COMMONWEALTH SERUM LABORATORIES AMENDMENT BILL 1979

Date Introduced: 11 October 1979
House: House of Representatives

Purpose

The Bill

(a) expands the CSL's role so that with Ministerial approval it may produce non-biological products as well as biological ones;

(b) distinguishes the CSL's commercial activities from its national interest activities so that the Government may meet net losses incurred on the latter items;

(c) enlarges the size of the Commission.

Background

The CSL is Australia's sole source of insulin, sole processor of blood fractions, sole manufacturer of human vaccines; it has a large capacity to produce penicillin and is a major manufacturer of veterinary vaccines; it is a World Health Organization reference centre for influenza and brucellosis and the national rare blood group reference centre and the rabies diagnostic centre for Australia. Under current legislation, however, the CSL is limited to producing biological products prescribed under the Act. For some years, some senior officers and directors of the CSL have maintained that its charter should be extended to include the easily produced, high sales, high profit synthetic non-biological products which form the bulk of modern medicines.

In October 1977 the Government established an independent Inquiry into the CSL which was to report upon its purposes, functions, structure, financial viability and other matters. These references were widened in 1978 to include the relationship between CSL and the Government pharmaceutical companies, Fawmmac, (which had been purchased by the Labor Government in 1975) and the question of whether
Fawnmac should be retained or sold by the Government.

The major findings of that Inquiry which relate to CSL are incorporated in this Bill. Despite the Inquiry's recommendation that the Fawnmac companies should not be sold off nor merged into the CSL, the Government is making arrangements for their sale.

Provisions

Cl.2 provides for this Act to come into effect on 1 July 1980. Transitional arrangements are specified in cl.30.

Cl.6 amends s.8 so as to increase the number of CSL Commissioners from 4, including a registered medical practitioner, to between 4 and 8, including a registered medical practitioner. Commissioners may be either part-time or full-time, and the Governor-General shall appoint one to be Chairman and another to be the Vice-Chairman of the Commission.

Proposed s.8(8)(a) prevents the appointment of Commissioners who have direct or indirect financial interests in a company or business enterprise that is carried on in the wider pharmaceutical field. Proposed s.8(8A) prohibits Commissioners from being appointed or from continuing their appointment as Commissioner after attaining the age of 65 years.

Cl.8 proposes that remuneration for Commissioners shall be determined by the Remuneration Tribunal, or as prescribed if no appropriate Tribunal determination is in effect. Allowances are to be as prescribed.

Cl.10 makes a significant alteration to the functions of the Commission by inserting a new s.19. Whereas previously the Commission was limited in its operations to biological products the amendment extends its operations to pharmaceutical products. A 'pharmaceutical product' is defined in s.4 to include a product fit, or capable of being fit, for therapeutic use. It thus includes non-biological products. The new s.19 specifies the functions of the Commission as to produce, buy, import, supply, sell or export and to conduct research into prescribed pharmaceutical products (para. 19(1)(a)); to carry out certain determinations of the Minister (para. 19(1)(b)); to provide with the approval of the Minister technical assistance to foreign governments and organizations and international organizations; and carry out the undertaking known as the Commonwealth Serum Laboratories.
Proposed s.20 (cl.11) limits the authority of the Commission to enter into contracts for the sale or purchase of pharmaceutical goods in excess of $500,000, or contracts concerning any other matter in excess of $250,000, without the Minister's approval.

Cl.12 repeals ss.21 and 22 and inserts a new s.21 which empowers the Minister to give written directions to the Commission regarding the performance of its functions and the exercise of its powers.

A number of amendments (cl.13 and 14) are made relating to the position of Director of CSL. Cl.14 inserts new ss.23A, 23B and 23C: s.23A enables remuneration of the Director to be determined by the Remuneration Tribunal, s.23B enables the Minister to grant leave of absence to the Director and s.23C enables the appointment of an acting Director.

Proposed amendments to s.26 and s.27 (cl.16 and 17) remove from the Commission the sole authority to set terms and conditions of employment for the Commission's permanent and casual employees, and requires them to be determined by the Commission with the approval of the Public Service Board. Cl.18 repeals s.28 and s.29 which has the effect of removing the prohibition on the application of the Public Service Arbitration Act 1920 to the employees of the Commission. Industrial awards made pursuant to the Public Service Arbitration Act 1920 will now apply to CSL employees.

The Bill proposes a number of significant changes to the financial basis of the Commission (cl.19-26). The important amendment is cl.24 which inserts new ss.37 and 38. New s.37 requires the Commission to prepare estimates of receipts and expenditure each year in such form as the Minister directs. New s.38 provides for the Commission to be reimbursed by the Commonwealth for the net cost of operations carried or pursuant to para. 19(1)(b) (at the direction of the Minister) or para. 19(1)(c) (technical assistance to foreign governments and international organisations) if requested in writing by the Minister for Foreign Affairs. If a pharmaceutical product is subsequently produced for commercial purposes following research carried out at the Minister's direction the profits derived are payable to the Commonwealth (sub.s.38(2)).

Cl.19 and 20 amend ss.32 and 33 relating to the working capital of the Commission and its repayment to the Commonwealth. Cl.21 inserts new ss.34, 34A and 34B: s.34 relates to Commission borrowing from the Commonwealth, s.34A to borrowing other than from the Commonwealth and s.34B
requires the Minister after consultation with the Commission to determine the percentage of capital that would represent a reasonable return to the Commonwealth from the operations of the Commission. The Commission is expected to pursue policies to enable it to pay the percentage determined (sub.s.34B(3)).

Cl.25 inserts new s.39, s.40 and s.41. These provide for the surplus profits (excluding payments under s.33(1) and s.38) of the Commission to be applied as the Minister decides, after consultation with the Commission, for the proper keeping of accounts, and for the Auditor-General to inspect and audit the accounts and to report to the Minister on his examinations.

Proposed new s.42(1) provides for the Commission to be liable to pay all rates, tax and charges under any Commonwealth, State or Territorial law. Previously it was not subject to State or Territory tax to which the Commonwealth is not subject.

Proposed new s.44A (cl.28) enables the Minister to delegate his powers under the Act, other than the power of delegation, to officers of the Department that deals with matters arising under this Act.

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Education and Welfare Group
LEGISLATIVE RESEARCH SERVICE