MINISTRY OF HEALTH
SINGAPORE

Last updated: 22 November 2022

SINGAPORE'S NATIONAL MEDICINES POLICY

OBJECTIVES AND KEY COMPONENTS

1. Singapore's National Medicines Policy (NMP) defines common objectives for the domestic medicines landscape and identifies the Key Components (KCs) needed to achieve those objectives. The NMP is meant to outline the policy principles governing the access to, and the use of medicines in Singapore.

Objective 1: Access – Affordability and Availability

2. Clinically effective and cost-effective medicines should be made accessible to patients, while ensuring healthcare financing is sustainable.

a. KC 1: Improving Affordability. The healthcare financing system should strike a balance between improving affordability of medicines and ensuring that government support remains sustainable.

i. Where possible, the financing of medicines (e.g. subsidies, insurance) should be prioritised according to clinical need, safety, clinical effectiveness, and cost-effectiveness, with subsidies calibrated to the means of the patient.

ii. The budget impact of high-cost medicines which are clinically effective and cost-effective should be managed sustainably, using approaches like Value-Based Pricing (VBP) and Risk Sharing Agreements (RSA) where necessary.

iii. The use of generics and biosimilars should be encouraged by reducing barriers to entry and supporting cost-effective alternatives through national healthcare financing schemes (e.g. subsidy listing).

b. KC 2: Procurement and Supply Systems. The supply of medicines should be affordable yet resilient, such as through the following ways:

i. Strategies and action plans are to be put in place during peace time to ensure resilience in the event of supply disruption. Supply chains should be

diversified to include a variety of sources, to drive market competition and improve resilient access to medicines.

ii. The procurement of medicines for the public healthcare sector should be consolidated for economies of scale, and subject to a competitive bidding process to secure affordable prices for patients.

Objective 2: Quality, Safety and Efficacy

3. The regulatory regime should ensure the quality, safety and efficacy of medicines in Singapore.

a. KC 3: Regulation and Quality Assurance. There should be governance at all stages of the medicine lifecycle to ensure that appropriate practices are adhered to, and that any concerns are quickly escalated and remediated. The stages include manufacturing, registration, procurement, import, export, distribution, supply and sales, prescription, dispensing, product promotion, advertising, and safety monitoring.

i. Registration. To be registered, medicines should be evaluated to ensure that they meet the required standards of quality, safety and efficacy. The registration framework should be continually reviewed to facilitate timely access to good quality, safe and efficacious medicines.

ii. Market. Once registered, the supply / sales, advertising, prescribing / dispensing, distribution and storage of medicines (also related to KC 2: Procurement and Supply Systems) should be regulated to ensure safe and appropriate use.

iii. Post-market. All registered medicines should be subject to post-market surveillance to detect and manage safety or quality issues which were not detected during clinical trials. This includes monitoring global developments, risk-based product sampling, and testing for compliance to quality and safety specifications. Appropriate risk mitigation measures should be taken if products are found to be unsafe.

iv. Agile regulatory frameworks. Regulatory frameworks should be regularly reviewed to cater for new medicines and future models of care, in anticipation of future regulatory gaps.

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

4. Rational use means that patients receive medicines appropriate to their clinical needs, in doses necessary for their condition, for an adequate duration, and at an affordable cost to them and their community.

a. KC 4: Rational Use. Healthcare financing schemes, health practitioner training programmes, and patient education should help to promote the rational use of medicines.

i. Healthcare subsidies should be prioritised to support medicines assessed to be clinically effective and cost-effective using health technology assessment (HTA).
ii. Healthcare practitioners should be taught to prescribe medicines appropriately through in-service training and the publication of appropriate care guides. Benchmarking initiatives should also be considered at the practitioner and institutional level to promote the sharing of best practices.
iii. Patients and caregivers should have easy access to a common set of credible medicine-related information via various platforms (e.g. collaterals in healthcare settings, government healthcare websites and apps), as well as health coaching such as nutrition and lifestyle advice by pharmacists and other clinicians. Targeted consumer education campaigns on rational use and costs of medicines can also empower patients to make evidence-based medical decisions with their clinicians.
iv. Digital health solutions can also be explored to nudge patients to keep to their prescribed regimens and improve patient adherence, where appropriate.

Objective 4: Sustainability

5. To ensure that we continue to achieve the objectives of access (affordability / availability), quality / safety / efficacy, and rational use, there is a need to monitor developments, evaluate progress, anticipate changes, and research possibilities. These are further elaborated in the following 4 KCs.

a. KC 5: Research. There should be a clear research strategy for medicines, in support of the objectives of the NMP. This includes funding national strategic programmes [e.g. Programme for Research in Epidemic Preparedness And Response (PREPARE), National Clinical Translational Programmes (NCTPs), Translational Platforms and Open Fund – Large Collaborative Grants (LCGs)] to facilitate clinical translation and adoption and more effective commercialisation, in a way that improves affordability and access, and rational use (e.g. research on cost-effective alternatives to expensive treatments or clinical workflows, targeted and improved treatment through precision medicine).

b. KC 6: Digital health as an enabler. The medicines research strategy should also be supported by a robust data infrastructure and governance framework that enables the secure collection, storage, and use of data. The analysis and use of data could enable the discovery of novel associations that can influence the design of policy and enablers to improve health outcomes of the population. Digital tools and decision support systems can also support rational use e.g. capturing clinical indications and building decision support systems to nudge behaviours towards appropriate care.

c. KC 7: Emergency Preparedness. In the event of emergencies e.g. pandemics, the ability to secure early and safe access to relevant medicines or vaccines is essential. For example, HSA's Pandemic Special Access Route (PSAR) allows the interim authorisation of emergency therapeutic products if there is reasonable evidence suggesting that the benefits outweigh the potential risks for their use in public health emergencies and there is ongoing quality, safety and efficacy data

generated to support the eventual registration of the product. At the same time, contingency plans need to be in place to ensure resilience to potential disruptions of medicine supply chains.

d. KC 8: Monitoring, Evaluation and Collaboration. Progress towards the NMP's objectives should be evaluated regularly, while horizon scanning capabilities should be developed to identify emerging trends, such as new high-cost medicines. There should also be effective communication and collaboration between the key stakeholders such as government agencies, payors, practitioners, manufacturers, and patients.

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ANNEX A

VARIOUS AGENCIES OVERSEEING KEY COMPONENTS

The various agencies supporting these key components are summarised in **Table A1** below.

Table A1: Agencies supporting Key Components of the NMP

No.	Key Component	Agencies
I.	Improving Affordability	Ministry of Health (MOH), Agency for Care Effectiveness (ACE)
II.	Procurement and Supply Systems	MOH, ALPS
III.	Regulation and Quality Assurance	MOH, Health Sciences Authority (HSA)
IV.	Rational use	MOH, ACE
V.	Research [Medicines research and development (R&D)]	MOH, National Medical Research Council (NMRC)
VI.	Digital Health as an enabler	MOH
VII.	Emergency Preparedness	MOH, HSA, ALPS
VIII.	Monitoring, Evaluation and Collaboration	MOH, HSA, ACE and other agencies