



Governance of the Directorate of Drug Administration: Challenges & Way forward

(Executive Summary)

Research and report preparation
Md. Shahnur Rahman
Nazmul Huda Mina

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Research Advisors

Advocate Sultana Kamal

Chairperson, Board of Trustees, TIB

Dr. Iftekharuzzaman

Executive Director, TIB

Dr. Sumaiya Khair

Deputy-Executive Director, TIB

Mohammad Rafiqul Hassan

Director, Research and Policy, TIB

Research Supervisor

Md. Waheed Alam, Senior Program Manager, Research and Policy, TIB

Research and report preparation

Md. Shahnur Rahman

Program Manager, Research and Policy, TIB

Nazmul Huda Mina

Assistant Program Manager, Research and Policy, TIB

Research Associate

Md. Samiur Rahman, Research Assistant (former), Research and Policy, TIB

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For further information

Transparency International Bangladesh (TIB)

MIDAS Tower

House # 05 , Road # 16 (New) 27 (old)

Dhanmondi, Dhaka-1209

Tel: 880-2-9124788, 9124789, 9124792

Fax: 880-2-9124915

Web: www.ti-bangladesh.org

Governance of the Directorate of Drug Administration: Challenges & Way forward

Executive Summary¹

1. 1 Context and Background

Drugs are considered highly essential and sensitive consumer goods for saving human lives. Therefore, for such reasons high importance is given on regulation of drugs in every country. In Bangladesh, the Directorate of Drug Administration (DA) is responsible to regulate all functions relating to production, quality control and marketing of drugs. The main aims of this institution are to ensure availability of quality drugs in an affordable prices and ensure quality and efficacy of drugs produced locally and imported from abroad. At present, local manufacturers produce 97% drugs against demand. Thus, this sector is considered as most potential sector after garments sector whose average yearly growth has been 21.39%.

Recently, the government has taken some measures to strengthen DA's capacities. They include increase of manpower in field offices and measures to reconstruct central drug laboratory and its capacity building. Moreover, it has taken measures to implement directives given by the Parliamentary Standing Committee on Health to strengthen its operations to prevent flourish of fake and adulterated drugs, formation of an Ethics Committee as per the National Integrity Strategy 2013 and formation of an Innovation Team for bringing visible changes in its client service delivery.

Despite immense potentiality of this sector and above regulatory measures, some problems and anomalies persist in the drug sector. Although some companies are producing good quality drugs, allegations are rife against some companies that they are producing fake, low quality, adulterated and unessential drugs and some are not following good manufacturing practices. Even, there are common allegations against marketing and selling of drugs. They include weak monitoring of drug industry, lack of regulation on prices of drugs, selling of expired drugs and flourishing of illegal drug stores. Therefore, public health is now under threat because of this weak regulation and management deficit of Drug Administration in controlling fake, low quality and expired drugs. It is to be noted that during 1980-2013 a considerable number of children died because of swallowing of adulterated paracetamol. Because of these incidents, several times displeasures from policy level have been raised to regulate production of adulterated and fake drugs and accordingly some measures were taken. Despite those measures, production of adulterated and fake drugs continues. Although numerous news have been published in media on limitations, irregularities and corruption of Drug Administration, there is a dearth of research on examining its governance challenges. Moreover, Transparency International Bangladesh (TIB) has been giving emphasis on four sectors of which health sector is one of the major areas. As drug sector falls under health sector, TIB has decided to conduct this study titled Governance in the Drug Administration: Challenges and way forward.

¹ This is the summary of the study titled 'Governance of the Directorate of Drug Administration: Challenges & Way forward' released through a press conference on 15th January, 2015 at MIDAS centre, Dhanmondi, Dhaka

1.2 Study objectives and scope

The overarching objective of the study is to identify governance challenges of the Drug Administration (DA) in monitoring and regulating drug market (production, marketing and preservation) and provide recommendations to overcome them. The specific objectives are

- To review existing laws and policies in regard to drugs production, market regulation and monitoring and identify their implementation challenges
- To identify institutional limitations, problems and challenges in performing its functions and identify areas and extent of corruption in their operations
- To provide recommendations to strengthen and up hold its administrative and oversight mechanisms and prevent corruption and irregularities

1.3 Methodology and scope

It is a qualitative study. Information for this study was collected from both primary and secondary sources and analyzed them in line with study objectives. The methods applied to collect information from primary sources include key informant interviews, group discussions, case studies and observations. Primary sources of information were current and former officials of Drug Administration (both from central and local offices), members of different committees associated with DA, owners and officials of different companies, proprietors of retail drug stores, representatives of BPC, BPS, BAPI and BCDS, police officials, medical practitioners and experts and researchers on drug sector. Secondary sources were existing laws and rules, official documents, websites, research reports and articles and news published in different newspapers. The study was conducted during March 2014 - January 2015.

Among five types of medicines (allopathic, *unani*, *ayurved*, homeopathic and herbal), this study has dealt problems, irregularities and corruption associated with marketing and regulation of allopathic medicines. For examining governance challenges, information was collected and analyzed in line with some governance indicators like rule of law, transparency, accountability, participation, responsiveness, deficits in service provisions and corruption in DA. It is to be noted here that findings presented here does not equally applicable to all officials and employees of DA and other stakeholders rather they give an idea about existing problems, irregularities and corruption in the DA.

Research findings

2. Limitations and operational challenges of drug laws and rules

The regulation and monitoring of drug sector in Bangladesh are done with the help of Drug Act, 1940; Drug Rules, 1945; National Drug Policy 2005 and Drug Control Ordinance, 1982. The operations of DA are done based on these laws, rules and policies. Limitations and implementation challenges of these laws and polices are presented below:

2.1 Existing laws not adequate to address immerging issues and challenges

The Drug Act 1940 and Drug Control (Ordinance) 1982 are not adequate to address contemporary issues and challenges. Some sensitive items for human body like medical devices, food supplements and cosmetics are not included in both the laws. There are 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.

On the other hand, although directives and emphasis were given in the National Drug Policy 2005 regarding elevation of DA from a department to a directorate to bolster its administrative capacity, strengthening of its infrastructural facilities and building of its human resources; some limitations are also visible in it. There are obscurities in the guideline for updating the list of essential drugs and controlling drug prices. Moreover, there is a lack of policy incentive to encourage local and multinational companies to produce essential drugs. This policy gave manufactures the permission to produce any drugs as per the requests of foreign buyers. Because of these limitations, there have been regulatory inactions from DA's end to control drug prices and prepare update list of essential drugs including increased risk of producing non-essential drugs by companies. Besides, this policy gave emphasis on bioavailability and bio-equivalence information of imported drugs during their registrations; however, clinical trial of biological drugs is absent that might encourage import of drugs that would pose adverse health risks.

2.2 Formation criteria and operation process of different committees not mentioned

In the Drug Control Ordinance 1982, provisions to form different drug committees was mentioned; however, committees' formation criteria, operation processes, number of members were not clearly defined in the law. Because of these limitations, there are risks regarding selection of committee members on political considerations and surfacing of conflicts of interest among members and creation of ambiguities in performing their roles and responsibilities.

2.3 Absence of adequate and required number of drug testing laboratories

In the article 6 (1) of Drug Act 1940, establishment of a Central Drug Testing Laboratory was mentioned to ensure drug quality. Although it was pragmatic to have only one laboratory in the realities of those days, it is not adequate in current context given the industry's considerable growth and expansion. Even this reality did not receive considerable attention during formation of the Drug Control Ordinance 1982.

2.4 No specific timeline to issue gazette on drug prices

It was mentioned in Article 11 of Drug Control (Ordinance) 1982 that the government would issue gazette on maximum retail prices of drugs considering the prices of raw materials. However, no specific timeframe was mentioned to issue gazette notification. Because of this limitation, no legal action can be taken if drugs are sold in exorbitant prices. It is to be noted that no gazette in this regard has been published since 2000.

2.5 No rules and necessary updates were made on the Ordinance

Since promulgation of Drug Control Ordinance on June 12, 1982, no rules have been issued. On the other hand, two earlier rules on Drug Act 1940 (Drug Rules 1945 and Bengal Drug Rules 1946) have not been updated considering changed realities. Moreover, the rules for Drug Control (Ordinance) 1982 have not been issued. As rules

give guidelines for enforcement of laws; sometimes regulatory officials fall under confusion during enforcement of laws.

2.6 Regulation on doctors' prescription to prevent unjustified and misuse of drugs not mentioned

One of the prime objectives of drug laws is to control unjustified and misuse of drugs. It is possible to prevent any misuse of drugs by proper application of laws. However, nothing was mentioned in laws to regulate doctors' advices to prevent unjustified use of drugs. As a result, the regulatory officials cannot take any measures against retail shoppers for selling of drugs without doctors' advices.

2.7 Lack of punishment for production of drugs in unhealthy environment and advising non-approved drugs

Different terms of punishment were mentioned in the Drug Act 1940 and Drug Control (Ordinance) 1982 for producing fake, harmful and low quality drugs; but no punishment was mentioned for producing drugs in an unhealthy environment. On the other hand, as per the Drug Control (Ordinance); doctors were forbidden to prescribe non-approved drugs; however, no punishment was declared for such offence. Therefore, regulatory officers cannot take any legal measures if non-approved drugs are advised.

2.8 Absence of severe punishments and in some case inconsistency between punishments and fines

It is observe that punishments and fines mentioned in different laws and ordinances are not consistent considering current socio-economic reality, gravity of offences and financial capacity of offenders. For example, in the Drug Act 1940 maximum punishment was set 3 years jail and undefined fine for drug offences and 5 years jail and undefined fines for recurrence of same offences. On the other hand, in the Drug Control Ordinance maximum punishment was set 10 years jail and BDT. 2 lakh as fine.

2.9 Inordinate delay in discharging cases

To settle cases in the Drug Court and Lower Courts is quite lengthy. Once a Drug Inspector or Supervisor files a case in the Drug Court, the court summons defender to appear before the court. In such a case, the defender in person or his/her lawyer appears before the court and seek a time to defend. Then, the defender might go to the High Court and file a case giving a reference that freedom to pursue a profession or livelihood was violated enshrined in the Constitution. Accordingly, the High Court issues show cause notice to Lower Court and defer legal proceedings at lower court unless hearing at the High Court takes place. Because of such ruling from the higher court, legal process at lower court remains suspended for a longer time. Moreover, unless the ruling of higher court is settled, regulatory officials are disallowed to monitor and sample collection operations from concerned factory. Eventually, accused factory continues production of low quality drugs until the case is settled in the Higher Court.

3. Institutional problems and limitations of Drug Administration

3.1 Problem in infrastructures

There exist infrastructure problems in the Drug Administration. The department does not have its own places for its central office and field offices. District level offices are located in rented houses. There are shortages of field offices considering the demand. At present, there are 52 offices in 64 districts in Bangladesh including the central one to run

its regulatory operations. Moreover, there are shortages of space in central and field offices. Because of such space shortages, its operation are hampered for preserving drug samples, providing services to service recipients and keeping office files and documents.

3.2 Lack of adequate logistics for regulation and monitoring

There are lack of necessary logistics for Drug Supers and Inspectors for performing their regulatory and oversight activities for collecting drug samples and their preservation and transportation. The officials generally compel to use companies' vehicles for visiting factories. As a result, conflict of interest and opportunities of mutual corruption arises among the officials and companies. Moreover, there are problems at field offices to preserve drug samples. For lack of proper preservation and transportation facilities a portion of samples from field offices are damaged. Moreover, telephone and fax facilities for the Drug Supers are absent to perform their official correspondence with the central office.

3.3 Lack of manpower and accompanying problems

Shortages of manpower are also visible in the Drug Administration considering its operational and geographical reach. There should be one Drug Super and one Drug Inspector in each of 64 districts; but in reality, altogether there are 58 Drug Supers and 4 Drug Inspectors in central and field offices. Although it was elevated as a directorate four years back, its organ-gram has not been approved. Overall, 38% positions at different levels are vacant against approved positions. The organ-gram for the new Drug Testing Laboratory established in 2011 has not been approved yet. This laboratory has been in operation with manpower approved for the old laboratory. Moreover, only five technical staffs are working against 20 approved positions at Drug Testing Laboratory, Chittagong. The study found that because of manpower shortages two-thirds of the market are left unattended from regulation and similarly for shortages of manpower in drug laboratories a considerable portion (around 70% yearly) of drugs cannot be tested.

3.4 Lack of adequate skills and training for officers

Some central and field officers of Drug Administration along with technicians of laboratory do not have the required professional and technical skills. They can not maintain their monitoring roles and control standards in drug market. There are no regular trainings and in some case their needs and relevance have not been considered. Because of which they are unable to address contemporary challenges in market and have no clarity of complying existing laws and do not understand their responsibilities fully.

3.5 Weakness in information management and reporting

There is a lack of information giving services at the DA. Central and fields offices do not maintain modern and unified systems. For this reason, reporting and documentation systems remain weak. On the other hand, problems and inadequacies prevails in the reports sent to central office. On DA website there are shortages of service oriented and updated information; therefore, service recipients are deprived of necessary and updated information.

3.6 Lack of transparency in assignments distribution

The Director General (DG) is the Chief Executive Officer of DA. The organizational structure is designed with 370 employees under the helm of 4 Directors. Assignments at different layers of officials are supposed to be allocated as per organogram; however,

they are not properly done. Rather assignments are given as per the choice of DG and Directors. Due to this, anomalies take place in assigning inspections and monitoring assignments to officials. Some officials of DA select companies according to their own choice and call those companies in some 'sweet words'. Sometimes influential officials compete or indulge in collusion to get assignment to small and local companies. Again, some companies try to influence decisions so that they get their preferred official. Such a system encourages collusive corruption among officials; and thus corruption is institutionalized at DA. Eventually, accountability mechanism at DA is worsening and internal grouping among officials are getting momentum.

3.7 Lack of supervision and accountability of officials

As assignment distributions among officials have been done by the choice of DG and Directors, human resources management at DA has become precarious. As a result, regular monitoring and supervision roles of DG, Directors and field level Drug Superintendents have become less effective. Although it is the rule to perform field monitoring on 2 days in a week, some Drug Superintendents do not do that; and even some prepare and send reports without making regular field visits. There are allegations that some Superintendents do not stay in their duty station; instead perform their administrative and regulatory duties over mobile phone. Although senior officials at DA are cognizant about such anomalies, they do not take any measures because of this weak accountability mechanism. Moreover, some officials engaged in consultancy services with some companies violating government service rules. As a result, they try to interfere on many administrative and regulatory matters against the interest of their companies. Furthermore, if a company has done any illegal activities or made offense, these officials try to prevent regulatory measures against the offender. Due to such unethical practices, honest and enthusiastic official are becoming dissatisfied and loose animation to perform their roles and responsibilities. Thus, accountability and monitoring mechanism of DA is becoming weak.

3.8 Absence of permanent and contractual lawyers

The DA does not have its permanent and contractual lawyers to run litigation against offenders of drug laws. Therefore, Drug Superintendents have to depend on Public Prosecutors (PP) to run litigation on behalf DA. However, sometimes Public Prosecutors are changed in the middle of the litigation that might delay the prosecution. On the other hand, as PPs remain busy with many government cases, they cannot present their arguments in the court in an effective manner. Thus, their argument cannot prevail over smart and strong opponent lawyer and offenders escape due punishment or get bail easily. Moreover, Superintendents face undue influence from influential people like local politicians, higher government officials and business associations during taking and legal measures and run litigation. Sometimes, they are given physical and mental threats when they want to take any regulatory measures. Therefore, some Superintendents find it convenient to collude with these influential people and indulge in corruption and irregularities.

3.9 Inordinate delay in settling cases in the Drug Court

Inordinate delay is visible to settle drug offences in the Drug Court and Lower Courts. Whenever a Drug Inspector or Superintendent files a case, the court would order the accused to appear before the court. In such a case, the accused or his/her lawyer would appear before the court and request for a time. Getting this advantage, the accused would file a writ petition at the higher court giving reference to constitutional provision of not

to violate rights to pursuing a profession. In such a case, the higher court might take the writ into cognizance and suspend the proceedings of the lower court until the settlement of writ. As a result, settlement of the case in the lower court would experience an inordinate delay. In such a situation, the DA cannot collect samples from the accused factory and unwittingly allows it to continue production of fake and sub-standard drugs.

3.10 Lack of effectiveness of drug related committees

There are ten committees to facilitate the functions of DA effectively. However, there are limitations in the functions of these committees. They include no specific timeframe for conduction of meeting for all committees except the Adverse Drug Reaction Advisory Committee, formation of committees without giving attention to WHO guidelines, dominance of manufactures' association in committees and political influence in the decision-making of committees, absence of technical persons in the some committees and lack of transparency in the operations of committees. As a result, conflict of interest arises in the operations of committees particularly in setting drug prices and approving new manufacturing units.

3.11 Lack of political will

There has been a lack of political will to build up the capacity of DA. Despite its importance as drug regulatory authority, the organization has faced structural and manpower related problems for a long time. According to key informant interviews, if there was political will, these problems could have been solved. Although it has been four years after it was made a directorate from a department, 39 percent of its positions have not been filled up. WHO in 2010 proposed 947 positions for effective operations. However, policy makers ignored a proposal of 570 positions proposed by DA. Development budget for DA has been low. Analyzing the Health Ministry budget, it is found that only 0.18 percent was allocated for DA. Although the National Drug Control Laboratory came into operations, its budget is borne from the Institute of Public Health. For that reason, the laboratory cannot buy its necessary reagents for shortage of budget.

Moreover, existing laws are inadequate to address contemporary issues and challenges. Policy inactions have also been visible in these areas. The rules of Drug Act, 1940 have not been updated and no rules have been declared for Drug (Control) ordinance, 1982. In some committees (particularly the Project Evaluation Committee, Drug Control Committee, Price Fixation Committee, Drug Control Subcommittee), issue of conflict of interest is rife in the formation of some committees and there is a dominance of some manufactures. Despite being a competitor, owner of one company would play roles in evaluating another company's project. Unscrupulous influence of powerful members of drug companies in drug related committees can be attributed as obstacles in establishing good governance in DA.

4. Nature of Irregularities and Corruption in the Activities of Drug Administration

4.1 Registration of pharmaceutical companies

There are irregularities and corruption in the project registration and license renewal process. In some cases, the evaluation officer makes deliberate delay in calling meeting. However, if the company offers financial incentives, all the procedures are completed promptly. There are allegations of syndication among some members of some committees. Some members of the committee influence the approval process after

receiving bribe and gifts. On the other hand, collusive corruption and irregularities are pervasive during inspection before the final stage of approval. Some projects get approval in spite of their failure to maintain the necessary set up of the factory. Moreover, a number of officers of the DA serves as consultants in many companies which is a breach govenent servcie rules.

4.2 Approval of the recipe (formula)

During the recipe approval process, it is alleged that some officers of the DA delay the submission of application to the recipe approval committee if they are not bribed. Usually an officer of the Directorate is assigned to take the responsibility to call a recipe approval meeting, which is not maintained in all cases. In such cases, some influential officials influence the DG to conduct those tasks by themselves and take financial advantage from the respective company.

4.3 Registration of drug

In many cases, companies get drug registration with the help of bribe although necessary instrument or machine that are indicated in the portfolio to produce certain drugs. It is also alleged that without unauthorized payment some officers of the DA make delays in approving the name of the drug. The amount of the bribe mostly depends on the number of medicine applied for. On the other hand, some companies produce medicine without approval although registration of drug is obligatory.

4.4 Registration of foils, insert, label and pack

Every pharmaceutical company has to submit prescribed information such as a drug's generic and brand name, production and expiry date, ingredients, process and preservation of certain drugs etc. for approval of the foil, insert, label and pack. There is an allegation that the concerned officials of the DA often do not check during approval of the prescribed information, which has provided the opportunity to a number of local and small companies to copy brand names and foil of some famous companies. Again, in some cases, some officers of the DA intentionally hold back the file and demand bribe.

4.5 Approval of block list

During the block list approval process, every company or importer has to submit some necessary information containing objectives and purpose of importing raw materials, demand of the item and accounting of previous year's imported raw materials in a prescribed format. Some officers of the DA do not evaluate the necessary information of block list properly and grant primary approval in exchange of bribes. On the other hand, some influential members of the committee help some companies get approval by unfair means. Some companies or individuals import extra raw materials and sell in the open market. The DA has no role in investigating the quality and examining the raw materials, rather it only gives permission based on the bill of entry provided by the importers.

4.6 Approval of literature

In some cases, some companies mention about some ingredients or usefulness in the literature, which are not actually related to that drug. These types of literatures get approval with collusion of some officers of the DA. Again, some of the companies sell their products in market without any literature approval from DA. Some officers, being fully aware of these events, ignore them due to bribe.

4.7 Quality control and sample testing

Although there is a provision to collect samples from market from each batch of a company's promoted drugs, usually it is not maintained, and even when maintained, random sampling method is ignored. Some laboratory officials are involved in collusive corruption with companies and give false certificate without testing drugs. It has also been found that most of the companies especially the small ones lack proper system to preserve raw materials and manufactured drugs, and therefore, they bribe the drug inspectors for hiding these irregularities. Moreover, although according to law it is mandatory that ingredients used in drugs must be included in any journal of British Pharmacopeia (BP), some companies do not maintain the British Pharmaceutical Codex (BPC) or United States Pharmacopeia (USP). The BP or USP indications are used on medicine foil to indicate quality of medicine. However, the DGDA does not examine and evaluate those before providing a certificate.

4.8 Pricing of drugs

The authority of the DGDA for determining the price of drugs remains only on papers. The pharmaceutical companies usually determine the price of the drugs manufactured by them. The DA only determines the price of 117 essential drugs although many of those are not yet in production. Since 2001, the DGDA has been playing a nominal role in determining the price of the essential drugs, and companies themselves determine the price after acquiring the approval of the Drug Pricing Committee. Pharmaceutical companies submit an application to DA for pricing certificate after determining the price and responsive officer of DA adds VAT according to system and then submits it to the pricing committee for analyzing.

It is observed that some importers are included as members of the Drug Pricing Committee. They have a strong role in influencing other members of the committee while determining the price. However, importers in collusion with foreign companies show inflated price of imported product to the DA. It is also observed that higher priced products sometimes get approval due to lack of skill and proper supervision of DA.

4.9 Good Manufacturing Practice (GMP) Certificate

GMP certificates are given to pharmaceutical companies on the basis of auditing by the DGDA. Our research finds that in some cases the DGDA does not provide it although there is a rule that the DA must provide a GMP guideline to companies. It is alleged that, although required by the DA, many companies do not maintain it for making more profit. The respective officials of the DA give GMP certificates without inspection or hiding irregularities after inspection. A World Bank research report states that lack of skill of drug administration officials and political pressure remains in GMP certificate approval.

4.10 No Objection Certificate (NOC)

NOC system has generally been maintained in import of foreign drug and medical instrument as per doctor advice or in laboratory for research purpose. There are allegations of collusion between importer and some DA officials to import more than needs. It is also alleged that some influential officials of DA retain power of NOC for long time.

4.11 Drug license (retail and wholesale drug store)

According to the rule of drug license an applicant must have certificate of 'C' grade pharmacy course. However, according to the Pharmacy Council, the number of

registered C grade pharmacists was 60,000 in 2014, while at present there are 1,12,218 registered retail and wholesale drug stores all over the country. Our research revealed that more than 25-30 thousand new drug licenses have been issued during 2001-2014. During these years registrations were used two/three times for different districts to get approval of drug license. On the other hand, if any individual applies for a license, the drug supervisor has an obligation of evaluating information mentioned in the application form and submitting it to the District Drug License Committee. However, in some cases, the drug supervisor does not foster this responsibility properly; rather he gives primary approval after collusion with the individual or drug store. Moreover, the concerned Drug Super does not maintain proper system in monitoring and evaluation, and takes bribe to disregard various regulations and stipulations.

5. Irregularities and Corruption of Pharmaceutical Companies

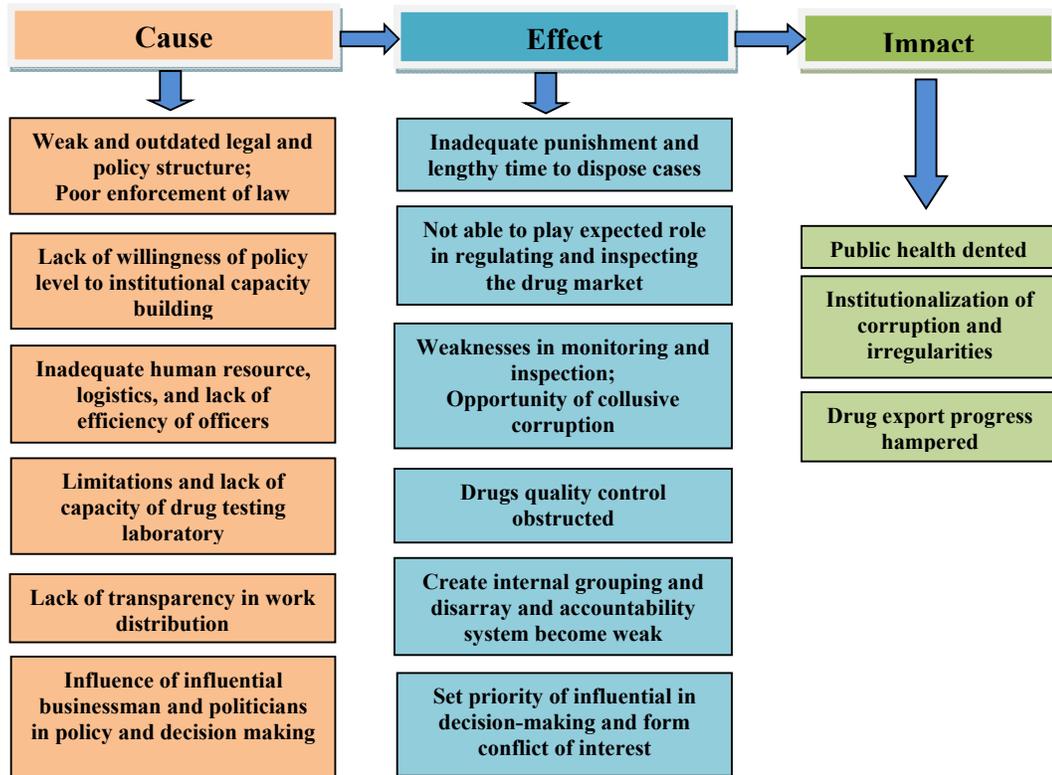
Allegations of irregularities and corruption in the managing activities of some pharmaceutical companies are there because of lack of inspection and monitoring of the DA. It is alleged that some pharmaceutical companies use raw materials of different standards to produce drugs for consumption within and outside the country. Some companies use raw materials of higher standard for export, and lower standard for the local market. It is also alleged that some companies do not maintain proper procedure of separating toxic ingredients from the drugs during production. These ingredients are very harmful for human body and cause different types of diseases including carcinoma. Besides, some companies do not maintain pharmacopeia (USP, BP etc.), but mention it on the foil and pack. Some members from some pharmaceutical companies have strong influence in approving the block list and determining the price of drugs. Moreover, according to the law there is an obligation of mentioning place of production in drugs foil and pack, which a number of local and foreign drug manufacturing companies often violate. There is also allegation that some companies market drugs before getting the registration and permission of price.

6. Alleged amount of unauthorized payment in the different activities of DGDA

Service	Amount of unauthorized payment (Tk)
Registration of project/company	5-10 lakhs
License renewal	50 thousand-1 lakhs
Project transfer/shifting	10-15 lakhs
Approval of recipe	4-5 thousand (per recipe)
Registration of drug	1-1.5 lakhs
Approval of foil, insert, label and pack	7-9 thousand (draft and final)
Approval of block list	2-2.5 thousand
Approval of literature	4-5 thousand
Price determination	5-6 thousand (per product)
Export License and GMP certificate	20-30 thousand (both)
Sample testing and quality control	6-7 thousand (per sample)
Drug license	10-15 thousand
Renewal of drug license	5 hundred- 1 thousand

7. Causes, effects and impact of the lack of good governance in the Drug Administration

Figure: Cause-Effect-Impact Analysis of Lack of Governance in the DA



It can be said that the institutional capacity of the DA is not adequate considering the scope, geographic coverage and expansion of the drug market. There are institutional limitations in terms of human resource, infrastructure, logistics and skill for operating its activities properly. Moreover, the present legal structure is not sufficiently strong for monitoring and controlling the drug market and for facing contemporary challenges. There is also lack of proper implementation of the law. There is lack of transparency and accountability in terms of operating the mandate of the DA. This includes disproportionate distribution of tasks following the organogram, lack of transparency in distribution of work, and lack of monitoring and accountability of the officials in delivery. As a result corruption is somewhat institutionalized at almost every point of service delivery through collusive corrupt practices, and especially small pharmaceutical companies resort to such practices more than the rest. On the other hand, the influence of representatives of the large pharmaceutical companies strengthens the collusive nature of corruption through their inclusion in different committees. Finally, it can be said that there are lack of political will in strengthening the capacity of the DA at the policy-making level. This is reflected in various aspects such as not increasing the human resource over the years, not improving the logistics and other facilities, not increasing the allocation, and not taking measures for legal reforms to face contemporary challenges in monitoring and controlling drugs.

8. Recommendations

Law & Policy related

1. A revised policy and a unified law must be adopted considering the limitations and challenges in the Drug Act, 1940 and Drug (Control) Ordinance, 1982. The revised law must address the following -
 - Medical devices, food supplements, and cosmetic products in the law should be covered;
 - The time of gazette notification of drug pricing in law should be specified;
 - The structure and working procedure of different DA related committees should be specified and incorporated; and
 - Inconsistencies in terms of punitive measures for different offenses should be eliminated, and rigorous punishment should be included.

Administration and management related

2. At least one position of drug inspector has to be created in each district offices considering the market size and workload and the vacant positions of each tire should be filled up as early as possible.
3. Drug administration's own infrastructure should be set up in every district and logistical support and transport facilities for inspection should be ensured.
4. Transparency of work distribution process based on organogram and job description has to be ensured.
5. Training based on need assessment to develop the capacity of staff should be arranged.
6. Different types of information including registration of drugs and pharmaceutical company need to be updated and incorporated.
7. A uniform and online based reporting system for field offices should be introduced.
8. One stop and online services for pharmaceutical companies should be launched.
9. Participation of common people in working procedure of DA should be ensured. A toll-free hot-line may be launched in this regard.

Reduce corruption and irregularities

10. Positive and negative incentives and codes of conduct for the employees have to introduced to reduce irregularities and corruption in drug administration.
11. Representation of the pharmaceutical owners in different drug related committees (especially drug control committee, manufacturing license committee, drug pricing committee, and block list approval committee) should be avoided.
12. Pharmaceutical companies producing sub-standard, fake and adulterated drugs should be identified and legal actions have to be made against them.