DEPARTMENT OF THE SENATE
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Clerk of the Senate

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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

JOINT COMMITTEE OF PUBLIC ACCOUNTS

ONE HUNDRED AND FOURTH REPORT

COMMONWEALTH SERUM LABORATORIES COMMISSION

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JOINT COMMITTEE OF PUBLIC ACCOUNTS

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The Senate and the House of Representatives appointed their Members on 22nd February, 1967.

(1) Appointed 23rd August, 1967.
(2) Deceased 2nd August, 1967.
(3) Resigned 26th February, 1969.
(4) Appointed 26th February, 1969.

DUTIES OF THE COMMITTEE

Section 8 of the Public Accounts Committee Act 1951-1966 reads as follows :-

8. The duties of the Committee are -

(a) to examine the accounts of the receipts and expenditure of the Commonwealth and each statement and report transmitted to the Houses of Parliament by the Auditor-General in pursuance of sub-section (1.) of section fifty-three of the Audit Act 1901-1950;

(b) to report to both Houses of the Parliament, with such comment as it thinks fit, any items or matters in those accounts, statements and reports, or any circumstances connected with them, to which the Committee is of the opinion that the attention of the Parliament should be directed;

(c) to report to both Houses of the Parliament any alteration which the Committee thinks desirable in the form of the public accounts or in the method of keeping them, or in the mode of receipt, control, issue or payment of public moneys; and

(d) to inquire into any question in connexion with the public accounts which is referred to it by either House of the Parliament, and to report to that House upon that question,

and include such other duties as are assigned to the Committee by Joint Standing Orders approved by both Houses of the Parliament.

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JOINT COMMITTEE OF PUBLIC ACCOUNTS

ONE HUNDRED AND FOURTH REPORT

THE COMMONWEALTH SERUM LABORATORIES COMMISSION

Chapter 1

Introduction

In pursuance of Section 8 of the Public Accounts Committee Act 1951-1966, Your Committee resolved to inquire into the accounts of the Commonwealth Serum Laboratories Commission.

2. During the inquiry we obtained a number of statements from the Department of Health and the Commonwealth Serum Laboratories Commission. These are listed in Appendix No. 1 to this Report.

3. The Statements received and other information available to Your Committee were made the subject of a public inquiry at Parliament House, Canberra, on:-

Thursday 25 May 1967
Friday 26 May 1967
Monday 26 February 1968

4. The following witnesses representing the Department of Health and the Commonwealth Serum Laboratories Commission were sworn during the public inquiry and were examined by Your Committee:

Department of Health

Mr. R.A.B. Ashwell	-	Acting Director (Finance)
Mr. M. Carroll	-	Assistant Director-General
Dr. G.M. Redshaw	-	Deputy Director-General

Commonwealth Serum Laboratories Commission

Mr. F.J. Davis	-	Chairman
Dr. W.R. Lane	-	Director
Mr. P.V. Sullivan	-	Deputy Director (Commercial)

5. During our inquiry we were assisted by the following observers:

Auditor-General's Office	-	Mr. J.K. Lawrence Mr. A.K. Ragless
Department of Health	-	Mr. L.B. Holgate
Public Service Board	-	Mr. G.N. Vanthoff
Department of the Treasury	-	Mr. C.J. Balfour Mr. M.C. Cowie Mr. C. Monaghan Mr. G.R. Virtue.

6. As part of our investigations we made the following inspections of facilities of the Commonwealth Serum Laboratories Commission located in Victoria:

Field Stations, Woodend and Broadmeadows - Thursday 3 August 1967
Commonwealth Serum Laboratories, Parkville - Friday 4 August 1967.

7. Information submitted to Your Committee as at 26 February 1968 and additional material made available subsequent to that date constitute the basis of the present report.

8. Although the present Inquiry is concerned primarily with the Commonwealth Serum Laboratories Commission, the laboratories which are operated by the Commission have a lengthy history from 1916 to 1961 during most of which period they were directly under the administrative control of the Department of Health. For this reason and in order to ascertain the nature and condition of the facilities acquired by the Commission at its inception Your Committee considered that it should examine, during the course of the Inquiry, the history of the laboratories prior to 1961.

Chapter 2

The History of the Commonwealth Serum Laboratories Prior to the Establishment of the Commission

9. While Calf Lymph (smallpox vaccine) was being produced as early as 1883 at a vaccine depot controlled by the Victorian Government at Royal Park, the witness for the Department of Health indicated that no evidence could be found of any other sera production in Australia prior to 1914. The major sources of imports of these products at that time were the United Kingdom, the United States of America and Canada. Sera products imported in 1913 included diphtheria and typhoid antitoxins; anti-tetanic serum; influenza, staphyloccocal, streptococcal, gonococcal, tuberculosis and pneumacoccal vaccines and tuberculins for testing. Qs.9 to 27 and Committee File 1967/1

10. Serious difficulties were experienced in obtaining supplies of vaccines, sera and other bacteriological products from European or American sources to meet Australian requirements following the outbreak of World War I. In 1913 the value of these products imported into Australia was $30,612 while the value of similar imports had declined to $16,812 in 1914. While the shortage of shipping facilities at this time was a contributing factor, we were informed that the principal reason for the decline in imports was the fact that serum institutes in other countries were required to supply the allied armies with large quantities of tetanus antitoxin. Exhibit 104/1 Q.26 and Committee File 1967/1

11. Representations were made to the Government for the establishment of a Federal Institute for the production of anti-toxins, sera and vaccines to meet Australian requirements. In September 1915 the Metropolitan Hospital Board of Supplies, Melbourne, supported the representations and suggested that there be one Institute for Australia in order to meet any sudden demand which might be made in any part of the country; that adequate supply be available at the least cost; that products be standardised throughout Australia; and that supplies be regularly available at important points throughout the country. It was stated that it had always been considered that there were certain products which would Exhibit 104/1 Qs.15 and 16

need to be produced by a Government authority, the demand being dependent on the state of health of the population at any given time. Following approval by the then Commonwealth Minister for Health, the Laboratories were established under the administration of the Quarantine Branch of the Department of Trade and Customs. Administration of the Laboratories was transferred to the Department of Health on the establishment of the Department in 1921.

Exhibit 104/1 and Q.12

12. The first Director of the Laboratories, Dr. W.J. Penfold, arrived from England in November 1916 and commenced work at the newly completed Walter and Eliza Hall Institute for Research in Pathology and Medicine at the Melbourne Hospital. The Institute was under the control of a Board consisting of representatives of the Walter and Eliza Hall Trustees, the Council of the University of Melbourne and the Committee and medical staff of the Melbourne Hospital. Dr. Penfold and his staff occupied initially the top floor of the Institute which had been prepared as bacteriological laboratories for the preparation of vaccines and sera.

Exhibit 104/1 Q.19 and Committee File 1967/1

13. Prior to taking up duty as Director of the Laboratories, Dr. Penfold visited Laboratories in England, France and America in order to obtain the latest information to ensure that the Commonwealth Serum Laboratories would be built and equipped on the most modern lines. The visit was also made to enable effect to be given to the twofold purpose of the laboratories, first the production of sera, vaccines and other bacteriological products and secondly, research in relation to these products. This twofold purpose has been the basic approach to the activities of the Laboratories since their inception and explains their national importance.

Exhibit 104/1

Parliamentary Debates (H. of R), 11 May 1961, Pp. 1779-1780.

14. When the Commonwealth Government moved into the field of bacteriological products it took over a vaccine lymph depot already established at Royal Park which had been conducted by the Victorian Metropolitan Board of Health prior to 1883. Calf Lymph had been produced under Commonwealth control on the site at Royal Park since 1912. For these reasons Royal Park was selected as the site for the laboratories. Whilst the first vaccines were produced in 1917 at the Walter and Eliza Hall Institute, the production of these products was transferred to the newly established laboratories

Qs.14 and 31 and Committee File 1967/1

at Royal Park in July 1918.

15. When the Laboratories were established, there were few, if any, commercial firms capable of producing its products, which, it was said, were evolving from the stage of research to production. We were told that there is no record of opposition having been offered by commercial firms to the establishment of the Laboratories, and that existing manufacturers of the Laboratories' products would not have been denied a market for their products because their output lacked an assured market. It was also said that it would always have been considered that the laboratories' products should attain a recognised standard and that their supply should be assured regardless of the level of demand for them. Qs.15 to 18

16. We were informed that it has always been recognised that the most important part of the function of the Commonwealth Serum Laboratories is inquiry and research into the cause of disease, the organisms that cause various outbreaks of unknown fevers and the improvement of methods of producing vaccines, toxins or anti-toxins to combat those diseases. It was said that while it is often quite a simple task to identify a project as "original" or "developmental", there exists a not inconsiderable area of work which cannot be so arbitrarily classified. We were told that the collected papers of the Laboratories which contain original articles written by Dr. W.J. Penfold as early as 1920, confirm that from the earliest days the Laboratories were contributing to "original" research. The duties of Dr. W.W. Hurst, who was appointed to the Laboratories in May 1924, included research into cancer. Q.33 and Committee File 1967/1

17. When asked if some reasonable accurate measure of the amount of funds and time devoted to research work in the early years of the Laboratories' history was available it was stated that this would be difficult to determine as records of the period had not been kept. The records for a later period which are clearer were said to reveal that approximately one half of the time of medical officers of the Laboratories was spent on research and one half on production. Q.34

18. The first list of the Laboratories' products, covering twelve human bacterial vaccines and smallpox vaccine, appeared early in 1918. Insulin was isolated in 1922 by Banting and Best at the Toronto University in Canada. In 1923 the Commonwealth Serum Laboratories were one of four such institutes entrusted with its preparation on a large scale. The first issue of a handbook of veterinary products appeared on the market in 1920. Exhibit 104/1 Qs.35,51 to 54,58 and Committee File 1967/1

19. It was stated in the 1923 handbook of the Laboratories that, at that time, Australia was well suited to the development of the manufacture of serum, the raw materials being fodder, horses and trained labour. It was also said that at that time Australia was probably better equipped for this than any other country in the world and that the Laboratories represented a settled activity of the Commonwealth Government in that there was no temptation to follow a mercenary policy which would place questions of public health in a secondary position to those of commercial profit. Exhibit 104/1

20. Prior to 1926, Australia had been largely dependent on imported veterinary products, many of which had been arriving in poor condition. In addition, these products had not been made from strains of bacteria isolated from local diseases and little attention had been paid by overseas manufacturers to the need for local investigation of animal enzootics and consequently, specific agents for their prevention or treatment had not been devised. Exhibit 104/1

21. We were informed that in 1925 the Commonwealth Serum Laboratories pioneered the use of human blood products in the processing, for therapeutic purposes, of blood collected from people who had recovered from poliomyelitis, measles, and scarlet fever. We were also told that Australia was the only country to adopt routine blood grouping of all service personnel. To meet this increased demand, the Laboratories were called on to prepare, test and supply very large quantities of blood grouping serum. Committee File 1967/1

22. The activities of the Laboratories continued to develop and expand and in 1936 a farm of 325 acres was purchased at Broadmeadows, nine miles from Melbourne for the purpose of breeding and holding horses in connection with serum production. Exhibit 104/1 and Qs.62 and 63

23. Extensive new buildings were planned and completed between 1937 and 1942. This involved mainly additions to existing buildings at Parkville, except for work carried out at the farm at Broadmeadows. We were unable to establish the extent of increased capacity resulting from these extensions although we were informed that much of the extension work had been allocated to research functions and would not have increased production capacity, as such. Exhibit 104/1 and Qs.68 to 70

24. At the outbreak of the war in 1939 there was an additional and unprecedented demand for biological products. It was said that this had been largely foreseen in that much of the developmental work connected with Defence Force requirements was pressed forward at the Laboratories before both the commencement of hostilities and the Munich crisis. Tetanus prophylactic was being developed and tested in 1938 and prepared in quantity in 1939. During the same years, large stocks of sera and vaccines were being accumulated for use in a serious emergency. It was said that while a major part of these stocks was held at Parkville, the products were dispersed throughout the State branches of the Commonwealth Department of Health. Exhibit 104/1 and Qs.64 to 66

25. Although pooled human serum was first produced in the Laboratories on a small scale in the 1930s, general production commenced in 1940 when the Australian Red Cross Society organised a donor service and the collection of human blood and serum on a regular basis. In 1952 Serum fractionation was commenced for the production of Albumen, fibrinogin and gamma globulin and later again for the antihaemophilic factor. Exhibit 104/1Q72 and Committee File 1967/2

26. The successful development of penicillin in 1943 inspired the Laboratories to commence the immediate preparation of this new type of biological product. Penicillin was made experimentally at the Laboratories in that year, and was supplied first to the Services and when sufficient supplies became available,

was supplied, on a restricted basis, to the civilian population in July 1944. It was said that Australia was the first country to make penicillin available for civilian use.

27. In 1956 an urgent need arose for the production in Australia on a large scale of inactivated poliomyelitis vaccine. It was said that probably no other biological product has a more rigid and painstaking control in the production process. This vaccine was produced at the Laboratories and used in large scale antipoliomyelitis campaigns. Exhibit 104/1 Q.74, and Committee File 1967/1

28. Because of the non-availability of additional land at the site of the Broadmeadows farm, it became necessary for a farm of 1,361 acres to be purchased at Woodend in Victoria in 1959. We were informed that a number of sites had been canvassed and inspected at that time and that the Woodend site had been considered the most suitable. It was said that although the purchase price of this farm probably had been a determining factor in its selection, its location and area were the two main elements which influenced its selection. It was said that the Woodend farm was needed for the breeding of horses required for serum production and resting from production processes. The farm was also to be utilised for the decentralization of certain production processes and the breeding of other livestock required for the Laboratories' activities. We were informed that apart from the collection of blood from horses, none of the processing of the primary product, blood, to the finished product would take place at Woodend. Exhibit 104/1 and Qs.75 to 77

29. The witness representing the Department of Health was asked if, when an expansion of farm facilities in 1959 was under discussion, consideration had been given to the economic advisability of disposing of the small Broadmeadows farm which was incapable of further expansion. We were told that it had always been intended that portion of the Broadmeadows farm which had been replaced by the Woodend farm, would be disposed of and that smaller animals such as rabbits, guinea pigs and monkeys should continue to be retained at the Broadmeadows farm. Q.81

30. By 1961 the wide area of activity of the Laboratories had involved substantial capital investment and development. The Laboratories occupied a 23 acre site at Parkville, operated a 325 acre farm at Broadmeadows, and a 1,361 acre farm at Woodend. The capital invested in these locations exceeded $12 million, with an annual turnover of approximately $4.8 million and a staff of approximately 1,000.

Exhibit 104/1 and Q.78

Chapter 3

The Establishment of the Commission

31. Section 7 of the Commonwealth Serum Laboratories Act 1961 provides for the establishment of the Commission in the following terms:

> "(1) There shall be a Commission by the name of the Commonwealth Serum Laboratories Commission.
>
> (2) The Commission -
> (a) is a body corporate, with perpetual succession;
> (b) shall have a seal;
> (c) has power to acquire, hold and dispose of real and personal property; and
> (d) may sue and be sued in its corporate name.
>
> (3) All courts, judges and persons acting judicially shall take judicial notice of the seal of the Commission affixed to a document and shall presume that it was duly affixed."

32. During the Second Reading Speech on the Commonwealth Serum Laboratories Bill, the Minister for Health, the Honourable Dr. Donald Cameron, referred to the growth of the Laboratories into a large-scale undertaking devoted to production and research designed to prevent disease and treat serious illness in the Australian community.

Parliamentary Debates (H.of R.) 11 May 1961 Pp.1779-1782.

33. The Minister indicated that it was a matter of national importance that the Laboratories continue to maintain their position in the various health fields and to meet changing and growing needs, a flexible and efficient management was necessary to direct the affairs of such a large and important undertaking in a business-like fashion. He added that while the Laboratories had reached a high status in the Australian and overseas communities within the framework of departmental methods and administration, it had been felt that this form of administration was no longer the most effective for the purposes for which the Laboratories existed. The production and research activities undertaken by the Laboratories by 1961 ranged over a much larger and essentially more specialised field than in earlier years and problems of marketing, research, administration and management had become increasingly complex.

34. The Minister explained that the Government had been conscious of the increasing growth and complexity of the Laboratories'

activities and had examined very carefully ways and means to improve their overall administration. He emphasised that this review had been designed to ensure the continued progress and development of the Laboratories as an integral part of the activities of the Commonwealth Government in the field of public health. Following this review the Government had come to the conclusion that the establishment of a statutory commission comprising both business and medical men of wide experience would provide the most flexible, effective and therefore efficient form of administration.

35. It was proposed that the biological products to be manufactured and sold by the Laboratories would be prescribed by regulation. In accordance with the usual approach adopted in business activities of this nature, the Commission would adopt a policy aimed at obtaining sufficient revenue from the sale of products to cover the expenditure of the Commission plus a reasonable return on the capital invested, i.e., the Commission would follow accepted business lines in relation to this aspect of its activities. It was also intended that all products marketed by the Commission at that time would continue to be produced. The Minister added that the Government was fully seized of the importance of the research activities of the Laboratories and special provision had accordingly been included in the Bill for the Commission, in accordance with a determination of the Minister, to undertake research appropriate to its functions. Special provision was to be made for the Commonwealth to meet the cost of this research where the Commission's operations resulted in a loss.

Parliamentary Debates (H. of R.) 11th May, 1961, P.P. 1779-1782

36. In order to ensure that ample production capacity or stocks of products were maintained by the Commission to meet any particular emergency, such as an outbreak of smallpox or to meet the health requirements of the community generally, the Government proposed to permit the Commission, subject to the determination of the Minister, to take the necessary steps in this direction with financial support from the Commonwealth. Quite a large proportion of the production of the Laboratories was being purchased at that time by the Commonwealth Government. It was proposed that this should continue and provision was accordingly sought for the prices of these products to be determined by the Minister after consultation with the Commission.

37. An important consideration in the transfer of the activities of the Laboratories to the control of a Commission related to the position of the staff employed by the Laboratories at that time. The Minister stated that this matter had been considered carefully by the Government and provision was being made for the existing officers of the Commonwealth Serum Laboratories to retain their existing rights as public servants and in particular their rights to furlough, superannuation and compensation.

38. It was also proposed that the assets of the Laboratories, including such items as plant, machinery, equipment, book debts and a wide variety of other items, would be transferred to the Commission. The value of these assets plus the net amount of capital provided from moneys appropriated by the Parliament for the purposes of the Commission would represent the capital of the Commission. However, the Minister added that while it was not proposed that the Commission would pay any interest to the Commonwealth on its capital, it would make payments out of its annual profits to the Commonwealth. He added that the Commission's advice would be taken into account in determining the amounts of these payments.

Parliamentary Debates (H. of R.) 11th May, 1961. P.P. 1779-1782

39. The Commonwealth Serum Laboratories Bill provided that the profit of the Commission should be determined in accordance with normal accounting principles for an organisation of the type of the Commonwealth Serum Laboratories. As with other statutory commissions of this kind, the accounts and records of the financial transactions of the Commission were to be subject to inspection and audit by the Auditor-General who would have the usual rights and responsibilities in this regard. The Minister added that the Commission would be subject to taxation under the laws of the Commonwealth but not to taxation under State or Territorial law to which the Commonwealth is not subject. In order to ensure that the Parliament is fully apprised of the activities of the Commission it was also proposed that the Commission should prepare and furnish an annual report to the Minister for submission to the Parliament.

40. We were informed in evidence that while the Department of Health was primarily responsible for the formulation of the Commonwealth Serum Laboratories Bill, in collaboration with the Attorney-General's Department, the Prime Minister's Department, the Department

of the Treasury and the Public Service Board had also been consulted during the formative stage of the Bill. The Auditor-General, however, was not consulted at that time. In this regard the Audit Observer, Mr. Lawrence, informed us that the formation of the legislation had preceded the date on which the Auditor-General had made representations to the Attorney-General's Department and the Department of the Treasury in respect of the Audit Office being consulted in advance of legislation being prepared. As a consequence of those representations, Treasury Circular 1964/67 of 5 August, 1964, had been issued advising departments that before referring legislative proposals affecting accounting and audit to the Parliamentary Draftsman, they should consult the Auditor-General's Office and the Treasury, and that the departmental advice to the Parliamentary Draftsman should indicate that this consultation had been effected. The Circular also requested that if amendments of legislation affecting other than accounting and audit provisions are under consideration, the Treasury and the Auditor-General's Office should, if practicable, be informed so that opportunity may be taken to review the provisions affecting accounting and audit procedures. Mr. Lawrence confirmed, however, that sections 41 and 44 of the Commonwealth Serum Laboratories Act which relate to the audit of the Commission's accounts and financial statements associated with the Commission's annual reports are consistent with modern legislation and are generally acceptable to the Auditor-General.

Qs.174 to 177

41. The Commonwealth Serum Laboratories Act was assented to on 2 June 1961 and, in accordance with Section 2 of that Act, came into operation on 2 November 1961 by proclamation.

42. The details of the sections of the Commonwealth Serum Laboratories Act to which your Committee directed its examination are set out in the following chapters of this Report.

Chapter 4

The Constitution of the Commission

43. Section 8 of the Commonwealth Serum Laboratories Act provides as follows:-

"(1.) The Commission shall consist of -

(a) four Commissioners, one of whom is a medical practitioner registered under a law of a State or a Territory of the Commonwealth providing for the registration of medical practitioners; and

(b) the Director.

(2.) The Commissioners referred to in paragraph (a) of the last preceding sub-section shall be appointed by the Governor-General.

(3.) The Governor-General shall appoint one of the Commissioners appointed by the Governor-General to be the Chairman, and another of the Commissioners appointed by the Governor-General to be the Vice-Chairman, of the Commission.

(4.) The Commissioners first appointed by the Governor-General shall be appointed to hold office -

(a) in the case of two such Commissioners - for four years; and

(b) in the case of the other two such Commissioners - for two years.

(5.) After the appointment of the four Commissioners first appointed by the Governor-General, each further appointment of a Commissioner by the Governor-General shall, subject to this section, be for a period of four years.

(6.) In the event of a Commissioner appointed by the Governor-General ceasing to hold office before the termination of the period of his appointment, another Commissioner may be appointed in his place for the remainder of that period.

(7.) A Commissioner appointed by the Governor-General is eligible for re-appointment.

(8.) A person who -

(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 or wholesale distribution of pharmaceutical products (including biological products of a kind used for therapeutic purposes); or

(b) is a director, officer or employee of a company that is so engaged,

shall not be appointed under this section as a Commissioner

(g) The exercise or performance of the powers or functions of the Commission is not affected by reason only of there being a vacancy in the office of a Commissioner."

44. In regard to this section we questioned the witnesses on the matter of the inclusion of the Director of the laboratories as a member of the Commission and the changes that had occurred in the membership of the Commission since its inception. In relation to the position of the Director we were informed that it is not unusual for the occupant of such an office to enjoy membership of a Commission and it was thought that the underlying intention was that the Director would be entitled to be present at all meetings of the Commission and to be fully advised on the Commission's intentions as regards its policies and activities. At the same time the Director would be in a position to state his views on matters under Commission consideration and hence to influence the decisions taken. Qs.181 to 185

45. In regard to membership of the Commission we were informed that the Commission comprised originally Mr. C.S. Butt, C.M.G., as Chairman; Mr. J.A. Hancock, as Vice-Chairman; Mr. O.G. Meyer, O.B.E., E.D.; Professor E.S.J. King and Dr. G.W. Greville, who was the Director of the Laboratories. Details of changes in the membership of the Commission since the first appointments were made have been as follows: Mr. C.S. Butt was appointed for two years with effect from 2 November, 1961, and was re-appointed for four years with effect from 2 November, 1963. Mr. Butt resigned on the grounds of ill health and his resignation was accepted with effect from 1 May, 1967. Mr. F.J. Davis was appointed for the remainder of Mr. Butt's term as Chairman and was reappointed for a period of four years commencing 2 November, 1967. Mr. J. A. Hancock was appointed for four years with effect from 2 November, 1961. Mr. Hancock has been Vice-Chairman since his appointment. Professor E.S.T. King was appointed for four years with effect from 2 November, 1961, and was re-appointed for four years with effect from 2 November, 1965. Professor King died on 23 March, 1966, and Dr. J.L. Frew was appointed on 15 March, 1966, for the balance of Professor King's period of office until and including 1 November, 1969. Mr. O.G. Meyer was appointed for two years with effect from 2 November, 1961, and re-appointed for four years with effect from 2 November, 1963. Q.186 and Committee File 1967/1

46. Sections 10 and 11 (1.) of the Commonwealth Serum Laboratories Act provide as follows:-

" 10. The Minister may grant leave of absence to a Commissioner appointed by the Governor-General upon such terms and conditions as to remuneration or otherwise as the Minister determines.

11. - (1.) Where the Minister grants leave of absence under the last preceding section to a Commissioner appointed by the Governor-General, the Minister may appoint a person to act as a Commissioner during that absence, and a person so appointed has all the powers and functions of a Commissioner."

47. The evidence showed that leave granted under these sections had been as follows: Q.187 and Committee File 1967/1

Mr. Butt was granted leave from mid-May 1963 for a period of 2½ months and from the end of February 1966 for a period of two months, on both occasions to conduct official business on behalf of the Commission. Mr. Hancock was granted leave from 12 May, 1962 until 31 July, 1962 and from 3 May, 1967 to 1 July, 1967. Mr. O.G. Meyer was granted leave from 7 September, 1963 until early October, 1963 and from 26 August, 1965 until 14 October, 1965.

48. On two occasions in 1967, Mr. D.G. Dunlop, First Assistant Director-General, Department of Health, acted as temporary replacement on the Commission during the absence of Mr. Hancock and Mr. Meyer overseas. On both occasions Mr. Dunlop received his usual Public Service remuneration only. Qs. 672 and 673

49. Section 12 of the Act provides for the remuneration of Commission Members in the following terms:-

" 12. A Commissioner appointed by the Governor-General shall be paid such remuneration (if any) and such allowances (if any) as the Governor-General determines."

50. We were informed that remuneration is paid on an annual basis. Approvals for leave granted to Commissioners have included the provision that the remuneration would continue. Rates of remuneration and allowances paid to Commissioners, were submitted to us in confidence. We were informed that one change in the rate of remuneration had been made in July, 1965. All Commissioners, Qs.188 to 192

Qs.674 and 675 and Committee File 1967/1

excepting the Acting Commissioner at the time of our inquiry, Mr. Dunlop, an officer of the Department of Health, were paid travelling allowance at the same rate and subject to the same conditions as travelling allowance payable to a permanent head of a Commonwealth Department. It was stated that there has been no alteration to this principle since the formation of the Commission.

51. Section 15 (2) and (3) of the Commonwealth Serum Laboratories Act provides as follows:-

> "(2) A Commissioner who is directly or indirectly interested in a contract made or proposed to be made by the Commission, otherwise than as a member, and in common with the other members, of an incorporated company consisting of not less than twenty-five persons, shall, as soon as possible after the relevant facts have come to his knowledge, disclose the nature of his interest at a meeting of the Commission.
>
> (3) A disclosure under the last preceding sub-section shall be recorded in the minutes of the Commission, and the Commissioner -
>
> (a) shall not take part after the disclosure in any deliberation or decision of the Commission with respect to that contract; and
>
> (b) shall be disregarded for the purpose of constituting a quorum of the Commission for any such deliberation or decision."

52. We were informed that periodically the Secretary of the Commission requests that Commissioners declare their holdings and interests in other companies. It was said that on two occasions in the past four years Commissioners had declared an interest in a contract made or proposed to be made by the Commission. One was related to the selection of insurance brokers and the other was in respect of a supplier of raw materials to the Commission. We were assured that similar action could be expected should similar circumstances arise in the future. Qs.705 and 706

53. Section 16 (2), (3) and (4) of the Commonwealth Serum Laboratories Act provides as follows for Meetings of the Commission:-

> "(2) The Chairman shall not permit a period exceeding five weeks to elapse between a meeting of the Commission and the next meeting of the Commission.

(3) The Chairman shall, on receipt of a written request signed by a Commissioner, convene a meeting of the Commission.

(4) The Minister may at any time convene a meeting of the Commission."

54. The Commission supplied us with a copy of the dates of meetings held by the Commission since its establishment, and also of the attendance of Commissioners at meetings. It was noted that on many occasions the Commission had met at least twice in one month while on other occasions the intervals between meetings have approached the limit provided. It was said that while the provision of this sub-section is obviously to ensure that regular meetings of the Commission are held there are occasions on which meetings need to be held more frequently. It was also said that circumstances had arisen whereby a meeting of the Commission had been convened in order to comply with this provision of the Act. The witness representing the Commission said that in his experience the provision of Section 16 (3) had not been invoked. It was noted, however, that without statutory provision the situation could arise where the Chairman would not call the Commission together. Qs.291, 292 and 709 to 713, 766 and Committee File 1967/1 Q.766

55. With respect to Section 16 (4), the witness representing the Department of Health was unaware of the full circumstances under which this provision might be used. The Minister has called only one meeting of the Commission, the first to be convened. Q.198

56. Section 17 of the Commonwealth Serum Laboratories Act provides as follows:-

"17. (1) The Commission may, either generally or in relation to a matter or class of matters and either in relation to the whole of the Commonwealth or to a State or part of the Commonwealth, by writing under its seal, delegate all or any of its powers under this Act (except this power of delegation).

(2) A power so delegated may be exercised by the delegate in accordance with the instrument of delegation.

(3) A delegation under this section is revocable at will and does not prevent the exercise of a power by the Commission."

57. While the Commissioner's power of delegation is effectively unlimited, and formulated by the Commission itself, a major part of Qs.199, 200, 205 and 293 to 297

the delegation, at the time of our public hearing of 25 May, 1967, was concerned with establishment matters. At the same hearing, it was said that the existing delegations, produced in 1961, and in the form of a written detailed authority, had been made to Dr. Lane, Director of the Laboratories, to the Deputy Director (Commercial), the Marketing Manager, and to a limited extent, to the Deputy Director (Technical). It was said that these delegations had become somewhat obsolete because of staff, organisational and other changes. The opinion was expressed, however, that a more flexible scheme of delegation was desirable and it was said that delegations of this kind were in the process of being prepared.

58. During the final hearing of our Inquiry, held on 26 February, 1968, we were informed that in a functional sense a good deal of progress had been made in the preparation of delegations. Although a written authority had not been prepared, officers to whom delegations have been made were fully aware of what the delegations involve and were carrying out their functions under the delegations. While it was claimed that the system was working very satisfactorily, it was said that a written form of authority would probably need to be prepared and that a decision on the matter could be made within a year. Qs.714 and 715

Chapter 5

The Functions of the Commission

59. The functions of the Serum Laboratories Commission are set out as follows in Section 19 of the Commonwealth Serum Laboratories Act 1961:-

"(a) to produce and sell such biological products of a kind used for therapeutic purposes as are prescribed and to undertake research in connection with any such prescribed product;

(b) if the Minister so determines -

(i) to undertake research towards the products of a kind used for therapeutic purposes, being products other than products prescribed for the purpose of the last preceding paragraph; and

(ii) to install or maintain plant or equipment capable of being used for the production of biological products, and to produce and hold stocks of biological products, for purposes other than immediate sale of those products,

in accordance with the determination; and

(c) subject to the last two preceding paragraphs, to carry on the undertaking known as the Commonwealth Serum Laboratories,

and are exercisable for or in relation to any purpose of the Commonwealth including any of the following purposes:-

(d) the defence of the Commonwealth;

(e) external affairs;

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

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

(h) quarantine; and

(i) a Territory of the Commonwealth.

60. The witness representing the Department of Health said that the functions provided for by Section 19 (a) would be similar to those carried out by the Laboratories prior to the formation of the Commission. It had been envisaged that the Commission should be perfectly free to embark on research work associated with prescribed products. Qs.206 and 207

61. Section 19 (b) (i) enables the Commission to undertake pure Q.209

research not associated with foreseen production in accordance with avenues that the Minister may consider desirable. It was said that this sub-section provides for pure, as opposed to commercial research. For example, a project based on ideas received from another country, or one originated in the Laboratories of the Commission may or may not lead to benefits in the general prevention of disease and morbidity or mortality, but which, as seen at the outset, would not be directed towards the production of an actual commercial product.

62. Section 19 (b) (ii) provides for the production and holding of stocks of biological products for purposes other than their immediate sale. An example of stocks prescribed by this sub-section is that of calf lymph held for use should an outbreak of smallpox occur in Australia. Q.209

63. The view was expressed that the broad effect of section 19 was to confine, restrict and limit the activities of the Laboratories in that there is no provision for flexibility of operation or opportunity to diversify production. Q.763

Production

64. Calf lymph was produced under Commonwealth control between 1912 and 1915, prior to the establishment of the Commonwealth Serum Laboratories. It was said that immediately the Laboratories' new buildings were occupied in 1918, production commenced to the extent of the installed capacity. Production figures for the Laboratories' early years are not available. Qs. 30 to 32

65. While existing records do not disclose when actual developmental work on veterinary products commenced, the Laboratories' products appeared on the market in 1920. Details of production of selected human and veterinary products by the Laboratories for the years 1946-47, 1956-57 and 1960-61 are given in Table No. 1 Q.54 and Committee File 1967/1

Table No.1

Commonwealth Serum Laboratories

Production of Selected Human and Veterinary Products (1946-47: 1956-57: 1960-61)

Product	Unit of Measurement	Year		
		1946-47	1956-57	1960-61
Penicillins	Million mega	0.12	7.04	5.2
Bacterial Vaccines (Human)	Doses	250,000*	500,000*	2,900,000
Prophylactics (Human) (Single and Mixed)	Doses	1,100,000*	1,500,000*	2,900,000
Virus Vaccines (Human) (Excluding Polio)	Doses	425,000	804,000	1,441,000
Poliomyelitis Vaccine (Salk)	Doses	-	5,465,000	2,000,000
Anti-toxins	Million units	660	914	1,990
Antivenenes	Million units	1.49	14.17	74
Hyperimmune Sera	Litres	95.6	53.5	119
Insulins	Million units	114.0	229.0	448**
Blood (Human) for Fractionation	Litres	0	14,202	21,768
Virus Vaccines (Veterinary)	Doses	933,000	3,520,000	4,000,000
Bacterial Vaccines (Veterinary)	Doses	8,000,000*	10,700,000*	16,400,000
Tissue Culture Agents				
(a) Materials	Litres	0	0	635
(b) Cell Preparations	Cultures	0	0	75,000
Pharmaceutical Type Preparations				
(a) Capsules	-	0	0	0
(b) Tablets	-	0	2,500,000*	5,400,000*
(c) Suspensions	Litres	0	0	1,570
Tuberculins (old Tuberculin, Purified Protein Derivative and Synthetic Media)	Doses	1,184,000*	2,492,000*	3,443,000*
Diagnostic Agents	ml.	42,000	n.a.	145,000
Media	Containers	103,000	207,000	300,000

n.a. - Not available * - Estimated production ** - Treatment of pancreas glands to avoid deterioration. Excess production stored in bulk and not sent to Packing Department.

Source: Department of Health

66. Sera, vaccines and other biological products produced by the Laboratories between 1918 and 1961 ranged over those used in protection against quarantinable diseases such as smallpox, cholera, plague and yellow fever; domestic infectious diseases such as diphtheria, whooping cough, tetanus; non-infectious or mildly infectious diseases such as staphylococcus infections, boils and skin diseases and other products of metabolic interest such as insulin for diabetes, thyroid production and pituitary production from the pituitary gland which concerns growth and associated mechanisms. The Laboratories commenced the production of veterinary products with the addition to its products of vaccines used in the prevention of exotic diseases such as black leg.

67. Details of the range of human sera vaccines and other human biological porducts produced by the Laboratories between 1919 and 1961 are given in Table No.2 while those of veterinary products produced between 1920 and 1961 are given in Table No.3

Table No.2

Commonwealth Serum Laboratories

Human Sera Vaccines and other Human Biological Products Produced

(Selected Years)

Product	Number in Category*							
	1919	1920	1925	1935	1939	1943	1953	1961
Bacterial Vaccines	13	16	26	29	29	24	14	12
Smallpox Vaccines	1	1	1	1	1	1	1	1
Sera	6	10	17	21	23	26	14	12
Media	15	15	26	48	51	31	45	58
Tuberculins	1	3	7	7	7	9	7	6
Diagnostic Agents	---	27	64	73	67	114	116	180
Allergen Products	---	---	71	122	178	188	196	202
Endocrine Products								
Insulin	---	---	1	1	1	2	4	7
Other	---	---	1	3	3	3	5	4
Antivenenes	---	---	---	1	1	1	1	6
Prophylactics	---	---	---	---	3	11	17	12
Antibiotics								
Penicillin	---	---	---	---	---	5	7	7
Other	---	---	---	---	---	---	---	2
Diluents	---	---	---	---	---	4	4	4
Total:	36	72	214	306	364	420	431	513

* Varying strengths of a product have not been counted separately.
Source: Department of Health

Q.35 and Committee File 1967/1

Table No. 3

Commonwealth Serum Laboratories

Veterinary Sera Vaccines and other Veterinary Biological Products Produced
(Selected Years)

Product	Number in Category*							
	1920	1922	1927	1934	1939	1946	1952	1961
Media	---	---	---	**	**	**	**	**
Tuberculins	2	4	6	7	8	6	5	2
Diagnostic Agents	---	---	---	---	---	2	2	3
Sera	---	1	2	4	5	6	6	10
Bacterial Vaccines	---	3	9	12	12	14	14	11
Endocrine Products	---	---	---	**	**	**	**	**
Antivenenes	---	---	---	---	---	---	---	**
Virus	---	---	---	---	2	4	8	6
Penicillin							** ***1	** ***1
Diluents							*	*
Total:	2	8	17	*** 23	*** 27	*** 32	*** 36	*** 33

Q.35 and Committee File 1967/1

* Varying strengths of a product have not been counted separately.

** Human preparations are also used in this range.

*** Human preparations used for veterinary purposes would be additional.

Source: Department of Health.

Penicillin

68. There are two primary manufacturers of penicillin G and penicillin V in Australia. These are Glaxo-Allenbury's (Australia) Pty. Ltd., located at Port Fairy, Victoria, and the Commonwealth Serum Laboratories. The two common forms of penicillin, G and V, are both subject to very precise standards set by the World Health Organisation, the British Pharmocopoeia and the United States Pharmacopoeia. All manufacturers must conform to these standards. The production of penicillin begins with the growth of mould in a tank, the contents of which consist of concentrated penicillin. The potential volume of production from a talk of concentrated penicillin is variable, depending on the strain of mould used and growth conditions in the tank. A first step in increasing productivity is to

Qs.781, 315 and Pp. No. 221 of 1962-63

develop a strain of mould and growth conditions which will maximise the yield from a given input of raw materials. Another stage in which productivity may be increased is during the various processes in which penicillin is extracted from the material in the tank and converted into the final product. It was said that improvements of the latter kind had increased efficiency by some 15 percent. The increase in the in-tank yield, however, had been a very much higher percentage than that.

69. Although the Laboratories commenced production of penicillin G in 1943, it was first made available to the civilian population in Australia on a restricted basis in July, 1944. Production by the Laboratories of penicillin V commenced in 1955-56. During our inquiry into Expenditure from the Advance to the Treasurer for 1961-62, it was stated that the level of production of penicillin by the Laboratories depended on its demand. Details of penicillin production in the years 1946-47 to 1960-61 are given in Table No. 4

Q.71, Committee File 1967/1 and Pps. No.152 of 1962 and No.221 of 1962-63.

Table No. 4

Commonwealth Serum Laboratories

Penicillin Production: 1946-47 to 1960-61

(Million mega units)

Year	Quantity	Year	Quantity
1946-47	0.12	1954-55	5.23
1947-48	n.a.	1955-56	5.38
1948-49	0.20	1956-57	7.04
1949-50	0.54	1957-58	8.10
1950-51	0.87	1958-59	12.5
1951-52	1.72	1959-60	17.12
1952-53	5.51	1960-61	5.26*
1953-54	5.58		

Q.32 and Committee File 1967/1

n.a. - Not Available

* - Plant shut down January-June (inclusive) 1961.

Source: Department of Health

70. During our inquiry into Expenditure from the Advance to the Treasurer 1960-61 it was said that an emergency meeting had been called at the Laboratories in October, 1960 at which it had been decided that production of penicillin would be reduced. Production subsequently began to decline in October and ceased at the end of December of that year. Evidence given at our inquiry into Expenditure from the Advance to the Treasurer for the following year indicated that the estimates for that year had provided for the production of 135 tanks of penicillin. However, production did not commence until February and only 82 tanks were completed during the year. Pp. No.112 of 1961 Pp. No.152 of 1962

71. The Commission advised the Tariff Board during the Board's inquiry into the penicillin industry in 1962 that a considerable sum had been spent in the years prior to the inquiry in improving production methods, seeking technical knowledge, negotiating license agreements, and generally developing the ability of the organisation to produce penicillin to meet the needs of the community. However, following the accumulation of substantial stocks resulting from lower sales due to increased competition from imports following the removal of import licensing controls in February 1960, the Laboratories suspended production of all penicillins on 1 January 1961 and did not resume production until late February 1962. Pp.No.221 of 1962-63

72. It was indicated during our present inquiry that the reason for the reduced output of penicillin at that time was the successful efforts made to increase the productivity of the plant which coincided with a marked increase in the availability of imported penicillin. When asked why the Department of Health and the Laboratories had been unable at the time to make a realistic assessment of the quantity of output arising from the improved methods of production, it was said that the success of research activities was such that they "overtook" the production methods. Although the introduction of improved methods of production was a continuing process they were said to have become apparent in 1960-61. Qs.89, 91 and 92 and Committee File 1967/1

73. In the Commission's Report for 1961-62 it was said that the operation of the penicillin fermentation plant recommenced in late February 1962. In four months, by the use of some new equipment and high yielding strains of penicillin producing mould, the productivity of the plant was raised very considerably above previous levels. While process improvements contributed materially to reduce production

costs during 1961-62, full advantage could not be taken of these during the period because sales only warranted operation of the plant at less than half its capacity.

74. The Commission reported that during 1962-63 there had been a steady improvement in penicillin fermentation, extraction, and purification yields and that there had been an increase in production of benzathine penicillin G. The range of penicillin products was increased during this year to include benzathine penicillin G tablets, "Optifen" brand of phenethicillin and "Aquacaine G" brand of disposable syringe of penicillin G. The Commission's Report for 1963-64 indicated that the production of various penicillins continued with high yield being maintained during that year. Although the level of activity in the fermentation stages did not require the full capacity of available fermentation plant during 1963-64, it was noted in the Commission's Report for that year, that an increase in the scale of this work occurred, particularly during the last quarter of the year, to meet a greater demand for bulk penicillin. The range of penicillins produced by the Laboratories was increased with the introduction of new preparations of semi-synthetic penicillins during 1963-64.

75. The Tariff Board reported, in March 1963 that the two Australian manufacturers had the combined capacity to produce the main types of primary penicillins in quantities exceeding the total demand and that capacity existed for the dispensing and packing of preparations of penicillin on a scale in excess of the requirements of the market. The Board also noted that the production of the main types of penicillins had been rationalised by the industry on the basis that for the time being at least, one manufacturer would concentrate on the production of penicillin G whilst the other would concentrate on the production of penicillin V. P.P. No.221 of 1962-63

76. During 1964-65 the commissioning of a new 25,000 gallon penicillin fermentation tank was completed and trial runs on a second 25,000 gallon tank commenced later in the same year. It was reported by the Commission in the following year that a marked increase in demand for formulated penicillin products in capsule, tablet and suspension forms had overtaxed existing facilities and steps were taken to obtain additional production equipment. Large export orders for bulk penicillin during 1966-67 were met by operating the plant at

almost maximum capacity for several months. It was said that the demand for formulated penicillin products in capsule, tablet and suspension forms necessitated the working of three shifts, seven days a week for a large part of the time. The introduction of a new broth stripping plant was said to have reduced the loss of solvent by forty five per cent in 1966-67. It was said that this process involves the recovery of penicillin from an organic solvent and its re-use by purification and distillation. It was indicated that reductions in operating costs, due to the introduction of this procedure, involved some $43,000 in the first half of the financial year 1966-67. Q.757 and 758

• Insulin

77. As noted in Chapter 2 , the Laboratories commenced production of insulin in 1923. In the financial year 1923-24, 1.5 million units of insulin were produced, while in 1934-35, 39.2 million units were produced and in 1945-46, production had increased to 174.0 million units. Details of insulin production in later years are given in Table No. 5 Q.32 and Committee File 1967/1

Table No. 5

Commonwealth Serum Laboratories

Issues of Insulin from Production Department to Packing Department

(1946-47 to 1960-61)

Year	Quantity
	(Millions of Units)
1946-47	144.5
1947-48	170.5
1948-49	181.3
1949-50	197.5
1950-51	224.8
1951-52	245.3
1952-53	257.8
1953-54	276.0
1954-55	274.7
1955-56	254.6
1956-57	229.0
1957-58	216.7
1958-59	242.0
1959-60	211.0
1960-61	166.0

Q.32 and Committee File 1967/1

Source: Department of Health.

78. Raw material for the production of insulin is the pancreas gland of cattle, preferably calves. Except for a very small percentage, these glands are discarded as being of no value during the slaughtering process. Preparation of the glands for the production of insulin necessitates their removal and separation within minutes of slaughtering, involving an additional operation in the slaughtering procedure. An approach to the relevant unions by the Laboratories resulted in the unions extending their full co-operation in the matter. Qs.375 and 376

79. The price, determined by the large meat works, for pancreas glands supplied to the Laboratories was said to be commensurate with the procedures involved in their recovery. Extensive negotiations have taken place between the Laboratories and abattoirs in this matter and a reasonably satisfactory price has been agreed upon. It was indicated, however, that the position is such that if the abattoirs cannot obtain a satisfactory price from their point of view they prefer not to supply the glands to the Laboratories. Qs. 375 and 376

80. The Commission's Report for 1961-62 indicated that the Laboratories were, at that time, the only basic manufacturers of crystalline insulin in Australia and that capacity at that time was such that Australia's requirement of insulin as well as a surplus for export could be produced. It was also noted in that Report that Australia had one of the largest readily available supplies of pancreas glands in the world for the manufacture of insulin.

81. During 1962-63 the Commission's insulin plant was inoperative because of the availability of imported insulin. Formulation of insulin products during this period was continued, however, by drawing from accumulated stocks of crystalline insulin. The Commission's Report for 1964-65 indicated that subsequent to a 'shut down' period of more than four years, extraction of insulin from pancreas glands had been resumed in a relocated and modernized plant capable of meeting the total requirements of the Commonwealth. We were told in evidence that a very large reserve stock of what could be termed the final stage intermediate insulin, had been held by the Laboratories at the beginning of the 'shut down' period. For this reason the primary manufacture of insulin was discontinued and the Q.351

plant was used intermittently for the production of other biological products.

. Blood Products

82. The Commonwealth Serum Laboratories pioneered the use of human blood products when in 1925 blood which had been donated by people who had recovered from poliomyelitis, measles and scarlet fever was first processed for therapeutic purposes. The methods used to obtain the sera were adopted on a large scale when blood products were required during the 1939-45 war. The Laboratories have always worked in close and satisfactory co-operation with the Australian Red Cross Society and its Blood Transfusion Service. Committee File 1967/1

83. Pooled human serum was first produced at the Laboratories on a small scale in the 1930's. General production of serum was commenced in 1940 when the Australian Red Cross Society organised a donor service and the collection of human blood and serum on a regular basis. Details of human and bovine blood fraction products produced at the Laboratories in the period 1953-54 to 1960-61 are given in Table No. 6 Q.72 and Committee File 1967/1

Table No. 6

Commonwealth Serum Laboratories

Human and Bovine Blood Fraction (1953-54 to 1960-61) Q.32 and Committee File 1967/1

Year	Human						Bovine	
	Plasma Received	Albumin	Gamma-globulin	Fibrin-ogen	Pooled Human Serum	Packed Red Cells	Plasma Received	Albumin Produced
	(litres)	(bottles)	(litres)	(gms)	(litres)	(units)	(litres)	(gms)
1953-54	3,387	-	-	-	2,508	-	61	-
1954-55	10,159	7,590	12	-	2,117	-	95	600
1955-56	14,131	8,060	11	-	2,083	-	508	6,850
1956-57	14,202	9,560	13	1,300	2,238	-	700	9,400
1957-58	16,670	10,800	46	980	2,175	-	2,144	9,000
1958-59	17,320	13,790	176	1,185	1,844	-	1,636	22,200
1959-60	18,960	19,610	238	1,810	1,762	587	1,969	37,600
1960-61	21,768	19,690	375	2,767	1,476	2,268	2,279	34,200

Source: Department of Health

84. Human plasma and placentae are the sources of blood fractions. During 1962-63 the volume of human plasma and placentae received from the State Divisions of the Red Cross Society increased and fractionation of plasma supplied from New Zealand and return of the resultant fractions was placed on a routine basis. Commissioning of an enlarged serum fractionation plant in a new location was completed in 1964-65. Committee File 1967/1

. Other Human Products

85. As shown in Table No. 2 the number of products produced and classified as Bacterial Vaccines increased from 13 in 1919 to 29 in 1935 and then declined to 12 in 1961. An underlying cause of the decline in the number of products produced in this group was related to research which indicated that certain vaccines should be discarded. Another reason given for the decline in the number of bacterial vaccines produced was the consolidation of various vaccines into multiple purpose vaccines. A similar trend in the number of products produced in the group classified as "sera" was said to be due to similar factors. Q.558

86. The Commission reported that the production of antitoxins and antivenines was satisfactory for the year 1961-62 and that the production of Heparin became fully established during that year. Several new allergen extracts including insect, mould, pollen and bacterial vaccines were made available for issue in 1961-62.

87. In its Report for 1963-64 the Commission noted that there had been an increase in the output of prophylactics for human use such as BCG vaccine and triple antigen and that a number of mixed allergen extracts had been prepared to facilitate testing for allergies. The range of diagnostic agents was further developed during 1963-64 to satisfy the more specialised procedures practiced in hospital diagnostic laboratories.

88. In 1964-65 progress was made by the Laboratories in the development of more specific diagnostic reagents, particularly those used in the detection of enteric infections. During that year work was undertaken on the preparation and purification of human hormone preparations on behalf of institutions concerned in the application of those products in medicine. This work was said to exemplify the

successful integration of the Laboratories research and production activities.

89. In its Report for 1965-66 the Commission noted that its production of tissue culture media material had increased markedly during that year to meet the demands of laboratories in Australia.

- Veterinary Products

90. Details of the number of veterinary products produced by the Laboratories during the period 1920 to 1961 are shown in Table No. 3. It was said that the increase in the number of products, from 2 in 1920 to 36 in 1952 was due mainly to the introduction of new and better products. During 1961-62 more economic production of a number of veterinary vaccines resulted from the introduction of larger tanks for the preparation of an improved pulpy kidney vaccine. In that year the Laboratories' production of other veterinary vaccines was increased to meet the demand, including export demand, for products such as tuberculin in synthetic medium. Q.594

91. New veterinary products introduced by the Commission in 1962-63 included pulpy kidney-tetanus vaccine for use in the treatment of sheep and "Pencommas Blue", a brand of penicillin. In that year there was an increase in the production of various virus vaccines for the poultry industry. New veterinary products marketed by the Laboratories during 1963-64 included canine distemper vaccine, "Trespen", a multi-purpose penicillin, and "Eryvac", a vaccine for the prevention of swine erysipelas. During 1963-64 the Laboratories co-operated with agricultural and veterinary authorities in Queensland in the development of a bivalent botulinum vaccine. During 1965-66 additional purified, concentrated and mixed veterinary vaccines were brought into routine production by the Laboratories. Veterinary vaccine production was maintained at a very high level in the earlier months of the financial year 1966-67 in order to meet the increased demand from primary producers following the easing of the drought conditions.

Quality Control

92. It was said that having regard to the nature of the Laboratories and the Commission's highly developed sense of public Qs.364 and 744

responsibility, the highest possible safety precautions both in production and quality control are maintained. For most of the Laboratories' products there are prescribed British Pharmacopoeia or British Veterinary Codex standards which must be met. It was said that as, in a sense the Laboratories provide a standard of comparison, the prescribed standards are in some instances exceeded, to the point of being extremely high.

93. The total number of batches of all products tested by the Laboratories during 1966-67 was significantly higher than in 1965-66. The increased work load involved was reflected by the number of batches of parental products tested for sterility during the year i.e. 8,969 as against 7,825 in the previous year. The Laboratories' membership of the National Association of Testing Authorities resulted in more than 160 assays being conducted for clients within Australia during 1966-67.

Capacity

. Penicillin

94. Details of capacity for the production of penicillins were submitted in confidence to the Tariff Board by Glaxo-Allenburys (Australia) Pty. Ltd. and the Commonwealth Serum Laboratories Commission during the Board's inquiry into that industry. On 29 March 1963, the Board reported that these manufacturers had the combined capacity to produce the main types of primary penicillins in quantities exceeding the total demand and that capacity existed for the dispensing and packing of preparations of penicillin on a scale in excess of the requirements of the market. P.p. No.221 of 1962-63

. Other Products

95. In its 1963-64 Report the Commonwealth Serum Laboratories Commission stated that the transfer of the blood fractionation activities of the Laboratories to a modern production area which was nearing completion would permit an expansion of the volume of blood plasma processed on behalf of the Australian Red Cross Society. Important works commenced or completed for the Laboratories during that year included the mechanisation of some production processes.

96. During 1964-65 improvements were made in the efficiency of production in several fields and these in turn permitted plant

capacity to be more effectively utilised. During that year general modifications to production areas and plant were undertaken to facilitate larger batch scale production. Commissioning of the enlarged serum fractionation plant was completed during 1964-65 and it was said in the Commission's report for that year that the modernised insulin plant was capable of meeting the total requirement of the Commonwealth. The commissioning of one of the new 25,000 gallon penicillin fermentation tanks was also completed and trial runs on a second 25,000 gallon tank commenced late in the year.

97. During 1964-65 a site at parkville was cleared for a new dispensing-storage-despatch building. It was said that at that time packing facilities had been substantially unaltered for many years, and were located on various floors of the building not designed for the purpose. As production increased these facilities became increasingly inadequate. These problems were overcome when the capacity provided by the new packaging building became available. In some areas of production, the packaging facilities were said to be fully occupied at periods of peak demand and apart from one limited area, the Laboratories' packaging facilities are not used by other manufacturers. Qs.354 to 356

98. In its Report for 1965-66 the Commission noted its responsibility to maintain and extend the capacity of the Laboratories to develop products essential to the health of the nation. During that year the Commission installed production capacity to meet defence and national emergency demands for a number of key products. In the same year plans were drawn up to overhaul and modernize certain of the Laboratories' production plant and equipment. During December 1965 dispensing, storage and despatch functions were transferred to a modern new building, designed and constructed to improve the efficiency of these operations.

Protection of the Laboratories' Products

99. Licensing in respect of imports of bacteriological products and sera became effective from 8 March, 1952. Until 31 July 1957 imports of these products were admitted on a quota basis, except for the period between 1 April and 30 September 1954, when quantitative restrictions were removed from some products within this category. Licences for quota goods were issued up to a percentage Qs.85 to 87, 586 to 593 and Committee File 1967/1

of imports in a specified base year, the percentage fluctuating from time to time in accordance with variations in the level of overseas funds.

100. We were informed that prior to 1957, availability of local production was, in general, not taken into account in the granting of import licences, except in those cases where applications were made for special licences to import in excess of quotas. Factors considered in the granting of special licences were said to have been essentially, local availability, and availability of overseas funds. Committee File 1967/1

101. On 1 August 1957, the quota system was replaced by an arrangement whereby permission was required to be obtained from the Department of Trade to import each shipment of bacteriological products and sera. This procedure was varied on 1 June, 1958, to provide for these products to be imported on a replacement basis. We were advised that the incidental protection afforded by import licensing would virtually cease for any goods falling into this category. It was indicated, however, that as far as the Commonwealth Serum Laboratories were concerned, only Bacteriological Products and Sera were ever included in this category. Qs.85 to 87, 593 and Committee File 1967/1

102. For most of the period between 1952 and 1964, penicillin in bulk form and, to a lesser degree preparations containing penicillin, and also insulin, were subject to "administrative" licensing arrangements. Licences granted under these arrangements were considered individually by the Central Licensing Administration and were not necessarily related to pre-determined quotas. Licences for the import of pharmaceutical products subject to "administrative" arrangements were generally granted on the same basis as special licences until 1959 when importers were allowed to obtain up to 30 percent of their requirements from overseas sources.

- Insulin

103. Details of licensing arrangements for the import of insulin are given in Table No.7

Table No. 7

Licensing Arrangements for the Import of Insulin
(1952-53 to 1963-64)

Year	Arrangements
1952-53	Administrative licences.
1953-54	Administrative licences to 30.9.1953 then no quota required.
1954-55	No licence required to 31.3.1955 then for 100 percent of 1954 imports.
1955-56	Licence required for 100 percent of 1954 imports.
1956-57	Licence required for 100 percent of 1954 imports to 31.3.1957 then for 120 percent of 1954 imports.
1957-58	Licence required for 120 percent of 1954 imports.
1958-59	Licence required for 120 percent of 1954 imports to 30.11.1958 then administrative licences.
1959-60	Administrative licences.
1960-61	Administrative licences to February, 1960, then no restrictions.
1961-62	No restrictions.
1962-63	No restrictions.
1963-64	No restrictions.

Q.592 and Committee File 1967/1

Source: Department of Health.

. *Penicillin*

104. Details of licensing arrangements for the import of bulk penicillin is given in Table No.8 and for penicillin preparations in Table No.9

Table No.8

Licensing Arrangements for the Import of Bulk Penicillin
(1952-53 to 1963-64)

Year	Arrangements
1952-53	Administrative licences.
1953-54	Administrative licences until 31.3.1954, then no quota required.
1954-55	No licence required until 30.9.1954, then Administrative licences.
1955-56	Administrative licences.
1956-57	Administrative licences.
1957-58	Administrative licences.
1958-59	Administrative licences.
1959-60	Administrative licences.
1960-61	Administrative licences until February 1960, then no restrictions.
1961-62	No restrictions.
1962-63	Licensing required for 20 percent of 1962 imports from 3.8.1962 to 3.6.1963.
1963-64	No restrictions.

Source: Department of Health.

Q.592 and Committee File 1957/1

Table No. 9

Licensing Arrangements for the Import of Penicillin Preparations (1952-53 to 1963-64)

Year	Arrangements
1952-53	Administrative licences
1953-54	Administrative licences to 30.9.1953 then no licence required.
1954-55	No licence required to 31.3.1955 then required for 100 percent of 1954 imports.
1955-56	Licence required for 100 percent of 1954 imports.
1956-57	Licence required for 100 percent of 1954 imports to 31.3.1957 then for 120 percent of 1954 imports.
1957-58	Quota required for 120 percent of 1954 imports.
1958-59	Quota required for 120 percent of 1954 imports to 30.11.1958 then administrative licences.
1959-60	Administrative licences.
1960-61	Administrative licences to February, 1960, then no restrictions.
1961-62	No restrictions.
1962-63	Licences required for 20 percent of 1962 imports from 3.8.1962 to 3.6.1963.
1963-64	No restrictions.

Q.592 and Committee File 1967/1

Source: Department of Health

105. Public inquiries were held by the Tariff Board in January, February and March, 1961, into the question of assistance to the Australian penicillin industry and into the dumping of penicillin G and its salts and veterinary penicillin. The Board reported on 31 August, 1961, that it had received no public evidence at these inquiries which could be regarded as sufficient to warrant determination on other than purely commercial grounds of the question of affording assistance to the production of penicillins. The Board recommended that assistance be not accorded the Australian industry

P.p. No.126 of 1961

producing primary penicillins. It noted, however, that the protective needs of that section of the industry producing preparations containing penicillins were lower than those of the section producing the primary materials.

106. The Board found in terms of the provisions of the Customs Tariff (Industries Preservation) Act 1921-1957, that detriment was being caused to the Australian industry by exports to Australia of penicillin G from Britain and France and of preparations containing penicillin G (including veterinary preparations) from Britain and Denmark at prices below their fair market values at the time of shipment. The Board said that although the question of dumping of penicillin V was not under reference, it was considered appropriate to point out that evidence had been received which suggested strongly that penicillin V and its salts and preparations containing penicillin V had been and/or were being exported to Australia from Britain at prices below fair market values in that country. The Government accepted the Tariff Board's Report and action was taken to impose dumping duties as recommended by the Board.

107. A further report by the Deputy Chairman of the Tariff Board dated 8 January 1962, recommended that urgent action be taken to protect the Australian penicillin industry in relation to imports of penicillin, salts of penicillins and preparations containing penicillin. These recommendations involving both sliding scale and ad valorem duties were adopted by the Government. P.p. No. 14 of 1962

108. A report by the Special Advisory Authority on penicillins, dated 27 July 1962, advised that temporary sliding scale duties imposed on primary penicillins and the temporary ad valorem duties imposed on preparations of penicillin had not achieved their objective. It was recommended that the termporary duties be replaced by temporary quantitative restrictions designed to restrict imports of primary penicillins and preparations of penicillin to a level equivalent to about 10 percent of the demand in the case of primary materials and 20 percent by quantity of each importer's imports during the year ended 30 June 1962, in the case of preparations of penicillin. These recommendations were adopted. The temporary duties were removed and temporary import restrictions were imposed on penicillins and preparations of penicillin made in Australia with P.p. No. 72 of 1962

effect from 3 August 1962.

109. The Commission's Report for 1962-63 stated that the result of this protection was to increase considerably the use in Australia of locally manufactured penicillin and during the year ended 30 June 1963, the sales of bulk penicillin manufactured by the Laboratories increased substantially. In the same Report it was said that the increased sales of penicillin resulting from protection given by quantitative import restrictions had materially assisted in the elimination of trading losses.

110. The Report of a second inquiry by the Tariff Board into the penicillin industry was presented on 29 March 1963. The terms of reference were limited to the determination of the extent of assistance necessary and the means by which it could most appropriately be accorded the production of antibiotics in Australia. The Board reported that evidence submitted showed that although the local penicillin industry had the capacity to meet the total demand for the prinicpal types of penicillins, its share of the market decreased substantially after the import licensing controls were removed in February 1960. During the year ended 30 June 1962, the total value of sales by Glaxo-Allenburys (Australia) Pty. Ltd. and the Commission of goods under reference (penicillin and streptomyacin) was 50 percent below the level achieved during the year ended 30 June 1960. The Board considered that effective protection could be afforded the industry by increased tariffs. P.p. No.221 of 1962-63

111. In June 1963, quantitative restrictions were removed and existing tariffs were raised. In its report for 1963-64, the Commission noted that over a trading period of intense activity, sales of products other than poliomyelitis vaccine showed an encouraging increase. The Commission reported that during the financial year 1966-67 production in some departments reached the highest levels in the history of the Laboratories and large export orders for bulk penicillin were met by operating the plant at almost maximum capacity for several months. The demand for formulated penicillin products in capsule, table and suspension forms necessitated three shifts to be worked at the Laboratories seven days per week for a large part of this time.

Distribution and Promotion.

112. The Commission markets some 400 products and given the various strengths of these, some 1,300 inventory lines are carried by the Commission. Q.339

113. Prior to 1954 promotion of the Laboratories' products was undertaken by one officer only. This officer travelled throughout Australia and New Zealand in the promotion of the Laboratories' products. In 1954 a second representative was appointed to the sales promotion staff and in 1957 a third was appointed to specialise in the promotion of veterinary products. By 1959 it was felt that sales were being lost to competitors because of inadequate promotional activity. It was said that consideration had been given to this problem at the time but in view of a substantial fall in sales and the Government's decision to curtail temporarily the production of penicillin and insulin, the proposed re-organisation of the sales promotion staff was held in abeyance and remained at three until the formation of the Commission. Q.329 and Committee File 1967/1

114. Prior to the establishment of the Commission and in the first year or two of its operation, the Laboratories' products were distributed through the State offices of the Commonwealth Department of Health. The Commission subsequently established its own State offices for the distribution of its products. Q.313

115. In its Report for 1961-62 the Commission said that the principal trading difficulty of the Laboratories had been the steady and substantial fall in sales during the previous three years. The main reason for this decline was said to be the relaxation of import licensing. A contributing factor, however, was said to be the virtual absence of an effective marketing organisation within the Laboratories. Action was taken during the year to increase marketing efficiency and to improve the competitive position of the Commission's products. Q.311

116. The net profit of the Commission for the financial year 1962-63, $240,614, was achieved over a difficult trading period. It was during that year the Commission opened branches in each capital city throughout Australia, making available a full range of its products in each city branch. It was claimed that the Commission's

marketing organisation is now adequate in numbers and effective in function. Q.311

117. Subsequent to promotional activity, sales of all the Commission's products increased substantially during the financial year 1966-67. During this year export sales continued to be negotiated through the Commission's agents in established markets. P.p. No.178 of 1967

118. Effective distribution of the Laboratories' diagnostic bacteriological media and other products to country areas was maintained during 1966-67 including that effected through the co-operation of Government Health Laboratories at Cairns, Townsville, Rockhampton, Toowoomba and Lismore. This assistance, which had been given prior to the establishment of the Commission, involves the maintenance of stocks for distribution to hospitals in the area. The total fee paid by the Commission for this service amounts to some $16,000 per annum. It was said that in Victoria, South Australia and Tasmania this service is not required but that the possibility of a similar service being established in Western Australia is under examination. Qs.750 to 754

119. The Commission's products are distributed mainly through wholesalers for distribution to chemists, and directly to hospitals. It was said that these products were not of the type or range to justify the introduction of the Laboratories' own distribution network to chemists and dispensaries. It was claimed that it is far more economical for the Commission to distribute a large proportion of its products through wholesalers. Excluding those products sold under the national health service, a very considerable body of the Commission's products are sold direct to users. Qs. 528 and 529

120. In an endeavour to increase the level of the Commission's exports, information in respect of export markets is obtained through various sources including the Trade Commissioner Service. Visits to overseas countries have been made by executives of the Commission and suitable agents have been appointed. During the financial year 1966-67 the Commission negotiated several new or extended agency and distribution arrangements.

. Sales

121. The value of sales of the Commission's products during the period 1961-62 to 1966-67 is shown in Table No. 10

Table No. 10

Commonwealth Serum Laboratories Commission

Sales by Value: 1961-62 to 1966-67

Year	Value
	$
1961-62*	2,842,698
1962-63	6,078,830
1963-64	5,718,574
1964-65	6,370,902
1965-66	7,134,509
1966-67	7,151,716
Total	35,297,229

* - for the period 2 November 1961 to 30 June 1962.

Source: C.S.L. Annual Reports

122. The Commission reported that its trading profit for the financial year 1963-64, $369,169, was achieved over a period of intense activity when sales of its products, other than poliomyelitis vaccine showed an encouraging increase. In the following financial year, 1964-65, the Commission reported a great number of changes, and in particular, that sales of bulk materials had declined, due to competitive pressures, while sales of dispensed products bearing the C.S.L. trademark had shown a considerable improvement. It was said that this reflected an increased acceptance of the Commission's brand name in the market. Qs.336 to 338

. Export Sales

123. Detailed records of exports, either by quantity or value are not available in respect of the early years of the Laboratories' operations. There is evidence, however, of exports to New Zealand as early as 1920 and prior to the 1939-45 war regular supplies of the Laboratories biological products were sent to the South Pacific, Q.329 and Committee File 1967/1

New Zealand, and parts of India and China. Subsequent to the war, exports were made to Egypt, India, Singapore and Indonesia. The value of export sales in the four years immediately prior to the formation of the Commission are shown in Table No.11

Table No.11

Commonwealth Serum Laboratories

Exports by Value: 1957-58 to 1960-61

Year	Value
	$
1957-58	387,000
1958-59	645,000
1959-60	367,000
1960-61	197,000
Total	1,596,000

Source: Department of Health

Q.329 and Committee File 1967/1

124. The Commission reported that during the period November 1961 to June 1962 a wide variety of vaccines were exported to the Pacific and Asian areas and large quantities of B.C.G. vaccine for immunisation against tuberculoses and tuberculin for testing purposes were supplied to Singapore. Exports of the Laboratories' products continued to increase during 1962-63 including substantial quantities of cholera and diphtheria vaccine to Asian markets. Details of the Commission's exports by destination and value for the years 1961-62 to 1966-67 were submitted in confidence.

Committee File 1967/1

125. During the financial years 1961-62 and 1962-63 the Commission's exports to Britain consisted mainly of bulk insulin crystals needed to overcome a shortage of this product in Britain in those years. The Commission's total export sales continued to increase during 1963-64 and again included substantial quantities of vaccines to Asia. Large export orders for bulk penicillin were met by the Laboratories during the financial year 1966-67 as well as substantial orders for tetanus antitoxin, mainly from Indonesia. Evidence in respect of aspects of the Commission's current export activities were also submitted to the Committee in confidence.

Q.725 and Committee File 1967/1

Research and Development

. Section 19 (a)

126. Research under section 19 (a) of the Commonwealth Serum Laboratories Act during 1963-64 was directed mainly towards additions and improvements to the range of biological preparations. In that year methods were developed for the manufacture of a group of improved clostridial vaccines together with a bivalent botulinum vaccine. Investigations were made of the El Tor strains of cholera and a vaccine containing these was prepared for field trials by the Commission's laboratory at Wewak in Papua-New Guinea.

127. Work was undertaken during 1963-64 on simian virus infections and improvements were made on the then current type of influenza virus vaccine. The influenza centre conducted by the Laboratories for the World Health Organisation isolated a new strain of influenza virus which had caused an outbreak of influenza in Australia at that time.

128. In the field of biochemistry in 1963-64 research undertaken under section 19 (a) was on the improvement of various aspects of the preparation of some semi-synthetic penicillins and the adoption of these for large scale manufacture. A survey was completed on the incidence of potentially allergenic spores in the atmosphere on a seasonal basis. The investigation of blood groups in the native populations in the Pacific region was continued in the Blood Group Reference Laboratory. Laboratory work and field trials continued the evaluation of veterinary vaccines produced during the year and work on veterinary virus vaccines used in the poultry industry was continued.

129. Research under section 19 (a) during 1964-65 made substantial contributions to the extension and improvement of the Commission's range of biological products. Products of which new or improved forms were developed included influenza virus vaccine, tetanus toxoid, small-pox vaccine, a number of agents for the prevention of canine and poultry disease and diagnostic agents. Improvements were also made in veterinary clostridial vaccines and a number of new veterinary vaccines for sheep and cattle, particularly those of a purified type, were developed.

130. During that year the World Health Organisation designated the Commission's Blood Group Reference Laboratory as the National Blood Group Reference Laboratory for Australia. Work on racial genetics in the Pacific area by means of blood group studies was continued. Viruses causing influenza epidemics in Australia and New Guinea during the year were identified.

131. Research during 1965-66 continued to effect improvements in the quality, potency and range of biological products. A number of human vaccines were studied intensively, resulting in probable improvements in these preparations. An extensive examination and recasting of the range of diagnostic sera was undertaken and several new diagnostic agents were piloted into production.

132. Substantial contributions were made during the year to the improvement of antibiotic products and formulations. Design and modified production data was provided to guide the installation of improved antibiotics manufacturing equipment. Evaluation of levels of immunity in humans in response to tetanus prophylactics and studies of diphtheria immunity of adult populations continued.

133. Biophysical procedures, including electron microscopy provided important ancillary contributions to many projects and the effects of gamma-irradiation as a means of sterilization of biological products were studied in the bacteriological, biochemical and cell culture fields.

134. Field investigations at the Woodend Field Station and the Study of optimal production conditions substantially improved the quality of veterinary products. An outbreak of equine disease, not controlled by vaccination, was investigated by both clinical and laboratory studies. Work associated with veterinary virus vaccines made favourable progress in the development of new methods of production and field trials of modified vaccines were carried out. A study of optimal routes of inoculation of poultry viral vaccines and response characteristics was also made during 1965-66.

135. In its Report for 1966-67 the Commission noted that research under section 19(a) of the Commission's Act covers basic and applied investigations in the fields of bacteriology, virology, immunology,

serology, biochemistry and biophysics, and that significant progress was made during the year in several of these fields. Research activities during 1966-67 effected further improvements in the quality and potency of bacterial and viral vaccines and several new diagnostic agents were developed.

136. The biophysical services available at the Laboratories were used extensively during 1966-67 by outside scientific establishments, including the University of Melbourne and a number of hospitals. Studies of immunity in the population, including the measurement of specific antibody levels against tetanus, influenza and poliomyelitis were continued. Techniques were developed to assay the quality of the various antibody classes in human serum, and these were applied to assess the quality of the various gamma globulins. Cell culture techniques and the number of tissue culture lines were extended to cope with increasing demands for the production of viral vaccines.

137. The work of the World Health Organisation Reference Centres located at the Laboratories continued throughout 1966-67. These Centres are the Influenza Centre, which types virus strains in Australia and New Guinea and provides basic data for the formulation of new vaccines; the Blood Group Centre, which assists pathologists and clinicians with difficult cross-matching problems and is conducting a programme of blood group genetic studies of South-West Pacific racial groups. During 1967 the centre made available anti-Rh (D) Gamma Globulin for use in the prevention of Rh-haemolytic disease of the new-born. The third centre, the Brucellosis Centre, assists veterinarians throughout Australia in establishing the diagnosis of brucella infection and in the typing of different strains of the organism.

Section 19 (b)

138. During 1962-63 the following four research projects were approved to be undertaken by the Laboratories.

The investigation of Australasian soils for antibiotic producing moulds and the clinical evaluation of any new antibiotics discovered.

The investigation and testing of human and veterinary viruses and the methods of isolation and identification of these for new vaccines.

The identification of types of staphylococci involved in bovine mastitis for the preparation of a vaccine; and

The investigation of factors concerned with the pathogenicity of micro-organisms and the purification of bacterial antigens.

139. Work on the following projects was undertaken during 1963-64.

The investigation of Australian soils for antibiotic-producing moulds.

The development of inactivated and attenuated strains of virus for a measles vaccine.

The development and testing of a vaccine for staphylococcal bovine mastitis.

The investigation of factors concerned with the pathogenicity of micro-organisms and the purification of bacterial antigens; and

Biochemical factors involved in antibiotic resistence in staphylococci.

140. Research under Section 19. (b) was directed to the following projects in 1964-65.

The nature of essential antigens of pathogenic micro-organisms.

Bacteriological problems associated with human disease in New Guinea.

Biochemical factors concerned or associated with antibiotic resistence.

The nature of immunological response to viral vaccines and factors influencing such response.

141. The bacteriological research unit at Wewak, New Guinea, established by the Commission for the purpose of investigating problems of bacterial disease among the indigenous population became fully operative during 1964-65 and the following projects were undertaken.

A survey of fungi from soil and skin diseases.

Investigation of the incidence of diarrhoeal disease and a survey of past infections by the examination of sera.

Examination of water supplies for evidence of the presence of cholera.

Field trials of cholera vaccine.

142. The following section 19 (b) research was undertaken by the Laboratories during 1965-66.

The nature of essential antigens and the enzymes of pathogenic organisms.

Biochemical and genetic control of factors associated with antibiotics and antibiotic resistence.

The nature of immunological response to viral vaccines and factors influencing such response.

Bacteriological problems associated with human disease in New Guinea.

Characterisation and investigation of biological use of enzymes found in naturally occurring venoms.

143. The Research Unit at Wewak was engaged on the following projects during 1965-66.

The incidence of diarrhoeal disease including a survey of carrier rates among selected populations.

A survey of fungi found in soil and in skin diseases.

The examination of water supplies from the West Irian border for evidence of cholera contamination.

The examination of settlement water supplies and of domestic animals and rodents for evidence of other water-borne diseases; and

Field trials of cholera vaccine.

144. In its Report for 1966-67 the Commission reported that research under section 19(b) resulted in progress in the following fields.

Studies towards reducing undesirable side effects of pertussis vaccines.

The release of penicillinase by staphylococci.

The preparation of specific antisera.

A new factor for the treatment of haemophilia; and

The growth of a live measles virus and rubella virus in tissue culture.

Chapter 6

The Powers and Duties of the Commission

145. Section 20 of the Commonwealth Serum Laboratories Act 1961 sets out the powers of the Commission as follows:-

"(1.) Subject to the next succeeding sub-section, the Commission has power to do all things necessary or convenient to be done for or in connection with the performance of its functions.

(2.) The Commission shall not, except with the approval of the Minister, purchase or dispose of capital assets for a consideration exceeding twenty thousand pounds."

146. During our inquiry attention was directed to the significance of sub-section (2.). We were informed that the amount provided for in this sub-section, $40,000, is a measure of the responsibility the Government was prepared to place on the Commission in respect of transactions involving the purchase or disposal of capital assets. It was said that probably, there is no formula from which the amount was derived. Witnesses representing the Department of Health were unaware of any difficulties in the operation of the sub-section which is applied to individual capital assets in excess of $40,000. It was said that the disposal or purchase of assets is generally dealt with in the Commission's estimates to the Minister. While similar provisions are provided by the Australian Coastal Shipping Commission Act and the Australian National Airlines Act, different amounts are prescribed.

Qs.211, 230 to 241 and Committee File 167/1

147. We noted in particular that as purchases and disposals of capital assets without Ministerial approval are not

Qs.236 to 241

limited by the sub-section to forty thousand dollars during a specific period of time, i.e. twelve months, the Commission could, if it so desired, in any financial year purchase or dispose of substantial capital assets, providing individual purchases or sales were below the forty thousand dollar limit, without the approval of the Minister.

148. At the time of our Inquiry the Department of Health had not reviewed the amount provided for in this sub-section and representations in respect of this matter had not been received from the Commission.

Duties

149. Section 21 of the Commonwealth Serum Laboratories Act 1961 lays down the duties of the Commission in the following terms:-

> "The Commission shall, in relation to biological products prescribed for the purpose of paragraph (a) of section nineteen of this Act, pursue a policy directed towards securing revenue from the sale of those products sufficient to meet all its expenditure (including expenditure in undertaking research) in connection with those products that is properly chargeable to revenue, and to permit the payment to the Commonwealth of a reasonable return on the capital of the Commission."

150. During our inquiry we examined specifically the requirements laid down in this section relating to a reasonable return on the capital of the Commission. While the Department of Health witnesses were unable to define the meaning of a reasonable return on funds, the Treasury Observer, Mr. Virtue, felt that such a definition would depend on the situation of the particular Statutory Authority concerned in relation to its competitors and on other circumstances that have a bearing on its ability to make a profit. He expressed the view that on a commercial basis, the long term bond rate would represent a reasonable gross return on capital for the Commission. At the time of our inquiry the Commission had not made payment of any return to the Department of the Treasury on its capital funds.

Qs.242 to 249,253 & 416

Qs.421 and 422

151. The Serum Laboratories Commission witnesses expressed the view that as the Laboratories are engaged partly in commercial activities and partly in public health activities it would be necessary to dissect the capital employed by the Commission into two categories, one relating to research and public health activities and the other relating to commercial activities in order to determine a reasonable return factor on capital employed on commercial activities. The Treasury Observer, Mr. Virtue, agreed that unless such a dissection of capital were made it would be difficult to determine any measurement for a reasonable return on funds. Qs.415 and 416

Prices

152. Section 22 of the Commonwealth Serum Laboratories Act 1961 provides:-

> "The Minister shall, after consulting the Commission, determine the prices to be paid for products supplied by the Commission directly to the Commonwealth or a State or a person on behalf of the Commonwealth or a State."

153. The Department of Health witness informed us that this section enables the Minister to fix a price for the Salk poliomyelitis vaccine, a product manufactured entirely by the Laboratories for the purposes of the Commonwealth, and that while this is the main purpose for which it has been used, the Minister is required to exercise his powers under this section on any occasion on which the Laboratories are supplying products to the Commonwealth. Qs.212 and 213

154. A large proportion of the products manufactured by the Commission are on the national health list. The Department of Health, in negotiations with members of the pharmaceutical industry, including the Commonwealth Serum Laboratories Commission, fixes the prices of products available under the scheme. The Commission's witness stated that it would resist strongly any suggestion that national health scheme prices be set below the Commission's cost of production. Qs.370, 371 and 394

155. On examining the annual report for 1963-64 we noticed that whilst the Commission's sales other than those of poliomyelitis vaccine had shown an encouraging increase, its sales revenue had declined compared with the 1962-63 level and that a loss of profit on penicillin and heparin had ensued from a voluntary reduction in selling prices. We were informed by the Commission's witnesses that the term "voluntary price reduction" connoted a decision by the industry to reduce prices by approximately ten per cent. Itwas explained that up until that time the Australian penicillin manufacturers and distributors had suffered from import competition. Arising from an inquiry held by the Tariff Board, the Board had recommended protection for the industry but it also expressed the wish to be assured that the manufacturers would retain their incentive to reduce costs. Qs.314, 315 and 344

156. As a voluntary price reduction had been made by the industry, we questioned the witnesses as to whether a price agreement or an association arrangement existed between local suppliers in relation to price levels. We were informed that, in a loose and special sense, there is an association but that if a reduction is to be made in the price of any item on the national health scheme list, such a reduction would be the result of negotiations between officials of the Department of Health and the manufacturers of the particular item. The witness denied that the Commission was a member of a drug industry monopoly although he indicated that the Commission is a manufacturer of pharmaceuticals, or of a particular kind of pharmaceuticals and in that sense is one of the organisations with whom negotiations are undertaken in order to bring about price reductions under the national health scheme. In regard to items outside that scheme, prices were said to be determined by competitive forces. Qs.388 to 394

Relationship between Sections 19,21 and 22 of the Commonwealth Serum Laboratories Act.

157. The Chairman of the Commission, Mr. Davis, referred to the relationship between Sections 19, 21 and 22 of the Commonwealth Serum Laboratories Act. He stated that Section 19 confines, restricts and limits the activities of the Laboratories in such a way that the Commission does not have the flexibility of operation and the opportunity to diversify that are available in private enterprise. Section 22 places an obligation on the Minister to determine the price of all products supplied directly to a government or to a person on behalf of a government after conferring with the Commission, while Section 21 directs the Commission or the Commissioners to follow a policy which, among other things, will produce a reasonable return on capital employed. It was stated that a conflict exists between these sections in that limitations are placed on the sale of biological products in which a very considerable area of the Commission's sales is affected directly and indirectly by prices which are beyond the actual control of the Commission. The Commission is gravely handicapped when it seeks to carry out the duty imposed on it of also showing a profit. Mr. Davis claimed that whatever progressive efficiencies are made in any one area of the organisation, this dilemma will remain until the Government or the Parliament amends the Commonwealth Serum Laboratories Act to make it clear that the Commission is either primarily a part of the public health service of the community with a section devoted to commercial activities or is primarily a commercial activity with limited Government responsibility. He informed us that the question of capital allocation, and the definition of commercial activities as distinct from Government activities, had been under Commission examination. Qs.763 and 827

158. The Director of the Commission, Dr. Lane, felt that while Section 21 of the Act could be deleted, it would be more sensible if, by some method, the Government were to subsidise that portion of the Commission's activities that is inherently non-profitable. Q.785

Chapter 7

The Staffing of the Commission

159. The total staff employed by the Department of Health at the Laboratories during the twelve years prior to the establishment of the Commission are shown in Table No. 12

Table No 12

Commonwealth Serum Laboratories

Staff Employed by the Department of Health

(1950-1961)

YEAR	STAFF EMPLOYED
(as at 30th June)	
1950	647
1951	737
1952	749
1953	762
1954	742
1955	755
1956	861
1957	934
1958	919
1959	1,032
1960	1,052
1961	966

Source: Department of Health

Q.84 and Committee File 1967/1

160. The increase of 106 to 861 in staff numbers between 1955 and 1956 was said to be due to large-scale production of Salk polio vaccine which commenced in the financial year 1955-56. The increase of 113 to a total of 1,032 staff members between 1958 and 1959 was required mainly to supply sera for the anti-influenza campaigns being conducted at that time, although 15 of the additional number were for the small animal Sections, 7 for polio vaccine production, 7 for research and 10 for the administrative staff. The decline in staff members, by 86 to 966 between 1960 and 1961 was due to the closing down of the penicillin plant at that time as well as to other factors including the installation of new packaging equipment which required 22 per cent less staff than that

Q.565

previously needed.

161. The staffing of the Commission is provided for by Sections 24 to 30 of the Commonwealth Serum Laboratories Act. The relevant sections, for the purposes of our inquiry, are set out below.

162. Section 24 of the Act provides -

"The Commission may appoint such officers as it thinks necessary for the purposes of this Act."

163. Details of staff employed by the Commission for the years 1961 to 1967 are given in Table No.13.

Table No. 13

Commonwealth Serum Laboratories Commission

Staff Employed (Including Casual)

(1961 to 1967)

Qs.302 to 307 and Committee File 1967/1

	1961	1962	1963	1964	1965	1966	1967
			(as at 30th June)				
Production	297	281	282	276	277	275	245
Research	108	100	97	98	99	98	96
Quality Control	73	75	70	71	66	63	61
Veterinary Services	100	99	73	70	70	63	60
Packaging	95	94	92	86	82	82	79
Administration	154	153	147	136	141	142	145
Engineering	82	79	78	80	82	89	90
Marketing	57	52	69	82	98	110	114
Extended Leave	.	7	7	9	4	3	9
Total:	966	940	915	908	919	925	899

Source: Commonwealth Serum Laboratories Commission.

164. The total number of staff as at 30th June, 1967

comprised 209 officers of the Public Service(who are also officers of the Commission) 174 officers of the Commission,506 employees of the Commission and a casual staff of 10 people. The staff engaged in production of the Laboratories' products decreased by 52, from 297 to 245 between 1961 and 1967 while in the same period there was an estimated 60 per cent increase in the volume of the Laboratories' production. It was said that the decline in the number of research staff, from 108 in 1961 to 96 in 1967 did not indicate a declining emphasis or declining result from research undertaken by the Laboratories. The number of staff employed in Quality Control declined from 73 in 1961 to 63 in 1966 and to 61 in 1967. We noted from the Commission's Report for 1966-67, however, that the total number of batches of all products tested during that year was significantly higher than in the previous year, and we were told that the reason for the decline in staff numbers in this section was the introduction of more effective 'instrumentation' methods of testing.

Qs.298 to 304 and Committee File 1967/1

Qs.722 to 724

165. Staff in the Veterinary Services group are employed at Woodend and Broadmeadows in the breeding and care of various types of animals for experimental purposes, and in the production of various vaccines and antisera. Staff at Woodend are also engaged in general farming operations which have enabled the Commission to obtain revenue from the sale of surplus fodder,straw, and wool from its sheep flock,while at Parkville the Veterinary Services Group maintain and care for animals under test and experimental conditions.

Qs.302 to 307 and Committee File 1967/1

166. The reduction of staff employed in veterinary services, from 100 in 1961 to 60 in 1967, was said to have been due to the cessation of production of Salk Poliomyelitis vaccine, which during its production in the years 1961-62 required the employment of sufficient attendants for the maintenance of some 4,000 to 5,000 monkeys for production and testing purposes. As well as the reduction in the number of attendants needed following the cessation of Salk vaccine production, a further reduction of staff needs accompanied the

Qs.717 and 718

introduction of mechanical methods of feeding and watering for the animals.

167. The reduction of staff employed in packaging, from 95 in 1961 to 79 in 1967 occurred while the volume of materials handled in the same period had almost doubled. This was due to the availability of a new packaging building providing a more efficient plant. The increase in the number of staff engaged in marketing activities, from 57 in 1961 to 114 in 1967 was due to the opening in 1962 of the Commission's state branch offices and the development of its own marketing and distribution system. Q.302 and Committee File 1967/1

168. The reasons for which staff have been granted extended leave were said to be for the purpose of undertaking full time post-graduate studies, special leave without pay for personal reasons, and for sick leave prior to retirement.

169. Section 26 of the Commonwealth Serum Laboratories Act provides -

"(1.) Subject to this section, the terms and conditions of employment of officers appointed by the Commission shall be such as are determined by the Commission.

(2.) The Commission shall not, except with the approval of the Minister, determine the salary of a position at a rate exceeding Two Thousand five hundred pounds per annum.

(3.) Before giving or refusing his approval for the purposes of the last preceding sub-section, the Minister shall consult the Public Service Board.

(4.) Where a Commissioner, the Director or an officer appointed in pursuance of this Act was, immediately before his appointment, an officer of the Public Service of the Commonwealth -
(a) he retains his existing and accruing rights;
(b) for the purpose of determining those rights, his service as a Commissioner, as the Director or as an officer of the Commission shall be taken into account as if it were service in the Public Service of the Commonwealth; and

(c) the Officers' Rights Declaration Act 1928-1959 applies as if this Act and this Section had been specified in the Schedule to that Act."

170. In regard to Sub-section (2.) of Section 26 we were informed that the salary rate of Two thousand five hundred pounds per annum referred to was approximately the equivalent of the Class 8 salary range within the Commonwealth Public Service at the time the Commission was established. The Public Service Board Observer, Mr.Vanthoff stated that a similar salary level is specified in several Acts constituting Commonwealth Statutory Authorities. Qs.256 to 258

171. The Public Service Board Observer Mr.Vanthoff was asked to explain the full extent of the relationship provided for between the Public Service Board and the Commission by Section 26 (2.) and (3.) and the manner in which it has developed from that which existed prior to the creation of the Commission. He stated that prior to the establishment of the Commission, the Laboratories, as part of the Commonwealth Department of Health, were of direct concern to the Public Service Board in association with the Permanent Head of that Department and that at that time the Board's interest in the Laboratories was similar to that which it has in relation to Commonwealth Departments under the Public Service Act. In this regard the Board was concerned with the determination of classifications and establishments required to carry out the functions of the Laboratories as approved by the Minister or Cabinet of the day. Since the establishment of the Commission, however, the powers of the Public Service Board have been restricted to advising the Minister, should he consult the Public Service Board as provided for by Section 26 (3.) of the Commission's Act. He said that in practice, however, there is a far greater liaison between the Commission, the Public Service Board and the Department of Health than would be suggested by the statutory provisions. For example, discussions involving the Public Qs.220 and 256 to 258

Service Board have occurred from time to time in the determination of salary ranges which, under Section 26 (2.) of the Act, require the approval of the Minister and which, under Section 26 (3.) of the Act, require reference to be made by the Minister to the Public Service Board. The Commission also receives copies of various circulars, memoranda and determinations made by the Public Service Board relative to salary levels. Mr.Vanthoff emphasised that in giving its advice to the Minister, the Public Service Board is exercising its obligation under Section 26 (3.) of the Act, but the Minister may have other considerations to take into account. In relation to staff, the Board's advice protects, as far as any comparison is concerned, the position of the Commission's staff when compared with those of the Commonwealth Public Service. Q.227

172. Mr.Vanthoff said that the provision of Section 26 (4.) is not peculiar to the Commission, and noted that it provides not only for the retention of certain rights and privileges, but also guarantees an officer appointed to the Commission's staff the right, if he so desires, to return to the Commonwealth Public Service under certain conditions. Mr.Balfour, the Treasury Observer, added that the Commission is an "approved authority" under the Superannuation Act. Members, officers and employees of the Commission, who are eligible to contribute to the Superannuation Fund contribute under the provisions of the Superannuation Act. Qs.228 and 229

173. Section 27 of the Commonwealth Serum Laboratories Act provides -

> "The Commission may employ such temporary or casual staff as it thinks fit, on such terms and conditions as the Commission determines."

174. We were informed that, in general, the terms and conditions under which all staff of the Laboratories are employed are at least equal to those of the Commonwealth Public Service and in some areas additional minor fringe benefits are available. In the case of temporary staff, Qs.304 and 305

terms and conditions of employment are similar to those within the Public Service.

175. In addition to temporary staff, the Commission also employs casual staff for periods of one to three months depending on peak production requirements. Total staff figures quoted by the Laboratories include all staff. Q.305

Chapter 8

The Finances of the Commission.

176. This Chapter relates to evidence taken in connection with Division 5 of the Commonwealth Serum Laboratories Act No. 38 of 1961 and other evidence connected with the analysis of financial information relating to the Commission.

Sections 31 and 32

177. Section 31 provides for the transfer to the Commission of assets and the assumption by the Commission of liabilities of the laboratories. Section 32 defines the capital of the Commission. The details of these Sections are set out below:

"31.- (1) Upon the commencement of this Act -

(a) the Minister shall transfer or cause to be transferred to the Commission assets owned by the Commonwealth and held or used in connexion with, or arising from the business of, the undertaking known as the Commonwealth Serum Laboratories; and

(b) the Commission is, by force of this section, liable to pay, satisfy, observe, perform and discharge the debts, liabilities and obligations of the Commonwealth in connexion with, or arising from the business of, that undertaking.

(2) The Commission shall indemnify the Commonwealth, and keep the Commonwealth indemnified, from and against all actions, claims, demands, proceedings, suits, damages, expenses and costs that may be brought against, or incurred by, the Commonwealth at any time for or in respect of a debt, liability or obligation that the Commission is liable to pay, satisfy, observe perform or discharge under paragraph (b) of the last preceding sub-section.

(3) In this section, "assets" includes -

(a) plant, machinery, equipment, office furniture, fittings, motor vehicles and stock in trade;

(b) book and other debts due to the Commonwealth and the benefit of any securities for those debts;

(c) the benefit that is capable of assignment of all pending contracts;

(d) the amount standing to the credit of the Commonwealth Serum Laboratories Trust Account at the commencement of this Act;

(e) all other property, rights or interests to which the Commonwealth is entitled and which it may assign; and

(f) all appropriate records maintained by the Commonwealth,

but does not include -

(g) land (including buildings on land); and

(h) stocks of biological products that are not prescribed for the purpose of paragraph (a) of section nineteen of this Act.

32. The capital of the Commission at any time is an amount equal to the sum of -

(a) the value, as determined by the Treasurer and notified by him to the Commission, of the assets transferred to the Commission under the last preceding section; and

(b) such amounts as have been paid to the Commission by the Treasurer out of moneys appropriated by the Parliament for the purposes of the Commission,

less any amounts of capital that have been repaid to the Commonwealth by the Commission."

178. We questioned the witnesses representing the Department of Health as to the reasons for the exclusion of land (including buildings on land) and stocks of biological products not prescribed for the purposes of section 19(a) of the Act from the definition of assets under section 31(2) of the Act. We were informed that had the land been transferred to the Commission it would have been subject to alienation by any other Commonwealth or State authority with power to resume land for its own purposes. As the buildings remain the property of the owner of the land, they also remained the property of the Commonwealth under this arrangement. In relation to the exclusion of biological products, it was stated that, in effect, no products of the Laboratories were affected by this Section Q.259

of the Act as all of the items being produced when the Commission was established were prescribed by regulation and automatically became assets of the Commission. Additional capital provided to the Commission from the Consolidated Revenue Fund between 1 November, 1961, and 30 June, 1968, amounted to $4,075,000.

Section 33

179. This section provides in the following terms for payments to be made by the Commission to the Commonwealth -

"(1) Interest is not payable to the Commonwealth on the capital of the Commission but the Commission shall pay to the Commonwealth, out of the profits of the Commission for a financial year, such amount as the Treasurer, after consulting the Minister, determines.

(2) The capital of the Commission is repayable to the Commonwealth at such times and in such amounts as the Treasurer, after consulting with the Minister, determines.

(3) In the making of a determination under either of the last two preceding sub-sections, the Treasurer shall have regard to any advice that the Commission has furnished to the Minister in relation to the financial affairs of the Commission."

180. This section of the Act is related to Section 21 which was discussed in Chapter 6 and which requires the Commission to pursue a policy directed towards securing revenue from the sale of biological products prescribed under section 19(a) of the Act, sufficient to meet all of its expenditure properly chargeable to revenue and to permit the payment to the Commonwealth of a reasonable return on its capital.

181. When questioned in connection with section 33, the Treasury Observer, Mr. Virtue, expressed the view that the Treasurer can only determine the amount that would be paid to the Consolidated Revenue Fund but that the Treasurer could not determine whether the amount to be so paid would be a reasonable amount. The section however, provides for the Treasurer to make his determination after consultation with the Minister and in this regard a witness representing the Commission informed us that the Commission is required to submit to the Minister by 31st March

Qs.250,251, 260, 261, 707 and 708.

each year an estimate of its income and expenditure for the ensuing 12 months. At that stage an estimate of profit is made for the current financial year i.e. for the remaining 3 months and consideration is given to the funds requirement for the following financial year. If at the close of a financial year the Commission showed a substantial profit and had substantial cash reserves beyond its forecasted requirements, it would take up with the Minister the question of making a payment to the Commonwealth. So far, however, the Commission has not been in such a position due to the expansion of the laboratories and the demands that it has made for funds.

Section 34

182. This Section provides in the following terms for borrowing by the Commission -

"(1). The Commission may, with the consent of the Treasurer, borrow moneys for temporary purposes on overdraft from the Reserve Bank of Australia or from such other bank as the Treasurer approves.

(2). The Treasurer may, out of moneys appropriated by the Parliament for the purposes of this Act, make advances to the Commission of such amounts, and on such terms as he thinks fit.

(3). The Commission may, with the consent of the Treasurer, borrow moneys, whether for a temporary purpose or not, otherwise than in accordance with the preceding provisions of this section.

(4). The Commission shall not borrow moneys otherwise than in accordance with this section."

183. The Treasury Observer, Mr. Virtue, informed us that this provision is somewhat different from that applying to other Commissions in that no limit is placed by section 34 on the amount that the Commission may borrow, there is no requirement that the Minister must consent to the borrowing, although the Treasurer's consent is required, and no provision is made regarding the rate of interest at which funds may be borrowed. In the case of other legislation governing trading enterprises Qs.262 to 266

such as the Australian National Airlines Commission and the Australian Coastal Shipping Commission provision is made for each of these matters.

184. The Commission witnesses advised us that until 30th June, 1966, the Commission had not had occasion to exercise its borrowing powers under section 34 but during 1966-67 had borrowed, on overdraft terms an amount of $300,000 for the purpose of general working capital. Qs.515 to 519

Section 37

185. This section provides as follows -

> "The Commission shall, not later than the thirty-first day of March in each year, prepare and submit to the Minister estimates, in accordance with such form as the Minister directs, of its receipts and expenditure for the financial year commencing on the following first day of July."

186. In relation to this requirement the witness representing the Department of Health drew attention to the fact that the Minister is responsible to the Parliament for the operation of the Commission. He is not, however, required to approve the estimates. The witness added that when the estimates are provided to the Minister, the Minister approves particular projects or sales or purchases by the Commission as referred to in section 20(2) of the Act. It is the general practice, also, when the estimates are being presented to the Minister, for the Commission to present to him the research proposals to be undertaken in accordance with section 19(b) which is subject to ministerial determination. Therefore, the three types of functions are generally processed concurrently and the purposes generally can be regarded as a presentation by the Department of Health of a summary of the Commission's activities for the forthcoming financial year for the consideration of the Minister. Q.267

187. The Treasury Observer, Mr. Virtue, informed us that the estimates of the Commission are not forwarded to the Department of the Treasury, notwithstanding that they could affect the

Consolidated Revenue Fund. We therefore questioned the Department of Health witnesses further on the Commission's estimates and we were informed that when the estimates are received by the Department of Health they are subjected to close examination and, if required, additional information is obtained from the Commission so that the Minister can be informed adequately. The witness added that although the estimates do not require the approval of the Minister, the Minister would be required to exercise a judgement as to whether sufficient funds will be generated to adequately cover research expenditure under section 19(b) of the Act and also that the capital programme proposed by the Commission would be capable of accomplishment within the trading result expected. Qs.268 to 270

Section 38

188. This section, which relates to loss resulting from compliance with determinations made by the Minister, is as follows -

"Where -

(a) the Commission undertakes research, installs or maintains plant or equipment or produces or holds stocks of a biological product in accordance with a determination by the Minister under section nineteen of this Act;

(b) the Commission satisfies the Minister that the operations (including the undertaking of research) carried on by the Commission in accordance with the determination have been so carried on at a loss in a financial year; and

(c) a loss results in that financial year from the whole of the operations of the Commission,

the Commission is entitled to be reimbursed by the Commonwealth to the extent of the first-mentioned loss or to the extent of the second-mentioned loss, whichever is the less."

189. Although in the period to 30th June, 1966, the Commission has not incurred losses on its operations we explored the course

that would be adopted if this situation were to arise. The Treasury Observer, Mr. Virtue, informed us that although, under Section 37 of the Act, the Department of the Treasury does not receive the Commission's estimates, that Department would expect to be consulted if the estimates were to show a need for an appropriation such as envisaged by section 38. Qs.271 to 274 During 1966-67, in accordance with determinations by the Minister under section 19(b) of the Act, the Commission expended $316,347 on research relating to the production of biological products other than those prescribed and $15,126 on the production and holding of biological products other than for immediate sale. The expenditure on these operations represented a loss of $331,473 to the Commission and, as the whole of the Commission's operations resulted in a loss in excess of that amount, the Commission became entitled to reimbursement by the Commonwealth of $331,473 under section 38 of the Act. The amount concerned was actually paid to the Commission in 1967-68.

Section 39

190. This section which relates to the profits of the Commission, is as follows:-

"(1.) For the purposes of this Act, the amount of the profits of the Commission for a financial year is the amount (if any) remaining after deducting from the revenue received or receivable in respect of that financial year the expenditure properly chargeable against that revenue.

(2.) For the purpose of the last preceding sub-section, the expenditure of the Commission properly chargeable against the revenue received or receivable in respect of a financial year includes -

(a) charges and expenses accrued in that year but not paid;

(b) provision made in that year for obsolescence and depreciation of assets;

(c) provision made in that year in lieu of insurance;

(d) provision made in that year for staff superannuation; and

(e) provision made in that year for income tax,

but does not include expenditure charged against amounts provided out of revenue of a previous year or expenditure in payment of charges and expenses accrued in a previous year.

(3.) The profits of the Commission for a financial year shall be applied in the first place in payment of such sums as have been determined by the Treasurer under sub-section (1.) of section thirty-three of this Act and the balance (if any) shall be applied in such manner as the Minister, with the concurrence of the Treasurer, determines.

(4.) In the making of a determination under the last preceding sub-section, the Minister and the Treasurer shall have regard to any advice that the Commission has furnished to the Minister in relation to the financial affairs of the Commission."

Section 40

191. This section expressed in the following terms, requires proper accounts to be kept by the Commission:-

"The Commission shall keep proper accounts and records 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 its assets and the incurring by it of liabilities."

192. We were informed that prior to the establishment of the Commission in 1961, all receipts and payments of moneys of the Laboratories were brought to account in the Commonwealth Serum Laboratories Trust Account. The Trust account was used for operating and capital expenditure and the purposes of the Trust Fund, as defined by the Treasurer, were the production, distribution and sale of biological products, payment of expenses in relation to these matters, scientific investigations relating to biological products, construction of additions to the equipment of the Laboratories and payment of any unrequired balance to the Consolidated Revenue Fund. Receipts and payments relating to the operation of the cafeteria at the

Laboratories were made through the Cafeteria (Health) Trust Account. The Sub-Treasury, Melbourne, was advised monthly of the amounts paid to these accounts. Capital works proposals were carried out under the Commonwealth's work programming arrangements but during World War II and up to 1951-52 expenditure thereon as shown in the Estimates papers was recovered from the Commonwealth Serum Laboratories Trust Account. However, working advances of $100,000 and $457,950 were made to the Laboratories in 1950-51 and 1951-52 respectively. Proceeds from the sale of the Laboratories' products were sufficient to cover costs, new works and expenditure on plant during that period.

Q.98 and Committee File 1967/1

193. From 1952-53 onwards, expenditure on plant and new works required at the Laboratories was debited to Commonwealth appropriations and payments from appropriations for reimbursement of expenditure in relation to World Health Organisation influenza activities and for research were also made to the Laboratories. Salaries and other production and operational costs were recovered from the Trust Account up to the time of the establishment of the Commission.

Q.98 and Committee File 1967/1

194. Until 1949 the Laboratories operated a single entry system of accounting but, commencing in that year, a system of double entry commercial accounting was introduced and improvements in accounting techniques were made in subsequent years. It was claimed that with improved accounting techniques, improved costing procedures were also implemented although in the early 1950's costing techniques were hampered by insufficient staff. By 1953, only 60 per cent of the Laboratories' total production was costed on an actual cost basis. However, by the time the Commission was established, costing procedures had been developed to a more acceptable level and some 55 cost departments or centres were maintained, enabling accurate costing to be undertaken for Laboratory products and services.

Q.138 and Committee File 1967/1

195. All activities were costed on a departmental basis. Costs were accumulated on an actual basis (labour, material and expense); on a standard basis (the distribution of small animals, and other service department costs) and on an allocated basis assessed on usage, as for certain laboratory overhead.

Committee File 1967/1

Where products were manufactured in large batches and on a continuous basis, process costing was employed while batch costing was employed for products not produced on a continuous basis. The maintenance section of the Laboratories employed a Job Cost system. In addition to carrying out all maintenance of plant and equipment, that section also manufactured stores and plant items and converted plant. It had been the practice to determine a standard cost for each product and it was said that this cost was continually reviewed and was reviewed specifically in the event of exceptional changes that occurred in a cost component.

196. Following the introduction of the double entry system of commercial accounting, trading, and profit and loss statements and balance sheets were prepared and submitted to the Department of Health to indicate the profitability of the Laboratories for approximately the last 10 years of their existence as a departmental activity and did not attract certification by the Auditor-General. Qs.99 and 100

197. During our inquiry we examined the revenue accounts and balance sheets of the Laboratories, as published by the Auditor-General, for the five years prior to the establishment of the Commission. We found that the form in which this material had been published made its analysis exceedingly difficult. In this regard we were informed that, by that stage the Laboratories were in competition with other very active and astute commercial organisations. Although the Laboratories were a part of the Department of Health, it had been considered that they should not publish more information in relation to their trading activities, particularly on the commercial side, than would be published by members of the pharmaceutical industry.

198. At our request the Department subsequently tendered in confidence, comparative manufacturing, trading and profit and loss statements of the Laboratories, in columnar form, for the years 1956-57 to 1960-61 and for the period 1st July to 1st November,

1961, and a chart of accounts for the Laboratories as at 30th June, 1961.

199. The witnesses representing the Commission informed us that, since the establishment of the Commission, accounting records in accordance with accepted commercial principles and practices have been introduced and every endeavour is being made to keep abreast of developments in modern accounting techniques. It was claimed that in the specific area of costing, the Commission's approach had been based on a departmentalised cost centre principle including some 53 individual cost centres which embrace not only productive costs but services to production and overheads. Costs are accumulated on a direct cost basis, where practical, to each of those cost centres. Unfortunately, within each cost centre both public health and commercial products are produced side by side. The Commission had come to the conclusion, however, that it must introduce a system that would enable it to divide the Laboratories not only into more controllable cost centres but which would enable a greater degree of management efficiency by cost responsibility to be achieved and which would also enable the basic non-profit making research type and commercial activities to be segregated into two broad groups. Qs.439 and 442 Qs.340 to 342

200. We were informed that by November, 1967, the Commission had completed a new standard costing procedure layout. Progress had been made to the stage where controls over labour had been introduced to measure labour efficiency and particularly to measure dead time. However, the resignation of the Finance Manager of the Commission had impeded temporarily the implementation of the system. Q.805

201. On the question of the analysis of the Commission's accounts so as to isolate the costs of non-profit making research-type activity, the Chairman of the Commission informed us that such an analysis forms part, and one part only, of a review of the whole activities of the Commission in relation to the legislation under which the Laboratories operate. He added that until the basis of the legislation and its details are examined and Q.735

adjusted to meet current realities, the development of more refined accounting will not achieve its full purpose.

202. To assist us in our analysis of its financial results the Commission tendered at our request, comparative balance sheets as at 2nd November, 1961, and 30th June, 1962 to 1966 and statements relating to the source and application of its funds, asset disposals, movements in its Plant and Machinery *Account and Depreciation Reserve for the years 1961-62 to* 1965-66. The Commission also tendered a chart of its accounts as at 30th June, 1968.

203. Our examination of this material had been preceded by an analysis of the financial information presented to the Parliament in the Commission's Annual Reports and the Reports of the Auditor-General. In surveying this published material we had regard to recognised accounting devices for measuring the efficiency of the financial management techniques employed within the Commission, i.e. working capital ratios, liquid fund ratios, returns on employed capital, the existence and adequacy of provisions, rates of stock and debtors' turnover, etc.

204. In keeping with its position as an organisation in competition with commercial enterprise, we found that the results of analytical calculations which could be derived from previously published information differed in some instances materially from the results calculated from material tendered to us subsequently. However, in each instance, it appeared that the latter results indicated the employment of skilled management techniques and that public funds were being employed in a satisfactory manner. Indeed, such additional information as statements of the source and disposition of funds (prepared on a confidential basis), statements of asset disposals, consolidated movements in working capital and the Commission's chart of accounts indicated that a precise and detailed historical accounting record had been maintained and that the Commission procedures compared favourably with the sophisticated accounting techniques employed by commercial enterprise. In addition, the

evidence we received indicated that accounting systems were still being refined within the Commission and that eventually it was intended that clearer results would become available despite the previously mentioned necessity to account for materials produced for the public benefit in conjunction with other products that are sold by the Commission in competition with private drug manufacturers.

Section 41

205. This section which relates to the Audit of the Commission's accounts and records of financial transactions, is as follows:-

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

(2) The Auditor-General shall, at least once in each year, report to the Minister the result of the inspection and audit carried out under the last preceding sub-section.

(3) The Auditor-General or an officer 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 of the Commission.

(4) The Auditor-General or an officer authorized by him may make copies of or take extracts from any such accounts, records, documents or papers.

(5) The Auditor-General or an officer authorized by him may require a Commissioner or an officer of the Commission to furnish him with such information in the possession of the Commissioner or officer or to which the Commissioner or officer has access as the Auditor-General or authorized officer considers necessary for the purposes of an inspection or audit under this

Act, and the Commissioner or officer of the Commission shall comply with the requirement."

206. During the course of our inquiry we examined the Reports and Supplementary Reports of the Auditor-General for each of the years 1961-62 to 1965-66 in respect of the Laboratories. Three of these Reports in particular attracted our attention.

207. In Paragraph 76 of his Report for 1961-62 the Auditor-General stated that the Commission had commenced operations on 2nd November, 1961. As at that date the Commonwealth transferred to the Commission, in accordance with Section 31 of the Act, the assets and liabilities associated with the Laboratories except the land and buildings and the stocks of products not prescribed for purposes of the Commissions functions. Assets transferred included the cash and the Trust Fund Balances amounting to £235,966 ($471,932) as shown in the balance sheet of the former Administration. A further advance of £500,000 ($1,000,000) from Division 881 Item 03 had been made to the Commission as additional working funds. At the time of preparation of the Report, however, the Treasurer had not determined the value of the assets transferred as required by Section 32(a) of the Act. Pp. No.80 of 1962

208. In Paragraph 14 of his Supplementary Report for the same year the Auditor General indicated that the statements had not been made available for audit pending completion of the action required for the Treasurer's determination of the value of the assets transferred to the Commission from the Laboratories. In regard to this delay we were informed by the Treasury Observer, Mr. Virtue, that it had been necessary to establish the assets which the Commission would take over as it did not require all of the assets that had been maintained by the previous departmental administration. Assets no longer required were declared for disposal. The second problem had related to the valuation of the assets that were, in fact, taken over by the Commission. This had required consultation between the Department of the Treasury, the Department of Health, the Commission and the Auditor-General's Office. He assured us that the Treasurer's determination had been made as quickly as possible in the circumstances. Pp. No.127 of 1962 and Q.309

209. In Paragraph 7 of his Supplementary Report for 1964-65 the Auditor-General stated that Section 31 of the Commonwealth Serum Laboratories Act excluded land (and buildings on land) from assets transferred to the Commission by the Commonwealth. In accordance with an arrangement between the Commission and the Departments of Health and the Treasury, expenditure by the Commission on land and buildings owned by the Commonwealth had been deducted from the Commission's capital liability to the Commonwealth. The Auditor-General's Office had questioned the legality of the deductions made from capital, having regard to sections 32 and 33 of the Act in respect of capital and repayments of capital to the Commonwealth. At a conference of officers representing the Commission, the Departments of Health and the Treasury and the Auditor-General's Office, it had been considered that capital expenditure, to be borne by the Commonwealth, should be provided by appropriation for the purpose and provision had been made accordingly in the Estimates for 1965-66.

210. We were informed by a witness representing the Commission that the practice of deducting expenditure by the Commission on land and buildings owned by the Commonwealth from its capital liability to the Commonwealth had been accepted from the formation of the Commission. The Auditor-General, however, had re-examined the matter and sought a legal opinion on it. Arising from this, the matter had been discussed by the parties concerned and it had been resolved to revert to the present system. The Audit Observer, Mr. Lawrence, agreed that the matter had been corrected, through discussion. Qs.334 and 335

Chapter 9

The Reports of the Commission

211. Under the provisions of sections 43 and 44 of the Commonwealth Serum Laboratories Act 1961 the Commission is required to furnish reports to the Minister and the Minister is required in turn to present the reports to the Parliament. The provisions of sections 43 and 44 are set out below.

"43. (1.) The Commission shall from time to time inform the Minister concerning the general conduct of its business.

(2.) The Commission shall furnish to the Minister such information relating to its operations as the Minister requires.

44. (1.) The Commission shall, as soon as practicable after each thirtieth day of June, prepare and furnish to the Minister a report of its operations during the year ended on that date, together with financial statements in respect of that year in such form as the Treasurer approves.

(2.) The report shall deal specifically with any operations of the Commission in respect of which a determination by the Minister under section nineteen of this Act was in force during the year and the financial statement shall show separately the financial results of any such operations.

(3.) Before furnishing the financial statements to the Minister, the Commission shall submit them to the Auditor-General, who shall report to the Minister-

(a) whether the statements are based on proper accounts and records;

(b) whether the statements are in agreement with the accounts and records and show fairly the financial operations and the state of the affairs of the Commission;

(c) whether the receipt, expenditure and investment of moneys, and the acquisition and disposal of assets, by the Commission during the year have been in accordance with this Act;

(d) as to the adequacy of provision in the nature of reserves made in the accounts of the Commission; and

(e) as to such other matters arising out of the statements as the Auditor-General considers should be reported to the Minister.

(4.) The Minister shall lay the report and financial statements of the Commission, together with the report of the Auditor-General, before each House of the Parliament within fifteen sitting days of that House after their receipt by the Minister."

212. During the course of our inquiry we examined each of the Reports of the Commission that had been tabled in the Parliament and we questioned witnesses representing the Department of Health and the Commission as to the adequacy of those reports.

213. We were informed by the Department of Health witnesses that while the Minister would require a reasonable form of Report from the Commission, the question of the extent to which reports should be made would be a matter for the Commission itself. It was added that while the Reports of the Commission were considered by the Department to be adequate and to have covered all of the necessary functions and operations of the Commission, the Department would examine the Reports specifically in the context of the needs of the Parliament. During the final hearing of our inquiry we were informed that the Minister had raised with the Commission the question of the adequacy of the Reports. Qs. 278, 279, 281 and 692 to 694.

214. During an examination of Commission witnesses we were informed that, as the Commission is engaged in competition in the marketing of a range of products the question of the form and content of its Reports, particularly in relation to financial detail and in relation to matters which, if disclosed

might operate to the benefit of its competitors, was a matter for judgment and was essentially a question of Commission policy. At the same time, however, the witnesses concerned agreed to examine the form and content of the Commission's reports, in the context of the needs of the Parliament. Qs. 822 to 825

Chapter 10

Regulations

215. Section 45 of the Commonwealth Serum Laboratories Act 1961 provides as follows:-

> "The Governor-General may make regulations, not inconsistent with this Act, prescribing all matters required or permitted by this Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to this Act."

216. As Section 19 (a) of the Act provides for the prescription of biological products we examined the witnesses in regard to the formulation of regulations. We were informed that the Department of Health proposes such regulations as would seem necessary to it but that this would be done in full consultation with the Commission. The witness added that while it is an administrative responsibility of the Department of Health to provide the machinery for the implementation of regulations, most of the proposals would be initiated by the Commission. At the time of our inquiry, no proposed regulations relating to the Commonwealth Serum Laboratories Act were outstanding with the Attorney-General's Department and in respect of the more recent regulations promulgated, prompt attention had been given to the matter by that Department.

Qs.280 and 697 to 699

Chapter 11

Summary and Conclusions

217. Your Committee's inquiry shows that the Commonwealth Serum Laboratories were established during World War I, mainly to meet Australian requirements of anti-toxins, sera and vaccines on a standardised basis at minimum cost. At the same time inquiry and research into the causes of disease and the improvement of methods of producing vaccines and anti-toxins to combat disease have always constituted an important part of the functions of the Laboratories.

218. Originally established under the Quarantine Branch of the Department of Trade and Customs, the administration of the Laboratories was transferred to the Department of Health in 1921, where it remained until 1961 when it was transferred to the control of a Commission.

219. Commencing with the production of vaccines in 1917, the range of products produced by the Laboratories had been extended to twelve human bacterial vaccines and smallpox vaccine in the following year. By 1923 the production of insulin had been added to the range of products, while in 1925 the Laboratories pioneered the use of human blood products in the processing, for therapeutic purposes, of blood collected from people who had recovered from poliomyelitis, measles and scarlet fever.

220. The activities of the Laboratories continued to develop and expand, and in 1936 a farm of 325 acres was acquired at Broadmeadows, near Melbourne, for the purpose of breeding and holding horses in connection with serum production. Extensive new buildings, involving mainly additions to existing buildings at Parkville, were completed between 1937 and 1942.

221. Tetanus prophylactic was being developed and tested in 1938 and prepared in quantity in 1939. The outbreak of war

in that year created an unprecedented demand for biological products. This, however, had been largely foreseen and much of the developmental work connected with Defence Force requirements had been completed before the war began.

222. The successful development of penicillin in 1943 inspired the Laboratories to commence the immediate preparation of this new biological product and supplies were first made available, on a restricted basis, to the civilian population in 1944.

223. In 1952 serum fractionation was commenced for the production of albumin, fibrinogen and gamma globulin, and later for the antihaemophilic factor. Because of the non-availability of additional land at the site of the Broadmeadows farm, it became necessary for a further farm of 1,361 acres to be acquired at Woodend in 1959.

224. By 1961 the wide area of activity of the Laboratories had involved substantial investment and development. The Laboratories occupied a 23-acre site at Parkville and operated a 325-acre farm at Broadmeadows and a 1,361-acre farm at Woodend. The capital invested in these locations exceeded $12,000,000, with an annual turnover in the vicinity of $4,800,000 and a staff of approximately 1,000.

225. By 1961 the Government recognised that it was a matter of national importance that the Laboratories continue to maintain their position in the various health fields. The Government also recognised that, to enable the Laboratories to meet changing and growing needs, a flexible and efficient management was necessary to direct the affairs of such a large and important undertaking in a business like manner. Being conscious of the increasing growth and complexity of the Laboratories' activities, the Government examined ways and means to improve their overall administration and came to the conclusion that the establishment of a statutory commission comprising both business and medical men of wide experience would provide the most flexible, effective and, therefore, efficient form of administration.

226. In the Bill placed before the Parliament it was proposed that the biological products to be manufactured and sold by the Laboratories would be prescribed by regulation; that the Commission would adopt a policy aimed at obtaining sufficient revenue from the sale of products to cover the expenditure of the Commission plus a reasonable return on the capital invested; and that all products marketed by the Commission at that time would continue to be produced. Provision was also made for the Commission, in accordance with a determination of the Minister, to undertake research appropriate to its functions and for the Commonwealth to meet the cost of this research where the Commission's operations resulted in a loss. It was also proposed that the assets of the Laboratories would be transferred to the Commission, their value plus the net amount of capital provided from moneys appropriated by the Parliament for the Commission's use representing the capital of the Commission. While it was not proposed that the Commission would pay interest on its capital, it was proposed that it should make payments out of its annual profits to the Commonwealth.

227. Your Committee's inquiry into the operations of the Commission was undertaken having regard to the history of the Laboratories from their inception and the policy objectives stated at the time of its establishment.

228. With the removal of import licensing on penicillin and insulin in February 1960, the Commission has found itself confronted not only by local competition in respect of penicillin, but also by competition from imports. In this trading environment the Commission has been engaged in the expansion of its volume and range of products and in the improvement of local marketing and export arrangements. Currently the Commission is making available a full range of its products in each capital city, distribution being made mainly through wholesalers to chemists and directly to hospitals. Excluding those products sold under the National Health Service, a very considerable proportion of the Commission's products is sold direct to users.

229. Since its establishment the Commission has also been active in the field of research and development associated with biological products. Details of this work in recent years are set out in Chapter 5 of this Report.

Conclusions

230. *Your Committee notes that since their establishment, the* Commonwealth Serum Laboratories themselves have been located on one site at Parkville in Victoria. Your Committee further notes the view expressed by the Director of the Laboratories that there is no intention to resume any further land in Royal Park, Parkville. While the progressive development of that site over the intervening years would undoubtedly have yielded substantial economies compared with the development of laboratories on a geographically dispersed basis, Your Committee believes that the stage may now have been reached where, for strategic reasons, consideration should be given to a greater decentralisation of development of production facilities for vital sera.

231. So far as the constitution of the Commission is concerned, our attention was attracted to section 16(2) of the Commonwealth Serum Laboratories Act, which provides that the Chairman of the Commission shall not permit a period exceeding five weeks to elapse between meetings of the Commission. While undoubtedly the purpose of this provision is to ensure that regular meetings are held, we were informed that circumstances have arisen whereby a meeting of the Commission has been convened merely to comply with this provision in the Act. In order to obviate the need for meetings convened only for that purpose, Your Committee believes that in the interests of flexibility in the convening of Commission meetings the Department of Health should confer with the Commission to assess whether an amendment to Section 16(2.) of the Act is desirable.

232. In regard to section 17 of the Act, which confers the power of delegation on the Commission, the evidence showed that the delegations in existence at the time of our hearing in May 1967, and which had been formulated in 1961, were somewhat obsolete due to staff, organisational and other changes that

had occurred. In February 1968 we were informed that progress had been made in the development of a more flexible scheme of delegations, although this had not been committed to written form at that stage. Your Committee believes that, in the interests of efficient administration, the Commission should complete the re-development of its scheme of delegations in written form at the earliest opportunity.

233. During our inquiry we examined specifically the requirements laid down in section 21 of the *Commonwealth Serum Laboratories Act* that the Commission shall, in relation to biological products prescribed in section 19(a) of the Act, pursue a policy directed towards securing revenue from the sale of those products sufficient to meet all of its expenditure in connection with those products that is properly chargeable to revenue, and to permit the payment to the Commonwealth of a reasonable return on the capital of the Commission.

234. We were disturbed to find that representatives of the Department of Health, which had framed the legislation, were unable to define the meaning of a reasonable return on funds.

235. Beyond suggesting that, on a commercial basis, the long term bond rate would represent a reasonable gross return on capital for the Commission, the Treasury Observer felt that the definition of a reasonable return on funds would depend on the situation of the particular statutory authority concerned in relation to its competitors and on other circumstances that have a bearing on its ability to make a profit. In any case, it appears from the evidence that it would be necessary for the capital employed by the Commission to be dissected so as to isolate the capital employed in commercial activities in order to determine a reasonable return on such capital. Your Committee believes that the Department of Health and the Department of the Treasury should seek to clarify for the

guidance of the Serum Laboratories Commission the meaning of the expression 'reasonable return on capital'.

236. Your Committee has also given careful consideration to the relationships that exist between sections 19, 21 and 22 of the Commonwealth Serum Laboratories Act. In regard to these sections the Chairman of the Commission drew attention to the fact that section 19 confines, restricts and limits the activities of the Laboratories in such a way that the Commission does not have the flexibility of operation and the opportunity to diversify that are available to private enterprise. Section 22 places an obligation on the Minister to determine the price of all products supplied directly to a government or to a person on behalf of a government after conferring with the Commission. Section 21 directs the Commission to follow a policy which, among other things, will produce a reasonable return on capital employed. The Chairman claimed that a conflict exists between these sections in that limitations are placed on the sale of biological products in which a considerable area of the Commission's sales is affected, directly and indirectly, by prices beyond the actual control of the Commission. For this reason the Commission claims to be gravely handicapped when it seeks to carry out the duty imposed on it of also working towards a profit. Your Committee notes the view expressed by the Chairman of the Commission that this dilemma will remain until it is made clear that the Commission is to be regarded either primarily as a part of the public health service of the community with a section devoted to commercial activities, or is primarily a commercial activity with limited government responsibility.

237. So far as the accounts of the Laboratories are concerned, the evidence shows that it was not until 1949 that a system of double entry commercial accounting was introduced. From that point onwards improvements were made in the Laboratories'

accounting techniques and by the time the Commission was established in 1961 some 55 cost departments or centres were maintained, enabling accurate costing to be undertaken for laboratory products and services.

238. It appears that since the establishment of the Commission, accounting records in accordance with accepted commercial principles and practices have been introduced. In the specific area of costing, the Commission's approach has been based on a departmentalised cost centre principle, the individual cost centres embracing production costs, services to production and overheads. Costs are accumulated on a direct cost basis, where practical, to each of these cost centres. However, within each cost centre both public health and commercial products are produced side by side. We note that the Commission has reached the conclusion that it must introduce a system that will enable it to divide the Laboratories not only into more controllable cost centres, but which will enable a greater degree of management efficiency by cost responsibility to be achieved. While the Commission had completed a new standard costing procedure layout by November 1967 and had made progress with its implementation, it appears that the completion of this work was subsequently impeded by a staffing difficulty.

239. During our inquiry we examined the revenue accounts and balance sheets of the Laboratories, as published by the Auditor-General, for the five years prior to the establishment of the Commission, and we also examined the revenue accounts and balance sheets furnished each year by the Commission in its annual reports. However, both the Department of Health and the Commission have taken the view that they should not publish more information in relation to the trading activities of the Laboratories, particularly on the commercial side, than would be published by members of the pharmaceutical industry.

While we accept this view, we nevertheless found it necessary to obtain from the Department and the Commission, confidential copies of revenue accounts and balance sheets adequate in form and detail to enable a full financial analysis to be made. The analysis indicated the employment of skilled management techniques and that public funds were being employed in a satisfactory manner. Indeed, the statements of the source and disposition of funds, statements of asset disposals, consolidated movements in working capital and the Commission's chart of accounts indicated that a precise and detailed historical accounting record had been maintained. They also indicated that the Commission's procedures, while capable of further refinement, compare favourably with accounting techniques employed by commercial enterprise.

240. In view of the opinion expressed by the Chairman of the Commission that a conflict exists between sections 19, 21 and 22 of the Commonwealth Serum Laboratories Act and the claim that the introduction of more refined accounting techniques will not achieve their full purpose until the costs of non-profit making research-type activities have been isolated in the Commission's accounts, Your Committee believes that a useful purpose would be served if the Government were to review the relationship between sections 19, 21 and 22 of the Act. We also believe that the Commission would be assisted greatly in its future activities if the relationship between it and the Department of Health were to be altered in such a way that the Department would become a client of the Commission in respect of all section 19(b) production and research activities. We would envisage, under such a relationship, that the Department would seek funds under its own votes to meet the costs of those activities. Apart from the fact that the level of expenditure involved would be clearly identifiable to the Parliament each year, we also believe that the Commission would be able, more readily, to meet the requirements of section 21 of the Act which, inter

alia, requires the payment of a reasonable return on the capital of the Commission to be made to the Commonwealth.

241. Following its far reaching inquiry into the Australian Aluminium Production Commission in 1954-55, Your Committee made recommendations not only relating to the conduct of the Commission's affairs but relating also to statutory authority legislation generally. The latter recommendations related to the need to achieve uniformity as between statutory authorities, particularly in regard to such matters as the audit of their accounts; the question of responsibility for the form of accounts of statutory corporations and Government trading undertakings and the need to clarify the position with regard to pecuniary interest of members of statutory corporations. The subsequent Treasury Minute relating to these Reports showed that the need to achieve sensible uniformity between statutory corporations had been recognised and appropriate action taken. Nevertheless, it appears to Your Committee from the evidence tendered in this inquiry that further scope exists for the refinement of statutory authority legislation in the area of Government trading undertakings. The evidence shows that there is no requirement under section 34 of the Commonwealth Serum Laboratories Act that the Minister must consent to borrowing by the Commission. No limit is placed on the amount that may be borrowed and no reference is made as to the rate of interest at which borrowings may be made. In the case of the Australian National Airlines Commission and the Australian Coastal Shipping Commission, however, limits have been set as to the amounts that may be borrowed and the Minister must approve of the borrowings. In the case of the Australian Coastal Shipping Commission the legislation makes reference to a rate of interest on borrowings. In these circumstances, Your Committee considers that all statutory authority legislation governing trading enterprises should be examined

PPs. No.69 and 69A of 1954-55

PP. No.127 of 1964

critically with a view to achieving uniformity of arrangements as between the enterprises concerned wherever practicable.

242. During our inquiry we examined carefully the question of the adequacy of the Commission's annual reports in the context of their value as information documents for members of the Parliament. In general, we accept the Commission's viewpoint that the form and content of its annual reports is a matter requiring careful judgment as it is engaged in the marketing of a range of products in competition with other suppliers to the Australian market. Subject to this general qualification, however, we believe that the Commission should, wherever possible, provide in its reports as much information as possible regarding its activities for the benefit of the Parliament and the public. We would emphasise the importance of this matter as we found that, while the annual reports of the Commission had provided figures of total staffing until 1963-64, no reference to staff numbers employed had been made in the reports for the two subsequent years. As the witnesses representing the Commission were unable to suggest reasons why these omissions had occurred, Your Committee believes that there is scope within the Commission for the exercise of greater care to ensure that material is not inadvertently withheld from reports. Your Committee notes with satisfaction that, prior to the conclusion of our public hearing, the Minister had raised with the Commission the question of the adequacy of its reports.

For and on behalf of the Committee,

RICHARD CLEAVER
Chairman.

DAVID N. REID
Secretary,
Joint Committee of Public Accounts,
Parliament House,
CANBERRA . . . . A.C.T.

27 February, 1969.

Appendix No. 1

Index to Exhibits

Exhibit No.	Title
1.	Submission by the Department of Health on the History of the Commonwealth Serum Laboratories.
2.	Public Supplementary Submission by the Department of Health.
3.	Confidential Supplementary Submission by the Department of Health.
4.	Public Supplementary Submission by the Commonwealth Serum Laboratories.
5.	Confidential Supplementary Submission by the Commonwealth Serum Laboratories.