Challenges of Good Governance for Medicine in Bangladesh: The Directorate of Drug Administration

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Background

• Transparency International Bangladesh (TIB) has been working since 1996 to create demand for and supply of good governance through social mobilization and influencing policy and practices through research based advocacy.

• Health sector is one of the priority sectors of TIB for which it has been working to increase accountability and transparency at grassroots level through its ‘Committee of Concerned Citizens’ (CCC) in 45 local districts/sub-districts of the country.

• In many of the local service centers in these CCC locations TIB successfully campaigned for changes in policy and practices.
Background

• TIB instruments for change included, inter alia, use of social accountability tools like CRC, engaging volunteers and other CS stakeholders, and various other forms of advocacy with local authority as well as developing local to national policy advocacy linkages

• Among some of the successes of TIB includes contributing towards introduction of specially marked packages for medicine, regular hanging of available medicine lists, increased information on various services available, attendance and cleanliness in the hospitals, narrowing scope for illegal payment etc

• The cumulative impact of all these initiative resulted in better service delivery including increased availability of medicine
Background

- However it is increasingly felt that establishing GG for medicine and ensuring access to safe and effective drug is a multi-stakeholder multifaceted issue.
- In Bangladesh medicine is imported, produced and distributed through three major channels: the public channel, the formal private channel and the non-formal private channel.
- A major component of out-of-pocket expenses for healthcare are on medicine and during last 20 years the pharmaceutical sector has been growing increasingly to meet domestic demand.
- At present, 97% of country’s demand of medicines is produced locally mainly by about 300 national pharmaceutical companies.
- The Directorate of Drug Administration (DA) is responsible to regulate all functions relating to import, production, quality control and marketing/distribution of drugs both of private and public channels.
Background

• The main aims of DA is to ensure availability of quality drugs in an affordable price and ensure quality and efficacy of drugs

• Considering its crucial role in ensuring good governance in medicine both at national as well as local level TIB decided to conduct a “diagnostic study” on DA

• The major objective of the study was to indentify governance challenges of the Drug Administration (DA) in monitoring and regulating the drug market and

• To provide evidence based recommendations and make advocacy based on such recommendations to contribute to improve overall medicine governance in the country
Study method and time reference

• A qualitative study
• Information collected from both primary and secondary sources.
• The methods applied to collect information from primary sources include
  • Key informant interviews (KI)
  • Group discussions (GD)
  • Case studies and observations
• Primary sources of information included
  • Current and former officials of DA
  • Members of different committees associated with DA
  • Owners and officials of different pharmaceutical companies
  • Representatives of associations e.g. BPC, BPS, BAPI, BCDS
  • Individual proprietors of drug shops, police officials, medical practitioners, experts and researchers on drug sector.
• The study was conducted during March 2014 - January 2015 and most information are updated to this period.

• Note: The findings are indicative, no generalization is possible
Major Findings: Key challenges/constraints for Drug Administration in Establishing GGM

- The legal framework for monitoring and supervision of drug sector is based on following policies/acts:
  - Drug Act 1940
  - Drug Rules 1945
  - Bengal Drug Rules 1946
  - Drug Control Ordinance 1982
  - National Drug Policy 2005

- However policy and legal framework has become outdated and remain weak in many respects and proved inadequate to comply with the present day diversified health sector demand and to address contemporary challenges.
For example, some sensitive items for human body like medical devices, food supplements and cosmetics – that have phenomenal growth in terms of popular consumption to meet supposed or actual health needs during recent years - are not included in the laws.

There are therefore no clear guidelines to regulate such items and they are not included in the functions of DA. As a result, if anybody produces, imports and markets low quality and risky medical devices, food supplements and cosmetics, the DA cannot take any legal measures.
Major Findings: Key challenges/constraints for DA in Establishing GGM (Cont.)

• Regarding weakness, for example

  ✓ There are lack of clear guideline for updating the list of essential drugs and controlling drug prices
  ✓ There is a lack of policy incentive to encourage local and multinational companies to produce essential drugs
  ✓ The manufactures are given the permission to produce any drugs as per the requests of foreign buyers.

• These limitations created scope for regulatory inactions on DA’s behalf to control drug prices, prepare update list of essential drugs, and increased risk of producing non-essential drugs by companies.
Another example of weakness or inadequacy of law is that it does not clearly delineate the details on formation criteria and operational process of various committees.

The DA currently forms 9 committees/sub-committees/cells at national level and each of them has very important role in establishing good governance in medicine in the country. These are

1. The Drug Control Committee
2. The Technical Sub-committee of the Drug Control Committee
3. The Project Evaluation Committee
4. The Committee for Determination of Drug Price
5. The Herbal Medicine Committee
6. The Committee on Import of Pharmaceuticals
7. The ADR Advisory Committee
8. The ADR Advisory Council
9. The ADR Monitoring Cell

Besides there is a District Drug Licensing Committee in each of the districts.
Major Findings: Key challenges/constraints for DA (Cont.)

• However the laws does not provide clear guideline on committees’ formation criteria, operation processes, number of members etc.

• Currently DA forms such committees based mostly on directives as provided by the Ministry through circulation

• This has created and increased risks/opportunities for appointing members on political considerations and with conflict interests

• It may be mentioned that the representatives of the organization of pharmaceutical industry owners of Bangladesh (BAPI) have been included in all above committees (except for the district level committee)
Major Findings: Key challenges/constraints for DA (Cont.)

• Although the existing policy emphasizes need for availability of bio-equivalence information of imported drugs during their registrations, it doesn’t make clinical trial of biological drugs mandatory. This increases risk of import of drugs with adverse health effects.

• The existing laws/policies do not promote rational use of drugs by making prohibitive/punitive measures against prescription of irrational, unjustified drugs by the physicians. They also mention nothing about prescriptions as prerequisite for selling drugs. Therefore DA can’t take legal measures with this respect.

• Various other important limitations of the existing laws include:
  • Absence of guideline on increasing number of quality testing facilities in accordance with changing demand/need; according to law establishing only one such central laboratory has been made mandatory
  • Absence of timeframe of gazette notification on maximum price of a drug for which DA can’t take legal actions if a company is selling medicine at higher prices (the last gazette notification was made in 2000!)
  • Absence of update of rules and formulation of new rules
Major Findings: Key challenges/constraints for DA (Cont.)

• Various other important limitations of the existing laws include:
  ▪ Absence of guideline on increasing number of quality testing facilities in accordance with changing demand/need; according to law establishing only one such central laboratory has been made mandatory, no provisions for local level testing labs or branches
  ▪ Absence of timeframe of gazette notification on maximum price of a drug for which DA can’t take legal actions if a company is selling medicine at higher prices (the last gazette notification was made in 2000!)
  ▪ Absence of update of rules and formulation of new rules
  ▪ Absence of stringent/severe punishment (the recent media report) (2-3 years to highest 10 years RI and BDT from 10-200,000 fine either or both) (Given that media reports on death due to use of sub-standard drug and tendency to repeat offences by sellers)
  ▪ Absence of provision specific punishment for production of drugs in unhygienic conditions and for prescribing non-approved drugs
Key challenges/constraints for DA (Cont.)

- Capacity Constraints: Infrastructural, Logistic, Institutional, and other limitations/problems in face of huge growth the pharmaceutical sector
  - Own HQ premise yet to be completed, present office lacks sufficient space
  - Inadequate logistics support: Collecting samples, preservation of samples, transportation are hampered (factory visit by vehicles owned by factories)
  - Shortage of manpower: 58 Supers instead of 64, 4 Inspectors instead of 64, total 54% positions remain vacant, Directors not appointed,
  - Lack of professional knowledge and regular training provisions for relevant field staff (e.g. supervisors)
  - Lack of inadequate skilled manpower at testing labs
  - Limited communication and collaboration between central and field offices
  - Absence of unified reporting format (reporting by the field offices to the HQ)
  - Inadequate number of district offices (47 out of 64) (Bigger districts needs more than one)
  - Lack of own legal staff for conducting litigations (dependence on PP)
Lack of Transparency, Accountability, Responsiveness and Existence of Irregularities/Corruption

- Various types of lack of transparency, accountability, responsiveness and existence of irregularities/corruption include, inter alia:
  - Lack of transparency in assignment distribution
  - Responsibilities not distributed according to the organogram but as directed by the DG
  - Additional responsibility assigned/desk changed at DG’s will
  - Often also by the Directors a.i. assign works
  - For all above the supervision and accountability chain has become less effective at DA
  - But the officials reportedly engage in consultancy illegally at pharmaceutical industries
  - Information provided in the official website not updated
Existence of Irregularities/Corruption (Cont.)

- Supervisors do not undertake regular field visits, sometimes even report without field visit (fake reporting); stay away from duty stations, maintain contact with field office over mobile phone.
- There exists lack of transparency in working of committees.
- Allegations of syndicated corruption by some committee members influencing approval process in collaboration with DA staff (exerting influence on DA staff too).
- There exists delay in service provision to pharmaceutical manufacturers – meeting for approval not called, meeting quickly set if applicant company pays bribe.
- Submission of recipe approval application to the Committee is delayed if bribe not paid.
- Companies get drug registration by paying bribe although they actually lack machines/equipment mentioned in the dossier.
- Other areas of bribe include approval of literature registration of foil, insert, label, pack, approval of block list – approval given without appropriate checking of documents submitted.
Irregularities/Corruption (Cont.)

- Bribe is taken for providing certificates for good manufacturing practices even without inspection/hiding facts found in inspection
- Providing false drug testing certificates in return for bribe (sample from each batch not taken, randomness not maintained, and certificates provided without testing)
- Providing drug license in return for drug (according to the BPC eligible number of pharmacists is 60,000 whereas number of those got registration is 112,218)
- Money involved in corrupt transaction per incident ranges from several thousands to 1.5 m in local currency
Impact of Irregularities/Corruption on Pharmaceutical Production

- Role of DA in price fixing has become very nominal
- In fact there are instances that product is brought to market and sold at a price which is yet to be approved
- Committees become week, ineffective and lack of technically skilled members
- GMP not practiced (e.g. in 2007 DA gave 30 companies GMP certification but a subsequent UN agency study showed that only 6 – 2 of them partly following GMP
- Mention of BP/USP without actually following such formulary properly
- Not separating very harmful toxic elements fully
- Not mentioning specific plant of manufacture on packet
- Influencing/capturing price setting individually and in collusively with other companies
- Using different quality raw materials for home and export market
Recommendations

1. Laws need to be strengthened by introducing and increasing punitive measures in some cases and updating to address contemporary challenges

2. Effective enforcement of laws has to be ensured through appointment of legal professionals for DA, and making arrangement for clear disposal of cases

3. To ensure responsiveness, transparency and accountability
   - One stop service center have to be set up
   - Responsibilities to be assigned as per organogram
   - Additional responsibility/desk change need to be done through due process
   - Website need to be updated
   - A unified reporting format need to be developed
   - A central server to be set up

4. Increase staff: Number of Drug Super and Inspectors need to increased and vacant positions of Drug Inspectors need to be filled-in immediately

5. Own HQ premise completion need to be expedited and office need to be set up in all districts / adequate space and logistics support need to be ensured

6. Introduction of positive and negative incentives to reduce corrupt practices of drug officials and employees

7. Steps to be taken to prevent illegal consultancy of officials in manufacturing companies

8. Take measures to make various committees effective
Growth of Pharmaceutical Sector in Recent Years

• During recent years the sector had an average annual growth of about 21 percent.
• According to available data the total size of the pharmaceutical market of Bangladesh is estimated to be approximate Tk. 113 bn.
• Now the industry meets 97% of total local demand whereas about 20 years ago 75% drugs needed to be imported.
• About 300 pharmaceutical companies are registered as producers.
• The industry manufactured about 5,600 brands of medicines in different dosage forms.
• About 112,000 wholesale and retail registered seller (but the actual number operating is much higher than that).
• During 2003 to 2013 period the value of export has had a growth of about 957% in local currency.