Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: 65 6866 1111
Website: www.hsa.gov.sg

MEDICAL DEVICE POLICY

OBJECTIVES AND KEY COMPONENTS

Objective 1: Access – Affordability and Availability

KC 1: Improving Affordability The healthcare financing system should balance improving affordability of medical devices whilst ensuring sustainable government support.

Healthcare financing for medical devices should prioritise clinical need, safety, clinical effectiveness, and cost-effectiveness, with subsidies calibrated to patient means. For high-cost medical devices that demonstrate clinical and cost-effectiveness, budget impact should be managed through value-based procurement, outcome-based contracts, and risk-sharing agreements with manufacturers. The policy should encourage adoption of cost-effective alternatives and support local innovation in medical device development where clinically appropriate.

KC 2: Procurement and Supply Systems Medical device supply chains should be affordable yet resilient through diversified sourcing strategies and competitive procurement processes.

Peacetime strategies must ensure supply chain resilience during disruptions, particularly for critical medical devices. Procurement for public healthcare should be consolidated for economies of scale whilst maintaining quality standards. The policy should establish strategic reserves for essential medical devices and develop alternative supply arrangements during emergencies.

Objective 2: Quality, Safety and Efficacy

KC 3: Regulation and Quality Assurance Comprehensive governance across the medical device lifecycle from manufacturing through post-market surveillance.

Registration processes should evaluate medical devices against rigorous quality, safety, and efficacy standards whilst facilitating timely access to innovative technologies. Market oversight should regulate distribution, sales, clinical use, and maintenance of medical devices. Post-market surveillance must monitor device performance, adverse events, and safety signals through robust reporting systems. Regulatory frameworks should remain agile to accommodate emerging technologies like AI-enabled devices, digital therapeutics, and personalised medical devices.

Objective 3: Rational Use – Appropriate, Safe and Cost-Effective

KC 4: Rational Use Healthcare practitioners, institutions, and patients should be supported in making evidence-based decisions about medical device utilisation.

Healthcare subsidies should prioritise medical devices assessed through health technology assessment for clinical and cost-effectiveness. Healthcare practitioners require training on appropriate device selection, proper usage, and maintenance protocols. Institutions should implement benchmarking initiatives to share best practices in device utilisation and outcomes. Patient education should focus on understanding device benefits, risks, and proper use, supported by digital health solutions that improve adherence to device-based treatments.

Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: 65 6866 1111
Website: www.hsa.gov.sg

Objective 4: Sustainability

KC 5: Research and Innovation A clear research strategy should support medical device innovation aligned with national health priorities.

National research programmes should facilitate clinical translation of medical device innovations, support local medical device development capabilities, and promote cost-effective alternatives to expensive imported devices. Research should focus on precision medicine applications, digital health integration, and devices addressing Singapore's demographic and epidemiological needs.

KC 6: Digital Health Integration Robust data infrastructure should support medical device connectivity, interoperability, and evidence generation.

Digital health frameworks should enable secure data collection from connected medical devices, support real-world evidence generation, and facilitate device integration with electronic health records. Decision support systems should guide appropriate device selection and usage patterns whilst protecting patient privacy and data security.

KC 7: Emergency Preparedness Emergency frameworks should ensure rapid access to critical medical devices during health crises.

Emergency authorisation pathways should enable swift deployment of essential medical devices during pandemics or disasters. Contingency plans must address supply chain disruptions, alternative sourcing arrangements, and surge capacity for critical care devices. Strategic stockpiling and maintenance protocols should be established for emergency-critical medical devices.

KC 8: Monitoring, Evaluation and Collaboration Regular evaluation of policy objectives with effective stakeholder collaboration.

Progress monitoring should track access, affordability, safety outcomes, and innovation metrics. Horizon scanning should identify emerging medical device technologies and their implications for healthcare delivery. Collaboration frameworks should engage government agencies, healthcare institutions, device manufacturers, healthcare practitioners, and patients in policy development and implementation.

Implementation Framework

The policy should create clear governance with agencies assigned to each main part, following the medicines policy model. Regular review cycles should ensure the policy remains responsive to technological advances and changing healthcare needs whilst maintaining focus on patient safety and healthcare sustainability.

Last updated: 17th December 2025