

From Purchase to Functionality

Improving access to quality-assured medical devices and IVDs through a life-cycle approach

Assistive Technology, medical devices, including in vitro diagnostics, are essential for universal health coverage, health security, effective primary health care, rehabilitation, and emergency preparedness.

When devices, diagnostics, and assistive products are unavailable, unaffordable, unsafe, or non-functional, patients face delayed diagnosis,

inappropriate treatment, avoidable referral, higher out-of-pocket expenditure, and poorer outcomes.

Improving access requires ensuring that devices and diagnostics remain available, appropriate, safe, functional, and fit for purpose throughout their lifecycle.

RC79 Agenda Item 8.4 encourages moving from one-time purchasing to life-cycle governance.

THIS INVOLVES PLANNING FOR ALL STAGES OF AN ASSET'S LIFECYCLE



Practical Implementation

Member States may consider five linked actions:

- 1 Embed essential lists into planning and budgets**
Institutionalize National Essential Diagnostics Lists, medical device lists, and assistive product lists within UHC benefit packages, PHC service packages, national health plans, budgets, procurement systems, and emergency preparedness arrangements.
- 2 Strengthen regulation and market oversight**
Advance national road maps, WHO benchmarking tools, market surveillance systems, reliance and work-sharing mechanisms, and regional cooperation through SEARN, including attention to IVDs, digital health, AI, software as medical devices, nomenclature, and post-market surveillance.
- 3 Procure for long-term functionality**
Link procurement to service needs and long-term use through standardized specifications, improved forecasting, strategic stockpiles, pooled or coordinated procurement where feasible, leasing/rental models, bundled service contracts, and stronger supply-chain resilience.
- 4 Institutionalize maintenance and HTM systems**
Strengthen health technology management units, digital asset inventories, preventive maintenance schedules, service-level agreements, spare-parts planning, biomedical engineering workforce development, SOPs, and routine reporting on functionality and downtime.
- 5 Use procurement mechanisms realistically**
The WHO Catalogue* may support access to selected quality-assured products where relevant items are available. Any future catalogue strengthening—such as improved specifications, lifecycle information, or wider product coverage—should be treated as an area for coordinated technical discussion, not as a current guaranteed capability.

Supported by WHO

WHO can support Member States and partners through:

- Country policy dialogue on implementing the life-cycle approach;
- Technical support for NEDL, medical device list, and assistive product list implementation;
- Regulatory strengthening through SEARN, benchmarking tools, reliance mechanisms, and market surveillance;
- Support for HTM, biomedical engineering, maintenance systems, and digital inventories;
- Knowledge exchange on practical service, maintenance, leasing, procurement, and functionality models.

Connect



- Request a country dialogue;
- Nominate a technical focal point;
- Express interest in essential-list or life-cycle implementation support;
- Share good and replicable practices;
- Document procurement, maintenance, or functionality challenges;
- Join future regional knowledge exchange.

*NB: References to the WHO Catalogue should be understood as part of a broader life-cycle implementation agenda. Catalogue strengthening is a possible area for coordinated future work and should not be interpreted as a commitment that all devices, maintenance services, training, warranties, or local support are currently available through the catalogue.

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