Steering Committee Meeting

Ensuring Essential Medicines for All

29.11.2011

Deficit Areas

- Private Sector accounts for 80% of out-patients and 60% of in-patients.
- 79% of Healthcare costs financed by Out of Pocket (OOP) expenditure.
- 70% of Out of Pocket expenditure on drugs.
- 68% of Indian population do not have access to affordable healthcare/medicines (WHO).

Deficit Areas

(Contd.)

- Limited price control/regulation of drugs.
- Irrational use of medicines – prescription of branded generic - irrational FDCs.
- Potential barriers to production and use of generics – Section 3(d) of the Patents Act/Data Exclusivity/FTA.
- Weak Drug and Food Regulatory Mechanisms.

Main reasons for Deficit Areas

- Out of 4.5% of GDP spend on Health, only 1.2% is public spend.
- Total public spend on Health is just around 4.4% of total Government spending.
- Public spend (Central and State govt.) on drugs procurement is only around 0.1% of GDP.
- Availability of essential medicines in Public Health Facilities (PHFs) is poor and limited, characterised by acute shortages and chronic stock-outs of medicines.

Main reasons for Deficit Areas
(Contd.)

- Lack of appropriate prescription and dispensing practices and use of medicines.
- Greater need for use of quality generics.
- Lack of use of TRIPS Inbuilt flexibilities – Compulsory Licensing.
- Low priority for streamlining of Drug and Food Regulatory Machinery – Centre and States
- Multiplicity of jurisdictions related to pharmaceutical production and regulation.

Working Group Recommendations

- Provision of "Free Medicines for All" in Public Health Facilities (PHF).
- On an average, around 20-25% of population currently access healthcare in PHF, with wide variations across states.
- Target that 52% of Indian population access healthcare in PHFs (remaining 48% to be covered as part of UHC).
- Proposal is based on the successful Tamil Nadu Medical Services Corporation (TNMSC) model.
- Total estimated cost for the provision of free supply of medicines during the 12th Plan period would go up from the present 0.1% of GDP to 0.25% p.a of GDP (0.5% under UHC plan).
- Funding pattern will be shared 85 : 15 between the Centre and States (if UHC, then entire financial burden to be borne by C. Govt).

Working Group Recommendations (Contd.)

- The provision of free supply of Medicines will be part of NRHM/NUHM/UHC.
- MoU to be made with the States will include :
  - An autonomous institutional mechanism/agency to be set up for bulk procurement of quality generic medicines linked to key criteria.
  - Specific instructions on prescription and dispensing practices/ Standard Treatment Guidelines to be issued.
  - States to contribute their share up-front (15%).

Working Group Recommendations (Contd.)

- Generic medicines based on Essential Drug List to be procured.
- Public Health Infrastructure under NRHM/UHC will continue to be strengthened.

- Expected outcomes will be :
  - Increased access to essential drugs.
  - Significant reduction in irrational manufacture, prescription and dispensing of medicines;
  - Reduced burden on Out of Pocket Expenditure (OOP).
  - Increased financial protection for households.
  - Substantial reduction in impoverishment.

Other Related Issues.

- Stricter approval regime for FDCs.
- An institutional Mechanism within DTAB to carry out review of existing FDCs and their phased weeding out.
- Sensitizing and capacity building for Drug Regulatory Authorities and other stakeholders on the impact of irrational medicines, drug resistance, prescription, etc.
- Code for preventing unethical promotion of drugs by pharma companies – voluntary or mandatory.
- Whether prescription of generics/STGs to be made mandatory.
- Need for strengthen of Pharmacovigilance Programme.

Policy Options

- Provision of free supply of medicines in PHFs.
- Effective Price Control of Essential Medicines (NELM and cost-based pricing must continue)
- Efficient and effective Drug and Food regulatory systems – need for central financial assistance to the States.
- Department of Pharma or at least NPPA to be brought under the Ministry of Health & Family Welfare.
- Policy framework for enhanced investment in R&D and bulk drug production.

Policy Options (Contd.)

- Important to safeguard IPR, but patent regime should not compromise access and affordability.
- Protection and use of inbuilt TRIPS flexibilities – Section 3 (d) of Patents Act - Data Exclusivity – Compulsory Licensing.
- Check on takeover of Indian Pharma Companies by MNCs.