
This licence shall expire on [date].

[Signature]
(Licensing authority)


Form 3
Licence to hawk medicines

(Issued pursuant to the Medicines Act 1981)

Licence No:
Name of licensee:
Address of licensee:
Names of responsible persons:

The *licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to hawk the following medicines:

*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

(1) All sales shall be made in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
(2) The stock of medicines held by the licensee or responsible person shall be stored only at the following place or places:
(3) The records of sale shall be kept at the following premises:
(4) Sales shall only be made within the following geographical area:
(5) Sales shall only be made to the following persons or classes of persons:
(6) [Further conditions imposed by the licensing authority]:

This licence shall expire on [date].
Form 3—continued

[Signature]
(Licensing authority)
Form 4
Licence to sell medicines by wholesale
(Issued pursuant to the Medicines Act 1981)

Licence No:
Name of licensee:
Address of licensee:
Name of responsible persons:

Address of business premises:

The *licensee or every responsible person named above is hereby
authorised pursuant to section 51 of the Medicines Act 1981 to sell
by wholesale the following medicines:

*Delete whichever does not apply.

The authority granted by this licence is subject to the following
conditions:
(1) The sale of the above medicines shall not take place other than
at the business premises set out above.
(2) All sales shall be made in accordance with the Medicines
(3) [Further conditions imposed by the licensing authority]:

This licence shall expire on [date].
Form 4—continued

[Signature]
(Licensing authority)


Form 5
Licence to sell medicines by retail

(Issued pursuant to the Medicines Act 1981)

Licence No:
Name of licensee:
Address of licensee:
Name of responsible persons:

Address of business premises:

The *licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to sell by retail, and supply in circumstances corresponding to retail sale, the following medicines:

*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

(1) The sale of the above medicines shall not take place other than at the business premises set out above.

(2) All sales shall be made in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.

(3) [Further conditions imposed by the licensing authority]:

This licence shall expire on [date].

180
Form 5—continued

[Signature]
(Licensing authority)


Form 6
Licence to pack medicines

(Issued pursuant to the Medicines Act 1981)

Licence No:
Name of licensee:
Address of licensee:
Names of responsible persons:

Address of business premises:

The *licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to pack or label for the purpose of sale, and sell by wholesale the following medicines:

*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

(1) The packing, labelling, or sale of the medicines shall be carried out in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.

(2) [Further conditions imposed by the licensing authority]:

This licence shall expire on [date].
[Signature]
(Licensing authority)


Form 7

Licence to operate pharmacy

Section 51, Medicines Act 1981

Licence No:
This licence to operate a pharmacy is granted to [full name of person or body corporate] of [address] and authorises—

• the establishment of a pharmacy at [location] (or in the following part or parts of [location]: [specify relevant part or parts]); and

• the carrying on of pharmacy practice in that pharmacy.

*Names of responsible persons for body corporate:

*Delete if inapplicable.

The pharmacy must be operated in accordance with the duties and obligations in the Medicines Act 1981.

This licence is subject to the following conditions:

(a) the holder of this licence must not request or require any pharmacist who is employed or engaged in duties at the above-named pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice:

(b) [specify any other conditions].

This licence expires on [date].

[Signature]
(Licensing authority)

Schedule 3

Loose sheet data sheet requirements

[Revoked]

Schedule 3: revoked, on 1 August 2011, by regulation 29 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Schedule 4

r 56(2)(a)

Hawker’s Medicines book

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Form</th>
<th>Strength</th>
<th>Page</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and address of supplier of medicine</th>
<th>Order No</th>
<th>In</th>
<th>Out</th>
<th>Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Name and address of person to whom medicine sold</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

185
Schedule 5  
Analyst’s certificate under the Medicines Act 1981

I, [name], an analyst under the Medicines Act 1981, certify that on [date] there was submitted to me by [name and address of the officer from whom the sample was received] an officer within the meaning of that Act, a sample of [name or description of sample] for analysis in a [nature of the package in which the sample was enclosed, and how it was labelled, marked, and sealed] and that the same has been analysed and that the result of the analysis is as follows [analysis and observations]:

Date:

[Signature]
Analyst
Schedule 5A

**Licence fees**


<table>
<thead>
<tr>
<th>Licence Type</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 An application for a licence to manufacture medicines</td>
<td>$13,750</td>
</tr>
<tr>
<td>2 An application for a licence to pack medicines</td>
<td>$845</td>
</tr>
<tr>
<td>3 An application for a licence to sell medicines by retail</td>
<td>$845</td>
</tr>
<tr>
<td>4 An application for a licence to sell medicines by wholesale</td>
<td>$1,054</td>
</tr>
<tr>
<td>5 An application for a licence to hawk medicines</td>
<td>$845</td>
</tr>
<tr>
<td>6 An application for a combined licence to pack, and to sell by retail, medicines</td>
<td>$300</td>
</tr>
<tr>
<td>7 An application for a licence to operate a pharmacy</td>
<td>$1,030</td>
</tr>
</tbody>
</table>
Schedule 6
Regulations revoked

Part A
Restricted drugs

Restricted Drugs Regulations 1964 (SR 1964/64)

Restricted Drugs Regulations 1964, Amendment No 1 (SR 1966/84)

Restricted Drugs Regulations 1964, Amendment No 2 (SR 1967/250)

Restricted Drugs Regulations 1964, Amendment No 3 (SR 1969/95)

Restricted Drugs Regulations 1964, Amendment No 4 (SR 1969/193)

Restricted Drugs Regulations 1964, Amendment No 5 (SR 1971/55)

Restricted Drugs Regulations 1964, Amendment No 6 (SR 1972/53)

Restricted Drugs Regulations 1964, Amendment No 7 (SR 1972/163)

Restricted Drugs Regulations 1964, Amendment No 8 (SR 1973/111)

Restricted Drugs Regulations 1964, Amendment No 9 (SR 1974/93)

Restricted Drugs Regulations 1964, Amendment No 10 (SR 1974/133)

Restricted Drugs Regulations 1964, Amendment No 11 (SR 1975/25)
Part A—continued

Restricted Drugs Regulations 1964, Amendment No 12 (SR 1977/130)

Restricted Drugs Regulations 1964, Amendment No 13 (SR 1978/52)

Restricted Drugs Regulations 1964, Amendment No 14 (SR 1979/37)

Restricted Drugs Regulations 1964, Amendment No 15 (SR 1979/273)

Restricted Drugs Regulations 1964, Amendment No 16 (SR 1981/120)

Restricted Drugs Regulations 1964, Amendment No 17 (SR 1982/32)

Restricted Drugs Regulations 1964, Amendment No 18 (SR 1982/248)

Restricted Drugs Regulations 1964, Amendment No 19 (SR 1983/132)

Restricted Drugs Regulations 1964, Amendment No 20 (SR 1983/289)

Restricted Drugs Regulations 1964, Amendment No 21 (SR 1984/78)

Part B
Restricted drugs licences

Restricted Drug Licences Regulations 1961 (SR 1961/39)

Restricted Drug Licences Regulations 1961, Amendment No 1 (SR 1963/123)
Part B—continued

Restricted Drug Licences Regulations 1961, Amendment No 2 (SR 1983/133)

Part C

Therapeutic drugs (permitted sales)

Therapeutic Drugs (Permitted Sales) Regulations 1978 (SR 1978/34)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 1 (SR 1978/230)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 2 (SR 1979/168)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 3 (SR 1980/114)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 4 (SR 1980/264)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 5 (SR 1981/119)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 6 (SR 1981/324)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 7 (SR 1982/189)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 8 (SR 1983/20)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 9 (SR 1983/73)
Part C—continued

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 10 (SR 1983/147)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 11 (SR 1983/205)

Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 12 (SR 1984/41)

P G Millen,
Clerk of the Executive Council.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in Gazette: 7 June 1984.
Contents
1 General
2 Status of reprints
3 How reprints are prepared
4 Changes made under section 17C of the Acts and Regulations Publication Act 1989
5 List of amendments incorporated in this reprint (most recent first)

Notes
1 General
This is a reprint of the Medicines Regulations 1984. The reprint incorporates all the amendments to the regulations as at 1 August 2011, as specified in the list of amendments at the end of these notes.
Relevant provisions of any amending enactments that contain transitional, savings, or application provisions that cannot be compiled in the reprint are also included, after the principal enactment, in chronological order. For more information, see http://www.pco.parliament.govt.nz/reprints/.

2 Status of reprints
Under section 16D of the Acts and Regulations Publication Act 1989, reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by the amendments to that enactment. This presumption applies even though editorial changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in the reprint.
This presumption may be rebutted by producing the official volumes of statutes or statutory regulations in which the principal enactment and its amendments are contained.

3 How reprints are prepared
A number of editorial conventions are followed in the preparation of reprints. For example, the enacting words are not included in Acts, and provisions that are repealed or revoked
are omitted. For a detailed list of the editorial conventions, see http://www.pco.parliament.govt.nz/editorial-conventions/ or Part 8 of the Tables of New Zealand Acts and Ordinances and Statutory Regulations and Deemed Regulations in Force.

4 Changes made under section 17C of the Acts and Regulations Publication Act 1989

Section 17C of the Acts and Regulations Publication Act 1989 authorises the making of editorial changes in a reprint as set out in sections 17D and 17E of that Act so that, to the extent permitted, the format and style of the reprinted enactment is consistent with current legislative drafting practice. Changes that would alter the effect of the legislation are not permitted.

A new format of legislation was introduced on 1 January 2000. Changes to legislative drafting style have also been made since 1997, and are ongoing. To the extent permitted by section 17C of the Acts and Regulations Publication Act 1989, all legislation reprinted after 1 January 2000 is in the new format for legislation and reflects current drafting practice at the time of the reprint.

In outline, the editorial changes made in reprints under the authority of section 17C of the Acts and Regulations Publication Act 1989 are set out below, and they have been applied, where relevant, in the preparation of this reprint:

• omission of unnecessary referential words (such as “of this section” and “of this Act”)
• typeface and type size (Times Roman, generally in 11.5 point)
• layout of provisions, including:
  • indentation
  • position of section headings (eg, the number and heading now appear above the section)
• format of definitions (eg, the defined term now appears in bold type, without quotation marks)
• format of dates (eg, a date formerly expressed as “the 1st day of January 1999” is now expressed as “1 January 1999”)
Medicines Regulations 1984  
Reprinted as at 1 August 2011

- position of the date of assent (it now appears on the front page of each Act)
- punctuation (eg, colons are not used after definitions)
- Parts numbered with roman numerals are replaced with arabic numerals, and all cross-references are changed accordingly
- case and appearance of letters and words, including:
  - format of headings (eg, headings where each word formerly appeared with an initial capital letter followed by small capital letters are amended so that the heading appears in bold, with only the first word (and any proper nouns) appearing with an initial capital letter)
  - small capital letters in section and subsection references are now capital letters
- schedules are renumbered (eg, Schedule 1 replaces First Schedule), and all cross-references are changed accordingly
- running heads (the information that appears at the top of each page)
- format of two-column schedules of consequential amendments, and schedules of repeals (eg, they are rearranged into alphabetical order, rather than chronological).

5 List of amendments incorporated in this reprint (most recent first)

Medicines Amendment Regulations 2011 (SR 2011/245)
District Courts Rules 2009 (SR 2009/257): rule 17.1
Medicines (Fees) Amendment Regulations 2006 (SR 2006/188)
Medicines Amendment Regulations 2006 (SR 2006/158)
Medicines Amendment Regulations 2005 (SR 2005/255)
Medicines Amendment Regulations 2004 (SR 2004/300)
Health Practitioners Competence Assurance Act 2003 (2003 No 48): section 175(3)
Medicines Amendment Regulations (No 2) 2002 (SR 2002/374)
Health and Disability Services (Safety) Act 2001 (2001 No 93): section 58(3)
Medicines Amendment Regulations 2001 (SR 2001/232)
Medicines Amendment Regulations 2000 (SR 2000/220)
Medicines Amendment Regulations 1997 (SR 1997/165)
Medicines Regulations 1984, Amendment No 6 (SR 1994/299)
Health Amendment Act 1993 (1993 No 24): section 38(3)
Medicines Regulations 1984, Amendment No 5 (SR 1992/43)
Medicines Regulations 1984, Amendment No 4 (SR 1991/134)
Medicines Regulations 1984, Amendment No 3 (SR 1990/221)