E Engage

L Listen

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HEALTH TECHNOLOGY ASSESSMENT IN AUSTRALIA

Overview

Health Technology Assessment

In Australia the Government regulates therapeutic goods, and subsidises the cost of health related goods and services to improve access to medical and surgical procedures, diagnostic tests, prostheses and medical devices, through different programs.

The three main questions asked in relation to Health Technology Assessment are:

- Is it safe?
- Does it improve health outcomes?
- Is it cost effective?

What is a therapeutic good?

A therapeutic good is any product that makes a claim to have a therapeutic use.

Health Technology Assessment in Australia

The Health Technology Assessment process in Australia comprises three main components: regulation, reimbursement and post market surveillance. All components are governed by the **Department of Health and Ageing** (DoHA) under a legislative, policy and program framework.

Regulation

The **Therapeutic Goods Administration** (TGA) is a regulatory and surveillance body responsible for ensuring that all therapeutic goods are safe before they enter the market and become available to the public. Once a therapeutic good is available, the TGA are also responsible for ongoing surveillance and removal of goods that are found to be unsafe are removed from the market.

To lawfully supply a therapeutic good in Australia it must be listed on the **Australian Register of Therapeutic Goods** (ARTG). Therapeutic goods must be listed on the ARTG before they are imported into Australia, exported from Australia or supplied within Australia. There are two types of entry on the ARTG – registered products and listed products. Registered products are prescription and over the counter medicines, vaccines and some complementary therapies, and have an AUST R number on their label. Listed products are complementary therapies such as vitamins and mineral supplements, nutritional supplements, traditional Chinese medicines and aromatherapy oils, and have an AUST L number. The TGA decides if products are suitable for listing or require registration.

Reimbursement

There are three mechanisms in which subsidies are offered to patients and the community. These include the **Pharmaceutical Benefits Scheme** (PBS)/**National Immunisation Program** (NIP), **Medicare Benefits Schedule** (MBS) and the **Prosthesis List**.

Decisions in relation to which medicines are reimbursed through the PBS and which vaccines are listed on the NIP are made by the **Pharmaceutical Benefits Advisory Committee** (PBAC). The PBAC have two sub-committees which support the decision-making process. These include the Drug Utilisation Sub Committee and the Economics Sub Committee.

Decision in relation to the medical services, devices, consultations or allied health services that are subsidised through Medicare and the **Medical Benefits Schedule** (MBS) are made by the **Medical Services Advisory Committee** (MSAC). If the MSAC needs additional advice to effectively undertake its role, it may establish sub-committees to support the decision-making process.

The Prostheses List contains prostheses and the benefit to be paid by private health insurers.

Products on the Prostheses List include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue. The list does not include external legs, external breast prostheses, wigs and other such devices.

Post market surveillance

The TGA have three main post market surveillance mechanisms including:

Monitoring and Alerts: The TGA monitor claims made in advertisements and issue fines, sanctions and alerts if advertising claims can not be supported.

Adverse events: The TGA records reports of adverse events and subsequent recall actions. Reports of adverse events are made by consumers, health professionals and industry.

Manufacturing: The TGA have mechanisms to inspect manufacturers of therapeutic goods to ensure compliance with Australian codes and the safety of therapeutic goods. These include sampling (TGA Laboratories undertake a continuous sampling program in all states of Australia. Products are purchased in the marketplace, or obtained from manufacturers or sponsors, and subjected to analysis and regulatory scrutiny); Good Manufacturing Practice Audits (inspections by the TGA's Manufacturer Assessment Section) and the Surveillance Unit of the TGA (The Surveillance Unit investigates breaches of the legislation and coordinates prosecutions).