23 January 2003

Mr Tony Hinton
Commissioner
Pharmaceutical Industry Investment Program Inquiry
Productivity Commission
PO Box 80
BELCONNEN ACT 2616

Dear Mr Hinton,

Productivity Commission Inquiry
Pharmaceutical Industry Investment Program

The terms of reference for the above inquiry require the Commission to "define the pharmaceuticals industry as all those who contribute to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia, thus including the bio-medical sector".

The Australian Nuclear Science and Technology Organisation (ANSTO) contributes to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia through the production and supply of radiopharmaceuticals and radioisotopes for use in medicine, specifically nuclear medicine, and medical/biotechnology basic and clinical research. ANSTO under the trading name ARI (ANSTO Radiopharmaceuticals and Industrials) is a member of the pharmaceuticals industry, as defined above.

ARI's products and services are subject to regulation by the Therapeutic Goods Administration (TGA) and our facilities are operated in accordance with the Australian Code of Good Manufacturing Practice.

In terms of the Productivity Commission Inquiry, ARI is quite unique in that it manufactures therapeutic goods as defined by the TGA. These are used in procedures, the cost of which are rebated under the Medicare scheme. That is, none of ARI output is supplied under the PBS scheme.

The purpose of this letter is simply to provide the Commission with information about a highly specialised area of the Australian pharmaceuticals industry. I have attached a short paper which describes the relevant ANSTO activities.

Yours sincerely

DR STUART W CARR
Director, Radiopharmaceuticals &
General Manager, ARI

Encl.

ANSTO RADIOPHARMACEUTICALS AND INDUSTRIALS

Background

The Australian Nuclear Science and Technology Organisation (ANSTO) was established by the *ANSTO Act 1987*, and is Australia's national centre for nuclear science and technology. It uses its HIFAR nuclear research reactor and the National Medical Cyclotron (NMC) to make more than 90 per cent of the radioisotopes that are used in nuclear medicine in Australia. These facilities are located at Lucas Heights, NSW and at Camperdown, NSW, respectively. Reactor-produced radioisotopes represent about 80 per cent of ANSTO's production.

Ionising radiation, in the form of x-rays, has been used in medical practice for more than 100 years to provide information about the anatomy, or structure, of the body and for external radiotherapy in cancer treatment. Nuclear medicine, which utilises radioisotopes as radiation sources, emerged in the 1940s, and is focussed on the physiology, or functioning, of the body. In nuclear medicine, carefully selected radioisotopes are formed into radiopharmaceuticals through chemical combination with carrier molecules which are chosen because they accumulate in the skeleton, specific body organs or abnormal processes, such as tumours..

The radiation emitted by a radiopharmaceutical in the part of the body that has been targeted is used for diagnosis, therapy or palliation of pain. In diagnosis, radiopharmaceuticals produce images that enable the function and living chemistry of the body to be evaluated. The information from these images indicates when functions are changed by the onset of disease, and is complementary to that provided by other imaging modalities and diagnostic procedures. Other Radiopharmaceuticals are designed for internal radiotherapy, because they accumulate in tumours and eliminate cancerous cells by selective targeting, without harming healthy cells. Bone-seeking radiopharmaceuticals are used for the palliative treatment of bone pain resulting from skeletal metastases (secondary cancers).

The techniques of nuclear medicine are effective in the diagnosis and management of a wide range of medical indications, including: cancer; heart disease; diseases of other organs, including the brain, lungs, liver and thyroid; skeletal injuries; and infections. Nuclear medicine is a very effective approach to patient management. It can reduce health care costs substantially because it improves the effectiveness of treatment while reducing overall costs and shortening treatment times. Moreover, it provides benefits to patients for whom the pain and distress of invasive procedures such as surgery are minimised or avoided altogether, and who can undergo many procedures on an outpatient basis.

ANSTO Radiopharmaceuticals and Industrials

ANSTO has established ANSTO Radiopharmaceuticals and Industrials (ARI) as its business arm for the manufacture and distribution of radioisotopes for use in medicine (our major market, by far), industry and research. ARI employs about 120 persons. In 2001-02, ARI's revenue grew by more than 10 per cent to $19.6 million, and revenue from export sales grew by 15 per cent to almost $3 million. ARI exports radiopharmaceuticals to more than 10 other countries in the Asia-Pacific region, including New Zealand, the Republic of Korea, and China.

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ARI uses one of Australia's most efficient "just-in-time" distribution systems to supply some 200 nuclear medicine facilities throughout the country with products that are subject to radioactive decay and, in many cases, have short half-lives. Many of these nuclear medicine facilities are in regional and rural areas.

ARI's processes are ISO9001 certified and are highly regulated. Production must meet the regulatory requirements of the Therapeutic Goods Administration and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) within the Department of Health and Aging. Products are also subject to a range of state and federal regulations governing their transport and use.

In August 2000, the Minister for Health and Aged Care signed an agreement with the nuclear medicine profession for the period to 30 June 2003. The agreement determines the funds that are available for nuclear medicine imaging (about 70 percent of all nuclear medicine procedures) during its period of operation. In turn, this agreement has the potential to affect ARI's revenue.

ANSTO estimates that in 2001-02, its radioisotopes benefited about 475,000 Australians, and that, on average, and at present levels of usage, every Australian will need one of its radioisotopes during his or her lifetime.

Research and Development

ANSTO has a strong local research commitment, with 25 researchers using modern techniques of drug design, including advanced computational chemistry, to develop novel radiopharmaceuticals for the diagnosis and therapy of disease. ANSTO's research program is currently examining new imaging and therapeutic agents and utilises facilities for safe radiolabelling, preclinical *in vitro* and *invivo* studies. ANSTO is able to draw on Australian universities for research support, through the Australian Institute for Nuclear Science and Engineering (AINSE), and has a large number of active collaborations with scientists and clinical researchers within Australia and internationally.

Replacement Research Reactor

As a result of a decision by the Government in 1997, ANSTO is constructing a modern, multi-purpose research reactor to replace HIFAR, which commenced operations in 1958 and which has, in effect, reached its capacity limits for production of radioisotopes. The replacement research reactor (RRR), which is expected to be commissioned in 2005-06, will have a much larger production capacity than HIFAR, and will be capable of producing new types of radioisotopes to treat a wider range of medical conditions than can be treated at present. The RRR will provide health benefits for Australians throughout the first half of the 21st century.

23 January 2003.