
# Development of Standard Specifications of Medicines and Bio-Medical Equipment

صحت زندگی

TRF
Technical Resource Facility

AZAD JAMMU & KASHMIR

Standardisation of specifications is a process to formulate clear generic guidelines to obtain the right type of equipment, disposables or medicines, to be used under specific conditions. Lack of equipment specification can compromise health and safety standards which can give rise to serious issues such as baby incubators catching on fire when electrical safety checks are not followed. Similarly, the specifications of medicines can miss out on generic names of drugs, their potency, formulation / packaging details and technical parameters. Furthermore, if the specification is not generic, this may lead to litigation/ grievances from the bidders and eventually the bid failing.

To address the above issues, Technical Resource Facility (TRF) hired consultants to make a compendium of standard/generic specification for disposables, medicines and medical equipment, which could be used as a guideline for central and provincial level procurements. A situation analysis was carried outin all four provinces, Gilgit-Baltistan and Azad Jammu and Kashmir to identify weaknesses in the procurement system.

## Situation Analysis

The situation analysis carried out indicated the use of outdated lists, lack of standard specifications, cumbersome renewal procedures, mismatch of budget and facility requirements, and lack of trained manpower, leading to an acute shortage of essential drugs, medical supplies and equipment throughout the country. It also revealed a large gap in budget allocation and its release resulting in procurement delays.

## Key Findings

Findings were more or less common to all provinces and special areas, and are shared below:

**a** Generally, staff was not skilled in the development of specifications which were made on an ad-hoc basis in line with the existing demand. The end result of this was either specification based on experience of end user or on a specified model which did not address the needs of the service provider and prevented quality purchase.

**b** Service providers suggested additions and improvements to the specification list based on their experience and in view of the existing specifications to be inappropriate.

**c** In many instances specifications were not updated/validated according to state of the art technology, lack of expertise, for example, anesthesia machines procured were not up-to-date, similarly, surgical instruments had out-lived their effectiveness but were still in use due to non-availability of standardised specifications for new purchases. Indent scrutiny was the key element missing in the supply chair leading to imbalances in supply and demand at various tiers of health services.

**d** Equipment cost was not taken into account at the time of PC-1 preparation and budgetary cuts were applied to the revenue portion – although this ensured the development of infrastructure but once completed the facility lacked quality equipment due to the following factors:

- Nomenclature being erroneousin PC-1 and equipment procured was not according to demand.
- Mismatch of facility and equipment/furniture.
- Budgeting was not rationalised in PC-1. There was no document available where prices could be rationalised and the demand justified.

**e** Health administrators had no reference document to consult in correcting errors nor had qualified staff to develop specification themselves.

**f** Drugs/medicines storage and inventory controls were manual and inconsistent with modern needs, leading to shortage or expiries.

**g** The DoH officials showed concern about existing specifications of drugs/medicines lists and stressed on improvement and designing of detailed standard specifications for ensuring supply of quality products. Involvement of service providers in development of technical and standard specifications should be minimal.

**h** Lack of standard specifications led to duplication which was irrelevant to the needs of end users.

**I** Environmental control particularly with reference to factors like heat, humidity and light which can lead to chemical and physical deterioration of drugs, wear and tear of equipment, stored at the primary and secondary care levels, was not covered in the specifications.

## Standard Specifications

Findings from the situational analysis led to the formulation of "Standard Specification of Medical Equipment, Drugs/Medicines and General Goods for Provincial and Special Areas Health Departments". This document entails specifications which serve as a guideline and reference point for procuring agencies throughout the health departments with modifications to customize to local needs and disease patterns.

Drugs are divided into 39 different therapeutic categories with specifications covering details such as therapeutic category, nomenclature, strength, unit size, labeling and packaging detail.

The medical equipment specification consists of 25 different categories. The specifications cover physical, technical and electrical characteristics to safety standards and accessories. (Table 1)

**Table 1: Specification of drugs and equipment's**

| Specification of drugs | Medical equipment specification |
|---|---|
| 1. Antipyretics / analgesics antacids / antiulcer drugs | 1. Anesthesia |
| 2. Anthelmintic | 2. Generalfurniture |
| 3. Anti-coagulants /anti-hemorrhagic | 3. Sterilisation equipment |
| 4. Antimalarial | 4. Dental equipment |
| 5. Antidiarrheal | 5. Endoscopy |
| 6. Antiemetic | 6. Furniture medical |
| 7. Anti-histamine, antipyretics analgesics | 7. Medical equipment general |
| 8. Antispasmodics | 8. House keeping |
| 9. Anti-viral | 9. Instruments |
| 10. Anti-asthmatic | 10. Pharmacy |
| 11. Antibiotics | 11. Kitchen |
| 12. Anticonvulsants / antiepileptic /psychotropic medicines | 12. Laboratory |
| 13. Antidepressants | 13. Monitoring |
| 14. Antidotes | 14. Neonatology |
| 15. Antiretroviral | 15. Office equipment |
| 16. Anti - thrombotic drugs | 16. Operation theater |
| 17. Anti - tuberculosis drugs | 17. Physiotherapy |
| 18. Cardiovascular / Anti-anginal drugs | 18. Radiology |
| 19. Contraceptives | 19. Refrigeration |
| 20. Dermatologicals | 20. Steel furniture |
| 21. Disinfectants / antiseptics | 21. Maintenance |
| 22. Diuretics | 22. Mortuary |
| 23. Drugs affecting bone metabolism | 23. Laundry |
| 24. Ergot alkaloid / anti - migraine | 24. General items |
| 25. Glucocorticoids | 25. ENT/eye equipment |
| 26. Gonadotropins & ovulation stimulants | |
| 27. Infusions | |
| 28. Insulin and other Anti diabetic Agents | |
| 29. Labour inducers / inhibitors | |
| 30. Laxatives | |
| 31. Lung surfactants | |
| 32. Multivitamins and minerals | |
| 33. Opthalmological / ear / nasal preparations | |
| 34. Oral rehydration salt | |
| 35. Plasma substitutes | |
| 36. Recombinant human erythropoietin | |
| 37. Sera / vaccines | |
| 38. Thyroid / anti thyroid hormone | |
| 39. Uterotropic drugs | |

## Benefits of Standard Specifications

Standardisation of specification helps to improve:

### Quality

- By ensuring that only products meeting defined standards are acquired without the need for additional cumbersome tests and checks.

### Procurement and logistics

- By limiting the number of spare parts, accessories, and consumables that are kept in stock for different types of equipment.
- By helping to rationalise sources of supply and supply routes, and save through bulk purchasing.
- By enabling staff to become more knowledgeable about the operation and maintenance of a limited number of products.

### After sales support

- By giving suppliers greater incentives to provide after-sales services and establish long-term relations with procuring entities due to bulk sales.

Standard specification for medical equipment, drugs and hospital supplies serves as a reference guide to be used by the procuring agencies throughout the health departments according to their own needs and disease patterns for enhancing quality, safety and appropriateness for procurement.

Technical Resource Facility
5B, Street. 1, F-7/3, Islamabad.
Ph: + 92 51 2610934, + 92 51 2610935
Email: info@trfpakistan.org

www.facebook.com/trfsehatzindagi
www.twitter.com/SehatZindagi
www.trfpakistan.org

TRF is funded by UKaid from the Department for International Development and DFAT, and managed by HLSP