An inquiry into the regulation of pharmaceuticals and medical practice in Sri Lanka

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ABBREVIATIONS

AO	Authorized Officer
CDD	Cosmetics, Devices and Drugs Act
CDDA	CDD Authority
CMC	Ceylon Medical Council
D (MT&S)	Director (Medical Technology and Supplies)
DDG (FSI)	Deputy Director General (Flying Squad and Investigations)
DDHS	Divisional Director of Health Services
DGHS	Director General of Health Services
DMO	District Medical Officer
DP	Divisional Pharmacist
DPDHS	Deputy Provincial Director of Health Services
DRA	Drug Regulation Authority
DRMO	Divisional Registered Medical Officer
ED	Enforcement Division
FDI	Food and Drug Inspector
FGD	Focus Group Discussion
FS	Flying Squad
IU	Investigation Unit
MOH	Medical Officer of Health
MoH	Ministry of Health
NDQAL	National Drug Quality Assurance Laboratory
OPD	Outpatient Department
PDHS	Provincial Director of Health Services
PHI	Public Health Inspector
PP	Private Practice
PTF	Presidential Task Force
RDHS	Regional Director of Health Service
SLMA	Sri Lanka Medical Association
SLMC	Sri Lanka Medical Council
SPC	State Pharmaceutical Cooperation
SPHID	Supervisory PHI (Divisional)
TAC	Technical Advisory Committee

ABSTRACT

In the absence of any in-depth studies on this issue, the present study attempted to assess the effectiveness of regulations of pharmaceuticals and medical practice in Sri Lanka. As an economic evaluation the study was undertaken from a societal point of view, encompassing costs and outcomes at organisational and social levels. Thus, prime concern was given to undertake an assessment of the capacity constraints faced by the regulating agencies in performing their duties, first, at organizational level, and then at socio-economic, cultural and political levels. In addition to screening official reports and records of regulating agencies, and discussions with key stakeholders and field officers, field investigations were undertaken in three locations, urban, semi-urban and rural, in the form of discussions and observations at a sample of pharmacies and focus group discussions with public doctors engaged in private practice. Neither pharmaceutical nor medical practice regulations have achieved their social objectives in an effective manner. Highly informal procedures are prominent amongst authorized officers who enforce pharmaceutical regulations, while controlling malpractice by public doctors has lost pace at the central level, with peripheral health authorities playing a highly passive role.

The study brings out several organizational, social, cultural and political constraints, which hinder effective implementation of regulations. Lack of human resources and skills, poor allocations, delays at the centre, lack of incentives, team approach and supportive services, legal restrictions and lack of support from consumers are common in the regulation of pharmaceuticals. A limited role played by regulators at the national level, lack of legislative power at central and peripheral levels, lack of organizational/management capacity of regulators, and social, cultural and political influences are common in the regulation of medical practice. A set of policy options and measures addressing these issues was identified to make the enforcement and monitoring of regulations more effective and efficient.

1. INTRODUCTION

1.1 Background

The general objective of this study was to undertake an assessment of the capacity of the Ministry of Health (MoH) for efficient and effective implementation of health sector regulations, with particular emphasis on pharmaceuticals and medical practice. Sri Lanka has a long history of state intervention in regulating pharmaceuticals and medical practice. However, the implementation of these regulations seems to be taking place in an ad hoc manner. No in-depth study has so far been undertaken on the effectiveness of regulations of pharmaceuticals as well as medical practice, an un-addressed issue for policy makers. Under such circumstances, firstly, it is worth mapping out the historical development of regulations and their institutional configurations. Such an exercise will lead to the identification of factors that influence the effectiveness of the regulations in reaching their social objectives. Further, an in-depth assessment of the effectiveness of the regulations could be undertaken in the form of an economic evaluation encompassing costs and outcomes at organisational and social levels. Such an analysis will lead on to the investigation of capacity issues related to enforcement and monitoring of, and compliance with, regulations.

1.2 Specific objectives

The study was undertaken in several steps as specific objectives, which are:

1. To map out the historical development of the Cosmetics, Devices and Drugs Act (CDD), other pharmaceutical regulations and regulations on medical practice, and their institutional configurations.

2. To estimate enforcement and monitoring costs of central and peripheral health authorities in relation to the regulation of pharmaceuticals and medical practice.

3. To estimate/identify transaction costs involved in the enforcement of regulations on pharmaceuticals and medical practice.

4. To undertake an enquiry into social costs involved in a) non-enforcement of pharmaceutical regulations and b) medical malpractice.

5. To assess compliance of a) field level authorised officers (AOs) to their obligatory tasks related to the enforcement of the CDD and b) pharmacy personnel to the CDD.

6. To assess compliance of a) responsible officers at central and peripheral levels to their obligatory tasks related to the enforcement of medical practice regulations and b) medical practitioners to the regulations on medical practice.

7. To assess the achievement of social outcomes such as equity, efficiency, safety and quality in relation to the stated aims of the CDD.

8. To assess the achievement of social outcomes such as equity, efficiency, safety and quality in relation to the stated aims of regulations on medical practice.

9. To identify organizational constraints on effective enforcement and monitoring of a) the CDD and b) regulations on medical practice.

10. To identify social, cultural and political constraints encountered by a) AOs and b) pharmacy personnel in complying with the CDD.

11. To identify social, cultural and political constraints encountered by a) AOs and b) medical practitioners in complying with the regulations on medical practice.

12. To reach some policy options, which address the capacity issues of MoH, for enhancing the implementation of a) pharmaceutical regulations with particular reference to the CDD and b) regulations on medical practice.

1.3 Conceptual framework

To achieve the general objective, it was envisaged to undertake the study within a framework of economic evaluation, in which an attempt was made to carry out the study at both organizational and social levels. In this context, five specific objectives were examined at organizational level (1,2,5,6 and 9), six at social level (3,4,7,8,10 and 11) and the last specific objective (12), on policy options and, hence, capacity issues, was examined at both of these levels. A summary of this framework is given in the following table:

Table 1.1: The levels at which investigations were undertaken for each specific objective

Level at which the specific objective was examined	What was examined in relation to the specific objective?*		
	Costs	**Outcomes**	**Capacity issues**
Organizational level	• Mapping (1) • Cost of enforcement and monitoring (2) • Policy options/ Capacity issues (12)	• Mapping (1) • Compliance rates (5 & 6) • Policy options/ Capacity issues (12)	• Mapping (1) • Organizational constraints (9) • Policy options/ Capacity issues (12)
Social level	• Transaction cost (3) • Social cost of non-enforcement (4) • Policy options/ Capacity issues (12)	• Social outcomes (7 & 8) • Policy options/ Capacity issues (12)	• Social, political and cultural constraints (10 & 11) • Policy options/ Capacity issues (12)

* Within brackets is the number/s of specific objective/s.

Within this economic evaluation framework, the mapping exercise was undertaken at organizational level, which constitutes the first component of the study. This exercise provided a strong foundation for undertaking the second component of the study, the economic evaluation. In this regard, as Table 1.1 shows, each specific objective, except the first and the twelfth, serves the economic evaluation by way of focusing on costs, outcomes or capacity constraints at organizational or social level. The completion of these two components led on to the third component, exploration of policy options and capacity issues, which was based on the findings of the first and second components.

1.4 Methodology

1.4.1 Approach

Focusing on the general objective of the study, the prime concern was to undertake an assessment of the capacity constraints faced by the regulating agencies in performing their duties, firstly at organizational level and then at socio-economic, cultural and political levels. Historical development, institutional framework as well as the level of capacity certainly affect the way in which regulations are enforced and monitored, and hence a) the cost of the implementation and b) the effectiveness of regulations. These linkages necessitated that the

mapping out exercise be followed up by two case studies on pharmaceuticals and medical practice for the examination of the costs and effectiveness of such regulations in a comprehensive manner.

1.4.2 Study area

With this broad framework, the study involved collecting data at both central and peripheral levels. For the latter, a purposive sample was selected, with one rural district (Polonnaruwa), one urban district[1] (Kandy) and one semi-urban district (Gampaha). In selecting districts for the sample due emphasis was given to bring out a representation of a) different socio-economic characteristics in the country and b) distribution patterns of pharmacies, public medical institutions and private health facilities. Within each district, a purposive sample was selected from each of the two categories of regulatees, pharmacies and medical practitioners, with a view to bringing out a representation of their highly heterogeneous characteristics. For instance, pharmacies range from licensed, well equipped and manned ones to unlicensed drug stores with a vast range of turnouts[?]. However, no data were readily available, even with local health authorities, particularly on the type, level and location of both types of regulatees. Due to these impediments, in selecting the sample of regulatees, assistance was sought from relevant health personnel such as Deputy Provincial Directors of Health Services (DPDHSs) and Food and Drug Inspectors (FDIs). As a result of this selection procedure, the sample of medical practitioners was confined to public doctors who were engaged in private practice[2].

1.4.3 Sources of data

i. Mapping exercise (Specific objective 1):

The mapping exercise was conducted by undertaking a) a literature review and b) interviews with officials of the Drug Regulation Authority (DRA) and Investigation Unit (IU), relevant former and current stakeholders of the MoH, and district and divisional level health managers of the selected districts. Further, an attempt was made to collect relevant information from professionals and professional bodies of the sector.

[1] Since none of the districts in Sri Lanka is considered as an urban area as a whole, the study was confined to the Municipal Council area of Kandy city, the second largest city of the island.

[2] This step was taken primarily due to the complexity of the private medical practitioner network, which ranges from private general practitioners, who conduct small clinics at village level, to specialists attached to highly sophisticated hospitals owned by foreign companies.

ii. Costing

a. Organizational costs (Specific objective 2)

Reports and financial records of the DRA, IU as well as the respective peripheral health offices were screened in order to estimate the cost of enforcement and monitoring of regulations on pharmaceuticals and medical practice.

b. Social costs (Specific objectives 3 and 4)

Data for the estimation of transaction costs and for the identification of social costs were collected from four sources:

a) Focus Group Discussions (FGDs) and informal discussions with public medical officers who were engaged in private practice.
b) Informal discussions with consumers of pharmaceuticals, and patients and their accompanying persons.
c) Observations and discussions conducted at pharmacies, and private and public clinics/ hospitals.
d) Newspaper reports and articles focused on medical malpractice.

Two FGDs were conducted in each sector with a total attendance of 35. Unlike the FGDs and formal discussions, no pre-designed checklists (or set of questions) was used for informal discussions with randomly selected respondents (above b), who were selected when observations were made at pharmacies and clinics/hospitals (above c). Those discussions were focused on the specific issues raised by respondents in relation to social consequences of the service concerned. National newspapers were screened for a period of one year and a set of articles and reports was selected to enrich some of the issues brought about by the sources a, b and c.

iii. Outcomes

a. Compliance at organizational level to CDD (Specific objective 5)

A set of compliance indicators based on CDD was estimated in investigating compliance at organizational level. The basic indicators were i) availability of and displaying the license and certificate of the pharmacist and ii) maintenance of a prescription register. The other indicators can be broadly divided into four categories: a) personnel, e.g. physical availability of a qualified pharmacist; b) premises, e.g. suitability for the purpose (i.e. space, design and construction), location (i.e. avoiding contamination from the surrounding) and pest control; c)

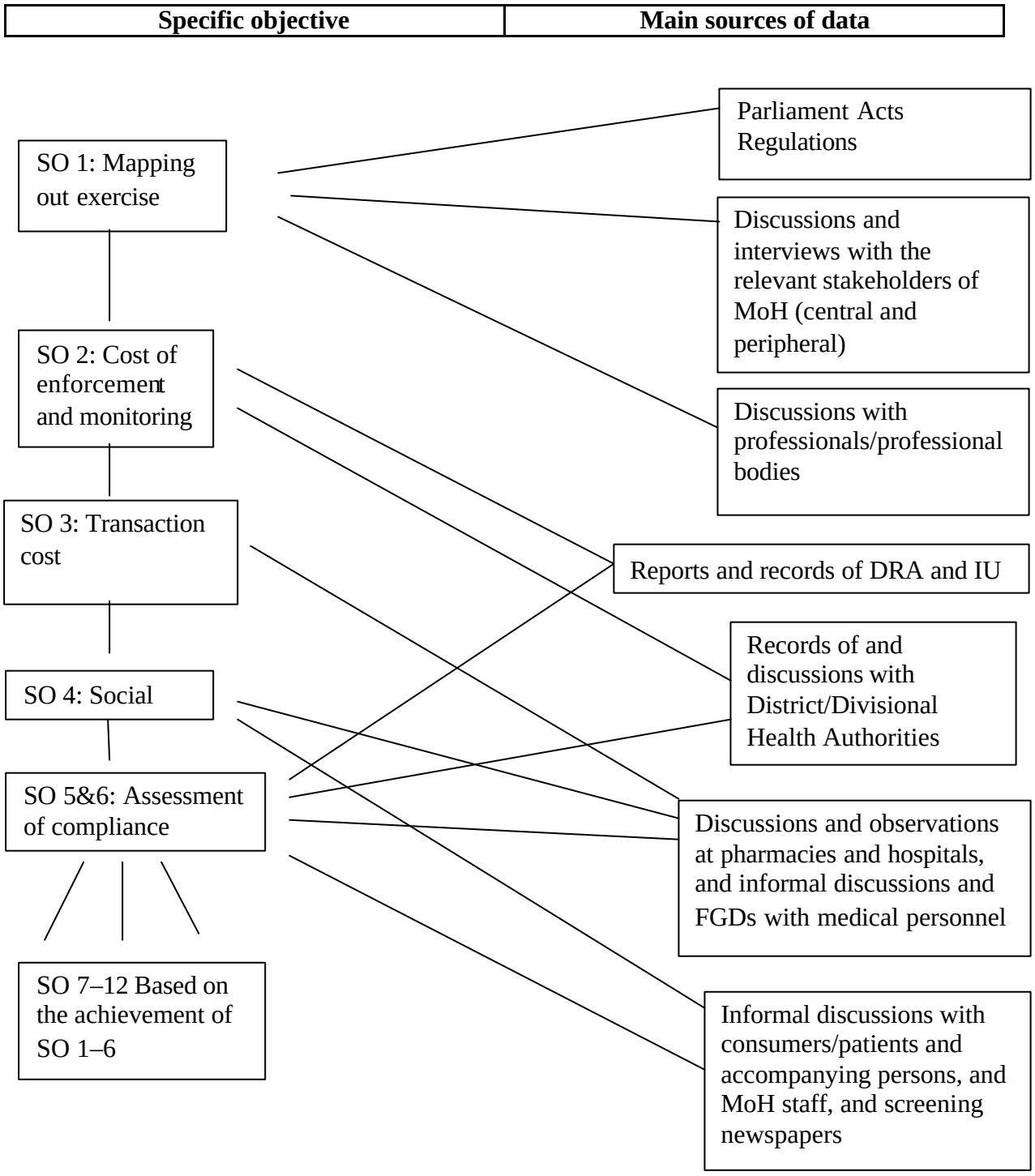
equipment, e.g. availability of proper storage facilities and their maintenance; and d) sanitation and hygiene, e.g. hygienic conditions of equipment, premises and personnel.

Previous records of AOs, including FDIs, Divisional Directors of Health Services (DDHSs) and Divisional Pharmacists (DPs), on their performance and the reports of the DRA were used for assessment of their compliance. Discussions were undertaken with these officers, using a pre-designed checklist, and data gathered, particularly from FDIs, were crosschecked through examining pharmacy records and discussions with the respective DPDHSs. For pharmacy personnel, the notes made by AOs on their supervisory visits were initially used for the assessment of their compliance; further information was collected through discussions with them and observing the conditions of pharmacies. A pre-designed checklist was used to assess the way in which pharmacy personnel were implementing CDD regulations in their day-to-day activities. Another source of information for this purpose was the discussions conducted with AOs. Qualitative methods such as observations and informal discussions were undertaken with randomly selected consumers at some pharmacies to collect more evidence on this issue.

b. Compliance at organizational level to medical practice regulations (Specific objective 6)

The relevant reports of IU were screened in order to assess the responsible officials' compliance in enforcing medical practice regulations. Special emphasis was placed on examining the extent to which investigations have been carried out in relation to public complaints. The discussions conducted with the responsible officials at central, district and divisional levels were also used to make an assessment of their compliance in enforcing regulations. An attempt was made to explore the views of regulatees on medical malpractice when conducting informal discussions and FGDs with them. Observations at clinics/hospitals and informal discussions with randomly selected patients (or persons were accompanying the patient) were also focused on exploring their views on this issue. However, it was not possible to estimate a performance indicator to elucidate the extent and the level to which responsible officers had accomplished their obligatory tasks in enforcing medical practice regulations due to the complexity of the data gathered through these sources. Therefore these data were used just for the purpose of bringing out the level and type of compliance, particularly, of regulatees.

Figure 1.1: Specific objectives and main sources of data



c. Achievement of social aims of CDD and medical practice regulations (Specific objectives 7 and 8)

The data collected for specific objectives 5 and 6 were examined in detail with a view to exploring social outcomes of compliance as well as non-compliance to regulatory measures,

namely, equity, efficiency, safety and quality. In this regard, the identification of social outcomes was supplemented by observations made at the premises of regulatees and informal discussions conducted with the receivers of services. In undertaking this exercise, whenever necessary, additional visits were made to the selected locations to collect necessary supplementary data.

iv. Capacity

a. Organizational constraints (Specific objective 9)

On the basis of the data collected under specific objectives 5 and 6, constraints encountered at the organizational level on the effective enforcement and monitoring of regulations on pharmaceuticals and medical practice were identified.

b. External constraints on organizations (Specific objective 10 and 11)

On the basis of the data collected under specific objectives 7 and 8, external constraints on organizations in complying with regulations on pharmaceuticals and medical practice were identified.

vi. Policy options (specific objective 12)

On the basis of the analysis undertaken under the first eleven specific objectives, an attempt was made to reach some policy options, particularly at organizational level.

2. HISTORICAL DEVELOPMENT AND INSTITUTIONAL CONFIGURATIONS

2.1 Introduction

In Sri Lanka, there has been government provision of allopathic health care services for nearly two centuries. With a view to providing health services to impoverished civilians, the very first public hospital was set up in Colombo in 1819, the predecessor of the present National Hospital. The earliest public dispensary outside Colombo was opened in the following year at Pandaterruppu. Meanwhile, a charity organization called the Friend-in-need Society, introduced by the British, took the initiative to set up hospitals or dispensaries in four cities, namely, Colombo, Kandy, Jaffna and Trincomalee, primarily with a view to serving the poor. In the middle part of the 19th century these medical centres were handed over to the government. With these developments a Civil Medical Department was established in 1858. However, the prime objective of its creation was to set up an organization to control communicable diseases, particularly small pox (Uragoda 1987).

Most of the legislative measures introduced during the British colonial period were focused on public health matters rather than regulating either the medical profession or pharmaceuticals, except for the introduction of legislations in 1905 to register western medical practitioners. One of the initial steps of the colonial government to regulate the health system was the enactment of Public Health and Suppression of Nuisances Ordinance No 15 of 1862. Three years later Municipal Councils Ordinance No 17 of 1865 was enacted giving public health responsibilities to these councils. Uragoda (1987) highlights the areas to which the British colonial rulers placed greatest emphasis: sanitation, water supply, drainage, burials and cremations, festivals, quarantine and nutrition. In 1926 a health unit system was established and a training system for public health personnel was introduced. Meanwhile, a branch of the British Medical Association was set up in 1887, the predecessor of the present Sri Lanka Medical Association (SLMA), which, among other things, looked into professional matters of medical practitioners. According to the first president of the association, its main objectives were "to bring the profession together, to facilitate investigations into matters of professional interest, and to promote discussions" (Uragoda 1987).

It is clear that since independence in 1948 until the early 1970s, neither policy makers of the sector nor political leadership felt the necessity of imposing a regulatory mechanism over medical practice and pharmaceuticals. By the time of independence, only a very few

pharmacies were operating in the main cities of the country (personal communication with a former MoH official) and most of them were run by British firms. Although the public sector doctors were engaged in private practice, it was not undertaken on a large scale but primarily on personal basis.

These developments took place in coherence with the ongoing inward-looking economic policy, in which the leading role was played by the state sector. This policy was dominant during the period from independence until 1977, with some diversions. The private sector was largely neglected and not encouraged, and the health sector was no exception: private practice by public medical officers was banned in the early 1960s. As a result of these disincentives, medical doctors were forced towards the "brain drain" process, along with other professionals. Price controls played a prominent role during this period, and prices as well as trade of pharmaceuticals were subjected to controls. In 1968, a price control act was enacted which classified drugs into two categories: drugs sold without prescription and drugs sold only under prescription. In 1970, in rapid response to the worsening foreign exchange situation, the government appointed a committee to formulate a plan and devise methods to overcome drug shortages without increasing foreign exchange allocations (Jayasuriya et al 1997). This resulted in the establishment of the State Pharmaceutical Cooperation (SPC) in 1971. The SPC was responsible for purchasing pharmaceuticals for the whole country and in 1974 it took over the entire private sector imports. However, the opening up of the economy along with the relaxation of the ban on private practice after 1978, led, firstly, to the mushrooming of private medical centres run by public medical officers and private pharmacies throughout the country, even in remote locations. "Channelling Centres"[3] became an essential component of the health system. Secondly, the extensive competition emerging in the medical market, particularly due to the escalation of private practice, gradually changed the attitudes as well as behaviour of public medical doctors who were engaged in private practice. The medical profession is now moving sharply towards a pure profit-oriented venture by neglecting its ethical considerations (Fonseka 2002a): this degeneration of the medical profession could be partly attributed to some social and cultural factors, which will be taken up later in section 3. These new developments have impelled policy makers to

[3] These are the centres at which public doctors started private practice in the early 1980s. At the initial stage, only drugs were prescribed at most of the channelling centres. Later, with the spread of private hospitals, channelling centres became an essential component of them.

introduce some regulatory mechanisms to at least slow down the progression of this unhealthy situation in the medical profession as well as the pharmaceutical market.

2.2 Pharmaceuticals

The Food and Drugs Act No 25 of 1949, which was introduced by the colonial rulers, was found to be highly limited in the context of the open economic policy. Firstly, the Act provided a very narrow interpretation for the term drug, whereby a 'drug' included medicine for internal or external use. Secondly, with a very comprehensive interpretation of the word "food", the Act paid more attention to food. Thirdly, local authorities were made the main competent authority to implement the Act. However, under certain circumstances, the Director of Health Services, the Excise Commissioner and the Principal Collector of Customs could also act as the competent authority. In the case of drugs, the Director of the Department of Health could give "any officer" of the department the status of an authorized officer. Fourthly, as the main competent authority for the implementation of the Act, each local authority had to pass bylaws (or a proposal) to carry out its provisions. Further, the responsibility of the authorized officers was largely confined to examination of samples of drugs and food items. Along with these limitations, finally, the Act was not properly implemented in all except one local authority, namely Colombo, mainly due to lack of financial allocations.

As a preliminary measure to meet the new challenges brought by the introduction of economic liberalization policies in the late 1970s, two separate legislative frameworks for food and drugs were enacted in 1980 as The Food Act and The Cosmetics, Devices and Drugs Act (CDD No 27). Later, CDD was amended in 1984, 1987 and 1993 as CDD No 38, No 25 and No 12, respectively. The regulations of CDD were gazetted on December 2, 1985 and another gazette notification was published on July 6, 1992, making some amendments to those regulations: January 1, 1996 was fixed as the operative date for CDD. Compared to the former Food and Drugs Act, one of the major features of the new Act is the provision of a very well formulated definition for drugs. However, Ayurvedic, herbal as well as homeopathic drugs are omitted from this definition, hence such drugs do not come under the control of CDD.

The main provisions of CDD are as follows:

a. Only cosmetics, devices and drugs registered with the Authority (i.e. CDD Authority) can be manufactured, imported, offered for sale or used in the country.
b. Licences are required for importation, manufacture, wholesale trade/retail trade, and transportation of drugs. Licences are required for importation and manufacture of cosmetics and devices.
c. All cosmetics, devices and drugs registered with the CDD Authority should conform to specified standards.
d. Labelling on the packs of all registered cosmetics, devices and drugs should conform to the guidelines specified.
e. All advertisements regarding cosmetics, devices and drugs should conform to the guidelines specified.

With these provisions, CDD intends to provide a legislative framework to control the use of cosmetics, devices and drugs with respect to: 1) Registration, 2) Manufacture, 3) Importation, 4) Transport, 5) Sale (wholesale and retail), 6) Labelling, 7) Advertising, 8) Distribution of samples, 9) Testing and 10) Destruction of outdated or spoilt cosmetics, devices and drugs. Meanwhile, the Poisons, Opium and Dangerous Drugs Ordinance, as amended by Act No 13 of 1984, regulates the importation, storage, distribution and use of poisons, opium and dangerous drugs.

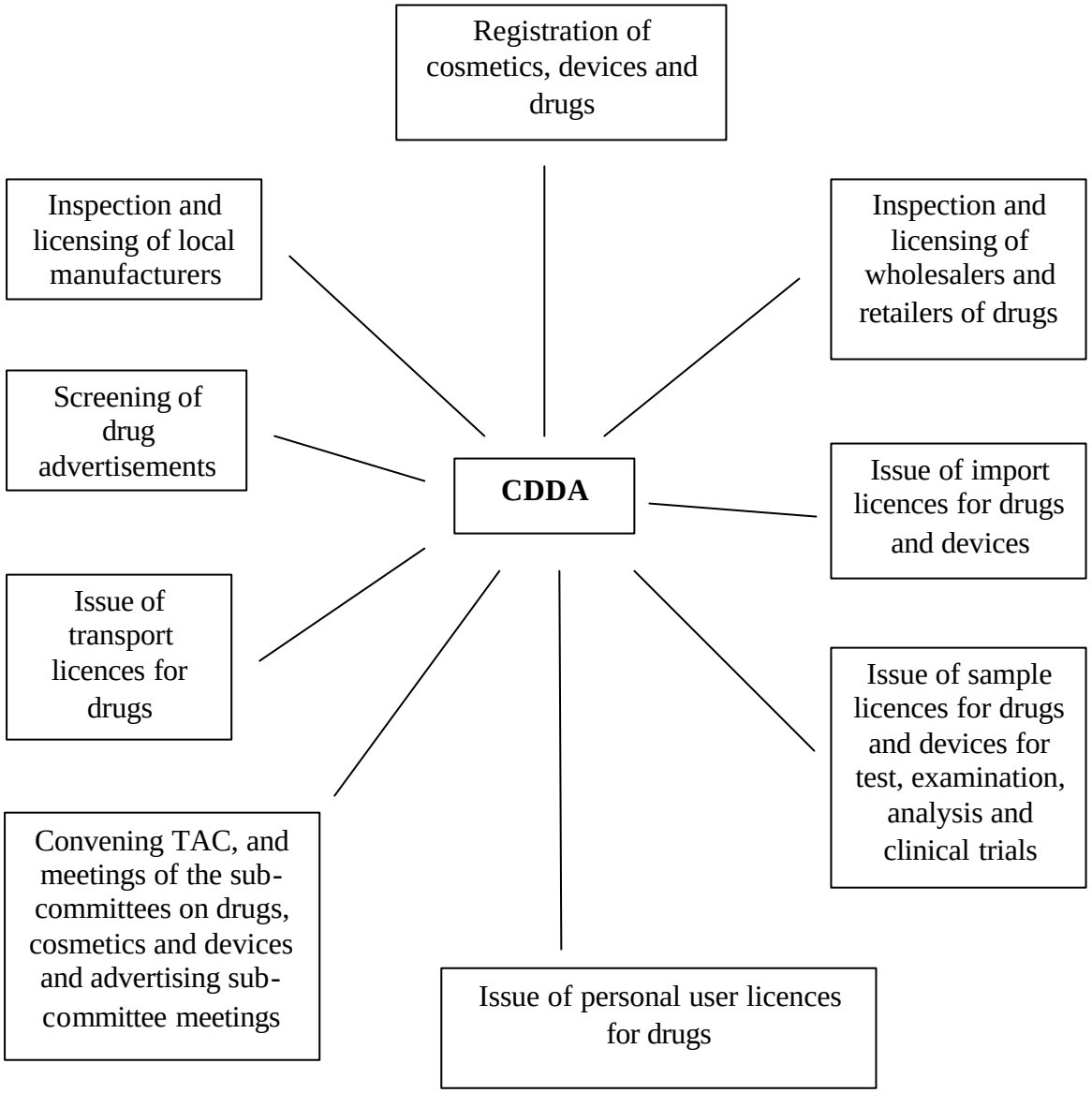
At the national level, the Director General of Health Services (DGHS) is vested with the responsibility for the effective implementation of the provisions of the act as the CDD Authority (CDDA). A Technical Advisory Committee (TAC), with the DGHS as Chairman, is appointed by the Minister of Health to advise the Minister on the subject. The composition of the TAC is given in Figure 2.1.

Figure 2.1: Composition of the TAC

• Chairman – DGHS • Secretary – Director, Medical Technology and Supplies [D(MT&S)] • Deputy Director General, Laboratory Services • Professor of Pharmacology, University of Colombo • Chairman, SPC • Director, Medical Supplies Division • Director, National Drug Quality Assurance Laboratory [D(NDQAL)] • Government Analyst • Consultant Physician (nominated by the Minister of Health) • Consultant Surgeon (nominated by the Minister of Health)
One representative from:
• Pharmaceutical Manufacturers' Association • Bureau of Sri Lanka Standards • Pharmaceutical Society of Sri Lanka • Sri Lanka Medical Association • Independent Medical Practitioners' Association • College of General Practitioners • College of Physicians • College of Obstetricians and Gynaecologists • Dental Association • Sri Lanka Pharmaceutical Traders' Association

At the central level, CDD is implemented mainly by two bodies: NDQAL and Enforcement Division (ED). Whilst NDQAL is mainly responsible for quality assurance of both finished products and raw materials through its drug quality assurance system, the chief Food and Drug Inspector of the ED, which comes under the D(MT&S), is engaged in ensuring the quality of those products through inspections. Thus, whilst the former is mainly involved in laboratory investigations, the activities of the latter largely consist of field visits and handling court cases. Only the CDDA has the authority to register and deregister pharmacies on the recommendations of the regional AOs, namely, DPDHSs. Further, it is responsible for the provision of directives to local AOs in the event of regulatees violating regulations.

Figure 2.2: Functions of the CDDA*

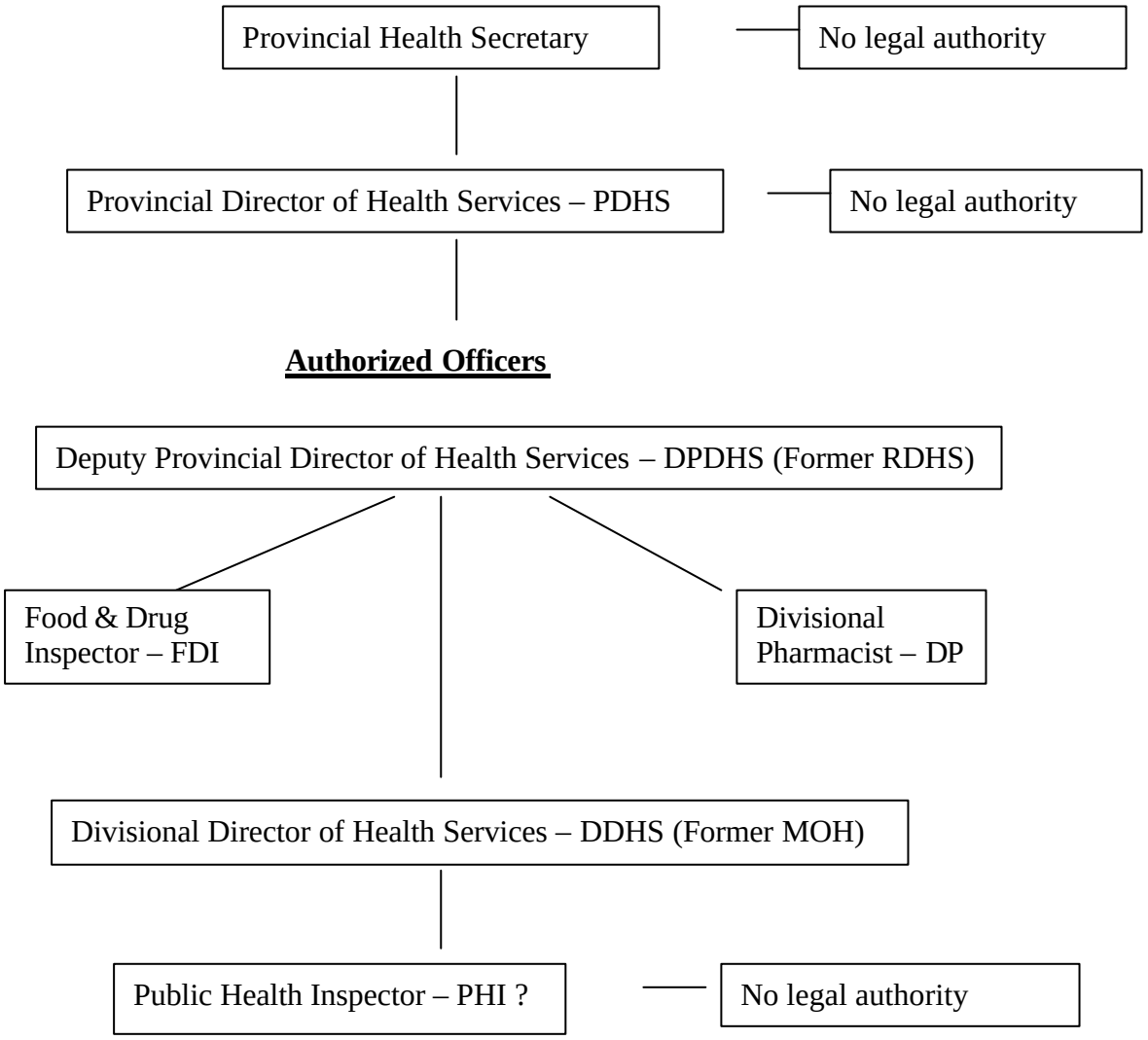


* In practice CDDA is the DRA.

At the provincial/district level, AOs of the implementation of CDD are the Regional Director of Health Service (RDHS), the Medical Officer of Health (MOH), the FDI and the Divisional Pharmacist (DP). The latter was given the status of AO in 1993 by the CDD Act No 12 of 1993; this was done due to the inadequacy of AOs to implement the Act. Public Health Inspectors (PHIs) were also named as AOs in the regulations but so far they have not been endorsed as AOs by the competent authority, DGHS. The implementation of CDD at peripheral level is primarily in the hands of FDIs attached to district health authorities and their activities are co-ordinated by the ED. With the implementation of decentralization policy in the late 1980s, firstly, responsibility for the enforcement of CDD regulations was

devolved to provincial/district health authorities. Secondly, the designations of RDHS and MOH were changed to DPDHS and DDHS. But so far no amendment has been made to CDD incorporating these changes. Therefore, in practice, the former designations (i.e. RDHS and MOH) are still used in legal procedures. Further, although PDHSs have authority over

Figure 2.3: Enforcement of CDD at Provincial/District Level



DPDHSs in the decision-making process, they do not have any legal authority as AOs because of the existence of a different administration system at the time of enactment of the CDD Act, which was based on districts rather than provinces. Provinces were introduced with the implementation of decentralization policy and so far no amendment has been made to the CDD regulations empowering the PDHS as an authorized officer. According to the CDD, the AOs are given the powers of a police officer. These powers are as follows:

a. Powers of police officer in terms of Section 180 of the Code of Criminal Procedure Act No. 15 of 1979.
b. Enter and examine any place where any article is manufactured, prepared, packaged and stored, and take samples.
c. Open and examine any receptacle or package that contains any article.
d. Seize and detain any article.

The structure of the implementation of CDD at provincial level is given in Figure 2.3.

2.3. Medical practice

2.3.1 Overall situation and the role of professional bodies

In Sri Lanka, regulating medical practice had not been a critical issue amongst professional bodies as well as the general public for over a century. The medical profession was considered to be a highly prestigious one. Self-regulation was prominent in the profession. It was only about a decade ago that malpractice of medical doctors, including medical negligence, began to draw considerable attention from professional bodies, policy makers as well as service receivers. As mentioned earlier, the opening up of the economy along with the rapid expansion of private practice resulted in a new behaviour pattern among medical practitioners. Initially, a hidden effort seems to have existed amongst professional bodies to safeguard their members against allegations. With the existence of a highly self-regulated practice for over a century, obviously, the professional bodies as well as the general public could have considered the initial malpractice allegations as isolated events or exceptions. Further, being a highly dominant and socially recognized profession, the professional bodies may have been reluctant to take any open action against their members as this could damage the social recognition of the profession.

Meanwhile, the service receivers were not aware of the means through which allegations could be made about medical malpractice. As anecdotal evidence indicates, service receivers, especially in semi-urban and rural areas, were highly reluctant to take action about malpractice by doctors on whom they are highly dependent in the event of illness. Further, they may not have any financial and social capacity to do so. In this context, the very first allegation of medical negligence was made against a medical professor, a well-known paediatrician, by a fairly well-off urban family in 1992, requesting compensation of Rs 5

million, with the allegation that the death of their four-year-old child was due to medical negligence (Prof. Priyani Soysa vs Rienzie Arsecularatne 2001). This case ended up at the Supreme Courts in 2000, with the decision that although the paediatrician was guilty of negligence, the plaintiff had failed to establish causation of death due to negligence. However, it did build confidence amongst service users as well as journalists that they could raise their voices against medical negligence. These developments have, on the one hand, tended to elicit a dialogue about medical malpractice in public media and, on the other hand, improved confidence in service receivers to seek justification more frequently from the courts in relation to grievances related to medical malpractice.

Even though the public voice and action did initiate a discourse over medical malpractice very recently, the very first attempt to bring the medical profession into a regulatory framework, albeit in a highly limited manner, was made in 1905, with the legislative council's approval of the Medical Registration Ordinance No 2 of 1905, the main objective of which was to register medical practitioners. During the same year this legislation incorporated the Council of the Ceylon Medical Collage by the Medical Collage Ordinance No 3 of 1905 (Samarasekera 1999). This ordinance had provisions for the Registrar of the Ceylon Medical Collage to register certain categories of persons to practice western medicine and surgery in Ceylon. At that time the Ceylon Medical Collage Council had control over the medical profession and medical education. In 1927 Medical Ordinance of No 26 was passed, and in 1929 the gazette notification of its regulations was published. This was the beginning of Ceylon Medical Council (CMC) in its present form as the main regulatory body of the medical profession. Thereafter this ordinance was amended on many occasions, and in 1988 the Medical (Amendment) Act of No 40 changed the title of CMC as Sri Lanka Medical Council (SLMC). Among other things, the SLMC has the sole authority for registration and deregistration of medical practitioners as well as imposing punishment on them in the case of professional misconduct. At present, the SLMC, which is normally referred to as the Medical Council, consists of the members presented in Figure 2.4.

Figure 2.4: Composition of the Sri Lanka Medical Council

- The president nominated by the Minister of Health
- A vice-president elected from among the members of the Medical Council by the Medical Council
- One member elected by the teachers of the Faculty of Medicine of each of the universities established or deemed to be established by the universities act No 16 of 1973
- One member elected by the teachers of the Faculty of Dental Services of each of the universities established or deemed to be established by the universities act No 16 of 1973
- Eight members elected by the registered medical practitioners
- One member elected by persons entitled to practice medicine
- One member elected by dentists
- Four members nominated by the Minister of Health, of whom at least two members shall not be in the employment of the government or in receipt of a pension from the government
- The Director General of Health Services
- The Director General of Teaching Hospitals

Throughout the history of over one century the amendments to the Medical Ordinance or Act have largely been focused on matters related to the registration of medical practitioners and other related categories such as dentists, dental surgeons, Assistant/Registered Medical Practitioners including government apothecaries and estate dispensers, midwives, pharmacists, nurses and para medical assistants. But it was only on 30 March 1993 that regulations pertaining to disciplinary inquiries against medical practitioners were gazetted. Under these regulations the SLMC elects two committees for conducting investigations about complaints. A complaint is first examined by the Preliminary Proceedings Committee, chaired by the Vice President of the Council and consisting of another four members of the Council who are elected by secret ballot at a meeting of the Council. Once the Preliminary Proceedings Committee has completed its report, it will be submitted to the Professional Conduct Committee to take a final decision on whether an inquiry needs to be conducted with the participation of the practitioner. This committee is chaired by the President of the Council and consists of another ten members of the Council, again elected by secret ballot at a meeting of the Council.

With these developments and the aggravation of malpractice amongst practitioners, in September 2000 the SLMC distributed a brief document amongst registered medical practitioners with the title *'Instructions on "serious professional misconduct" to medical practitioners and dentists registered in the Sri Lanka Medical Council'* (SLMC 2000). It details what constitutes professional and unprofessional conduct and personal behaviour for

the consideration of the professionals concerned under six headings as presented in Figure 2.5.

Figure 2.5: The SLMC identified areas of professional misconduct and personal behaviour

• Neglect or disregard by doctors of their professional responsibilities to their patients for their care and treatment
• Abuse of professional privileges or skills
• Derogatory professional conduct
• Advertising, canvassing and related offences
• Comment on professional colleagues
• Any other act of commission or omission deemed as unacceptable to the disciplinary committees of the Medical Council

Meanwhile a resolution was proposed to the annual general meting of the SLMA in 1985/86 on the decline in standards of ethics in the medical profession and a sub-committee was appointed to draft a code of ethics for the medical profession[4]. In 1987 it was distributed amongst the members of the SLMA as a booklet. Further in 2001, the SLMA published a Codes of Ethics for the medical profession, ethics which are related to three areas: informed consent, information provision and emergency treatment.

2.3.2 Role of the MoH

Whilst professional bodies were making an attempt to bring the medical profession into a regulatory framework, the MoH also came under pressure, particularly from the media, to take precautionary measures to curb medical malpractice. However, the MoH was initially concerned about the purely private sector, and during the early 1990s took the initiative to bring the private sector into a regulatory framework through the Private Medical Institutions (Regulatory) Act. Although this Act has so far not been enacted by parliament, some officials of the MoH and other members of the Presidential Task Force (PTF) for the Implementation of the National Health Policy, and its committees, raised the issue of malpractice by public sector medical officers at its meetings during the latter part of the 1990s. The report of the PTF suggested: a) amending the proposed legislations on the private sector (i.e., Private Medical Institutions (Regulatory) Act) and expediting its enactment, and b) the establishment of an authority under this legislation with a centre for information and complaints (PTF 1997). Thereafter it brought up, in a very equivocal manner, the necessity of phasing out the participation of public sector health personnel in the private sector by way of providing a)

[4] The SLMA is a professional body interested in matters related to the medical profession. However, it has no legal authority over the conduct of its members.

incentives and licensing schemes for the private sector, and b) implementing the necessary regulations. These developments finally led the President to raise the issue of medical malpractice at a cabinet meeting in 1997. The following is an abstract from the minutes of the Cabinet Meeting held on December 1, 1997:

"It was observed that administration of the government hospitals has been deteriorating and most of the doctors are not attending to their duties properly as they are involved in private practice during office hours. The Ministry of Health was instructed to organise several flying squads to take disciplinary action against wrongdoers. The Hon. Minister was also requested to discuss with the Attorney-General to explore the possibility of taking legal action against those who engage in private practice during their office hours and at their official quarters."

(Internal document of IU, MoH)

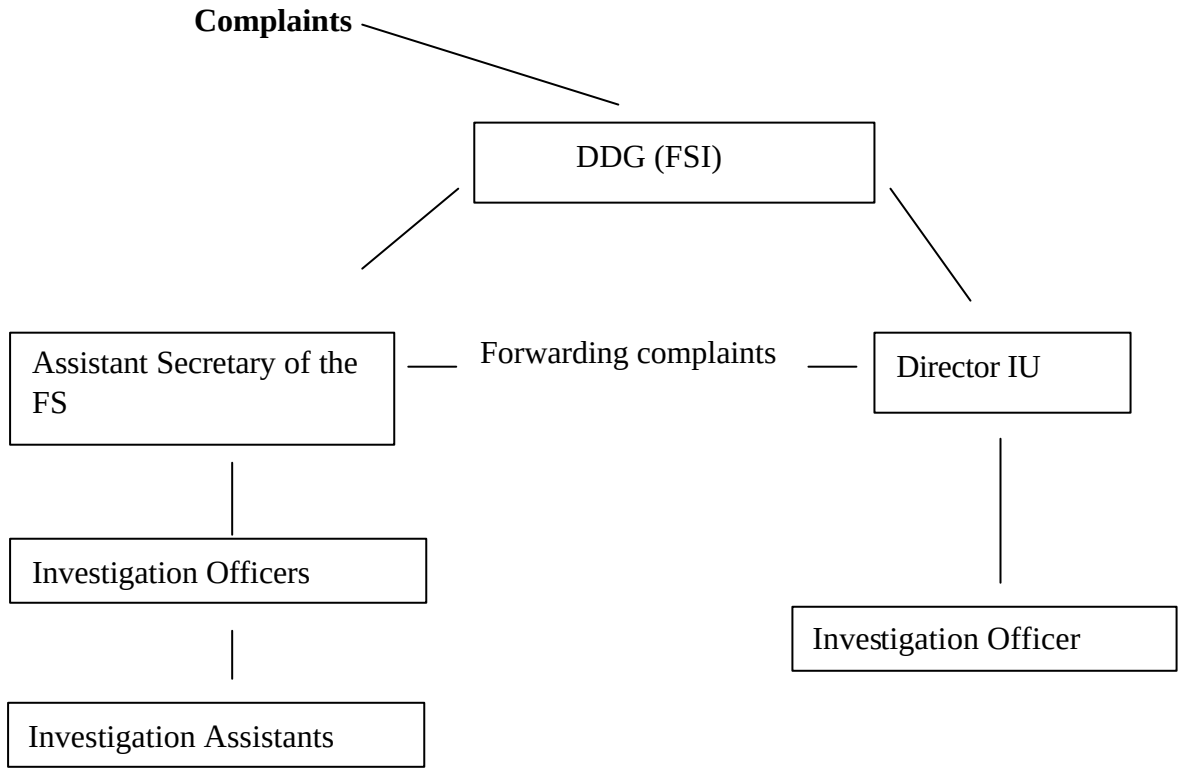
This cabinet decision resulted in the approval of the Cabinet Memorandum on December 31, 1997 to set up a flying squad unit at the MoH. According to the Cabinet Memorandum the main objective of this unit "will be to conduct surprise checks on the mal-practices of the staff attached to Hospitals, especially to detect those doing private practice during working hours utilising government resources". The Salaries and Cadres Committee later examined this matter and approved a cadre of 11 with 4 officials of the Sri Lanka Administrative Service. The Investigation Unit (IU) was set up in June 1998 under the control of Deputy Director General [Flying Squad & Investigations – DDG(FSI)], who was a senior administrative officer. However, the establishment of the IU was really a formalization of the activities of the already existed informal Flying Squad (FS) of the MoH. An informal FS had existed for a considerable time under the DDG (Examinations and Investigations), and with the setting up of the IU, responsibilities relating to investigations were transferred to the DDG (FSI). Along with the establishment of the IU, the MoH issued a circular on March 17, 1999 completely prohibiting engagement in private practice by public sector doctors during working hours.

Although this unit is called the IU, it consists of two units: the flying squad and the IU. Whilst the DDG(FSI) has the overall responsibility, an Assistant Secretary and a Director handle the activities of the FS and the IU, respectively. However, the FS handles a large portion of the activities of the whole unit. The FS conducts surprise checks as well as all investigations. When the IU receives complaints, they too are referred to the FS. These

complaints were largely forwarded by the general public through politicians and particularly through the Minister of Health. In emergencies, staff of the IU also assist the FS to carry out its activities. The organization of the IU is presented in Figure 2.6.

In early 2002, the MoH set up another unit, the Special Complaints Unit, to receive complaints from the general public on matters related to medical malpractice. This unit functions throughout the day with a hotline and is handled by an Assistant Secretary of the MoH. Throughout the day one senior officer is assigned to look after this unit. However, serious complaints received by the unit, for which further investigations are required, are forwarded to the IU.

Figure 2.6: Organizational structure of the IU



2.3.3 Private sector

The private sector has been expanding at an accelerated rate during the recent past. At present about 160 private hospitals and nursing homes are operating in all parts of the country, compared with 85 in 1992 (PTF 1992 and Personal communication with Director/Private Health Sector Development, MoH). There are about 800 registered full-time private medical practitioners, in addition to the majority of public sector doctors who are engaged in private

practice. This sector consists of 250 laboratories, and very recently five ambulance services and six private home nursing service centres also came into operation. Although a large number of private dental surgeons are also in the market, the number is unknown. According to the PTF (1992), there were over 10,000 traditional practitioners in addition to a large number of quacks, but the number is unknown.

The agony in the private sector is that unlike the public sector, no easily accessible mechanism is available either for the MoH to undertake investigations or for patients and their relatives to make formal complaints in the case of malpractice. During the recent past, only a very few wealthy families have sought justice from the courts for misconduct of doctors at private hospitals/clinics. Even though the MoH has been making a strenuous effort during the past decade to bring out new legislations to monitor and regulate the private sector, through the Private Medical Institutions (Regulation) Act replacing the outdated Nursing Homes Act No 16 of 1949, it has not yet shown results. In the few court cases, too, no punitive measures have been taken against the alleged offenders.

3. COST OF ENFORCEMENT AND MONITORING OF REGULATIONS

This section first makes an attempt to bring out the cost incurred by the regulators at the central and peripheral levels. Secondly, the cost incurred by the regulatees in complying with the regulations will be presented. Finally, some aspects of social cost due to non-compliance will be presented.

3.1 Pharmaceuticals

3.1.1 Enforcement and monitoring cost

At the central level, enforcement and monitoring of pharmaceutical regulations is undertaken by the CDDA, with its two main organizational units: NDQAL and ED. Table 3.1 shows a classification of the total cost of each of these units.

Table 3.1: Operational cost of CDDA, 2001

Item	NDQAL		ED		Total	
	Rs.	%	Rs.	%	Rs.	%
Salaries and wages	6,095,994	27.9	2,193,000	46.0	8,289,022	31.2
Travelling and transport*	1,680,496	7.7	1,529,782	32.1	3,210,285	12.1
Utilities	2,202,635	10.1	310,000	6.5	2,512,645	9.4
Maintenance	272,188	1.2	110,000	2.3	382,189	1.4
Laboratory cost	9,951,641	45.6	0	0.0	9,951,686	37.4
Security services	777,259	3.6	425,000	8.9	1,202,262	4.5
Miscellaneous	838,609	3.8	204,300	4.3	1,042,913	3.9
Total Cost	21,818,821	100	4,772,082	100	26,591,003	100
Percentage		**82.1**		**17.9**		**100**

* The terms travelling and transport refer to the travelling claims made for field visits, and the cost of vehicle maintenance and fuel, respectively.

Source: DRA.

In 2001, at the central level Rs.26.6 million was spent by the MoH for enforcement and monitoring of CDD. This amount, however, accounts for only about 0.14% of the total expenditure of the MoH. Further, it is only about 0.5% of the total cost of drugs, dressings, chemicals etc. to the MoH. Almost half of the total operational cost of the NDQAL was spent on laboratory services because it is primarily engaged in laboratory investigations related to new as well as registered drugs. In constrast, personal salaries and travelling and transport formed over 75% of the ED's expenses, primarily due to the involvement of the ED in field investigations extensively.

The ED is involved in a series of activities at the national as well as peripheral levels, ranging from matters related to registration, deregistration, raiding pharmacies and inspection of drug manufacturers to court cases. In this context, just for the purpose of indicating the value of services provided by ED in enforcement and monitoring of CDD, average cost per pharmacy was estimated. It stands at around Rs. 2,400 for the year or Rs. 200 per month (US$ 2.3).

Table 3.2: Cost of the regional authorities on enforcement and monitoring of drug regulations by study location, 2001

Item	Urban	Semi-urban	Rural	Total
	Rs.	Rs.	Rs.	Rs.
Authorized officers				
DPDHS	4,634	4,634	3,700	12,968
MOH	4,134	23,427	13,646	41,207
DP	8,700	1,740	1,740	12,180
FDI	146,440	439,320	99,072	684,832
Sub total	163,908	469,122	118,158	751,188
Other expenses				
Other officers	22,470	4,732	6,126	33,328
Transport, overheads etc.	27,957	85,294	12,428	125,679
Sub total	50,427	90,025	18,554	159,006
Total	214,335	559,147	136,712	910,194
Average cost				
Per pharmacy per year (Rs.)	2,003	2,237	7,595	2,427
Per pharmacy per month (Rs.)	167	186	633	202
Per pharmacy per month (US$)	1.9	2.1	7.1	2.3
Item	**%**	**%**	**%**	**%**
Authorized officers				
DPDHS	2	1	3	1
MOH	2	4	10	5
DP	4	0	1	1
FDI	68	79	72	75
Sub total	76	84	86	83
Other expenses				
Other officers	10	1	4	4
Transport, overheads etc.	13	15	9	14
Sub total	24	16	14	17
Total	100	100	100	100

Source: DRA.

At the peripheral level, on average, Rs 2,427 was spent by the regulatory authorities for enforcement and monitoring of pharmaceutical regulations in 2001. This amount equates to Rs. 202 per month, which is only US$ 2.3 (Table 3.2). In the three study areas, this average cost varies from Rs. 633 in the rural district to Rs. 167 in the urban area. There are two main

reasons for this variation. Firstly, whilst 3 FDIs were available in the semi-urban district, the other two areas had one each. Secondly, whilst the number of pharmacies in the rural district was only 18, it was 107 in the urban district. The semi-urban district, Gampaha, which is located adjoining the Colombo district, had 250-300 pharmacies including unlicensed ones (the exact number is unknown). These variations have resulted in the largest average figure per pharmacy in the rural district, Polonnaruwa. Although the total number of pharmacies in the urban district, Kandy, was 107, the number of pharmacies within Kandy city limits was only 40. The FDI was, however, looking after the whole district. This is the prime reason for reporting the lowest average cost per pharmacy from the urban area. In this context, proportions of resources allocated from the respective health budgets of these three areas for enforcement and monitoring of pharmaceutical regulations stand well below the national figure of 0.14%. Whilst 79% of the total cost in the semi-urban district is accounted for by salaries of FDIs, it stands at 72% and 68% in the rural and the urban districts, respectively. This indicates that at the peripheral level, the responsibility of enforcement and monitoring of pharmaceutical regulations rests primarily in the hands of FDIs. In all three locations, the proportion of time spent by the other AOs on pharmaceutical matters stood at very low levels. It was between 60% and 70% for FDIs, but only 1% and 0.5% for DPDHSs and DDHSs, respectively.

3.1.2 Transaction cost

On average, a pharmacy spent Rs. 365,839 or US$ 4,100 as transaction costs per month in 2001. Almost 72% of this cost can be attributed to personnel. However, the cost of personnel includes not only the salary payments made to qualified pharmacists but also the illegal payments made to individual qualified pharmacists for the purpose of displaying his/her certificate at the pharmacy for making a legal coverage for the business. This illegal payment varies between Rs. 1500 and Rs. 5000. Whether this can be regarded as a transaction cost or cost of compliance is indeed questionable. Or is it a cost of non-compliance? However, with the presumption that such pharmacies are forced to have this legal coverage under CDD, such illegal payments were also added to the transaction cost. Across the three study locations, Gampaha has reported the highest transaction cost (US$ 6,058) followed by Kandy (US$ 2,990) and Polonnaruwa (US$ 1,892). However, the composition of transaction costs is substantially different across the three locations. The rural district has reported the highest cost proportion of maintenance and supplies (34%) and the urban location, Kandy, had the lowest, at 14%.

Table 3.3: Cost of compliance with pharmaceutical regulations by study location, 2001

Item	Urban	Semi-urban	Rural	Total
Cost of compliance (Rs.)				
Licence Fee: MoH	1,692	1,842	773	1,519
Licence Fee: Local authorities	4,233	995	535	1,800
Payment for the pharmacist*	95,000	126,000	32,182	92,571
Salary of supporting staff**	129,000	255,600	77,455	172,771
Maintenance and supplies	37,379	157,480	58,255	97,178
Average cost per pharmacy per year (Rs.)	267,304	541,917	169,198	365,839
Average cost per pharmacy per month (Rs.)	22,275	45,160	14,100	30,487
Average cost per pharmacy per year (US$)	2,990	6,058	1,892	4,100
Average cost per pharmacy per month (US$)	249	505	158	341
Cost of compliance (%)				
Licence Fee: MoH	0.6	0.3	0.5	0.4
Licence Fee: Local authorities	1.6	0.2	0.3	0.5
Payment for the pharmacist*	35.5	23.3	19.0	25.3
Salary of supporting staff**	48.3	47.2	45.8	47.2
Maintenance and supplies	14.0	29.1	34.4	26.6
Total transaction cost	100	100	100	100

* Including the unofficial payment for the pharmacist to whom the certificate is issued and opportunity cost of the service provided by the owner when he/she works as the pharmacist.

** Including the opportunity cost of the service provided by the owner as a seller of drugs.

Meanwhile, Kandy reported the highest proportion of payments to pharmacists and supporting staff (83.8%). One main reason for this pattern is the necessity of making relatively high payments to qualified pharmacists and supporting staff in the urban and semi-urban locations. Further, most of the pharmacies in the rural area did not have a qualified pharmacist and therefore relatively low salaries were paid to unqualified staff. Similarly, the amount of illegal payments for pharmacist certificates was also substantially lower in rural areas. In this context, it is worth mentioning that the practice of displaying illegal pharmacist certificates was not very common in the rural set up, even in the case of the unavailability of a qualified pharmacist.

3.1.3 Social cost

Except for illuminating a few incidents of non-enforcement of regulations and their likely social repercussions, no attempt was made to quantify the social cost related to the implementation of pharmaceutical regulations. This was found to be a particularly challenging area, for which a strenuous attempt is required to make such quantifications, and further, it was indeed outside the scope of the study.

The ED has recently started making surprise raids on the pharmacies in selected areas, sometimes with the assistance of regional health authorities. Very recently a complaint was made by a patient against a pharmacy for dispensing an ear drop instead of an eye drop prescribed by a doctor. This complaint led to the raid of a dozen pharmacies in the Colombo suburbs and the results were published in a national newspaper (Daily News 2002a). From these 12 pharmacies, five types of unregistered drugs, eleven types of smuggled drugs and three types of unlabelled drugs were seized. The value of these drugs was around Rs. 200,000. Further, the stock of certain pharmacies consisted of physicians' samples, which are exclusively banned for sale. One pharmacy had a balm that it itself manufactured without registration. Only four of the 12 pharmacies possessed a licence and the others had not renewed their licences or sought permission to operate as a pharmacy.

The Divisional Registered Medical Officer (DRMO) of Kandy explained a brief survey on self-medication they had conducted in Nuwara Eliya, a city in the Central Province. On the basis of their findings, he explained that people now tended to purchase more and more drugs directly from pharmacies and omitted consulting doctors because of unaffordability. In one observation, they found that the parents of one six-month-old infant were looking for a drug from a pharmacy for an eye ailment of the infant, because they were asked to pay Rs. 7,500 for treatment at a small private hospital. He further explained that even some patients with hypertension and diabetes have developed a practice of purchasing drugs from pharmacies without having any understanding about the nature of their illness. It is the role of the pharmacist or the drug seller to ask questions of the patient and decide the drug/s given to them. During field investigations, one diabetic patient at a pharmacy in Gampaha stated that even if he goes to see the doctor, he takes only a few minutes to examine him and prescribes the same drug. "So why should I spend my time and money unnecessarily. I can easily get it from the pharmacy. Now I know the name of it. Now I'm OK. By getting drugs from the pharmacy I can save my money and time. Only when something goes wrong, I go to see a doctor."

Another patient at a pharmacy in Kandy had a different explanation for his adherence to pharmacy treatment. "Sometimes I get gastritis. Earlier I used to go to the doctor and spend a lot of money for treatment. But one day a friend of mine, who is running a pharmacy, told me that there was a new and cheap drug for gastritis. There are many varieties, but I was given

something called Omez. It is cheap and very effective. So now I take Omez from a pharmacy whenever I get the symptoms of gastritis." There were many more such incidents observed during fieldwork. These observations themselves indicate that quantification of the repercussions of dispensing unprescribed drugs by pharmacies is an enormous task.

3.2 Medical practice

3.2.1 Enforcement and monitoring cost

At the central level, the IU is the main body that conducts investigations on medical malpractice in the public sector. Table 3.4 shows a classification of the total cost of this unit. In 2001, the total operational cost of the IU stood at Rs.4.4 million. This amount, however, accounts for only about 0.023% of the total expenditure of the MoH. Further, it is only about 0.04% of the total expenditure on patient care services of the MoH. Almost half of this amount was spent on salaries and wages, and when the other personal emoluments such as travelling and examination charges were added, this proportion would rise to 60%.

Table 3.4: Operational cost of the IU, 2001

Item	Rs.	%
Salaries and wages	2,185,128	49.5
Examination charges	143,442	3.2
Travelling & transport*	761,265	17.2
Utilities	118,102	2.7
Maintenance	565,802	12.8
Cleaning and security service	110,269	2.5
Miscellaneous	529,745	12.0
Total	**4,413,752**	**100**

* Please see the footnote of Table 3.1.
Source: IU, MoH.

Unlike the case of pharmaceuticals, it is not viable to make any average cost estimate for the activities of the IU, which is involved in handling the complaints made during the same year as well as previous years. Whilst investigations on certain complaints last several years, some are completed during the same year. When it appears to be difficult to undertake an investigation for minor complaints, largely due to lack of evidence, no investigation is conducted. Even if a direct cost estimation method is adopted, it is not possible to estimate cost averages because most of the complaints are not of the same nature. However, a very approximate average cost figure could be estimated for one of the end results of IU, which is the average cost per investigation conducted during its total service period from 1998 to

2003. During this period, the IU has conducted 76 investigations on private practice during working hours. There are another 13 investigations on para-medical staff such as lab technicians. Since the IU is engaged in investigations related to other matters such as misuse of vehicles, it is reasonable to assume that, on average, about 70% of its resources are used for investigations related to private practice by public medical officers and Assistant/Registered Medical Officers. However, as mentioned above, almost 43% (33) of those investigations are still not completed. With these reservations, the average cost per investigation on private practice could be estimated as Rs.165,000 (US$ 2000).

At the peripheral level, responsibility for enforcement and monitoring of regulations on medical practice rests primarily in the hands of the PDHS and DPDHS. As was revealed during field investigations, these officers do not play any significant role in detecting, in particular, private practice undertaken during working hours. However, these officers and some of the DDHSs were found to be particularly vigilant about quacks and a few such incidents were reported during field investigations. Under such circumstances, cost of enforcement and monitoring of medical practice regulations is in fact negligible at the peripheral level.

3.2.2 Transaction cost

Some average cost estimates were made for the cost of compliance to medical practice. At the FGDs with medical personnel, it was enquired whether they had paid a registration fee and the response was all of them had done so. The other cost elements involved in compliance were categorized into two types: manpower and equipment. The former consists of the cost incurred by the practitioner to employ an assistant/s and a dispenser. On average, those who had male or female assistants spent about Rs.3000 a month on manpower. Dispensers were available for only those who worked at private hospitals; for the others, a male/female assistant, the wife of the practitioner or the practitioner himself/herself performed the duty of dispenser. Thus the salary of these assistants covers the cost of assistance as well as dispensing drugs.

With respect to medical equipment, the cost of a set of essential equipment, which all respondents possessed, was estimated. This equipment package consists of a thermometer, stethoscope, sphygmomanometer and surgical instruments. Although there were variations in the type of equipment used by different practitioners, on average, each practitioner had spent

about Rs.7,000 for their essential equipment. However, particularly in urban and semi-urban areas, some of the practitioners had a portable ECG machine, which costs about Rs.40,000. Another common feature, especially in the urban set up, was the glucometer, which costs around Rs.8,000.

3.2.3 Social cost

An attempt was made to identify the social cost of the non-enforcement of regulations. Firstly, inquiries were made as to whether patients were organized as consumer societies to raise their voice against malpractice. There was no such consumer society in either the semi-urban or rural study area. There was one Disabled Rehabilitation Society in Gampaha, the semi-urban location, but this was mainly concerned with tasks related to rehabilitation and not malpractice. Similarly, there were two societies in Kandy for Diabetes and Cancer, but again these were concerned with providing services and not with malpractice. Secondly, an attempt was made to review the available evidence about the patients' and their relatives' attempts to seek justice through the courts in the event of malpractice by practitioners, particularly regarding medical negligence. This was found to be an area for further work as it is only now that service receivers who are not in the upper social stratum are gradually coming forward to seek justice for medical misconduct. As mentioned earlier, until recently such attempts were made largely by a few urban affluent families.

A few examples of practitioner malpractice are presented below to indicate the depth and direction of the problem regarding social cost. Two females, a mother and her sister, who were interviewed near to a "channelling centre" in the urban area, commented on the way some public consultants behave: "My baby, who is now only 18 months old, was admitted to … hospital a few days ago with some symptoms of…. We used to go to the hospital to see him every day. We didn't see any improvement of the baby. When we inquired from the staff of the ward, they asked us to see the doctor. But we never got a chance to see the doctor as he was not there at the time of our visit. …A friend of mine suggested that I get an appointment as a patient and see him at his channelling centre. So we paid the necessary fee and went to see him today. Our number was the last one. When we were getting into his room, some other people also attempted to get into the room. Then the doctor came out and shouted at them 'Don't bring your reports to me. I'm seeing only those who have taken numbers.' You see what really happened was those people had been asked by the doctor to take some medical reports and they were waiting there (without numbers) to show them to him once he had

finished examining patients. We were also about to be chased out with them, but somehow I managed to tell the doctor that we had a number. Then he apologized, asked us to come inside and explained the present situation of my son." Can this kind of cost borne by the relatives be considered a social cost? And is private practice becoming a source for relatives to find out the condition of a patient receiving inpatient care at a public hospital?

Another dimension of private practice was explained by a patient who was returning after attending the OPD of a secondary level hospital in the semi-urban area: "You see the doctors here do private practice until about 9.30 in the morning. At the hospital, they just write a prescription and ask us to get drugs from the pharmacy. When a patient is admitted to the hospital in the morning, either the patient will be discharged in the evening or transferred to another hospital[5]. No treatment is given during that period. When you are transferred to another hospital, you have to hire a vehicle to go there because the ambulance is broken. So people who can afford it go to Gampaha (the main city of the district) to see a hospital doctor at a channelling centre, after making a payment of Rs.265, and get admitted to the hospital… Although people have to get together and do something to change the situation at this hospital, they are scared of doing so because in an emergency you have to go to this hospital."

The media has taken the initiative in the recent past to expose the different dimensions of the social cost of medical malpractice and particularly of medical negligence. Professor Carlo Fonseka, a former Dean of the Faculty of Medicine of the Colombo North Medical College and a well-known writer, has recently published a series of articles in a leading Sunday paper severely criticising the behaviour of medical practitioners (Fonseka 2002a). In one of these articles Fonseka, as a former teacher of two leading medical colleges, expresses his utter frustration over the present behaviour of medical doctors saying:

"They have chosen the medical profession not to act according to the principles of alleviating the agony of illness inherited by mankind but to grab as much as possible (financially) within the shortest possible time period. For this purpose they have tended to examine a patient even within one minute. Therefore I am getting highly frustrated when it comes to my mind why teachers like me taught medical students how to examine patients systematically."

[5] Early discharging and transferring patients to another hospital in fact reduces the case load of the doctor and hence provides more time for private practice.

He ended up this series of articles saying that, being a predominantly Buddhist country, the medical doctors should attempt to become Buddhists, indicating that they should get back to the principles of humanity, dignity etc. On another occasion, when delivering a memorial oration at the anniversary of the death of a former Dean of the Colombo Medical Faculty, with the title "Towards a concept of the ideal doctor for Sri Lanka" (Fonseka 2002b), he concluded:

"Accordingly, I conclude that the ideal doctor for Sri Lanka should be an embodiment of western medical science and Buddhist values represented by contentment over acquisitiveness; co-operation over competition; compassion over perfunctory sympathy; and altruistic service over selfish indulgence."

Figure 3.1: Published allegations of medical negligence during the five month period from February to June 2002

Date	Paper	Age	Sex	Incident
Feb. 13	*Lakbima*	25	F	Mother and her baby died after she was given "Sinto" for labour pains at the Negambo hospital
March 3	Sunday Leader	NA	F	Admitted after a heart attack, died at the Asiri hospital (a leading private hospital in Colombo) due to the alleged negligence of the attending physician.
March 6	*Dinamina*	30	F	Died at a private hospital in Matara (in the Southern Province) just two days after the delivery of her baby. Cause of death: the administration of a wrong injection.
March 6	Daily Mirror	NA	F	Died at a private hospital after a caesarean operation, due to a wrong injection.
March 9	*Divaina*	9	M	Lost his right arm due to timely treatment not being given at the Homagama and Colombo National hospitals.
March 25	*Lankadeepa*	39	M	A Sergeant of the Special Task Force, admitted to the CNH (Colombo National Hospital) for high blood pressure, died due to negligence in giving him timely treatment.
April 2	*Lankadeepa*	14	M	Admitted for appendicitis. Died at the Avissawella base hospital due to bowel infection caused by wrong medication.
April 8	*Lakbima*	3	F	Died at Dharga Town hospital due to the negligence of the medical staff.
April 19	*Lakbima*	NA	M	Admitted after an accident. Died at the Trincomalle hospital due to negligence in treatment.
April 20	Island	Infant	NA	Died at the Dharga Town hospital due to negligence of the staff.
April 24	*Lankadeepa*	26	F	Died at the Chilaw hospital after a caesarean operation.
April 29	*Lakbima*	39	F	Died at Matara hospital after a caesarean operation.

May 2	*Divaina*	37	F	Died after delivering her baby at the Homagama hospital.
May 15	*Lakbima*	2	M	Died at Kandy General hospital (a teaching hospital).
May 17	*Lakbima*	NA	Baby	Died after delivery at the Nagoda hospital. Mother (28) was in severe labour pains but the doctor did not transfer her immediately to the Castle Street Maternity Hospital (a leading maternity hospital).
June 2	*Divaina*	23	F	Died at the Ragama hospital (Colombo North Teaching Hospital) due to lack of proper medical care.
June 13	*Divaina*	15	M	Died at the Lady Ridgeway Children's hospital after being prescribed filarial tablets without identifying the real illness.
June 23	Island	NA	NA	Five pregnant women died at the Nagoda hospital after caesarean operations.
June 27	*Dinamina*	32	F	Died at the Nagoda hospital due to improper medical care.

Source: Liyanage (2002).

Although Professor Fonseka has played a leading role in this discourse, journalists too played a prominent role in instigating many aspects of medical negligence. Some recent articles in national newspapers on this issue have had titles such as "Getting to know medical negligence" (*Daily News* 2002b), "Taking docs to Court" (Sunday Observer 2002a), "Errant docs or faulty system?" (*Sunday Observer*, 2002b), "Doctors at Sri Jayawardanapura Hospital on a surgery racket" *(Rawaya* 2002) and "Maternity deaths at Nagoda hospital: irresponsibility is the reason?" (Weerarathne and Bungagamaarchchi 2002). Meanwhile, a tiny voice has come up in safeguarding the behaviour of the medical doctors as well (Aloysius 2001, 2002). But at present public allegations of medical negligence are becoming a leading feature in the media. One reporter in the *Sunday Observer* (Liyanage 2002) listed 19 incidents of medical negligence reported in the national newspapers during the period from February to June 2002 (Figure 3.1). These examples themselves indicate the depth of the social cost of medical malpractice, though it is impossible to quantify.

As a final illustration, another dimension of social cost is presented in the following box, which presents an incident reported very recently in a national newspaper.

Box 2.1: Seeking justice from the courts for medical negligence

Bandage in stomach
Teacher sues doctor for negligence

A music teacher yesterday filed a Rs.1.5 million (about £10,000) damages suit in the District Court against a doctor for professional negligence. The teacher has cited a doctor at the Mulleriyawa Hospital and a private hospital as first and second respondents. The teacher stated that she married on December 27, 1989 but had no children. She had obtained treatment from several doctors for infertility. The first respondent, on examining her, had suggested that a swelling in the fallopian tube be removed by surgery. Accordingly, the first respondent had performed the surgery at a private hospital on October 13, 2000. She was discharged on October 17, 2000. Later the teacher had developed complications. Although she obtained treatment from several doctors, no one was able to diagnose the disease.

Through an X-ray test, doctors at Ragama hospital (Colombo North Teaching Hospital) noticed an object in her stomach. Thereafter, an operation was performed on her at Ragama hospital where a piece of bandage left inside her stomach during the earlier operation was removed.

(*Daily News*, October 12, 2002)

4. AN ASSESSMENT OF COMPLIANCE WITH THE REGULATIONS

This section examines how regulators as well as regulatees are complying with the regulations. For pharmaceuticals, it begins with a look at regulatees and then at regulators, because an initial presentation of the field situation can provide a basis for clearly understanding the compliance of regulators. However, for medical practice, we start by exploring the role of regulators followed by regulatees.

4.1 Pharmaceuticals

4.1.1 Compliance of regulatees

Almost 85% of the pharmacies are conducted as joint business ventures, most frequently with a grocery (Table 4.1). When all the three locations were taken together, at least 70% of pharmacies had a separate grocery section. In the rural area, in addition to a grocery, selling of Ayurvedic drugs or textiles was also found at 27% of pharmacies. Confinement of the business to the pharmacy was found at 17% and 21% of the pharmacies in the urban and rural areas, respectively.

Table 4.1: Nature of the pharmacy by study location

Nature of the pharmacy	Urban		Semi-urban		Rural		Total	
	No.	%	No.	%	No.	%	No.	%
Pharmacy	2	16.7	4	21.1		0.0	6	14.3
Pharmacy & grocery	10	83.3	15	78.9	8	72.7	33	78.6
Pharmacy, grocery & Ayurvedic drugs		0.0		0.0	1	9.1	1	2.4
Pharmacy, grocery & textiles		0.0		0.0	2	18.2	2	4.8
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**

Table 4.2 shows details relating to availability and displaying of the pharmacy licence and the certificate of the pharmacist. Both were available at only 62% of the pharmacies observed during field investigations; this percentage in the rural area was the lowest with only 39%. But at least one of the documents was available at 27% of the rural pharmacies. It is worth mentioning that 33% of the urban dispensaries openly accepted that they did not have any of these documents. One explanation for not having the pharmacy licence in semi-urban and rural areas was that it had been sent for renewal (4.8 %) or was being framed (2.4%). Although 62% of pharmacies stated that they possessed both documents, compliance with the

regulation to display them was observed at only 43%. This proportion was, however, relatively high in the semi-urban location (73.7%): in the other two locations it was well below 20%. The disparity between the availability and display of these documents, in fact, raises some doubts about the validity of the answers on availability of licences for these pharmacies. Thus, it may not be invalid to make a general statement that at least half of the pharmacies in the urban location and almost three-quarters in the rural location are not licensed pharmacies. In this regard the only exception is the semi-urban area.

Similar results were found for the availability of a qualified pharmacist (Table 4.3). Whilst for the urban location, the proportion was 50%; once again almost 95% of the pharmacies in the semi-urban area had qualified pharmacists. In the rural area, it was just 27%. Thus, on average, 64% of all the pharmacies had qualified pharmacists. In this context, the poorest compliance was reported from the urban area, where 50% of pharmacies did not have

Table 4.2: Availability and displaying of the pharmacy licence and the certificate of pharmacist by study location

Item	Urban		Semi-urban		Rural		Total	
	No.	%	No.	%	No.	%	No.	%
Whether licences are available?								
Yes, both of them are available	7	58.3	15	78.9	4	36.4	26	61.9
Only pharmacy licence is available	1	8.3			2	18.2	3	7.1
Only the pharmacist certificate is available					1	9.1	1	2.4
No, neither of them is available	4	33.3	3	15.8	1	9.1	8	19.0
Pharmacy licence is available but it is:								
Sent for framing			1	5.3	1	9.1	2	4.8
Sent for renewal					1	9.1	1	2.4
Pharmacist has the certificate but it is with the pharmacist*					1	9.1	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Whether the licences are displayed?								
Both are displayed	2	16.7	14	73.7	2	18.2	18	42.9
Both are available but not displayed	5	41.7	1	5.3	2	18.2	8	19.0
Only the pharmacist certificate is available but is not displayed					1	9.1	1	2.4
Only the pharmacy licence is available and displayed					1	9.1	1	2.4
Only the pharmacy licence is available but is not displayed	1	8.3			1	9.1	2	4.8
Both are not available so not displayed	4	33.3	3	15.8	1	9.1	8	19.0
Both are available but sent for framing			1	5.3	1	9.1	2	4.8
It is with the pharmacist*					1	9.1	1	2.4
Only the pharmacy licence, but it is sent for renewal					1	9.1	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**

*At this pharmacy the pharmacist was not physically available at the time of field investigations.

Table 4.3: Physical availability of a qualified pharmacist by study location

Physical availability of a pharmacist	Urban		Semi-urban		Rural		Total	
	No.	%	No.	%	No.	%	No.	%
Yes	6	50.0	15	78.9	1	9.1	22	52.4
Yes, it is the owner			3	15.8	2	18.2	5	11.9
Yes, it is the owner but not available at the pharmacy					1	9.1	1	2.4
Yes, but not physically available at the pharmacy:								
- at least 1 assistant is following the pharmacist course					4	36.4	4	9.5
- no assistant is following the pharmacist course	5	41.7	1	5.3	1	9.1	7	16.7
Not at all	1	8.3			2	18.2	3	7.1
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**

either a qualified pharmacist or an assistant following a pharmacist course. In the rural area, whilst 27% of pharmacies had a qualified pharmacist, in another 36% of pharmacies at least one assistant was following a pharmacist course.

With respect to maintenance of a prescription register, in contrast, the rural area reported the highest number of pharmacies complying to this requirement, at 91%, followed by the semi-urban area with 84%. The lowest compliance rate was reported from the urban area, with 42% of pharmacies not maintaining a prescription register.

Basic features related to a) premises and b) storage facilities, maintenance and hygienic conditions are presented in Tables A4.1 and A4.2, respectively. With respect to premises, design, construction, location, pest control and adequacy of space were taken into account and the pharmacies were categorized as excellent, very good, good, average and weak. Equal weight was given for each indicator and the calculated averages of each study location are given in Table 4.4.

Table 4.4: Ranking of the basic features of the premises by study location

Rank	Study location			Total
	Urban	Semi- Urban	Rural	
Excellent	0.0	9.5	0.0	4.3
Very good	3.3	10.5	9.1	8.1
Good	71.7	40.0	50.9	51.9
Average	23.3	36.8	30.9	31.4
Weak	1.7	3.2	9.1	4.3
Total	**100.0**	**100.0**	**100.0**	**100.0**

It is worth mentioning that nearly half of the rural and semi-urban pharmacies had average or weak features with respect to the design, construction, location, pest control and space. In this regard, 75% of pharmacies in the urban area were reported as having good or better features, even though the physical availability of a qualified pharmacist was found to be a severe problem in this area. Whilst the majority of pharmacies in the urban area were well above average premises, wide variations were found in the pharmacies of the semi-urban area, ranging from excellent (9.5%) to weak (3.2%): pharmacies which obtained the rank of excellent were observed only in this area. Table 4.5 shows the availability of a refrigerator. It is worth noting that whilst all pharmacies in the rural and semi-urban areas had a refrigerator, 2 pharmacies (17%) in the urban area were functioning without a refrigerator. At one pharmacy, even though the refrigerator was not functioning, some drugs had been stored in it.

Table 4.5: Availability of a refrigerator by study location

Response	Study location			Total
	Urban	Semi- Urban	Rural	
Yes	83.3	100.0	100.0	95.2
No	16.7	0.0	0.0	4.8
Total	**100.0**	**100.0**	**100.0**	**100.0**

Once again equal weights were given for five factors related to storage facilities, maintenance and hygienic conditions of the pharmacy (see Table A4.2 for details), and the averages of the three study locations are given in Table 4.6. The five factors are: a) availability of proper storage facilities, b) maintenance, c) hygienic conditions of containers and utensils, d) hygienic conditions of the premises, and f) hygienic conditions of personnel.

Table 4.6: Ranking of storage facilities, maintenance and hygienic conditions by study location

Rank	Study location			Total
	Urban	Semi- urban	Rural	
Very good	0.0	10.5	16.4	9.0
Good	80.0	64.2	45.5	63.8
Average	16.7	25.3	32.7	24.8
Weak	3.3	0.0	5.5	2.4
Total	**100.0**	**100.0**	**100.0**	**100.0**

With respect to these factors, whilst the urban area was found to score highest, with 80% of pharmacies ranking as good, almost 38% of pharmacies in the rural area were ranked as either average or weak. Although 25% of the pharmacies in the semi-urban area were average, 10.5% of them gained the rank of very good.

The preceding information provides evidence on the extent to which the regulatees have complied with CDD regulations. Firstly, there seems to be a trade-off between a) non-compliance with major regulations such as obtaining a legal licence, employment of a qualified pharmacist and his/her physical availability, and b) maintenance of a hygienic and well-equipped pharmacy. This tendency was primarily observed in the urban location, where the prevalence of relatively high competition could underlie such behaviour. However, no such behavioural pattern could be attributed to the rural area, where low competition from only a few competitors might have caused regulatees to pay less attention to these complementary factors. Both of these behavioural patterns could be observed in the semi-urban area, in which relatively high compliance with legal permission could have made the regulatees pay less attention to those complementary measures, except in the city centres where competition was relatively high. Following these general remarks, in the following sub-sections, an examination will be made of the compliance of regulators both at national and peripheral levels.

4.1.2 Compliance of regulators

a. Central level

At the central level, until very recently the authorized officers were primarily engaged in national level matters related to registration of drugs, quality assurance etc. However, now the CDDA appears to be moving towards undertaking investigations in both sectors on quality and efficacy of drugs with the assistance of health officials, medical practitioners and dispensers. On May 17, 2002, the CDDA made a request of them through a press release (Daily News 2002c), asking them to inform the Authority about "drugs suspected to be of low quality or lacking in efficacy". The intention of this move is to conduct tests on such drugs at the NDQAL, and when a drug fails the test, steps will be taken either to withdraw the particular batch of the drug or for the complete withdrawal of the drug from the market. These tests are supposed to be done to World Drug Monitoring standards. The press release further says that during the first quarter of 2002, 43 drugs were withdrawn from the market because they failed quality assurance tests. The field level authorized officers are assigned to implement this task. This press release came just one week after a surprise visit to 12 pharmacies in the Colombo suburbs, as discussed in the previous section.

b. Peripheral level

As mentioned earlier, at the peripheral level, enforcement and monitoring of pharmaceutical regulations is primarily in the hands of FDIs. They are supposed to make at least one visit to each pharmacy every month, irrespective of their legal status. The data collected from FDIs in the three study locations were cross-checked with the records of the respective pharmacies and regional health authorities, and this clearly indicates that the FDIs perform their field visits in a satisfactory manner. Table 4.7 shows the frequency of such visits in the three study locations.

Table 4.7: Frequency of pharmacy visits by authorized officers

Frequency of visits	Study location						Total	
	Urban		Semi-urban		Rural			
	No.*	%	No.*	%	No.*	%	No.*	%
Twice a month	5	41.7	1	5.3	0	0.0	6	14.3
Once a month	6	50.0	15	78.9	11	100.0	32	76.2
Once in two months		0.0	1	5.3	0	0.0	1	2.4
Very rarely	1	8.3	2	10.5	0	0.0	3	7.1
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100**	**42**	**100.0**

* Number of pharmacies.

On average, monthly visits had been made to almost 76% of pharmacies by FDIs. But in the urban area, nearly 42% of pharmacies were visited twice a month, the reason being the location of these pharmacies in the near vicinity of the district health office. Some are located just opposite the health office. The FDI of Kandy district stated that after finishing the day's work, if he feels like it, he just makes a visit to a pharmacy on his way home. In the rural area, all pharmacies were visited once a month primarily due to their distant location.

When comparing the high frequency of pharmacy visits by FDIs with the relatively low level of compliance by the pharmacies to the regulations, a question arises as to what are the reasons underlying this low compliance amongst regulatees. Firstly, the explanations given by pharmacies for not displaying a licence are highly doubtful, and in this light, in total, nearly half of the pharmacies did not seem to have a licence. This percentage was highest in Polonnaruwa, the rural area. The Supervisory PHI (Divisional) in Kandy accepted the fact that sometimes several traders in the same area used a copy of the certificate of the same pharmacist. Further, he was aware of certain shops which sell drugs even without a name board detailing the certified pharmacist/assistant[?]. Meanwhile, the FDI of the same area stated that certificates of qualified pharmacists are sold for a price between Rs.3500 and Rs.

4000 per month in the urban area. According to his experience, they are largely sold to retired government officials, management level employees of private companies and those who have followed the pharmacist course in a private capacity and are not yet qualified as a pharmacist.

He brought up another aspect of FDI's passive attitude towards unlicensed pharmacies saying "When you are going to do something against unlicensed pharmacies, you have to look at them on humanitarian grounds." He attempted to justify his view in two ways. Firstly, many public doctors, who are engaged in private practice, maintain their own indoor pharmacies. They do not even pay any tax for running those pharmacies. This has really hampered sales at other pharmacies. Most of them are running at a loss. In this regard, one pharmacist in the semi-urban area brought up his grievances saying that he came to know from a drug wholesaler that a public doctor, who was doing private practice close to his pharmacy, used to buy about 100 bottles of *Digine* syrup for his indoor pharmacy every month. But this pharmacy could sell less than 10 bottles of the same drug in a month.

Secondly, if the pharmacies without licence were closed down, their employees will become unemployed. Therefore, according to this FDI, the closing down of an unlicensed pharmacy is ethically wrong. Further, he was very reluctant to take legal action against such pharmacies because it is a very long procedure. Therefore such pharmacies are warned and allowed a reasonable period to get a qualified pharmacist. Polonnaruwa FDI also had somewhat similar views. After accepting that most of the pharmacies in his district did not have a pharmacist physically available, he mentioned that unlicensed pharmacies located in rural areas in which a pharmacy is not available within a radius of 10 miles are given a time, normally one year, to get a qualified pharmacist. He further stated that AOs are always attempting to develop a very cordial relationship with pharmacy owners. According to this FDI, a ramification of this was the attending of private classes by at least one assistant in 4 out of 11 pharmacies in the Polonnaruwa district in preparation for the pharmacist examination. He mentioned the effectiveness of his approach, saying that one pharmacy in a channelling centre at "24th mile post" (the location of the pharmacy) was asked to find a qualified pharmacist; once they did, it was registered, and at this moment it was training three assistants. He further stated that at a remote place called Aralaganwila, a pharmacy was given a temporary licence because there was no pharmacy in the near vicinity. He came to a verbal agreement with the owner to take on a qualified pharmacist within a given period, but it was not possible to find such a person in this remote area and as a result a person who was going through a pharmacist training

programme was employed. According to the assessment of the FDI, the pharmacy was now functioning very well and would become the best pharmacy in the district in the near future.

In this context, it is worth mentioning that these trainees attend classes conducted by private organizations at city centres when preparing for the pharmacist examination. The contents of an advertisement for such a training class is given below.

Box 3.1: An advertisement for a private pharmacist training course

Pharmacy Training Course

- This is a class which begins from very basics in a very simple manner
- A systematic training is given for the external pharmacist examination
- There will be job opportunities after training
- Printed Tutorials will be provided
- Anyone above 16 years with GCE (O/L) can follow this course

……Place, Date and Time…….
CONDUCTED BY …….. (Registered Pharmacist)

The approach of FDIs towards pharmacies which do not comply with the regulations is very similar in the semi-urban area as well. One FDI of Gampaha stated that at the first visit, the pharmacy owners are made aware of the necessary requirements and if necessary warned. If they further do not follow the instructions, they will be taken to court. But the view of the FDI was that almost all of them follow their instructions. In the same district, when the FDI found that four pharmacies were operating without both a licence and a qualified pharmacist, all of the pharmacy owners stated that they were not aware of those requirements. Once they were given necessary instructions three of them closed down voluntarily.

In this way, AOs always attempt to avoid violators of regulations having to be brought before the courts. However, three such events were reported from Gampaha and Polonnaruwa. In the former, through court cases two pharmacies were closed down, and in the latter, one pharmacy was asked to close down without going to court. This pharmacy was allowed to sell the drugs in Schedule I but after a while it stared selling drugs belonging to Schedule II as well, thus it was closed down without the formal court procedure. The FDI accepted that there were at least 4 unlicensed pharmacies in the DDHS area of Polonnaruwa. He stated that he did not have any reason to close them down because so far no significant complaint had been made against them, but he accepted that this could be largely due to people's ignorance; they do not know whether they are given the correct drug.

Turning to the ways through which AOs conduct their investigations on drugs, the FDI of Polonnaruwa had a practice of getting samples from 10 drugs from each pharmacy every month in order to examine expiry dates, packing, registration etc. In the case of any fault being found, 20 drugs are then subjected to investigation. He stated that at one time he found one unregistered German drug from a pharmacy in Lankapura. Later it was decided to destroy the whole stock of that drug. He said that now he had another stock of expired drugs, which were seized from a pharmacy in Bakamuna, and when investigating a private clinic, an unregistered stock of drugs with a value of about Rs. 64,000 was found. He accepted that drugs were not properly dispensed at many pharmacies: workers do not use gloves; no polythene covers are used; and bottles are not properly closed. These observations are compatible with the field observations conducted by the research team at the pharmacies. But he mentioned that now there was an improvement in these practices due to his involvement in field visits. The Kandy FDI had similar experience; at some pharmacies there was no practice of closing bottles and he himself had done it when he was making visits to those pharmacies. He too stated that at some pharmacies, drug dispensers do not use a glove or even a spoon in dispensing drugs.

In the semi-urban area, maybe due to its close proximity to Colombo, more emphasis is placed on taking samples from dispensaries to send to the NDQAL for laboratory investigation. When a drug fails quality assurance tests two times, a circular is distributed throughout the district informing of the deregistration of that drug. Although Gampaha had a practice of purchasing samples, in Polonnaruwa, they were taken from the dispensaries without any payment due to lack of funds. Similarly Kandy FDI paid more emphasis on investigations such as expiry dates instead of sending samples for quality assurance. In this regard, the Kandy FDI stated that sometimes even though certain drugs were found to be unregistered, they were in good condition. In such situations the drugs were not seized unless an order had come from the national drug authority to seize them. One such example is vitamin-E capsules. According to some pharmacists as well as some officials of the MoH, some of these unregistered drugs come illegally from Middle Eastern countries. These drugs are relatively cheap. In the urban area, one pharmacist showed three types of crape bandages illegally brought from the Middle East. He said one Sri Lankan pharmacist, who was working in the Middle East, brought them when he was returning for a holiday. The price of the crape bandages was almost half the price of similar items in the market. Another dimension of this

issue is the selling of samples given by sales reps. Meanwhile pilferage of drugs from public health facilities also takes place but the extent of such transactions is not known. The Kandy FDI stated that a few years ago a stock of injections with a value of Rs.0.4 million was stolen from a public hospital and found in a pharmacy in Colombo. He further said that the storekeeper of one hospital in the Central Province was caught in the last year for stealing drugs with a value of about Rs. 50 million during a period of 10 years. Again, a pharmacist of a hospital in the Kandy district was found stealing drugs with a value of Rs.0.4 million and interdicted.

In light of these observations, it is clear that at the peripheral level the enforcement and monitoring of pharmaceutical regulations is largely undertaken by AOs in an informal manner. They are indeed very reluctant to go to the courts. When the regulatees are not listening to their instructions, justice is sought from the courts but only in the case of serious violations. In this context, the approach of AOs is to undertake their duties in a selective manner even though it was reported that they were making regular visits to pharmacies. One pharmacist in the urban area, who was running a very well organized pharmacy, stated that the FDI makes visits to his pharmacy very rarely because there is nothing to examine in his pharmacy. But later the study team found that he was also selling some illegal drugs and dressings. This practice was explained by one FDI in Gampaha saying that they had informally categorized the pharmacies into two sets, with more priority being given to the 2nd set, in which compliance is relatively low. As a final note it is worth mentioning that even though the AOs always attempt to carry out their tasks in an informal manner, all of them stated that hereafter pharmacy licences will be issued if, and only if, a qualified pharmacist is available.

4.2 Medical practice

4.2.1 Compliance of regulators

a. Central level

Just after the setting up of the IU in June 1998, it received a large number of complaints against medical officers. The recording system of the IU pays prime attention to the complaints for which in-depth investigations have been conducted. According to IU records, during the year 2001 it received 84 complaints. These complaints include a wide range of violations of regulations, including private practice (PP), medical negligence, scolding

patients, evasion of duties and frauds. Meanwhile, the DDG(FSI) stated that at the moment, the unit receives about 15 complaints in every month on PP. The IU maintains a collection of newspaper reports and articles on its press releases and interviews with the press. According to one news item on September 14, 1998 (*Lankadeepa* 1998), which was based on an interview with an IU officer, during the previous one and a half months 27 medical personnel[6] and 8 lab technicians were caught by the unit whilst they were engaged in PP during working hours, and the unit would be issuing charge sheets against them. In December in the same year, another press report (*Silumina* 1998) says that during the previous five months the IU had caught 38 medical personnel and 10 lab technicians whilst they were engaged in PP during working hours, and it had already sent the relevant files to the Public Service Commission to take action against them. In another press report in 2000 (*Daily News* 2000d), during the previous five months the IU had detected 96 medical personnel allegedly engaged in PP during normal working hours. The officer had told the press that eight such cases had been completed and those found guilty were punished: investigations into other cases were to be completed within two months. Further, another press report in 2001 (*Dinamina* 2001) says that 72 medical personnel were caught during the previous two years and 29 of them were punished: investigations on the rest were still ongoing. Even though the press releases and interviews of the IU do not seem to be consistent with each other, according to its latest progress report, during the five years of its operation it has initiated only 74 in-depth investigations relating to PP during working hours (Table 4.8). Of these, only two were conducted against practitioners in Colombo city or its suburbs (one against a Specialist and one a Medical Officer). All the others related to personnel from outstations.

[6] The term medical personnel includes Specialists, Medical officers, Medical Officers engaged in administrative/ management tasks, Dental Surgeons and Assistant/Registered Medical Officers.

Table 4.8: Designation of the medical personnel for whom investigations were conducted by location

Designation	LOCATION		Total	
	Colombo or suburbs	Outside Colombo	No.	%
Specialist	1	10	11	14.9
Medical Officer	1	13	14	18.9
DDHS/MOH		7	7	9.5
District Medical Officer (DMO)		12	12	16.2
Medical Officer In Charge		7	7	9.5
Judicial Medical Officer		1	1	1.4
Dental Surgeon		4	4	5.4
Registered Medical Officer		13	13	17.6
Assistant Medical Officer		5	5	6.8
Total	2	72	74	100.0

Source: IU, MoH.

Table 4.9: Type of hospital or institution to which the medical personnel belonged

Institution	No, of investigations	Percentage
Divisional health office*	7	9.5
Tertiary hospital	11	14.9
Rehabilitation hospital	1	1.4
Base hospital	7	9.5
General hospital	1	1.4
District hospital	25	33.8
Peripheral unit	7	9.5
Rural hospital	12	16.2
Central dispensary	2	2.7
School health	1	1.4
Total	**74**	**100.0**

*This refers to the office of DDHS.
Source: IU, MoH.

At outstations the majority of cases were reported from primary level medical institutions (64%). Does this necessarily mean that PP during working hours was substantially lower amongst medical personnel belonging to secondary and tertiary level hospitals? This is indeed an issue to be investigated. Firstly, these medical institutions are mostly located in large cities and therefore the service receivers may not get much opportunity to observe the behaviour of their medical personnel. However, in the case of primary level facilities, which are largely located in semi-urban and rural areas, service receivers and medical personnel are closer to each other. Secondly, some anecdotal evidence shows that even at some higher level hospitals, doctors belonging to outpatient departments (OPDs), in particular, have formed an informal rotating system, with the awareness of the medical officer in-charge, to get their duties undertaken by a limited number of doctors. This system allows the other doctors to do

either PP or to get involved in other activities during working hours, with less interruption to the patients and with less awareness of their absence by service receivers. Therefore, there seems to be unevenness or bias in the way the FS is conducting its surprise visits.

Table 4.10 shows the trend in the number of investigations conducted by IU on PP during working hours in its five years of operation. Almost 45% of the alleged offences relating to these investigations had taken place in 1998. From then onwards, a sharp decline in the number of investigations can be clearly observed. However, as was mentioned earlier, it is difficult to make a comparison between the number of complaints reported by IU to the press and the numbers presented in Table 4.10 because of the seeming irregularity in the recording system of the IU. When asked about this decline, the DDG(FSI) gave two explanations: firstly, most of the complaints did not give rise to in-depth investigations due to lack of evidence; secondly, at present most of the complaints are about medical negligence and officials have to give priority to these complaints. These performance figures, however, indicate that the enthusiasm existed amongst the officials of IU at its inception to undertake surprise visits, but since then investigations have gradually crumpled.

Table 4.10: The year in which the alleged offence occurred, for complaints investigated

Year	No of cases	%
1998	33	44.6
1999	14	18.9
2000	12	16.2
2001	3	4.1
2002	5	6.8
2003	2	2.7
Not available	5	6.8
Total	**74**	**100.0**

Source: IU, MoH.

Table 4.11: Outcome of the investigations of IU, 1998-2003

Outcome	No. of cases	Percentage
Proved	38	51.4
Accepted	5	6.8
Not guilty	8	10.8
Escaped or not available	4	5.4
Still going on	9	12.2
Referred to the Provincial Council	6	8.1
No details	4	5.4
Total	**74**	**100.0**

Source: IU, MoH.

The outcomes of the investigations conducted by the IU are given in Table 4.11. Whilst 51% of complaints were proved, in about 7% of cases, the accused had accepted their guilt. Amongst the medical personnel who were found guilty, the majority were DMOs (10) followed by Medical Officers (6) and Registered Medical Officers (5). When different categories of medical personnel are compared with respect to the percentage found guilty after investigation, the lowest amount is reported for Specialists (45%). For medical officers this number stands at 64%. In this regard, except for the one Judicial Medical Officer who was found guilty, the largest percentage is reported for DMOs (83%) followed by Dental Surgeons (75%). Although the percentages are relatively high for Registered Medical Officers (69%) and Assistant Medical Officers (60%), about one-third of their cases were referred to the respective Provincial Councils to take disciplinary action. Meanwhile, out of the nine cases for which investigations were not yet finished, three were reported in 2000, one in 2001 and three in 2002.

Medical personnel found guilty of violating regulations are punished mainly in two ways: deferment of one to three increments on the basis of the severity of the offence, and transferring to another hospital. In this way, 23% (10) were given the worst punishment of deferring three increments and a transfer (Table 4.12). This number is only 13.5% of the total number of investigations handled by IU. However, as the DDG(FSI) stated, the earlier practice was to interdict the medical officer when he/she was caught by the FS; this interdiction lasted until the investigations were completed. But this had led the accused to become engaged in PP at their official residence throughout the day, where they are required to stay in the case of an interdiction. Therefore, the recent policy of IU is to transfer the accused person to another hospital and to confirm the transfer once the allegation is proved.

Table 4.12: Punishments for medical personnel found guilty of private practice

Punishment	Found guilty	Accepted guilt	Total	%
Deferment of 3 increments and transferred	10		10	23.3
Deferment of 3 increments	2		2	4.7
Deferment of 2 increments and transferred	10	2	12	27.9
Deferment of 2 increments	1		1	2.3
Deferment of 1 increments and transferred	7	1	8	18.6
Deferment of 1 increment	2		2	4.7
Deduction of 1% from pension	1		1	2.3
Severely warned	1	1	2	4.7
Not yet decided	4	1	5	11.6
Total	**38**	**5**	**43**	**100.0**

Source: IU, MoH.

In the light of these observations on the performance of the IU during the past five years, the question arises as to whether the way it handled PP cases has indeed affected the behaviour of medical personnel. When the DDG(FSI) is saying that he still gets about 15 such cases in a month, it further raises doubts about the level of compliance of this regulatory body of the MoH.

b. Peripheral level

Under such circumstances, what is the response of the health management at the peripheral level to violations of regulations and service norms? In this regard, the DPDHS, Gampaha displayed a very passive attitude, saying "When there is a complaint, we normally do the necessary investigations." Meanwhile the Kandy DPDHS stated that when he is asked from Colombo to take action against quacks, he asks his FDI to do it because he is the only person at the district health office who is competent in legal procedures. During the recent past, five unregistered nursing homes in this area were given licences by asking them to make the necessary payment. One DDHS of Gampaha stated that when he receives a complaint about a quack, he first seeks clarification from the SLMC about whether this person is a registered practitioner. If not, he asks the assistance of the FDI to take action against such a person. But another DDHS of the same area expressed a very passive attitude towards taking action against medical malpractice: "I normally get into a problem of malpractice only when I receive a complaint through DPDHS or SLMC. Otherwise I don't like to get involved in queries about quacks. The reason is that thereafter no one is there to help me to face the repercussions. Why should I look into medical malpractice? It is a responsibility of the flying squad of the MoH."

While peripheral level health managers handle malpractice matters in a highly limited manner, they do not show such a reluctance to handle matters related to quacks. The MOH of Polonnaruwa mentioned his capturing of a quack in Lankapura, saying that the person had already been forwarded to the courts. The Kandy FDI explained why patients, particularly those in rural areas, prefer quacks: "They are very polite to patients and spend a lot of time per patient. They even make visits to the patient's house in the case of an emergency." He further stated that a set of quacks run medical centres for acupuncture in the district, displaying a certificate saying that they have followed a course of acupuncture at one tertiary level hospital: this course was conducted by a medical professor (he stated the name of the

professor). However, the health management is helpless in taking action against them because they always attempt to deceive officials as well as the general public by saying that they are involved in a social welfare service. In this regard the FDI further stated that for this "social service" these quacks are receiving some foreign assistance as well. Another incident was reported from Kandy where the quack was displaying a board on which MBBS-H was written in large letters in front of his name and in very tiny letters it was elaborated as Member of the Bio Medical Society – Homeopathy! He was caught but it was not possible to make any charge against him. The only possibility was to charge him for keeping drugs without a licence. Further, the fine for conducting a clinic without a licence is only Rs. 1000, which is indeed a meagre amount.

One DDHS of Gampaha, with the assistance of the FDI, had examined one Ayurvedic practitioner who had administered allopathic medicine to patients. Since this person accepted that he was not qualified, his clinic was closed down. Similarly, they examined another person who seemed to be a quack, but failed to take any action against him. It was reported from Polonnaruwa that during the period from 1997 to 2003, ten medical centres run by quacks were closed down, and in this regard the FDI had taken the initiative with the assistance of two MOHs. Two similar cases were reported from Kandy. Firstly, a person, who was working as the dispenser of a doctor, opened up his own dispensary after a few years and was caught. Secondly, in a similar manner, the pharmacist of a doctor's clinic had gradually he got himself familiar with prescriptions. He started his own clinic and treated patients in the evening after finishing his work as the pharmacist for the doctor. The doctor himself assisted the health authorities in his capture.

4.2.2 Compliance of regulatees

In undertaking FGDs an attempt was made to assess regulatees' awareness of regulations by asking whether they had read the small booklet produced by the SLMC titled "Instructions on serious professional misconduct" (SLMC 2000). Whilst almost half (49%) had not even seen it, 20% had seen the booklet but not read it. Only 31% had read it. Across the three study locations, the largest percentage of regulatees who had read the booklet was reported from the semi-urban location (43%), followed by the urban (33%) and the rural (17%). However, the largest percentage of respondents who had only seen the booklet was reported from the urban location (56%): this percentage was substantially lower in the other locations with 7%

for semi-urban and 8% for rural locations. This indicates that almost 75% of the regulatees in the rural location and 50% in the semi-urban location had not seen it.

Another important aspect examined at the FGDs was the regulatees' adherence to some standards of medical practice; firstly, the availability of a female assistant for those who were engaged in PP at their private clinics. It is an accepted norm or a self-regulatory measure that, at a private clinic, a male doctor should be supported by a female assistant. But only 46% of the private clinics had a female assistant; 82% of them were engaged in dispensing of drugs as well, with the doctor dispensing drugs at other clinics. Neither a dispenser nor an assistant was available at 14% of clinics, where the doctor played the role of the dispenser as well. Meanwhile, male assistants were available at 20% of clinics and they performed the duty of the dispenser as well, but nearly half of these clinics were conducted by female doctors. At another 13% of clinics, the wife of the doctor was the dispenser. The doctors who were engaged in PP at private hospitals (11%) were supported by the hospital staff and drugs were dispensed by the dispenser of the respective hospital. Across the three study locations, little variation was observed with respect to the employment of a female assistant and a dispenser. One exception was that utilization of the service of the wife or a male assistant was relatively high in rural and semi-urban locations. As mentioned in the previous section, however, almost all these practitioners had the minimum set of medical equipment consisting of a thermometer, stethoscope, sphygmomanometer and surgical instruments.

Table 4.13: Availability of an assistant and dispenser at private clinics

	Who dispensed drugs?					
Availability of an assistant	**Doctor**	**Female assistant**	**Male assistant**	**Wife**	**Hospital staff**	**Total**
No assistant	14.3 (100%)					14.3 (100%)
Female assistant	2.9 (6.25%)	37.1 (81.25%)		5.7 (12.5%)		45.7 (100%)
Male assistant	2.9 (12.5%)		20.0 (87.5%)			22.9 (100%)
Wife				5.7 (100%)		5.7 (100%)
Hospital staff					11.4 (100%)	11.4 (100%)
Total	20.0	40.0	16.7	13.3	10.0	100.0

Whilst private clinics of public doctors were found to maintain the minimum standards to some extent, except for poor compliance to employment of a female medical assistant, most

of the regulation violation incidents reported during field investigations were from public sector institutions. One middle-level non-medical officer at the Kandy DPDHS office revealed an incident at a hospital in a rural area, where patients were charged by the ambulance driver when they were transferred to the nearest tertiary level hospital; he made an allegation that the doctor in charge of this hospital was also involved in this practice. He further said that there was a notice in the ambulance asking patients to pay a specific amount to the driver. This practice was later detected by an audit quarry and the driver attempted suicide.

Some non-medical MoH employees raised another issue. At many secondary level hospitals, doctors have designed a method whereby they claim overtime for the total number of hours allocated for them, although work on overtime duties forms only a part of that time. It is difficult to detect such offences because of the lack of a proper recoding system.

Many more incidents of regulation violations were reported in field investigations. When one doctor in a rural area was engaged in PP at his official residence during an on-call period, he was informed by a nurse that a patient, who had got a pepper seed stuck in his nose, had came to the hospital; he asked her to send the patient to his residence. The patient was asked to pay Rs.300 for removing the seed. Later the patient made a complaint and the doctor was punished. One common observation, particularly in rural areas, was of engagement in PP whilst treating patients at the OPD. The doctor stops OPD work and attends the patient at his/her residence when he/she is informed that a patient is waiting there for treatment. Also, when a patient requests a medical certificate, some doctors have a practice of asking the patient to come to their official residence and charging the patient. Another complaint made by many respondents was that samples of blood, urine etc. of patients who attend the PP clinic are sent to the laboratory of the hospital, and the patient is charged. Further, when there is a small laboratory at the clinic of the doctor, the patient is asked to appear for unnecessary investigations. Finally, as was mentioned in the previous section, delay in doctors coming to the hospital after undertaking PP in the morning was found to be common at many semi-urban and rural hospitals. Obviously in such cases, all other employees of the hospital are waiting for the doctor, and it indeed delays and derails the OPD work of the hospital.

5. AN ASSESSMENT OF THE ACHIEVEMENT OF SOCIAL OUTCOMES AND IDENTIFICATION OF CONSTRAINTS IN THE ACHIEVEMENT OF THOSE OUTCOMES

5.1 Social outcomes

On the basis of the evidence presented in the previous two sections, an attempt will now be made to conduct the extremely difficult task of making a general assessment of the achievement of social outcomes, such as equity, efficiency, safety and quality, through the implementation of regulations on pharmaceuticals and medical practice. In the former case, the regulators play a passive role, with high reluctance to confront regulatees in the enforcement and monitoring of regulations. Almost half of the pharmacies were functioning without a qualified pharmacist. Some AOs attempted to justify their passive role by arguing that the social cost of having an unlicensed pharmacy in a remote area would be less than the social cost of its absence/closure. With the unavailability of a licensed pharmacy, these pharmacies perform an equity function, enabling the remote population to obtain necessary drugs within their vicinity - an achievement of the social objective of equity. They also serve the social objective of efficiency as well by reducing time and travel costs of the population. In this context, however, a question arises about safety and quality. These are indeed unanswered issues. It was revealed that even at the licensed pharmacies no prescription registers were properly maintained. Antibiotics and many other drugs, for which prescriptions are required, are easily available at many pharmacies. On one occasion, the investigators observed in the urban set-up the selling of an Indian version of Viagra (*sildenafil citrate*) without prescription. The pharmacist said that it was very popular and he obtained it from people who travel to India. The adherence to prescriptions is strictly maintained only at the outlets of Osusala, the pharmacies run by SPC. At a well-reputed supermarket in the urban area, it was observed that in the absence of the pharmacist, the pharmacy was run by a salesgirl, who used to serve at a normal sales counter when the pharmacist was on duty.

It is far more difficult to make any assessment of the achievement of social outcomes with respect to medical practice. It is true that almost all qualified allopathic medical practitioners maintain the minimum standards of treatment procedure when they are engaged in private practice. Further, it seems that responsiveness is rather high in private practice compared to public medical institutions. But, as was brought up in section 3, PP of public doctors is clearly moving away from ethical standards and tending towards being purely a business. As

the DDG(FSI) stated, due to stiff competition amongst, them some doctors are even making false (!) complaints to the IU about their rivals. Similar to the case of pharmaceuticals, the health management at the peripheral level is highly reluctant to take action against fellow doctors about regulation violations. Due to the existence of the IU, they easily evade their responsibilities, saying that it is the responsibility of the IU. In this context, the social cost of PP during working hours is indeed an area needing further investigation.

What about the cost of medical negligence at both public and private medical institutions? As mentioned in earlier sections, in the end, the cost of misdiagnosis could be death. While the health management at the periphery is distancing itself as much as possible from investigating medical malpractice, it was also found to have little control over quacks. According to official sources (PTF 1992), a large number of quacks are in operation, and they are functioning without any significant opposition from peripheral health authorities. The DPDHS Kandy stated that it was very difficult to catch them: when they make visits to such places, on most occasions, the quacks have already shifted to some other place. Since quacks have to pay only a tiny fine in the event that they are caught, the result is the restarting of the clinic at another location.

A respondent in the semi-urban area described another dimension of this issue. When he had a fever, he went to see a new doctor because his family doctor had closed her clinic on that day. This female doctor had all the necessary medical equipment of a western clinic. Since it was the first time he had visited her clinic, assuming that she was a public doctor, he asked her whether she was indeed in the public service. Her reply was that about 10 years ago she left the public service and started her own private clinic. He was given some allopathic medicine, which was very effective, and he recovered very soon. But after two days, he got a severe rash between his fingers. He made another visit to the doctor but before getting into the premises he happened to look at the name board. He saw she had only a local Ayurvedic degree, so he turned back and went to see his family doctor.

In another incident, a nurse belonging to a public hospital in Polonnaruwa was running a private laboratory in which patients were given x-ray reports. First the patient was put into a dark room and, a little later, informed that an x-ray was taken. Thereafter the patient was given an x-ray film of a similar anatomy taken at the hospital. Later it was found that he had stolen discarded films from the hospital. He was caught but the health authorities were unable

to prove the charges. Similarly, in an urban location, a child belonging to an upper-middle-class family fainted whilst he was playing. He was taken to a leading private hospital and was examined by a specialist, who then asked the patient some questions. His first question was "what is your father?" His decision was that the child had developed a heart ailment and he would have to have treatment for his whole life. This specialist was a cardiologist. The parents became highly disturbed and took the child to a leading Indian hospital. He recovered within a few days and the doctors of the Indian hospital challenged the decision of the Sri Lankan doctor. The child did not have any heart ailment and the reason for his sickness was reduction of the glucose level in the blood whilst he was playing. In light of such events, how can one make an assessment of the achievement of social outcomes of medical practice regulations? Helpless patients have to seek justice through the media.

5.2 Constraints on pharmaceutical regulations

5.2.1 Organizational constraints

The organizational constraints, which hinder the enforcement and monitoring of CDD, are detailed below.

Human resources

In this regard the only exception is Gampaha, in which one of the three FDIs had been assigned to five DDHS divisions. The DDHS of Gampaha also stated that they had sufficient staff for this task. However, only one FDI was available in each of the other two study locations. In Kandy in particular, this shortage was severe, with one FDI assigned to 107 pharmacies in the whole district. Sometimes the Kandy FDI has to look after the work of another district in the province, Nuwara Eliya, as well. Further he has to support the FDI of the adjoining district of Kurunegala in the North Western Province. He said: "How can one do all this work. Our area alone is 1906 square km with 107 pharmacies." The extent of Polonnaruwa district is about 3000 km^2 and one FDI has to cover the whole area, although the number of pharmacies is relatively very low.

Travelling facilities

From about a year ago, FDIs' engagement in their duties was restricted due to the imposition of a restriction on travelling expenditure. Now they can make travelling claims for only Rs. 1,900: previously it was Rs. 2,700. In this regard the FDI of Polonnaruwa stated "No sufficient allocations for travelling have been given since 2001 so we don't attend the

meetings held in Colombo and therefore we are not in a position to send samples to Colombo either." The Kandy FDI raised the issue of poor transport facilities, and stated that due to lack of such facilities, on some occasions, he had to make requests from the courts to postpone some cases. No separate vehicle is allocated for the activities of AOs and even in an emergency they have to take a vehicle from the pool of vehicles. This normally takes a considerable time and sometimes is not possible if they are being used for other activities. The Polonnaruwa FDI elaborated on this issue, saying that he has to travel with other people in the same vehicle, but as they are travelling for other matters, this involves a more circuitous route: "This has happened even when I was going to the courts. It takes a long time to reach where I want to go. This is also one reason for our hesitation for filing court cases against regulation violators."

No incentives for other employees who assist the FDI

The Kandy FDI raised this issue, pointing out that when he needs to get some other employee to help him in a court case, they are not paid any subsistence allowance. Therefore it is difficult to provide sufficient evidence in court cases. This restriction applies to labourers, clerks etc., although they are willing to help FDIs in conducting investigations. However, according to one FDI of Gampaha, a method had been developed in his division to pay subsistence to clerks and drivers for "spying" on suspected pharmacies.

Legal restrictions

Many FDIs raised the issue of the impossibility of getting assistance from PHIs in court cases. Although they have not yet been given legal authority, PHIs can play a vital role in the enforcement of CDD. The Kandy FDI raised another dimension of legal restrictions: "We don't have powers to stop the selling of Ayurvedic drugs which are mixed with some western drugs. For instance we know that prednisolone is mixed with *Arishta* (one way of preparing Ayurvedic drugs) by some Ayurvedic doctors…. The investigation should be done by the Police Narcotics Bureau."

Unnecessary delays by regulatees

In court cases, the pharmacy owners have a practice of not appearing before the courts, by instead producing medical certificates, which leads to delays in getting a court decision. The Kandy FDI brought up one such incident where a case was filed against a pharmacy but it was not closed down. Although the incident happened in January, the courts took it up in

November. The pharmacy owner caused delays by providing medical certificates while he continued his business.

Lack of team approach

The general view of AOs is that investigations must be done by a team. One of them stated that, "Now it is only myself making visits; it is not a challenge for them. So we are compelled to give them just advice rather than taking action against them. Who cares when one person is going with a file to make a visit to a pharmacy?" The team approach has another dimension in that when the FDI makes a visit to a pharmacy with another employee, he can run the case more effectively with the evidence of that employee. In Kandy at least, this situation has become worse due to the non-paying of any allowance to other employees when they go to court to give evidence.

Delays at the centre

Delays always occur in getting reports from NDQAL. Until the report is received, the suspected drug is sold on the market. The Kandy FDI was very concerned about this delay and stated that it normally takes about six months to get a report from NDQAL. Last year he had sent samples of eight *eau de colognes* but so far he had received the report of only one of them. Further, it takes a long time to get orders from NDQAL to prohibit some drugs and by the time the order comes a large quantity of the drug has already been sold.

Financial constraints

Several aspects of financial constraints were raised by AOs. The Polonnaruwa FDI stated: "How do we get samples without sufficient financial allocations? We get a limited number of samples free of charge from the pharmacies. In that way we get only about 100 even though it should be 300." Gampaha is an exception, where FDIs are reimbursed for what they have paid for purchasing samples. Further, FDIs have no allocation for telephone charges. The Kandy FDI stated that he made calls using his own money. His Polonnaruwa counterpart brought up the limitation imposed on telephone bills, at Rs. 1,500 per month per official telephone. This had restricted all his activities, including getting legal advice for court cases.

Lack of supportive facilities

The available storage facilities were insufficient to store the seized items. The Kandy FDI said that for this reason he had adopted a practice of taking them home and then bringing

them to the court. Further he said there was not even a labourer available to help him to get seized items to the office, which is located on the fourth floor of the district health office. So he himself has to take them up.

Other issues

It is extremely difficult to control the pilferage of drugs from public facilities. According to the views of AOs, some dispensers often issue a lesser number of drugs than that prescribed by the doctor and sell the rest to private pharmacies. But AOs do not have any means of controlling such activities, though they are aware of them by experience. Another issue raised by the FDI of Polonnaruwa was the unavailability of quarters for him. This had indeed limited his work and he was unable to pay any attention to pharmacies during weekends: according to him unregistered drug dealers distribute their drugs during weekends.

As a final note on organizational constraints two issues need to be mentioned. Firstly, as mentioned in an earlier section, MOHs are not very familiar with legal procedures; this was raised by almost all MOHs interviewed. Therefore, all legal matters, including those are related to medical malpractice, are passed on to FDIs, but they are indeed not empowered to take independent decisions. Although they are engaged in all practical work related to enforcement and monitoring of CDD, decisions are taken by district and central level authorities. Secondly, AOs lack supporting staff and facilities. This situation indeed raises an issue of lack of capacity of the field level authorized offers in carrying out their tasks.

5.2.2 Social and cultural constraints

Enforcement and monitoring of CDD are also hindered by social and cultural factors. Firstly, not only FDIs, but also other AOs are reluctant to examine what is happening at pharmacies run by public doctors' private clinics, but for different reasons. Whilst AOs with a medical background are reluctant to go against their fellows, FDIs are indeed unable to examine the activities of a medical officer who, on the one hand, holds a position above them and, on the other hand, has high social recognition. Therefore, unless a serious complaint is made by a patient, these pharmacies are not investigated and no such incident was reported during field investigations. Meanwhile, it is very rare for AOs to be threatened whilst they are making visits. This may be partly due to the fact that, unlike other business outlets, the majority of pharmacies, irrespective of their legal status, are owned by relatively more educated people.

Secondly, it should be mentioned that political interference in granting registration for pharmacies was found to be extremely low.

5.3 Constraints on medical practice regulations

5.3.1 Organizational constraints

The organizational constraints that hinder enforcement and monitoring of medical practice regulations are as follows:

Limited role of the regulators at national level

The main regulatory body of the profession, the SLMC, plays a highly limited role both in monitoring and in regulating practitioners. It is still very much concerned with the registration of practitioners rather than being directly involved in halting the deterioration in the behaviour of medical practitioners, although it has taken some steps in the past to make them aware of professional conduct.

Lack of legislative power at central level to regulate the private sector

As was mentioned in section 2, the MoH has been attempting for about a decade to bring the private sector into a regulatory mechanism by the introduction of the Private Medical Institutions Act. Its enactment has been hindered by certain social and political factors, but lack of organizational capacity at the MoH level could also be considered a prime reason for the delay.

Lack of capacity of the IU

Even though the IU, at its inception, was highly involved in controlling public doctors who were violating regulations, its activities have undergone a deceleration and redirection during recent years. Although one reason for this poor development is lack of sufficient manpower in the unit, as stated by its DDG, its officials appear to be insufficiently motivated for the attainment of its goals.

Lack of attitude amongst peripheral level regulators

Regional level health management is not very keen on taking the initiative to look into violations of medical practice regulations. With their other involvements and the existence of a national body, IU, to look into such matters, they try to fulfil just the minimum requirements.

Lack of legislative power for peripheral level regulators

The regional level health authorities are not armed with the necessary powers to investigate the practice of medical practitioners other than those who are engaged in allopathic medicine. The only possibility is to investigate whether they have a stock of allopathic medicine, and charges can then only be made for violating a CDD regulation. Many such cases were reported, and even in the case of a practitioner displaying his degree qualifications as MBBS-H (the homeopathic practitioner), a case was filed only for keeping drugs without a licence. There is no legal provision to ban the practitioner from practicing. Within this context, the MOH of Gampaha expressed his views: "I don't take actions against Ayurvedic practitioners. When there is a complaint, I forward it to the Ayurvedic Commissioner." He explained the fruitlessness of making an inquiry and going to the courts in the case of using pednisolone as a mixture in Ayurvedic drugs.

Lack of organizational/management capacity

Health management is still lacking the necessary organizational and management capacity to handle matters related to violation of regulations. In Kandy, the DPDHS indicated that it was futile to make an attempt to catch a quack. When he makes a visit, the quack has already changed his place of practice, because somehow he/she got to know about his visit. He said: "So I am helpless and since we don't have any other details we can't go beyond that." At a hospital in the semi-urban area, a patient pointed out that although the DMO was very polite, he did not have a personality suited to manage his staff. This statement refers to the PP of his doctors during working hours. It was observed that health managers still have not adequately moved into creative organizational and management practices and this has hampered the enforcement of their powers.

5.3.2 Social and cultural constraints

Unlike pharmaceuticals, enforcement and monitoring of regulations on medical practice is highly influenced by social, cultural as well as political factors. One highly appropriate example is the more than one decade long delay in the enactment of the Private Medical Institutions Act; a delay attributable not only to the poor organizational capacity of the MoH, but also to the many lobbying groups who played a critical role in revising the Act. The interferences of social and political factors are so high that it is not only malpractice but also illegal practices that are being undertaken without any obstacle. Abortion centres are a good

example: it was observed in an urban area that a private medical centre was engaged primarily in this activity. Within the medical profession, the social recognition acquired by the profession through its predecessors, until the opening up of the economy about two decades ago, is still acting as a protective factor for those violating regulations. As mentioned earlier, for instance, this has indeed made non-medical regulatory officers, such as FDIs and DPs, avoid inquiring into the private pharmacies of public doctors even though they have such powers. Patients too are reluctant to take steps against the malpractice of doctors who run clinics close to the patients' places of residence. These social constraints, however, are now gradually lessening, particularly with the acceleration of a) medical negligence in the recent past, and b) awareness of the general public about such allegations in the media.

6. POLICY OPTIONS

On the basis of the findings of this study, the following policy options and measures are suggested for the consideration of the policy makers of the MoH:

6.1 Pharmaceuticals

- The cadre provision of FDIs needs to be revised taking into account the land area, population and number of pharmacies in each district. An alternative to this suggestion is to take a policy decision to grant AO status to PHIs: according to the CDD, although they are enacted as AOs, so far they have not been given that status by a gazette notification. In introducing such a measure, however, PHIs need to be given an additional payment for their involvement in activities related to the CDD.

- Field investigations of FDIs are highly limited due to the reduction of their travelling payments in a governmental decision covering the whole public sector. Granting AO status to PHIs could be a solution to the limitation of travelling payments, as the activities could be divided among FDIs and PHIs, thus reducing the investigations conducted by the former.

- The provincial council authorities need to take a policy decision to pay a subsistence allowance to employees other than FDIs for their participation in either field activities or court cases.

- A performance-based payment system needs to be introduced for AOs. The absence of such a system was found to be a major reason for delays in handling cases and investigations against regulation violators.

- A team approach could be introduced to field investigations once PHIs are given AO status. In this way, the isolation of FDIs in making field visits could be avoided and such activities could be undertaken in a more effective manner.

- It is essential to take a policy decision at the provincial level to incorporate a consumer awareness programme into the district health programme, with a view to

making consumers aware of pharmaceutical regulations. As was attempted in Polonnaruwa district, such a programme could be extended to schools as well.

- It is essential to strengthen the capacity of NDQAL with more skilled manpower and laboratory facilities for undertaking lab investigations, in order to avoid delays in peripheral AOs getting the results of the samples that they send to it. In this way, immediate steps could be taken to withdraw drugs that fail in such investigations.

- To encourage the collection of random samples by AOs, provincial authorities need to take a decision to reimburse the payments made by AOs for purchasing samples, as is done in Gampaha district.

- The limitation imposed on the utilization of telephones by FDIs is the result of a government policy which applies to all government officials. However, the introduction of a performance-based payment system could help to resolve this matter to a certain extent, because under such a system the FDIs may find their own ways to have such facilities but in an accountable manner.

- The FDIs need to be provided with sufficient storage facilities with security to protect their seized items.

- It is essential to introduce a drug register at each pharmacy, particularly for early identification of expired drugs, and AOs can make it part of their investigations to check the maintenance of these registers during their field visits.

- It is essential that AOs other than FDIs are given training on legal procedures, through which the enforcement and monitoring of the CDD could be made more effective and efficient by reducing the current burden on FDIs.

- Finally, national level authorities, with external assistance, need to take measures to change the organizational culture of the peripheral health management (at present based largely on a hierarchical system), with a view to making them implement the CDD as one of their priorities and hence to move them towards developing and implementing a new teamwork approach.

6.2 Medical practice

- The approach of the SLMC in implementing regulations on medical practice needs to be assessed by itself, with a view to making it play a more active role in this endeavour. Instead of depending only on complaints, it could launch an awareness programme amongst the general public as well as practitioners about its role and functions with respect to the regulation of medical practice.

- The IU needs to be strengthened by the employment of more investigation officers.

- A performance-based payment system, in a form to motivate the investigation officers of the IU, needs to be introduced. Along with the introduction of such a system, all the officers of the IU need to be retained. The introduction of an in-service training programme with the assistance of an external agency could serve for this purpose.

- It is essential to take steps to change the passive approach of peripheral health management, including heads of medical institutions, towards regulating medical practice. Such an attempt needs to be incorporated within an in-service training programme which focuses on how to utilize their powers in regulating medical practice. Training programmes are further required to improve the peripheral health management's managerial skills, as well as their knowledge of legal procedures.

- With the initiation of the MoH, a document needs to be prepared which lists the offences made by public medical officers and the punishments for each type of offence. Doctors and the general public need to be made aware of this information, and especially for the latter, about the means through which complaints can be made.

- At the policy-making level, the MoH needs to examine the existing powers of the IU and take the necessary steps, with the concurrence of the government, to provide more authority to it in handling cases, with a view to expediting their outcomes.

- Finally, since the general public is now moving towards remonstrating against medical negligence, the IU needs to be reconstructed to look into such complaints in

an effective manner. Further, for the avoidance of making void complaints, a system has to be designed to assist the complainers at the initial stage to make an assessment of their complaints before forwarding them for further investigations, for which the media also could play a vital role.

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APPENDIX

Table A4.1 Basic features of the pharmacies by study location

Basic feature	Urban		Semi-urban		Rural		Total	
	No.	%	No.	%	No.	%	No.	%
Design								
Excellent		0.0	4	21.1		0.0	4	9.5
Very good	1	8.3	2	10.5	1	9.1	4	9.5
Good	9	75.0	4	21.1	5	45.5	18	42.9
Average	2	16.7	9	47.4	4	36.4	15	35.7
Weak		0.0		0.0	1	9.1	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Construction								
Excellent		0.0	2	10.5		0.0	2	4.8
Very good	1	8.3	5	26.3	2	18.2	8	19.0
Good	10	83.3	10	52.6	6	54.5	26	61.9
Average	1	8.3	2	10.5	2	18.2	5	11.9
Weak		0.0		0.0	1	9.1	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Location								
Excellent		0.0		0.0		0.0		
Very good		0.0	1	5.3		0.0	1	2.4
Good	10	83.3	13	68.4	6	54.5	29	69.0
Average	2	16.7	4	21.1	4	36.4	10	23.8
Weak		0.0	1	5.3	1	9.1	2	4.8
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Pest control								
Excellent		0.0		0.0		0.0		0.0
Very good		0.0		0.0		0.0	0	0.0
Good	4	33.3	3	15.8	5	45.5	12	28.6
Average	7	58.3	15	78.9	4	36.4	26	61.9
Weak	1	8.3	1	5.3	2	18.2	4	9.5
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Adequacy of space								
Excellent		0.0	3	15.8		0.0	3	7.1
Very good		0.0	2	10.5	2	18.2	4	9.5
Good	10	83.3	8	42.1	6	54.5	24	57.1
Average	2	16.7	5	26.3	3	27.3	10	23.8
Weak		0.0	1	5.3		0.0	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**

Table A4.2 Storage facilities, maintenance and hygienic conditions by study location

Condition	Urban		Semi-urban		Rural		Total	
	No.	%	No.	%	No.	%	No.	%
Availability of proper storage facilities								
Very good	0	0.0	4	21.1		0.0	4	9.5
Good	10	83.3	6	31.6	6	54.5	22	52.4
Average	2	16.7	9	47.4	5	45.5	16	38.1
Weak		0.0		0.0		0.0	0	0.0
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Maintenance								
Very good		0.0	1	5.3	2	18.2	3	7.1
Good	7	58.3	12	63.2	5	45.5	24	57.1
Average	4	33.3	6	31.6	3	27.3	13	31.0
Weak	1	8.3		0.0	1	9.1	2	4.8
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Hygienic condition of containers etc								
Very good		0.0	2	10.5	2	18.2	4	9.5
Good	11	91.7	15	78.9	4	36.4	30	71.4
Average	1	8.3	2	10.5	4	36.4	7	16.7
Weak		0.0		0.0	1	9.1	1	2.4
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Hygienic condition of premises								
Very good		0.0	3	15.8	1	9.1	4	9.5
Good	9	75.0	10	52.6	5	45.5	24	57.1
Average	2	16.7	6	31.6	4	36.4	12	28.6
Weak	1	8.3		0.0	1	9.1	2	4.8
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**
Hygienic condition of personnel								
Very good		0.0		0.0	4	36.4	4	9.5
Good	11	91.7	18	94.7	5	45.5	34	81.0
Average	1	8.3	1	5.3	2	18.2	4	9.5
Weak		0.0		0.0		0.0	0	0.0
Total	**12**	**100.0**	**19**	**100.0**	**11**	**100.0**	**42**	**100.0**