**Commonwealth Serum Laboratories Amendment Act 1980**

**No. 7 of 1980**

**An Act to amend the *Commonwealth Serum Laboratories Act* 1961**

[*Assented to 24 March 1980*]

BE IT ENACTED by the Queen, and the Senate and House of Representatives of the Commonwealth of Australia, as follows:

**Short title, &c.**

**1.** **(1)** This Act may be cited as the *Commonwealth Serum Laboratories Amendment Act* 1980.

**(2)** The *Commonwealth Serum Laboratories Act* 1961 is in this Act referred to as the Principal Act.

**Commencement**

**2.** This Act shall come into operation on 1 July 1980.

**3.** Section 4 of the Principal Act is repealed and the following section is substituted:

**Interpretation**

“4. (1) In this Act, unless the contrary intention appears—

‘appoint’ includes re-appoint;

‘approved bank’ means a trading bank as defined by sub-section 5 (1) of the *Banking Act* 1959 or another bank approved by the Treasurer;

‘Chairman’ means the Chairman of the Commission, and includes a Commissioner acting as Chairman under section 11;

‘Commission’ means the Commonwealth Serum Laboratories Commission established by this Act;

‘Commissioner’ means a member of the Commission and includes an Acting Commissioner;

‘Director’ means the person appointed under section 23 to be the Director of the undertaking known as the Commonwealth Serum Laboratories, and includes a person acting as Director under section 23c;

‘pharmaceutical product’ means—

(a) a product fit, or capable of being made fit, for therapeutic use; or

(b) a substance from which such a product may be derived;

‘technical assistance’ includes the secondment of personnel;

‘therapeutic use’ has the same meaning as in the *Therapeutic Goods Act* 1966;

‘Vice-Chairman’ means the Vice-Chairman of the Commission, and includes a Commissioner acting as Vice-Chairman under section 11.

“(2) For the purposes of this Act, the profits of the Commission for a financial year are the amount (if any) remaining after deducting from the revenue received or receivable in respect of that financial year the expenditure and provision for expenditure properly chargeable against that revenue.”.

**Determinations by Minister to be in writing**

**4.** Section 5 of the Principal Act is amended by omitting “or the Minister for Finance”.

**Application of Commonwealth Acts**

**5.** Section 6 of the Principal Act is amended by adding at the end thereof the following sub-section:

“(2) Notwithstanding sub-section (1), the Commission is bound by the provisions of the *Therapeutic Goods Act* 1966 and the *Customs* (*Prohibited Imports*) *Regulations*.”.

**Constitution of Commission**

**6.** Section 8 of the Principal Act is amended—

(a) by omitting sub-sections (1), (2) and (3) and substituting the following sub-sections:

“(1) The Commission shall consist of—

(a) not less than 4 nor more than 8 Commissioners, one of whom is a medical practitioner registered under a law of a State or Territory providing for the registration of medical practitioners; and

(b) the Director.

“(2) A Commissioner referred to in paragraph (1)(a) shall be appointed by the Governor-General as either a part-time or a full-time Commissioner.

“(3) The Governor-General shall appoint one of the Commissioners referred to in paragraph (1)(a) to be the Chairman, and another of those Commissioners to be the Vice-Chairman, of the Commission.”;

(b) by omitting paragraph (a) of sub-section (8) and substituting the following paragraph:

“(a) has a financial interest, whether direct or indirect, in a company that is engaged in, or a business enterprise that is carried on wholly or partly for the purpose of, the production, purchase, importation, supply, sale or exportation of pharmaceutical products; or”; and

(c) by inserting after sub-section (8) the following sub-section:

“(8a) A person who has attained the age of 65 years shall not be appointed as a full-time Commissioner, and a person shall not be appointed as a full-time Commissioner for a period that extends beyond the date on which he will attain the age of 65 years.”.

**Repeal of section 9**

**7.** Section 9 of the Principal Act is repealed.

**8.** Section 12 of the Principal Act is repealed and the following section is substituted:

**Remuneration and allowances**

“12. (1) A Commissioner appointed by the Governor-General shall be paid such remuneration as is determined by the Remuneration Tribunal, but, if no determination of that remuneration by the Tribunal is in operation, he shall be paid such remuneration as is prescribed.

“(2) A Commissioner appointed by the Governor-General shall be paid such allowances as are prescribed.

“(3) This section has effect subject to the *Remuneration Tribunals Act* 1973.”.

**Meetings of Commission**

**9.** Section 16 of the Principal Act is amended by omitting sub-section (8) and substituting the following sub-section:

“(8) At a meeting of the Commission, a quorum is constituted by a majority of the members for the time being holding office.”.

**10.** Section 19 of the Principal Act is repealed and the following section is substituted:

**Functions of Commission**

“19. (1) The functions of the Commission are—

(a) in respect of prescribed pharmaceutical products, or pharamaceutical products included in prescribed classes of pharmaceutical products—

(i) to produce, buy, import, supply, sell or export such products; and

(ii) to conduct research in relation to such products;

(b) where the Minister so determines—

(i) to conduct research in relation to pharmaceutical products;

(ii) to install or maintain plant or equipment capable of being used for the production of pharmaceutical products;

(iii) to produce, buy and import, and to hold stocks of, pharmaceutical products for purposes other than the immediate sale of those products; and

(iv) to operate as a reference centre for a government or organization, whether Australian or foreign, or an international organization,

in accordance with the determination;

(c) with the approval of the Minister, to provide technical assistance to foreign governments and organizations, and to international organizations, in relation to the production of pharmaceutical products; and

(d) subject to paragraphs (a), (b) and (c), to carry on the undertaking known as the Commonwealth Serum Laboratories.

“(2) Where the Commission has conducted research, in accordance with sub-paragraph (1)(b)(i), in relation to a pharmaceutical product to which paragraph (1)(a) does not apply, that product shall not be prescribed, or included in a prescribed class of pharmaceutical products, for the purposes of paragraph (1)(a) except after consultation between the Minister and the Commission.

“(3) The functions of the Commission may be performed for or in relation to any purpose of the Commonwealth, including, in particular, but without limiting the generality of the foregoing, any of the following purposes, namely—

(a) the defence of the Commonwealth;

(b) external affairs;

(c) trade or commerce with other countries or among the States;

(d) the provision by the Commonwealth of pharmaceutical, sickness or hospital benefits or of medical or dental services;

(e) quarantine; and

(f) any purpose in connection with any or all of the Territories.

“(4) In this section—

‘foreign’ means of, or pertaining to, a country other than Australia;

‘organization’ includes any body or association, whether incorporated or not.”.

**Powers of Commission**

**11.** Section 20 of the Principal Act is amended by omitting sub-section (2) and substituting the following sub-section:

“(2) The Commission shall not, except with the approval of the Minister—

(a) enter into a contract involving the purchase or sale of pharmaceutical products where the consideration under the contract would exceed $500,000 or such higher amount as is prescribed; or

(b) enter into a contract, other than a contract referred to in paragraph (a), where the consideration would exceed $250,000 or such greater amount as is prescribed.”.

**12.** Sections 21 and 22 of the Principal Act are repealed and the following section is substituted:

**Directions by Minister**

“21. The Commission shall perform its functions and exercise its powers in accordance with any directions given to it in writing by the Minister.”.

**Director of Commonwealth Serum Laboratories**

**13.** Section 23 of the Principal Act is amended—

(a) by omitting from sub-section (3) “The Director” and substituting “Subject to this Act, the Director”; and

(b) by omitting sub-section (4) and substituting the following sub-section:

“(4) Sub-sections 8(8) and (8a) apply in relation to the appointment of the Director in like manner as they apply in relation to the appointment of any other Commissioner.”.

**14.** After section 23 of the Principal Act the following sections are inserted in Division 3 of Part II:

**Remuneration and allowances**

“23a. (1) The Director shall be paid such remuneration as is determined by the Remuneration Tribunal, but, if no determination of that remuneration by the Tribunal is in operation, he shall be paid such remuneration as is prescribed.

“(2) The Director shall be paid such allowances as are prescribed.

“(3) This section has effect subject to the *Remuneration Tribunals Act* 1973.

**Leave of absence**

“23b. The Minister may grant leave of absence to the Director on such terms and conditions as to remuneration or other matters as the Minister determines.

**Acting Director**

“23c. (1) The Minister may appoint a person to act as Director—

(a) during a vacancy in the office of Director, whether or not an appointment has previously been made to the office; or

(b) during any period, or during all periods, when the Director is absent from duty or from Australia or is, for any reason, unable to perform the functions of his office,

but a person appointed to act during a vacancy shall not continue so to act for more than 12 months.

“(2) An appointment of a person under sub-section (1) may be expressed to have effect only in such circumstances as are specified in the instrument of appointment.

“(3) The Minister may—

(a) determine the terms and conditions of appointment, including remuneration and allowances, of a person acting as Director; and

(b) at any time, terminate such an appointment.

“(4) Where a person is acting as Director in accordance with paragraph (1) (b) and the office of Director becomes vacant while that person is so acting, that person may continue so to act until the Minister otherwise directs, the vacancy is filled or a period of 12 months from the date on which the vacancy occurred expires, whichever first happens.

“(5) The appointment of a person to act as Director ceases to have effect if he resigns the appointment by writing signed by him and delivered to the Minister.

“(6) While a person is acting as Director, he has, and may exercise, all the powers and shall perform all the functions of the Director.

“(7) The validity of anything done by a person purporting to act under this section shall not be called in question on the ground that the occasion for his appointment had not arisen, that there is a defect or irregularity in or in connection with his appointment, that the appointment had ceased to have effect or that the occasion for him to act had not arisen or had ceased.”.

**15.** Section 25 of the Principal Act is repealed and the following section is substituted:

**Requirements for appointment**

“25. A person shall not be appointed as an officer of the Commission unless the Commission is satisfied as to his health and physical fitness.”.

**Terms and conditions of employment**

**16.** Section 26 of the Principal Act is amended by omitting sub-sections (1), (2) and (3) and substituting the following sub-section:

“(1) The terms and conditions of employment of officers appointed under section 24 are such as are determined by the Commission with the approval of the Public Service Board.”.

**Temporary and casual employees**

**17.** Section 27 of the Principal Act is amended—

(a) by omitting “, on such terms and conditions as the Commission determines”; and

(b) by adding at the end thereof the following sub-section:

“(2) The terms and conditions of employment of persons employed under sub-section (1) are such as are determined by the Commission with the approval of the Public Service Board.”.

**Repeal of sections 28 and 29**

**18.** Sections 28 and 29 of the Principal Act are repealed.

**Capital of the Commission**

**19.** Section 32 of the Principal Act is amended—

(a) by omitting from paragraph (a) “and” (last occurring);

(b) by inserting in paragraph (b) “, not being amounts paid by way of loan under section 34 or 34a or by way of reimbursement under section 38,” after “amounts”;

(c) by inserting after paragraph (b) the following word and paragraph:

“and (c) any amounts transferred from the general reserve of the Commission to the capital account of the Commission in pursuance of directions given under sub-section (2),”; and

(d) by adding at the end thereof the following sub-sections:

“(2) The Minister may direct the Commission to transfer a specified amount from its general reserve to its capital account, and the Commission shall comply with such a direction.

“(3) In giving a direction under sub-section (2), the Minister shall have regard to any advice that the Commission has furnished to him in relation to its financial affairs.”.

**Repayment of capital to Commonwealth**

**20.** Section 33 of the Principal Act is amended—

(a) by omitting from sub-section (1) “for Finance, after consulting the Minister,”;

(b) by omitting from sub-section (2) “for Finance, after consulting the Minister,”; and

(c) by omitting sub-section (3) and substituting the following sub-section:

“(3) In making a determination under this section, the Minister shall have regard to any advice that the Commission has furnished to him in relation to its financial affairs.”.

**21.** Section 34 of the Principal Act is repealed and the following sections are substituted:

**Borrowing from Commonwealth**

“34. The Minister for Finance may, on behalf of the Commonwealth, out of moneys appropriated by the Parliament for the purpose, lend moneys to the Commission at such rates of interest and on such other terms and conditions as he determines.

**Borrowing otherwise than from Commonwealth**

“34a. (1) The Commission may borrow moneys (otherwise than from the Commonwealth) in such amounts, and on such terms and conditions, as the Treasurer approves.

“(2) Approvals for the purposes of sub-section (1) may be given in respect of particular borrowings or in respect of borrowings included within specified classes of borrowings.

“(3) The Commission may give security over the whole or any part of its assets for the repayment of amounts borrowed under this section and the payment of interest on amounts so borrowed.

“(4) The Treasurer may, on behalf of the Commonwealth, guarantee the repayment by the Commission of amounts borrowed under this section and the payment of interest on amounts so borrowed.

“(5) The Commission shall not borrow moneys except in accordance with section 34 or this section.

**Financial policy**

“34b. (1) The Minister, after consultation with the Commission—

(a) shall, before the commencement of each financial year, by notice in writing to the Commission, determine the percentage of the capital of the Commission that would represent a reasonable return to the Commonwealth from the operations of the Commission in that financial year; and

(b) may, at any time during a financial year, by reason of a change in circumstances, in like manner amend a determination made in relation to that year under paragraph (a).

“(2) Before making or amending a determination under sub-section (1) in relation to a financial year, the Minister shall take into account, in addition to any other relevant matters—

(a) any operations carried on or to be carried on by the Commission in that financial year in accordance with paragraphs 19(1)(b) and (c); and

(b) any submissions made to him by the Commission in relation to the financial affairs of the Commission.

“(3) The Commission shall, in the conduct of its operations, pursue a policy directed towards making, during each financial year, profits sufficient to enable the Commission to pay to the Commonwealth, out of those profits, an amount equal to an amount representing the percentage of its capital determined under sub-section (1) in relation to that financial year.”.

**Bank Accounts**

**22.** Section 35 of the Principal Act is amended by omitting sub-section (1) and substituting the following sub-section:

“(1) The Commission may open and maintain an account or accounts with an approved bank or approved banks and shall maintain at all times at least one such account.”.

**Application of moneys of Commission**

**23.** Section 36 of the Principal Act is amended by omitting sub-section (2) and substituting the following sub-section:

“(2) Moneys of the Commission not immediately required for the purposes of the Commission may be invested—

(a) on deposit with an approved bank;

(b) in Commonwealth securities; or

(c) in any other manner approved by the Treasurer.’’.

**24.** Sections 37 and 38 of the Principal Act are repealed and the following sections are substituted:

**Estimates**

“37. The Commission shall prepare estimates, in such form as the Minister directs, of its receipts and expenditure for each financial year and, if the Minister so directs, for any other specified period, and shall submit those estimates to the Minister not later than such date as the Minister directs.

**Reimbursement of certain expenditure**

“38. (1) Where, during a financial year, the Commission—

(a) carries on operations in accordance with paragraph 19(1)(b); or

(b) carries on operations in accordance with paragraph 19(1)(c) in pursuance of a request made to it in writing by the Minister for Foreign Affairs,

the Commission is entitled to be reimbursed by the Commonwealth for the cost of those operations incurred during that year less any revenue received or receivable in respect of that year by the Commission from those operations.

“(2) Where—

(a) the Commission conducts research in accordance with sub-paragraph 19(1)(b)(i) in relation to a pharmaceutical product other than a product to which paragraph 19(1)(a) applies;

(b) as a result of the research, the product becomes a product to which paragraph 19(1)(a) applies and the Commission produces and sells the product; and

(c) the revenue received by the Commission in respect of sales of the product exceeds at any time the expenditure (whenever incurred) and provision for expenditure properly chargeable against the revenue,

the amount of the excess is payable to the Commonwealth on or after a date determined by the Minister after consultation with the Commission, but the total amount of payments made under this sub-section in relation to the product shall not exceed the amount of the reimbursement received by the Commission under sub-section (1) in respect of the conduct of so much of the research as related to the product.

“(3) Interest, at a rate determined by the Minister, is payable by the Commission to the Commonwealth on an amount payable under sub-section (2), calculated from the date on which that amount became payable or, if the Minister determines another date (which may be a date before the first-mentioned date), from the date so determined.

“(4) The Minister may direct that an amount payable under sub-section (2) or (3) shall be paid by instalments in specified amounts and at specified times, and may vary such a direction from time to time.

“(5) For the purposes of sub-section (1), the cost of operations referred to in that sub-section shall be calculated in accordance with the accounting principles generally applied in commercial practice, but any amount paid or payable under a law relating to income tax shall be disregarded.”.

**25.** Sections 39, 40 and 41 of the Principal Act are repealed and the following sections are substituted:

**Surplus profits of the Commission**

“39. (1) The profits of the Commission for a financial year (other than any amount paid to the Commonwealth under sub-section 33(1) or section 38) shall be applied in such manner as the Minister determines.

“(2) In making a determination under sub-section (1), the Minister shall have regard to any advice that the Commission has furnished to him in relation to its financial affairs.

**Proper accounts to be kept**

“40. The Commission shall cause to be kept proper accounts and records of the transactions and affairs of the Commission in accordance with the accounting principles generally applied in commercial practice and shall do all things necessary to ensure that all payments out of its moneys are correctly made and properly authorized and that adequate control is maintained over the assets of, or in the custody of, the Commission and over the incurring of liabilities by the Commission.

**Audit**

“41. (1) The Auditor-General shall inspect and audit the accounts and records of financial transactions of the Commission and records relating to assets of, or in the custody of, the Commission and shall forthwith draw the attention of the Minister to any irregularity disclosed by the inspection and audit that is, in the opinion of the Auditor-General, of sufficient importance to justify his so doing.

“(2) The Auditor-General may, at his discretion, dispense with all or any part of the detailed inspection and audit of any accounts or records referred to in sub-section (1).

“(3) The Auditor-General shall, at least once in each year, report to the Minister the results of the inspection and audit carried out under sub-section (1).

“(4) The Auditor-General or a person authorized by him is entitled at all reasonable times to full and free access to all accounts, records, documents and papers of the Commission relating directly or indirectly to the receipt or payment of moneys by the Commission or to the acquisition, receipt, custody or disposal of assets by the Commission.

“(5) The Auditor-General or a person authorized by him may make copies of, or take extracts from, any such accounts, records, documents or papers.

“(6) The Auditor-General or a person authorized by him may require any person to furnish him with such information in the possession of the person, or to which the person has access, as the Auditor-General or authorized person considers necessary for the purposes of the functions of the Auditor-General under this Act, and the person shall comply with the requirement.

“(7) A person who contravenes sub-section (6) is guilty of an offence punishable, upon conviction, by a fine not exceeding $200.”.

**Liability to taxation**

**26.** Section 42 of the Principal Act is amended by omitting sub-section (1) and substituting the following sub-section:

“(1) The Commission shall pay all rates, taxes and charges under any law of the Commonwealth, a State or a Territory.”.

**Annual report of Commission**

**27.** Section 44 of the Principal Act is amended—

(a) by inserting after sub-section (2) the following sub-section:

“(2a) The report shall set out all directions given by the Minister to the Commission under section 21 during the year to which the report relates.”;

(b) by inserting in paragraph (a) of sub-section (3) “, in his opinion,” after “whether”;

(c) by inserting in paragraph (b) of sub-section (3) “, in his opinion,” before “show”;

(d) by inserting in paragraph (c) of sub-section (3) “, in his opinion,” after “whether”;

(e) by adding at the end of paragraph (c) of sub-section (3) “and”; and

(f) by omitting paragraph (d) of sub-section (3).

**28.** After section 44 of the Principal Act the following section is inserted in Part III:

**Delegation**

“44a. (1) The Minister may, either generally or as otherwise provided by the instrument of delegation, by instrument in writing, delegate to an officer of the Department that deals with matters arising under this Act any of his powers under this Act, other than this power of delegation.

“(2) A power so delegated, when exercised by the delegate, shall, for the purposes of this Act, be deemed to have been exercised by the Minister.

“(3) A delegation under this section does not prevent the exercise of a power by the Minister.”.

**Formal amendments**

**29.** The Principal Act is amended as set out in the Schedule.

**Transitional**

**30.** **(1)** Notwithstanding that the appointment of a person under section 8 of the Principal Act is terminated by the amendment of that section by this Act, such a person is eligible for re-appointment under that section as so amended.

**(2)** The terms and conditions of employment of officers appointed under section 24, and persons employed under section 27, of the Principal Act, as in effect immediately before the date of commencement of this Act, have effect, on and after that date, as if they had been determined under sub-sections 26(1) and 27(2), respectively, of the Principal Act as amended by this Act.

**(3)** Notwithstanding anything to the contrary in paragraph 34b(1)(a) of the Principal Act as amended by this Act, a determination in relation to the financial year commencing on 1 July 1980 may be made under that paragraph at any time after the commencement of this Act.

**(4)** Notwithstanding the repeal of section 38 of the Principal Act by this Act, that section shall be deemed to continue in force in relation to the financial year that commenced on 1 July 1979 as if it had not been repealed, but, in calculating the amount of any loss referred to in that section in relation to that year, any amount of income tax paid or payable on income derived by the Commission during that year shall be disregarded.

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**SCHEDULE** Section 29

FORMAL AMENDMENTS

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| --- | --- |
| Provision | Amendment |
| Paragraph 15(1)(b)  | Omit “(8) of section eight of this Act”, substitute “8(8)”. |
| Sub-section 15(2)  | Omit “not less than twenty-five”, substitute “more than 25”. |
| Sub-section 16(2)  | Omit “five”, substitute “5”. |
| Sub-section 23(2)  | Omit “five”, substitute “5”. |
| Sub-section 23(5)  | Omit “(1) of section fifteen of this Act”, substitute “15(1)”. |
| Paragraph 31(3)(h)  | Omit “(a) of section nineteen of this Act”, substitute “19(1)(a)”. |
| Sub-section 42(2)  | (a) Omit “(d) of section twenty-three” substitute “23(d)”. |
|  | (b) Omit “1936-1973”, substitute “1936”. |
| Sub-section 42(3)  | (a) Omit “1936-1973”, substitute “1936”. |
| (b) Omit “thirty-one of this Act”, substitute “31”. |
| (c) Omit “by the Minister for Finance under section thirty-two of this Act”, substitute “under section 32”. |
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| Sub-section 44(1)  | Omit “thirtieth day of June”, substitute “30 June”. |
| Sub-section 44(2)  | Omit “nineteen of this Act”, substitute “19”. |