EXPLANATORY STATEMENT

STATUTORY RULES 1985 NO. 297

ISSUED BY THE AUTHORITY OF THE MINISTER FOR HEALTH

THERAPEUTIC GOODS ACT 1966

THERAPEUTIC GOODS REGULATIONS

Paragraph 30(a) of the Therapeutic Goods Act 1966 ('the Act') provides that the Governor-General may make regulations providing for the establishment of committees to advise the Minister on matters relating to the importation into Australia of therapeutic substances and on such other matters as are prescribed, the functions and powers of those committees, and the payment of remuneration and allowances to members of such committees.

Part III of the Therapeutic Goods Regulations provides for the establishment of a number of committees and for the general provisions relating to them. Developments in the field of monoclonal antibodies have led to the need to establish an expert committee to advise the Minister on the regulation of the quality, safety and efficacy of monoclonal antibodies.

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Monoclonal antibodies are proteins which are capable of reacting with great specificity with parts of the body. The antibodies can, for example, react with cancer cells or be joined to drugs or radioactive materials to target them onto particular cellular locations. These monoclonal antibodies are produced by a complex biological procedure and there are a number of potential or postulated hazards attending their use. The hazards include contamination with mouse viruses, cancer producing agents and allergenic materials.

The Statutory Rules provide for the establishment of the Monoclonal Antibody Committee ('the Committee') under sub-regulation 19A(1). Sub-regulation 19A(2) provides that the Committee is to consist of

. the Chairman of the Australian Drug Evaluation Committee or a person authorised by the Chairman to attend a meeting or meetings on his behalf;

. an officer of the Department of Health appointed by the Minister or an authorised officer attending on that person's behalf;

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- one person with scientific experience in the manufacture of monoclonal antibodies, appointed by the Minister; and

- four other persons expert in one or more fields of biochemistry, molecular biology, immunology, protein chemistry and clinical medicine, also appointed by the Minister.

Sub-regulation 19A(3) enables the Minister to appoint one of the Committee members to be the Chairman of the Committee. The functions of the Committee will be to advise the Minister on matters affecting the quality, efficacy and safety of monoclonal antibodies and related products for therapeutic use.

Regulation 2 of the Statutory Rules amends sub-regulation 23(2) of the Regulations by adding an additional paragraph to provide that 4 members constitute a quorum of the Monoclonal Antibody Committee.

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The Statutory Rules will attract the general provisions of the existing Regulations relating to such matters as the tenure of office, powers and functions of the advisory committees where a vacancy occurs, sitting fees and travel allowance.

The Statutory Rules came into operation on the date of their notification in the Commonwealth of Australia Gazette.

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