Health technology assessment (HTA) policy

Outlines the process for review and assessment of new health technologies to Southern Cross Healthcare (SCH).

Who is the policy for?

All medical practitioners, medical suppliers, and hospital teams.

Why is it important?

SCH is committed to providing up-to-date and newly developed equipment and devices into its facilities. The policy ensures we meet the requirements of the Medicines Act regulations for the importing, supply, and sale of medical devices in New Zealand.

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Definition of Health Technology

Any new medical device, medicine, IT system, procedure or new model of care that is designed to solve a health problem and improve quality of life.

This includes any instrument, apparatus, appliance, article, or material of a kind intended to be used in or on human beings for a therapeutic purpose.

What this policy does not cover

The policy does not cover medical practitioners bringing medical devices such as individually owned equipment, implants, samples, items purchased from supplier, borrowed from other facility or homemade.

Refer to Bringing medical devices into Southern Cross Healthcare facilities policy.

Guiding principles

SCH is committed to providing up-to-date and newly developed equipment and devices into its facilities while adhering to the Medicines Act regulations for the importing, supply, and sale of medical devices in New Zealand. Medical Practitioners must advise the General Manager of any specific requirements for operations or procedures well in advance.

The use of newly developed equipment or devices is contingent on compliance with legislative requirements and Southern Cross Healthcare policies; Reference: Credentialing and Practice Guide: Access privileges and rules for health practitioners page 49.

Decisions made about the introduction of new health technologies in SCH is balanced by the available evidence, cost implications and the aspiration of private healthcare to provide contemporary high quality affordable clinical services.

SCH will apply a standardised Health Technology Assessment (HTA) framework with Request for Information (RFI) submissions being assessed by an HTA Committee. The HTA Committee will leverage the expertise of other SCH committees as required (e.g. NCGC, DSSG and NIPCC).

Framework for assessing Health Technology

In accordance with the International Network of Agencies for HTA (INAHTA) definitions, a Health Technology Assessment (HTA) is defined as:

> *"A multidisciplinary process that uses explicit and scientifically robust methods to assess the value of using a health technology at different points in its lifecycle. The HTA process is comparative, systematic, transparent and involves multiple stakeholders. The purpose of HTA is to inform decision-making to promote an efficient, sustainable, equitable and high-quality health system."*

Process to follow

National Support Office Procurement Team and General Manager of the relevant facility will be contacted when new medical devices, goods or services are required.

Without exception, the National Support Office Procurement Team must be contacted before any new product is introduced to any hospital and with sufficient time to appropriately review the regulatory, technical, and commercial information on the product(s).

Products introduced by visiting specialists and/or suppliers must be quarantined by hospital staff immediately and are not to be used; the National Support Office Procurement Team is to be advised as soon as possible of such activities and to take appropriate action. This includes individually owned equipment, implants, and samples, items purchased from supplier, borrowed from other facility or homemade.

For new consumables or single or multiple use products the following will apply

Suppliers must be directed by hospitals to provide all regulatory, technical, and commercial documentation direct to the National Office Procurement Team; hospital staff should not receive or collate any of this documentation from or on behalf of suppliers. This data includes, but is not limited to:

- e-PEHNZ form
- Relevant regulatory documentation including MedSafe WAND Notification and TGA and/or FDA and/or CE and/or GMP certification
- Product technical details including Instructions for Use (IFU), technical datasheets, cleaning and sterilisation instructions, Safety Data Sheets (SDS)
- The training requirements for Specialists and staff
- Health and safety risks eg handling and exposure related
- A complete list of product codes, descriptions, supplier code & description, purchase unit of measure (UOM), and/or unit of use (UOU) and costings
- Full supplier contact details

National Office Procurement Team will conduct a review based on clinical efficacy and perform a cost-benefit analysis and category review to ascertain if the product should be trialed and introduced or if viable alternatives are already present on the SCH National Product Catalogue. Specialist input will be sought e.g. SSD, IPC and H&S.

For replacement medical devices or equipment in use at SCH, the usual capex process applies.

For new medical devices not currently used in SCH, capital equipment, prosthetics or implants the following will apply

The SCH HTA framework is followed and the template sent to the supplier to complete. Within the RFI template they provide all regulatory, technical, and commercial documentation direct to the National Support Office Procurement Team; hospital staff should not receive or collate any of this documentation from or on behalf of suppliers.

Review of HTA RFI submissions

Stage 1

- Review by National Support Office Procurement Team and General Manager/s of applicable facility for completeness of the RFI application. Where multiple sites are nominated, one application is to be submitted.

Stage 2

- Initial review by subset of the HTA Committee, comprising of the Chief Operating Officer, Chief Medical Officer; GM Supply Chain & Procurement, National Business Performance Manager and applicable General Manager. This review will identify red flags which would discount further assessment.

Stage 3

- Full review by HTA Committee operating under a Governance Charter. The expertise of subject matter experts and or other SCH committees is sought as required (e.g. BCRC, NCGC, DSSG and NIPCC). The HTA RFI application is evaluated using a defined scoring matrix. A decision will be made if the product should be trailed before a final recommendation can be made.

HTA outcomes

- Recommended - *proceed with negotiating purchase options and present to ELT for approval to continue to business case / capex approval*
- Seek further information – *defer pending further evidence*
- Still in research – *insufficient evidence to make a decision; archive*
- Out of scope / not recommended - *decline*

Presenting the recommendation to the CEO and Board

Upon concluding the evaluation of the RFI the HTA Committee will finalise a recommendation on investment in the technology. This will be written in the format of a Board paper addressed to the CEO. A comprehensive summary will be provided with broad context to the recommendation.

If approved for purchase, where any new product is introduced to SCH, which complements any emerging or new procedure, which is a variation to the clinicians' scope of practice, the hospital General Manager shall ensure that the clinician applies for an extension to their current scope of practice.

Onboarding new supplier and medical device

Where a supplier is new to SCH and/or Joint Venture facility a is to be arranged with relevant details from SCH Finance Team.

Prior to use and where applicable the following applies:

- Any biomedical and/or electrical compliance testing has been undertaken
- Staff training for handling and use of new technologies has been completed

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Associated documents

- Credentialing and Practice Guide: Access privileges and rules for health practitioners
- Bringing medical devices into Southern Cross Healthcare facilities policy
- Supplier loan or consignment equipment checklist
- New supplier details required form
- Medical device product evaluation form
- Agreement for medical device evaluation

References

- Medicines Act 1981
- Ministry of Health – Health Impact Assessment resources
- World Health Organisation – Health Impact Assessment resources
- International Network of Agencies for Health Technology Assessment

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