STATUTORY RULES

1970 No. 165

REGULATIONS UNDER THE THERAPEUTIC GOODS ACT 1966*

I, THE GOVERNOR-GENERAL in and over the Commonwealth of Australia, acting with the advice of the Federal Executive Council, hereby make the following Regulations under the *Therapeutic Goods Act* 1966.

Dated this twenty-second day of October, 1970.

Paul Hasluck
Governor-General.

By His Excellency's Command,

Sgd. A. J. Forbes
Minister of State for Health.

THERAPEUTIC GOODS REGULATIONS

PART I.—PRELIMINARY.

Citation.

1. These Regulations may be cited as the Therapeutic Goods Regulations.

Commencement.

2. These Regulations shall come into operation on the day fixed under section 2 of the Act.

Parts.

3. These Regulations are divided into Parts as follows:—

Part I.—Preliminary (Regulations 1-4).
Part II.—Examination, Testing and Analysing of Goods (Regulations 5-16).
Part III.—Committees (Regulations 17-25).

Definitions.

4. In these Regulations, unless the contrary intention appears—

"official analyst" means the person holding, or performing the duties of, the office referred to in sub-regulation (1.) of regulation 9 of these Regulations or a person appointed to be an official analyst under sub-regulation (2.) of that regulation;
"the Act" means the *Therapeutic Goods Act* 1966;
"the Director-General" means the Director-General of Health.

PART II.—EXAMINATION, TESTING AND ANALYSING OF GOODS.

Interpretation.

5. In this Part, "authorized person" means a person appointed by the Director-General under the next succeeding regulation to be an authorized person.

Authorized person for the purposes of section 24 of the Act.

6. The Director-General may, by writing under his hand, appoint a person to be an authorized person for the purposes of this Part.

Power of authorized persons.

7. An authorized person is empowered, at all reasonable times and on production of his authority—

(*a*) to take, and to enter upon premises for the purpose of taking, samples of goods to which section 24 of the Act applies; and

* Notified in the *Commonwealth Gazette* on 29 Oct 1970.
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(*b*) to make examinations and inquiries with respect to matters relating to goods to which section 24 of the Act applies.

Appointment of laboratories.

8. The following laboratories are appointed as laboratories for the examination, testing and analysing of goods to which section 24 of the Act applies:—

(*a*) the National Biological Standards Laboratory; and

(*b*) any laboratory in the Department of Customs and Excise.

Appointment of official analysts.

9.—(1.) The person for the time being holding the office, or performing the duties of the office, of Director of the National Biological Standards Laboratory is an official analyst for the purposes of these Regulations.

(2.) The Director-General may, by writing under his hand, appoint a person who has the necessary qualifications to be an official analyst for the purposes of these Regulations.

Taking of samples for testing.

10.—(1.) Where an authorized person has taken a sample of goods to which section 24 of the Act applies, the authorized person—

(*a*) shall forthwith notify the person from whom the sample was taken of the intention of the authorized person to submit the sample to an official analyst for the carrying out of examinations, tests and analyses under these Regulations; and

(*b*) shall then—

(i) in a case where it is practicable so to do—divide the sample into three parts and fasten and seal each part in accordance with sub-regulation (4.) of this regulation; or

(ii) in any other case—fasten and seal the whole sample in accordance with sub-regulation (4.) of this regulation.

(2.) Where the sample is divided into three parts, the authorized person shall—

(*a*) forward one part to the person from whom the sample was taken;

(*b*) forward another part to an official analyst for the carrying out of examinations, tests and analyses under these Regulations; and

(*c*) retain the remaining part.

(3.) Where the sample is not divided into three parts, the authorized person shall forward the whole sample to an official analyst for the carrying out of examinations, tests and analyses.

(4.) Where, under sub-regulation (1.) of this regulation, a sample is required, or parts of a sample are required, to be fastened and sealed, the sample or parts of a sample shall be so fastened and sealed in a vessel or package marked with the name and address of the person from whom the sample was taken as to prevent the opening of the vessel or package, or the removal of that name and address, without breaking the seal.

Examination, &c., by official analyst.

11.—(1.) Subject to the next succeeding sub-regulation, an official analyst shall, as soon as practicable after the receipt by him of a sample or part of a sample of goods forwarded to him by an authorized person—

(*a*) carry out, at a laboratory appointed under regulation 8 of these Regulations, in accordance with any relevant tests, such examinations, tests and analyses as are necessary to establish the composition, strength, potency, stability, sterility, quantity, quality and method of preparation of the goods comprising the sample or part of the sample and to establish any other matter relevant to determining whether the goods from which the sample was taken comply with the standard or standards applicable to them; and

(*b*) examine the goods, the label relating to the goods and the manner in which the goods have been packed, including the container in which the goods were packed, to determine whether the goods comply with all or any of the labelling and packaging requirements applicable to the goods and having effect by virtue of an order made under section 15 of the Act.

(2.) Where, before an official analyst has completed all the examinations, tests and analyses of a sample of goods that, but for this sub-regulation, would be necessary for the purpose of paragraph (*a*) of the last preceding sub-regulation, the examinations, tests and analyses of the sample carried out by him show that the goods do not conform to a particular standard, being a standard applicable to the goods, the last preceding sub-regulation does not require the official analyst to carry out any further examinations, tests or analyses of the sample.

Certificate of official analyst.

12.—(1.) An official analyst who carries out examinations, tests and analyses of a sample or part of a sample of goods that has been forwarded to him by an authorized person—

(*a*) shall forward to the authorized person a certificate, signed by him, setting out the results of the examinations, tests and analyses;

(*b*) shall forward a copy of the certificate, being a copy signed by him, to the person from whom the sample was taken; and

(*c*) if required by the Director-General to do so, shall also forward a copy of the certificate, being a copy so signed, to the Director-General.

(2.) Subject to the next succeeding sub-regulation, where an official analyst forwards a copy of a certificate relating to goods as required by the last preceding sub-regulation and the name and address of—

(*a*) if the goods were imported into Australia—the importer of the goods; or

(*b*) in any other case—the manufacturer of the goods,

is known to the official analyst, the official analyst shall forward a copy of the certificate, being a copy signed by him, to the importer or manufacturer, as the case may be, of the goods.

(3.) The last preceding sub-regulation does not apply if the person from whom the sample of the goods was taken was—

(*a*) in the case of goods imported into Australia—the importer of the goods; or

(*b*) in the case of any other goods—the manufacturer of the goods.

(4.) Subject to sub-regulation (7.) of regulation 13 of these Regulations, in any legal proceedings under the Act or the *Customs Act* 1901-1968, a certificate of an official analyst issued under sub-regulation (1.) of this regulation or a copy of such a certificate, being a copy signed by an official analyst, is evidence of the facts stated in it.

(5.) A document purporting to be—

(*a*) a certificate of an official analyst issued under sub-regulation (1.) of this regulation; or

(*b*) a copy of such a certificate,

and to be signed by an official analyst shall, unless the contrary is proved, be deemed to be such a certificate, or a copy of such a certificate, as the case may be, and, unless the contrary is proved, the certificate, or the certificate of which the document purports to be a copy, shall be deemed to have been duly issued.

Review of examination, &c., of official analyst.

13.—(1.) Where a sample of goods to which section 24 of the Act applies, or a part of such a sample, has been examined, tested and analysed by an official analyst in accordance with this Part and the official analyst has stated in a certificate issued under sub-regulation (1.) of the last preceding regulation that the goods do not conform to a specified standard, being a standard applicable to the goods, a prescribed person may, not later than twenty-one days after receipt of a copy of the certificate, submit to the Director-General evidence in writing that the goods do conform to that specified standard and request that the result of the examination, testing and analysing be reviewed.

(2.) In the application of the last preceding sub-regulation to goods—

(*a*) the person from whom a sample of the goods was taken; and

(*b*) if that person is not the importer or manufacturer of the goods—

(i) in the case of goods that were imported into Australia—the importer of the goods; or

(ii) in any other case—the manufacturer of the goods,

are each a prescribed person.

(3.) Where a sample of goods has been divided into three parts, a person shall be deemed not to have submitted to the Director-General evidence that the goods conform to a particular standard unless he has submitted to the Director-General a certificate, under the hand of a duly qualified analyst, certifying—

(*a*) that the analyst has examined, tested and analysed a part of the sample of those goods;

(*b*) the results of that examination, testing and analysing; and

(*c*) whether the examination, testing and analysing was carried out in accordance with any relevant tests.

(4.) Where—

(*a*) after a certificate under sub-section (1.) of the last preceding regulation has been issued stating that specified goods do not conform to a specified standard, evidence that the goods do conform to that standard is duly submitted to the Director-General under sub-regulation (1.) of this regulation; and

(*b*) that evidence, being, in the case of goods in respect of which a sample was divided into three parts, the certificate in accordance with the last preceding sub-regulation that was submitted to the Director-General with respect to the goods, shows that any examination, testing and analysing of the goods for the purpose of establishing that the goods conform to the standard were carried out in accordance with any relevant tests,

the next succeeding sub-regulation applies to the goods.

(5.) Where this sub-regulation applies to goods, the Director-General shall, unless the results of the testing of a sample of the goods shows a lack of homogeneity in the sample, direct—

(*a*) if the sample of the goods had been divided into three parts—the authorized person who took the sample to forward the part of the sample that he had retained; or

(*b*) if the sample was not divided into three parts but part of the sample remains unimpaired—the official analyst to forward so much of the sample as remains unimpaired,

to an analyst agreed upon by the person who requested the review and the official analyst, or, in the absence of agreement, to an analyst nominated by the Director-General.

(6.) Where part of a sample is forwarded to an analyst in accordance with the last preceding sub-regulation, the analyst shall—

(*a*) examine, test and analyse the part of the sample of the goods in accordance with any relevant tests;

(*b*) forward to the person from whom the sample was taken a certificate, signed by the analyst, setting out the results of the examinations, tests and analyses; and

(*c*) forward copies of that certificate, being copies signed by the analyst—

(i) to the Director-General; and

(ii) if the person from whom the sample was taken was not the person who submitted evidence to the Director-General in relation to the goods—to the person who so submitted evidence.

(7.) A certificate stating the results of the examination, testing and analysing of a sample or part of a sample of goods issued by the official analyst under the last preceding regulation ceases to have effect upon the forwarding of a certificate in relation to those goods by an analyst under the last preceding sub-regulation.

(8.) In any legal proceedings under the Act or the *Customs Act* 1901-1968, a certificate of an analyst issued under sub-regulation (6.) of this regulation or a copy of such a certificate, being a copy signed by the analyst, is evidence of the facts stated in it.

(9.) A document purporting to be—

(*a*) a certificate of an analyst issued under sub-regulation (6.) of this regulation; or

(*b*) a copy of such a certificate,

and to be signed by an analyst shall, unless the contrary is proved, be deemed to be such a certificate, or a copy of such a certificate, as the case may be, and, unless the contrary is proved, the certificate, or the certificate of which the document purports to be a copy, shall be deemed to have been duly issued.

Relevant tests of goods.

14.—(1.) In this Part, a reference to any relevant test in relation to the examination, testing and analysing of goods shall be read as a reference to any test that is, by virtue of a succeeding sub-regulation of this regulation, a relevant test for the purpose of determining whether goods of a class in which those goods are included are of a particular standard.

(2.) Where the Minister has, by order under section 14 of the Act, specified a test in accordance with which a matter relating to a standard for a substance or article is to be determined, that test is a relevant test, in relation to the examination, testing and analysing of goods that consist, or are represented to consist, of the substance or article, for the purpose of determining whether the goods are of that standard.

(3.) Where goods are for human use, the goods are the subject of a monograph in the British Pharmacopoeia and a test for determining a matter relating to a standard for a substance or article of which the goods consist, or are represented to consist, is also set out in the monograph, the test so set out is a relevant test for the purpose of determining whether the goods are of that standard unless there is a relevant test for that purpose by virtue of the last preceding sub-regulation.

(4.) Where goods are for human use, the goods are the subject of a monograph in the British Pharmaceutical Codex and a test for determining a matter relating to a standard for a substance or article of which the goods consist, or are represented to consist, is also set out in the monograph, the test so set out is a relevant test for the purpose of determining whether the goods are of that standard unless there is a relevant test for that purpose by virtue of either of the last two preceding sub-regulations.

(5.) Where goods are for veterinary use, the goods are the subject of a monograph in the British Veterinary Codex and a test for determining a matter relating to a standard for a substance or article of which the goods consist, or are represented to consist, is set out in the monograph, the test so set out is a relevant test for the purpose of determining whether the goods are of that standard unless there is a relevant test for that purpose by virtue of sub-regulation (2.) of this regulation.

Payment for samples.

15.—(1.) Where a sample of goods to which section 24 of the Act applies is taken by an authorized person, payment for the quantity of goods taken as the sample shall be made by the Commonwealth to the person from whom the sample was taken or, where that person was not the owner of the sample, to the owner, at the current market value for which that person or the owner, as the case may be, could have supplied or sold the goods taken as the sample in the normal course of his business at the time the sample was taken.

(2.) The last preceding sub-regulation does not apply to a sample of goods if there is, for the purposes of the Act, a standard applicable to those goods and the sample does not conform to that standard.

Offences.

16.—(1.) A person shall not—

(*a*) make or present to the Minister or to a person performing a function or exercising a power under these Regulations a statement or document that is false or misleading in a material particular;

(*b*) molest, obstruct or endeavour to intimidate or influence an authorized person in the execution of his powers or the performance of his duties under these Regulations; or

(*c*) upon the request of an authorized person, refuse or omit—

(i) to show the authorized person the place at which any goods for therapeutic use are kept;

(ii) to admit the authorized person into a place at which goods for therapeutic use are kept;

(iii) to show the authorized person, or permit the authorized person to inspect, any goods for therapeutic use kept by the person;

(iv) to give a sample of goods for therapeutic use;

(v) to answer any inquiry made by the authorized person; or

(vi) to assist the authorized person in the execution of his powers or the performance of his duties under these Regulations.

Penalty: Two hundred dollars or imprisonment for six months.

(2.) A person is not excused from furnishing information in response to an inquiry by an authorized person on the ground that the information might tend to incriminate him, but his furnishing of any information in response to the inquiry is not admissible in evidence against him in any criminal proceedings, other than proceedings under the Act or these Regulations.

PART III.—COMMITTEES.

Therapeutic Goods Advisory Committee.

17.—(1.) There shall be a Committee to be known as the Therapeutic Goods Advisory Committee.

(2.) The Committee shall consist of—

(*a*) the Director-General;

(*b*) the person for the time being holding the position, or performing the duties, of the Director of the National Biological Standards Laboratory;

(*c*) an officer of the Department of Health, appointed by the Minister, not being the officer referred to in the last preceding paragraph;

(*d*) a person appointed by the Minister on the nomination of the Federal Council of the Australian Medical Association;

(*e*) a person appointed by the Minister on the nomination of the Council of the Australian Veterinary Association;

(*f*) a person appointed by the Minister on the nomination of the Federated Pharmaceutical Service Guild of Australia; and

(*g*) three persons appointed by the Minister on the nomination of the National Council of Chemical and Pharmaceutical Industries.

(3.) Subject to the next succeeding sub-regulation, the functions of the Committee are to consider—

(*a*) any matter referred to it by the Minister relating to the administration of the Act; and

(*b*) the standards applicable to any goods for therapeutic use, and the requirements with respect to labelling and packaging applicable to any such goods, in so far as those standards or requirements relate to the manufacture, distribution or use of goods for therapeutic use,

and to advise the Minister in relation to that matter or those standards.

(4.) The Committee is not empowered to consider any matters relating to, or arising out of the operation of, section 29 of the Act.

Therapeutic Goods Standards Committee.

18.—(1.) There shall be a Committee to be known as the Therapeutic Goods Standards Committee.

(2.) The Committee shall consist of—

(*a*) the Director-General;

(*b*) the person for the time being holding the position, or performing the duties, of the Director of the National Biological Standards Laboratory;

(*c*) an analyst appointed by the Minister on the nomination of the Comptroller-General of Customs and Excise;

(*d*) a person appointed by the Minister on the nomination of the Pharmaceutical Association of Australia; and

(*e*) seven other persons appointed by the Minister in accordance with the succeeding provisions of this regulation.

(3.) Subject to the next succeeding sub-regulation, the persons whom the Minister appoints in pursuance of paragraph (*e*) of the last preceding sub-regulation shall be expert in one or more of the fields of human therapeutics, veterinary therapeutics, pharmacy, pharmaceutics, pharmacology, bacteriology, pathology, epidemiology, virology, endocrinology, antibiotics, chemistry, biophysics or biometrics.

(4.) The persons to be appointed by the Minister in pursuance of paragraph (*c*) of sub-regulation (2.) of this regulation shall include—

(*a*) at least one person who is an expert in pharmacy;

(*b*) at least one person who is an expert in medicine; and

(*c*) at least one person who is an expert in veterinary science.

(5.) The functions of the Committee are to inquire into the standards and matters relating to the standards applicable to any goods for therapeutic use and the requirements with respect to labelling and packaging applicable to any such goods and to furnish advice to the Minister in relation to those standards or those requirements.

(6.) If the Minister becomes aware that a member of the Committee appointed by him will be unable to attend a meeting or meetings of the Committee, the Minister may—

(*a*) in the case of the member appointed on the nomination of the Pharmaceutical Association of Australia—appoint another person nominated by that Association; or

(*b*) in the case of a person appointed in pursuance of paragraph (*e*) of sub-regulation (2.) of this regulation—appoint a person who is an expert in the same field as the member or, if such a person is not available, a person who is an expert in one or more of the other fields specified in sub-regulation (3.) of this regulation,

to act instead of that member at the meeting or meetings from which he will be absent, and the person so appointed shall, while so acting, be deemed to be a member of the Committee.

(7.) The Committee may appoint a sub-committee consisting of such members of the Committee and such other persons, if any, as the Committee thinks fit for the purpose of inquiring into, and reporting to the Committee on, any matter that is within the functions of the Committee.

Australian Drug Evaluation Committee.

19.—(1.) There shall be a Committee to be known as the Australian Drug Evaluation Committee.

(2.) The Committee shall consist of not less than six and not more than eight members, who shall be appointed by the Minister.

(3.) The Minister shall, in appointing members of the Committee, ensure that the members include—

(*a*) not less than four persons each of whom is a medical practitioner eminent in his profession and of whom at least three are specialists in clinical medicine; and

(*b*) not less than two persons, each of whom is a pharmacologist or a person who has been admitted to a degree in science or a branch of science by an Australian university or an overseas university and has specialized in pharmaceutical science.

(4.) The Minister shall appoint one of the members of the Committee to be chairman of the Committee.

(5.) The functions of the Committee are—

(*a*) to make medical and scientific evaluations of such goods for therapeutic use as the Minister refers to it for evaluation;

(*b*) to make medical and scientific evaluations of other goods for therapeutic use if, in the opinion of the Committee, it is desirable that it should do so; and

(*c*) to furnish such advice to the Minister as the Committee considers necessary relating to the importation into, and the distribution within, Australia of goods for therapeutic use that have been the subject of evaluations made by the Committee.

(6.) The Committee may appoint a sub-committee, consisting of such members of the Committee, and such other persons, if any, as the Committee thinks fit, for the purpose of enquiring into, and reporting to the Committee on, any matter that is within the functions of the Committee.

Minister may seek further advice.

20. Where a Committee established under this Part has furnished advice to the Minister, the Minister may, if he considers it desirable in the circumstances to do so, forward a copy of that advice to another Committee established under this Part and that Committee may furnish the Minister with such comments in relation to that advice as the Committee thinks fit.

Chairmen of Committees.

21.—(1.) Subject to this regulation, the Director-General is the chairman of any Committee established under this Part of which he is a member.

(2.) The Director-General may, from time to time, by writing under his hand, appoint an officer of the Department of Health to act as a member of a Committee in his stead, and the officer so appointed shall, until his appointment is revoked, be a member and the chairman of the Committee in the place of the Director-General.

(3.) In this regulation, "Committee" does not include the Australian Drug Evaluation Committee.

Tenure of office of members.

22.—(1.) A member of a Committee established under this Part who is appointed by the Minister holds office for three years unless he is removed from office before the expiration of that period under sub-regulation (3.) of this regulation.

(2.) A member is eligible for re-appointment.

(3.) The Minister may, by writing under his hand, remove a member from office at any time.

Meetings of Committees.

23.—(1.) Meetings of a Committee established under this Part shall be held at such times and places as the chairman of the Committee directs.

(2.) At a meeting of a Committee—

(*a*) in the case of the Australian Drug Evaluation Committee—

(i) if less than seven members of the Committee are in Australia when a meeting is held—three members constitute a quorum; or

(ii) in any other case—four members constitute a quorum; or

(*b*) in the case of any other Committee—five members constitute a quorum.

(3.) The chairman of a Committee shall preside at all meetings of the Committee at which he is present.

(4.) In the absence of the chairman of a Committee from a meeting of the Committee, the members of the Committee present at the meeting shall appoint one of their number to preside at that meeting, and the member so appointed has and may exercise and perform at that meeting all the powers and functions of the chairman.

(5.) A question arising at a meeting of a Committee shall be determined by a majority of votes of the members present and voting on the question.

(6.) The chairman or other member presiding at a meeting of a Committee has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

Powers and functions of Committee where vacancy occurs.

24. The exercise and performance of the powers and functions of a Committee established under this Part is not affected by reason only of there being a vacancy in the office of a member of that Committee.

Remuneration and allowances of members of Committees.

25.—(1.) This regulation does not apply to a member of a Committee established under this Part who is an officer of the Public Service of the Commonwealth or of a State.

(2.) Subject to the next succeeding sub-regulation, the remuneration payable to a member of a Committee is—

(*a*) if the member is the Chairman of the Committee—Forty dollars; or

(*b*) in any other case—Thirty-five dollars,

for each day on which he attends a meeting of the Committee.

(3.) Where the duration of a meeting of a Committee on a day is less than three hours, the remuneration payable to a member of the Committee in respect of his attendance at the meeting on that day is—

(*a*) if the member is the Chairman of the Committee—Twenty-five dollars; or

(*b*) in any other case—Twenty dollars.

(4.) The chairman or a member of a Committee who is necessarily absent from his home overnight in connexion with his attendance at a meeting of a Committee shall be paid a travelling allowance—

(*a*) at a daily rate of Twenty-one dollars for each complete day during which he is so absent; or

(*b*) at an hourly rate that is one twenty-fourth part of the daily rate for each hour or part of an hour if the period during which he is so absent amounts to less than a day or consists of a day or number of days plus a number of hours.

(5.) The payment of travelling allowance under this regulation is in addition to the cost of transport fares.

(6.) The cost of return transport fares actually and necessarily incurred by a member of a Committee in travelling between his place of residence and the place where the meeting of the Committee is held shall be borne by the Commonwealth.

(7.) Subject to the next succeeding sub-regulation, this regulation applies to and in relation to a sub-committee of a Committee established under this Part as if—

(*a*) a reference to a member of a Committee were read as a reference to a member of such a sub-committee;

(*b*) a reference to a meeting of a Committee were read as a reference to a meeting of such a sub-committee; and

(*c*) a reference to the Chairman of a Committee were read as a reference to the Chairman of such a sub-committee.

(8.) Where a person attends a meeting of a Committee and a meeting of a sub-committee of the Committee on the same day, this regulation applies to and in relation to the member as if the second of those meetings that he attended on that day were a continuation of the first of those meetings that he attended on that day.

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