

**A country level report on the pharmaceutical sector in India  
Part One: Institutions involved in pharmaceutical regulation**

**A report commissioned by DFID, UK**

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## List of abbreviations

ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical
AYUSH	Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy
CAM	Complementary and Alternative Medicine
DCGI	Drug Controller General of India
DFID	Department for International Development
DMF	Drug Master File
DPCO	Drug Prices Control Order
DSPRUD	Delhi Society for Promotion of Rational Use of Drugs
EC	European Commission
EDL	Essential Drugs List
EMA	European Medicines Agency
FDA	Food and Drug Administration (US)
GMP	Good manufacturing practice

ICRC	International Committee of the Red Cross
IDMA	Indian Drug Manufacturers' Association
ILO	International Labour Organization
IMS	Intercontinental Medical Statistics
IPA	Indian Pharmaceutical Alliance
IPR	Intellectual property rights
IRDA	Insurance Regulatory and Development Authority
MeTA	Medicines Transparency Alliance
MNC	Multinational companies
MOHFW	Ministry of Health and Family Welfare
MRP	Maximum retail price
MSF	Médecins Sans Frontières
NEML	National Essential Medicines List
NHA	National Health Accounts
NIPER	National Institute of Pharmaceutical Education and Research
NMP	National Medicines Policy
NPPA	National Pharmaceutical Pricing Authority
OOP	Out-of-pocket
OPPI	Organisation of Pharmaceutical Producers of India
OTC	Over-the-counter
PHC	Public health centre
R&D	Research and Development
TRIPS	Trade related aspects of intellectual property rights
WB	World Bank
WHO	World Health Organization
TB	Tuberculosis
TNMSC	Tamil Nadu Medical Services Corporation
UNICEF	United Nations Children's Fund
UNOPS	United Nations Office for Project Services
US	United States of America

## Glossary of Terms

**Pharmaceuticals, medicines, drugs:** are used interchangeably to refer to a legal chemical substance used in the treatment of a condition or disease.

**Follow-on, or generic:** is chemically identical to a brand-name drug and should meet the same standards for safety, purity and efficacy.

## **Acknowledgements**

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## **EXECUTIVE SUMMARY**

As part of the Medicines Transparency Alliance (MeTA) initiative, the Department for International Development (DFID) commissioned a country level report on the pharmaceutical sector in India. This report is a summary of part one of the project. In part one, the project's purpose was to collect information on the regulatory environment, key institutions, legislation, licensing of pharmaceuticals, pricing policy and financing of pharmaceuticals.

The second part will take the discussion further on medicines, financial flows and cover the how the pharmaceutical market operates. Issues covered will involve information on the pharmaceutical industry such as consumption trends and price trends, the pharmaceutical supply chain (wholesalers, and retail pharmacies), policies on delivery mechanisms that influence providers at primary care to prescribe cost effective medicines, and the patient's ability to purchase medicines. Please see section 10.

Please see Annexe A for the terms of reference. A summary of this report's findings are presented below.

### **Overview of the Indian health system**

In India, health system delivery is a shared responsibility between the central, state and local governments, according to the Indian constitution (Peters 2002). Today, India has twenty-eight states and seven union territories. Delivery is effectively a state responsibility but decentralisation of state authority varies by state. State and local governments account for about 75% of public spending on health, but states vary widely in their budgets (Peters 2002). Total public spending, however, only accounts for one fifth of total health expenditure, which implies that private expenditure accounts for most of total health expenditure. Households account for the largest proportion of private expenditure and accounted for 72% of total health expenditure (WHO 2005). India's health care delivery system is divided into four levels of care: rural health centres, district hospitals, tertiary care hospitals and teaching hospitals (Roy Chaudhury, Parameswar et al. 2005).

Regulation of pharmaceuticals in India is found in the India Drugs and Cosmetics Act (1940) (WHO 2004). The main regulatory authorities involved in regulation are the Drug Controller General of India (DCGI) which falls under the Ministry of Health and Family Welfare (MOHFW); and the Department of Chemicals and Petrochemicals which falls under the Ministry of Chemicals and Fertilizers.

The DCGI is responsible for licensing and standards. There is a division of authority between the central drug controller and the state level drug controllers. The central authorities are responsible for approval of new drugs, provision of standards, quality control over imported drugs, and coordination of activities of state drug authorities. States, on the other hand, have their own system of licensure for the manufacture, sale, and distribution of approved drugs and are responsible for the approved drug's quality.

Within the Department of Chemicals and Petrochemicals, the National Pharmaceutical Pricing Authority (NPPA) is responsible for medicine pricing. The NPPA is responsible for price control of selected Active Pharmaceutical Ingredients (APIs) and formulations, monitoring drug prices, collecting price relevant data and studies in respect of pricing of drugs, and providing advice to government on drug policy and pricing (NPPA 2008).

The NPPA currently fixes the prices of 74 drugs listed in the Drugs Prices Control Order (DPCO) using a standard formula using cost information. These drugs account for 20% of the market by

value. There are no official guidelines for setting the prices of medicines not under price control (also known as non scheduled medicines). Prices of these drugs are monitored and prices increases of more than 10% are subject to government action.

The main issues arising from the current regulatory environment can be grouped into the following themes.

### **Division in pharmaceutical regulation**

Under the current arrangement, the main aspects of pharmaceutical regulation are divided between two ministries: the MOHFW (including the DCGI) and the Ministry of Chemicals and Fertilizers. The MOHFW's policy objective is to consider pharmaceutical issues within the context of health policy while the Ministry of Chemicals and Fertilizers focuses more on industrial policy. There are concerns that this division leads to problems in coordination between ministries.

### **Process for drug approval**

The bureaucratic process for drug approval requires different departments in addition to the DCGI depending on whether the application is for a biological drug or one that uses recombinant DNA technology. More coordination between departments is needed and the process should be more transparent. For instance, stakeholders would prefer that rejected decisions are justified in an open manner with the applicant.

### **Different levels of quality**

Meetings with stakeholders confirmed findings in the literature that quality control needs to be strengthened (World Bank 2002; WHO 2004). The issue of quality control suggests that there are different standards of quality. Exported drugs are of a higher quality to meet the importing country's standards (e.g. FDA approval or EMEA approval). In practice, a small to medium sized company can receive a license to manufacture without having to meet the required quality standards, which exacerbates the problem of counterfeit medicines in the Indian market. The World Health Organization (WHO) estimated that the range of counterfeit medicines was from 0.3% to 3% (Sheth, Reddy et al. 2007).

### **Drug procurement**

The central and state governments are responsible for drug procurement in public facilities where medicines are (for most states) free of charge. Studies have shown that procurement prices are low by international standards (WHO, 2006). In the current arrangement, lax procurement procedures may encourage the procurement of low quality medicines. This is because in practice not all manufacturers that receive licenses meet quality standards. This implies that even if procurement prices are low, patients in public facilities may be dispensed medicines of low quality. Procurement processes need to be strengthened.

### **Market environment**

Between the 1970s and 2005, the Indian pharmaceutical market was under a process patent regime, which fuelled the growth of the generics market. The Indian drug market is primarily dominated by branded generics. For any given generic product, there will be many competitors. Since January 1, 2005, however, India accepts products patents. Stakeholders suggest that the future prospects of the Indian patent system will encourage research and development (R&D) led by Indian companies and it will stimulate the creation of a pharmaceutical market that will have a bigger component of

innovation than only generic products.

### **Prices of medicines**

In the government's 2008 budget, excise duty on imported drugs was reduced from 16% to 8% in an effort to reduce the final retail price of a medicine. In practice, the net drop may be about 4% to 5% (see section 5). Drugs under price control have margins that are regulated for wholesalers (8%) and retailers (16%) but this only covers 20% of the market. Studies suggest that margins are likely higher (WHO 2006). The majority of drugs, however, are not under price control and their margins are not regulated. This implies that prices at the retail level have high mark ups, which raises implications for patient access to medicines.

### **Policy reform underway**

Some policies are under reform or being reviewed:

- **Increasing health insurance coverage:** The government has proposed to increase its insurance coverage for those who work in the unorganized sector of the market. This scheme will involve 75% central funding and 25% state funding. The plan is to roll out this programme over a five-year period.
- **Quality control:** A proposal to create a drug authority similar to the FDA in the United States (US) is in front of a parliamentary committee. This proposal is a welcome step to improve quality control but it remains to be seen how effective this institution will be.
- **Government support to the industry:** The government has proposed a number of initiatives to increase its financial support to the pharmaceutical industry. Some measures include encouraging grants to target neglected disease areas, tax rebates on R&D activities and loans to encourage collaboration with government research facilities.
- **Price control:** There is a proposal to change the basket of medicines under price review to better identify essential medicines that should be under price control. The proposal aims to increase the number of drugs under price control.

## 1. INTRODUCTION

The Medicines Transparency Alliance (MeTA) at the Department of International Development (DFID) is an initiative to increase access to high quality medicines in developing countries. Its work will involve a number of activities including stakeholder engagement, scoping exercises, analysis of regulatory frameworks on national drug policies and public reports on pharmaceutical policy.

As part of the MeTA initiative, DFID commissioned a country level report of federal pharmaceutical regulation in India. This report is a summary of part one of the project. In part one, the project's purpose was to collect information on the regulatory environment, key institutions, legislation, licensing of pharmaceuticals, pricing policy and government financing of pharmaceuticals. The second part will involve collecting information on supply chain issues, distributions, the role of doctors and pharmacists to provide medicines to patients (please see section 10). Please see Annexe A for the terms of reference.

For this report, the commissioned work required collecting information from the literature, relevant and available statistics and an on-site visit to India to meet with stakeholders. The on-site visit was carried out from March 10<sup>th</sup> to March 14<sup>th</sup>, 2008 and involved meeting government officials, industry, academic researchers, international donors and civil society representatives. Please refer to Annexe B for a complete list.

This report will cover issues concerning pharmaceutical regulation at the federal level. The report covers these issues as follows:

**Section 2** puts the Indian health system in context of the report and provides an overview of the pharmaceutical system of regulation.

**Section 3** describes the system of pharmaceutical expenditure, and sources of funding including insurance schemes for patients.

Next, **Section 4** turns to regulation concerning licensing of medicines and discusses implications of the current system of quality control and its weaknesses.

**Section 5** discusses the government approach to setting prices of medicines and government policies that affect the final retail price such as taxes and import duties.

**Section 6** turns to the pharmaceutical industry, the market environment, and the challenges it faces.

**Section 7** carries this discussion further and describes government industrial policy and intellectual property rights (IPR) issues to further stimulate growth in the industry.

**Section 8** illustrates the regulatory issues raised in the earlier sections and provides case studies of pharmaceutical regulation at the state level.

**Section 9** provides a discussion and summary of this report before turning to **Section 10**, which outlines issues that will be discussed and explored in part two.

## 2. OVERVIEW OF THE PHARMACEUTICAL SYSTEM IN INDIA

2.1. This chapter provides a brief introduction on the Indian health system of organisation and delivery. This section notes that the system is dominated by private sector provision which raises implications for regulation. The second part provides an overview of the pharmaceutical system of regulation and the key authorities involved before expanding these issues in the subsequent sections.

### Health system organisation

- 2.2. It is estimated that 1.3 billion people in low-income countries account for about 80% of all people who lack access to medicines (WHO 2004). The World Health Organization (WHO) estimated that 50 to 65% of the population in India lacks access (499-649 million people). Low access also correlates with problems in health system performance (e.g. health outcome, disability adjusted life expectancy).
- 2.3. Today, India has a population of just over 1 billion spread over twenty eight states and seven union territories. Under the Indian constitution, health system delivery is a shared responsibility between the central, state and local government (Peters 2002). Public health is delivered by the states but decentralisation of state authority varies by state. The central government delivers national programmes that target certain disease areas such as tuberculosis (TB), malaria, HIV/AIDS. India's health care delivery system is divided into four levels of care: rural health centers, district hospitals, tertiary care hospitals and teaching hospitals (Roy Chaudhury, Parameswar et al. 2005).
- 2.4. Health expenditure in India was about 4.6% of GDP in 2001-02, or Rs. 1,057,341 million, which is higher than most low-income countries (Roy and Howard 2007). Public health spending, however, is lower than other developing countries at 1.1% of GDP but the government has made a commitment to increase funds in health care delivery (Deolalikar, Jamison et al. 2007). Public expenditure financed from taxation accounts for 20% of total health expenditure, while private expenditure accounts for 77% of total health expenditure (WHO 2005). A disproportionate share falls on households: they account for 72% of total health expenditure.
- 2.5. India has public and private provision in health system delivery. In both sectors, the main area of expenditure is on curative services (74%), with the remaining spent on other services (e.g. family planning and maternal care) (WHO 2005). The public system has been characterised as needing more financial resources, not large enough to meet the health needs of the country, and requires stronger management (Peters 2002).
- 2.6. In the private sector, provision ranges in primary care and secondary care from solo practices and small inpatient facilities to large corporate hospitals and includes ancillary services (e.g. diagnostic centers, ambulance services and pharmacies). The private sector provides western medicine treatment (allopathic), which is the dominant form of provision, as well Complementary and Alternative Medicine (CAM) such as Auyurvedic and Unani.<sup>2</sup> Reliable estimates on the number of CAM practitioners are not available, however, CAM is believed to be widely practiced among patients (Kumar, Bajaj et al. 2006).
- 2.7. The private sector is growing quickly but is undirected and unregulated (Peters 2002). In 1947, the private sector was less than 10% in size; more recent estimates between 1981-1998

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<sup>2</sup> There are six systems of Indian medicine: Auyurvedic, Siddha, Yoga, Unani, Homeopathy, and Nature Cure (AYUSH, 2007).

suggest it is the dominant source of provision: the majority of doctors (80-85%), hospitals (93%) and the percentage of beds (63%) were found in the private sector (Peters 2002). Data on health care providers indicate that 70% of all funds flow to health care providers in the private sector while 23% was spent on public providers (WHO 2005).<sup>3</sup>

- 2.8. Compared with other low-income countries, the per capita number of health professionals (per 1,000) is low which will affect access. Physicians per capita, however, is about average (1.0) whereas the ratios for nurses (0.9), midwives (0.2) and hospital beds (0.7) are below average as shown in Table 2.0 below. Similarly, the data suggest that inpatient utilisation in the public and private sectors combined is lower than in low-income countries but outpatient is close to the average.<sup>4</sup>

**Table 2.0: International figures on health care work force, and health service utilisation, 1990-1998**

Country	Physicians	Nurses	Midwives	Hospital Beds	Inpatient	Outpatient
Public sector	0.2	-	0.2	0.4	0.7	0.7
Total	1.0	0.9	0.2	0.7	1.7	3.9
Low income countries	0.7	1.6	0.3	1.5	5	3

Note: Figures for physicians, nurses, midwives, and hospital beds is per 1,000

Note: Inpatient and outpatient figures are on a per capita basis.

Source: (Peters 2002)

### Pharmaceutical regulatory framework

- 2.9. Regulation of pharmaceuticals in India is found in the India Drugs and Cosmetics Act (1940). There are many actors in the pharmaceutical system. The main authorities involved at the central level are the Ministry of Health and Family Welfare (MOHFW), the Ministry of Chemicals and Fertilizers, the Ministry of Finance and the Ministry of Commerce and Industry. Other ministries include the Ministry of Environment and Forests, and Ministry of Science and Technology. The main areas of regulation are shown in Table 2.1 and Figure 2.0 illustrates the regulatory framework.

<sup>3</sup> Data on NGO providers is incomplete but work is underway to fill this gap.

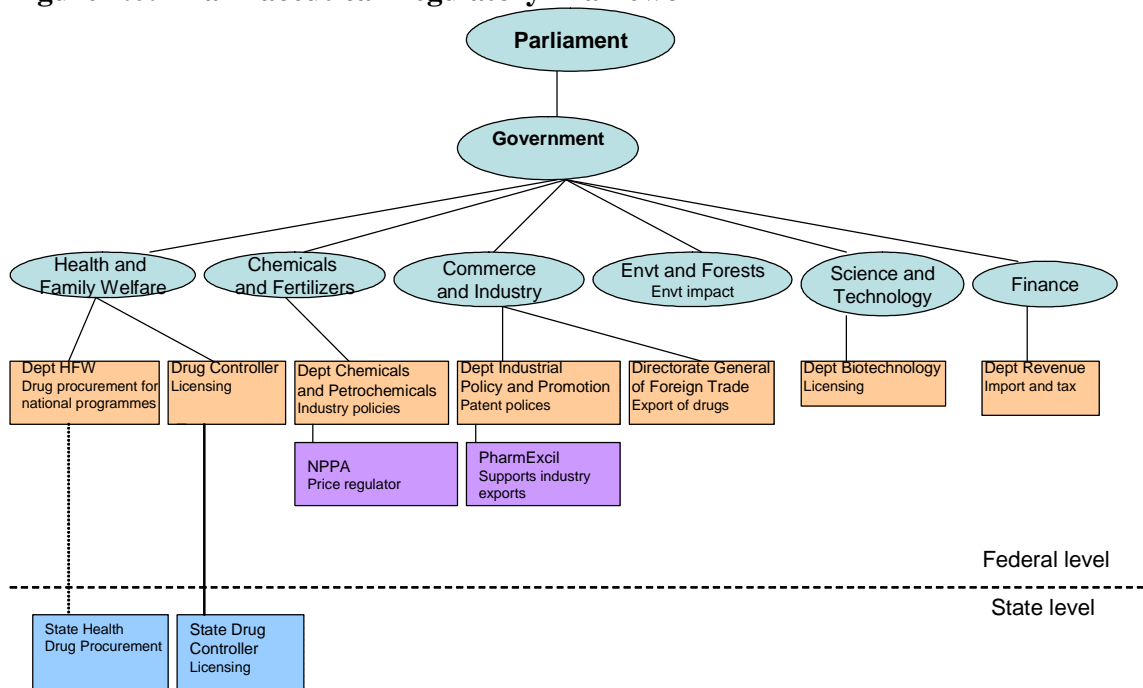
<sup>4</sup> It is important to treat these figures with caution because data on outpatient visits and hospitalisations do not necessarily capture disease levels accurately and differences in definitions and data collection methods in countries vary (Peters, 2002).

**Table 2.1: Key areas of pharmaceutical regulation**

Area	Authority responsible
<b>Financing of pharmaceuticals and procurement in public facilities</b>	<ul style="list-style-type: none"> <li>• MOHFW national programmes</li> <li>• State health authorities</li> </ul>
<b>Pricing Policy</b>	
Price controls	<ul style="list-style-type: none"> <li>• NPPA (Ministry of Chemicals and Fertilizers)</li> </ul>
Customs duty and taxes	<ul style="list-style-type: none"> <li>• Department of Revenue (Ministry of Finance)</li> </ul>
<b>Licensing and quality control</b>	
Market authorisation	<ul style="list-style-type: none"> <li>• Central Drug Controller (MOHFW)</li> <li>• Department of Biotechnology (Ministry of Science and Technology)</li> <li>• Department of Environment (Ministry of Environment and Forests)</li> </ul>
License to manufacture approved drugs and quality control	<ul style="list-style-type: none"> <li>• State Drug Controller</li> </ul>
<b>Industrial policy</b>	
Patent regulation	<ul style="list-style-type: none"> <li>• Department of Industrial Policy and Promotion (Ministry of Commerce and Industry)</li> </ul>
Drug Export	<ul style="list-style-type: none"> <li>• Directorate General of Foreign Trade (Ministry of Commerce and Industry)</li> </ul>
Government support to the industry	<ul style="list-style-type: none"> <li>• Ministry of Chemicals and Fertilizers</li> <li>• Ministry of Commerce and Industry</li> </ul>

Source: Author's analysis

**Figure 2.0: Pharmaceutical Regulatory Framework**



Note: At the state level drug procurement and licensing is carried out. State level drug controllers license drugs approved by the Central Drug Controller. They issue licenses for manufacture and regulate quality control. Dotted lines are shown to illustrate that State Health authority is the counterpart body responsible at the state level.

Source: Author's analysis

## National framework for medicines policy

- 2.10. A national medicines policy (NMP) outlines a country's goals and provides a framework for achieving them, setting out roles and responsibilities of the main actors in both public and sectors in pharmaceutical regulation (WHO 2004).
- 2.11. In India, the objectives of the NMP were set out in 1986 and revised as the Pharmaceutical Policy of 2002 to take account of changes for when India would become compliant to the agreement on Trade Related Aspects of Intellectuals Property Rights (TRIPS) in 2005 (Patel, Thawani et al. 2004). The policy document was prepared by the Department mainly responsible for industrial policy, the Department of Chemicals and Petrochemicals.
- 2.12. The policy's main objectives are the following (NPPA 2002):
- ensure availability of medicines at reasonable prices,
  - strengthen domestic capability in production and exports of pharmaceuticals by reducing barriers to trade,
  - ensure quality control, promote rational use of pharmaceuticals,
  - encourage R&D in the pharmaceutical sector and with a focus on diseases prevalent in India.
- 2.13. The policy document's main focus is on pricing policy. The guiding principle for price regulation is based on two components: whether the medicine has mass consumption and there is absence of sufficient competition for the medicine. Competition in the pharmaceutical market can be defined in different ways. The Indian pharmaceutical market is characterised by mainly generic drugs, which implies that competition is largely between medicines with identical active ingredients. Competition in pharmaceutical markets can take place between different categories of drugs. This is further discussed in the box below.

### Box 2.0: Competition in pharmaceutical markets

One standard approach to define markets for drugs is to use the Anatomical Therapeutic Chemical (ATC) classification devised by the European Pharmaceutical Marketing Research Association (EphMRA), and used by the European Commission (EC) (OFT 2007). The WHO maintains a similar classification.

Within the ATC system drugs are grouped according to the organ or system on which they are developed to target. This is the first level of classification (ATC1). The therapeutic, pharmacological and chemical properties are the second, third, fourth levels. A fifth level is used for an increased level of specification.

For example, the EC uses the therapeutic level (third level) a starting point for market definitions in competition cases. The EC recognises that analyses may require other levels of ATC to capture relevant economic markets. That is, they may be wider or narrower than the therapeutic level. The guiding principle should be that products should be included if they are substitutable for the same purpose of treatment. Furthermore, medicines with identical active ingredients may have different therapeutic uses depending on their delivery technology, and side-effects (OFT 2007).

- 2.14. In principle, medicines considered for price regulation are drawn from the MOHFW. The ministry's list of medicines come from the National Essential Medicine List (NEML), (354) and additional medicines that are considered important because of their use in national health programmes, and emergency care (173) (NPPA 2002; Kotwani and Levison 2007). In practice, over 30 drugs under price control are not on India's list of essential medicines. The NEML should also inform the development and use of formularies at the central and state level but the uptake of this information varies (Banaras Hindu University 2000; JSS College of Pharmacy 2000; Kilpauk Medical College 2000).
- 2.15. The NPPA is the department's price regulator. This includes monitoring of medicines under price control and those also outside price control. Price data are monitored using a sample of retail audit data. The NPPA has authority to intervene for prices not under price control if there are significant price increases. These issues are discussed in section 5.
- 2.16. The other key area of the pharmaceutical policy is to strengthen quality control, which is run by the MOHFW. The central and state drug controllers within the MOHFW are responsible for this task. The policy considers benchmarking regulatory standards against international standards, harmonising clinical testing practices, and streamlining procedures for quick evaluation of drug applications.<sup>5</sup> This is discussed in section 4.
- 2.17. The policy supports the ongoing development of the National Institute of Pharmaceutical Education and Research (NIPER). This institute is to achieve excellence in pharmaceutical sciences, technologies, education and training. The government intends to upgrade standards of pharmacy education and R&D through activities that include collaborative research with the industry in the area of drug discovery and development. This will be discussed in more detail in the second report.

## **Conclusion**

- 2.18. This section provided an overview of the Indian health system, the regulatory framework and key goals of its national pharmaceutical policy. The following chapters develop this regulatory framework, discuss the actors involved and highlight observations made in meetings with key stakeholders.

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<sup>5</sup> Fast track procedures have been recently implemented (Industry source).

### 3. PHARMACEUTICAL FINANCING AND SOURCES OF FUNDING

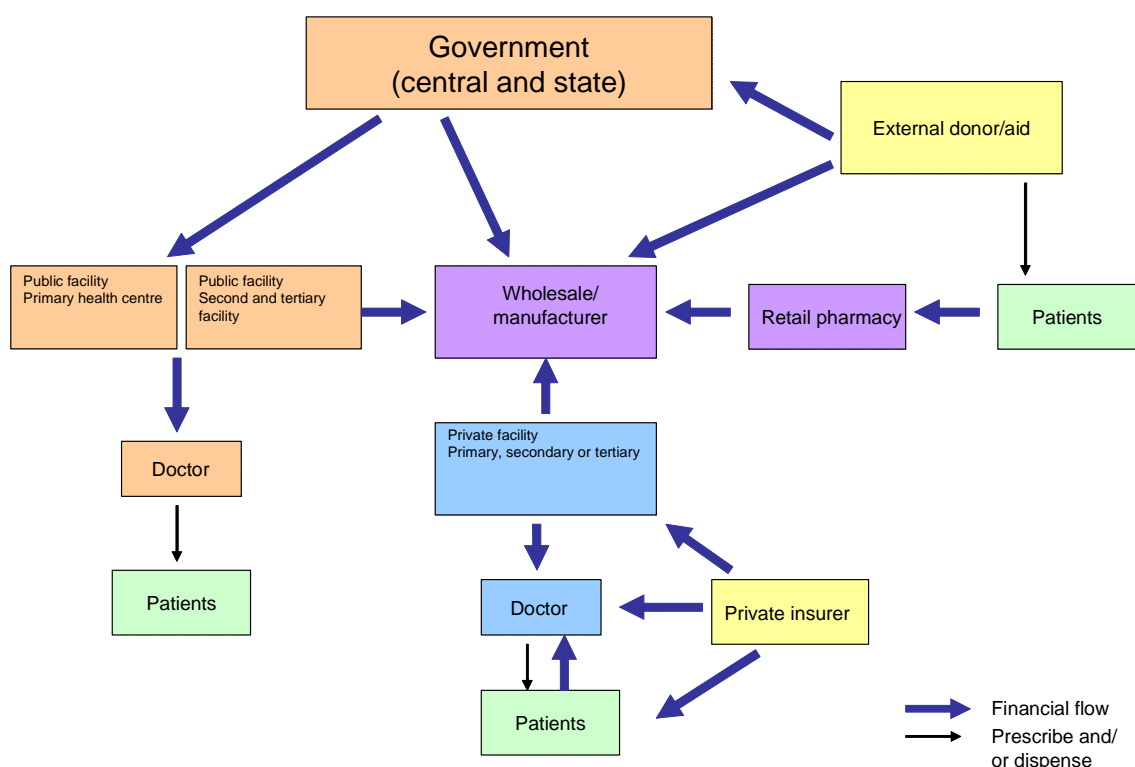
3.1. This section discusses components of pharmaceutical expenditure and sources of funding. It highlights the out-of-pocket (OOP) payments for pharmaceuticals that fall on patients. The government purchases medicines to be supplied in public facilities but as discussed later in section 8, stock levels in public facilities tends to be low. For the growing middle class, there has been a marked increase in private insurance providers and the number of insurance providers is expected to rise.

#### Overview of expenditure on medicines

3.2. Per capita spending on health and medicines is significantly higher in high-income countries but a much greater share of the medicines bill is publicly subsidized (WHO 2004). In the lowest-income countries, spending on medicines comes largely from household resources (e.g. high OOP payments). Pharmaceutical spending trends in some countries have fallen due to heavy debt burden and major epidemics such as HIV/AIDS.

3.3. In India, patients finance much of their care (Garg CC 2005; O'Donnell O 2005). The diagram below provides an overview of financial flows relating to expenditure on pharmaceuticals. The remainder of this chapter discusses pharmaceutical expenditure, the different sources of funding and government procurement.

**Figure 3.0: Financial flows of pharmaceuticals**



Note: For ease of exposition, public facilities include government run facilities for government employees. A primary health centre (PHC) is supplied medicines directly from the government central store. Retail pharmacies are reported to dispense medicines without a doctor's prescription. Public facilities and external donors may charge a nominal fee.

Source: Author's analysis

#### Breakdown of pharmaceutical expenditure

3.4. In 2001-02, households accounted for 72% of total health expenditure (3.5% of GDP), followed by state (13%), central (6%), private insurance (5%) and external aid (2%) (bilateral

or multilateral) (WHO 2005). The WHO estimates that 60% of the 80% of OOP is spent on medicines (WHO, 2004). A breakdown is provided in the tables below.

**Table 3.0: Total health expenditure (THE) in India, 2001-2002**

Source	Per capita in Rs.	% GDP	% of THE	Level in Rs 000s
Public	207	0.94	20.3	214,391,018
Private	790	3.58	77.4	818,104,032
External support	24	0.11	2.3	624,846,646
<b>Total</b>	<b>1,021</b>	<b>4.63</b>	<b>100.0</b>	<b>1,057,341,696</b>

Source: National Health Accounts, India 2001-02 (WHO, 2005)

**Table 3.1: Breakdown of total health expenditure (THE) in India, 2001-2002**

Source	% of THE	Level in Rs 000s
<b>Public</b>		
State	12.6	132,709,065
Central	6.4	67,185,399
Local bodies	1.3	14,496,554
<b>Subtotal</b>	<b>20.3</b>	<b>214,391,018</b>
<b>Private</b>		
Households	72.0	760,939,107
Firms	5.3	55,365,142
NGOs	0.1	799,783
<b>Subtotal</b>	<b>77.4</b>	<b>818,104,032</b>
<b>External support</b>		
Central	1.6	17,309,095
NGO	0.5	5,147,996
State	0.2	2,389,555
<b>Subtotal</b>	<b>2.3</b>	<b>24,846,646</b>
<b>TOTAL</b>	<b>100.0</b>	<b>1,057,341,696</b>

Source: National Health Accounts, India 2001-02 (WHO, 2005)

3.5. Medicine related expenditure is a small proportion of public budgets. In the MOHFW's budgets, it accounts for 1.4% (Rs. 392 million, or US\$ 8 million) out of Rs. 28,463.7 million (US\$ 598 million).<sup>6</sup> At the state level it accounts for 1.7%, Rs. 2,832.4 million (US\$ 59 million) out of Rs. 166,757.2 million (US\$ 3.5 billion). The National Health Accounts' (NHA) system of classification estimates overall expenditure to be Rs. 4,585 million (US\$ 96 million) or 0.4% out of total health expenditure, Rs. 1,057,341 million (US\$ 22 billion).

3.6. The World Bank (WB) estimates that average per capita expenditure on health is US \$38 (World Bank, personal communication). Public funds accounts for \$8 while \$30 is attributed to households. Out of total public spending (\$8), \$3 covers medicine expenditure. Central and state expenditure is \$1.5 each. Household expenditure on pharmaceuticals is estimated to be 40%, or \$12.

<sup>6</sup> The average annual exchange rate is taken from International Financial Statistics and corresponds with the year the data were collected (IMF, 2008).

## Government demand for medicines

- 3.7. Evidence suggests that developing countries do not necessarily procure low priced and good quality medicines. One study showed that international purchasing agencies achieve lower prices for generic drugs than do ministries procuring with national procedures (Van der Veen, Fransen, 1998). They reported that health ministries pay 3 to 6 times more for generic medications for sexually transmitted diseases. The recent WHO study revealed that procurement prices by selected states in India are low by international standards (WHO, 2006).
- 3.8. The government is responsible for drug procurement in public facilities where medicines are (for most states) free of charge. The central government procures medicines for its national programmes (e.g. HIV/AIDS, TB, malaria) that are delivered in public facilities. States are responsible to procure medicines for public facilities that offer primary, secondary and tertiary care. In the private sector, however, medicine costs are borne by patients. Evidence from state public facilities is presented in the box below.

### Box 3.0: Medicine prices at the state level

In a review of medicines in the state of West Bengal, Tripathi (2004) reports that co-payments/fees vary. In some states primary health care is offered free of cost. In some states, a nominal fee is charged. Treatment cost is borne by patients, although this may be subsidized at referral hospitals. In hospitals, medicines are free in public hospitals. Public facilities freely supply only drugs from the NEML (Tripathi, Dey et al. 2004).

Patel (2004) reports that in the state of Maharashtra, freedom fighters, and those that have a card indicating their income is below poverty level are exempt. These authors report that it is official policy to supply all medicines for free at the primary health care level.

Patel (2004) and Tripathi (2004) report the following medicines are freely provided in public facilities: TB, malaria, oral rehydration salts, family planning in both Maharashtra and West Bengal. Tripathi (2004) also reports that vaccines covered by the Universal Immunization Programme, iron, folic acid, simple antibiotics (e.g. amoxicillin, metronidazole); simple analgesics like paracetamol are freely provided in West Bengal.

- 3.9. At the state level, medicines are procured by central tender and supplied for health care delivery (Patel, Thawani et al. 2004). Secondary and tertiary facilities procure through central tender.
- 3.10. For example, the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) Special Committee has used a form of prequalification since 1995 and has achieved savings of approximately 30-35% in the purchases of essential drugs (Chaudhury, Parameswar et al. 2005). Delhi was the first state to develop a comprehensive Drug Policy, an essential drugs list (EDL), a centralized pooled procurement system, and activities to promote the rational use of drugs. Training programmes of providers led to a positive change in prescribing behaviour. Examples of procurement at the state level are discussed in section 8.

## Problems with procurement

- 3.11. A prequalification list gives advice on quality medicines and manufacturers to countries which cannot afford to provide their own inspection of good manufacturing practice (GMP) (WHO 2004). The WHO pre-qualification system has not been adopted in India. WHO guidelines for procurement, however, were adapted but there are problems with implementation. The procurement process needs to be more transparent, and the delivery and procurement of medicines experienced delays.
- 3.12. At the end of 2007, the government decided to address the procurement problems. A decision was taken to procure medicines for the government's national programmes of HIV/AIDS, TB and malaria from the United Nations Office for Project Services (UNOPS) (MSF, personal communication). As of 2008, medicines for these programmes are being procured from UNOPS.
- 3.13. Stakeholders were concerned with the policy shift in this area. They would have preferred the government to address the problems of a lax regulatory environment within the country, create a more open system for tenders, publish price information and allow for domestic capacity to absorb the procurement tenders. For instance, one stakeholder commented that a well known procurement process carried out in the state of Tamil Nadu by the Tamil Nadu Medical Services Corporation (TNMSC) could have been the role model for this process. The procurement process in Tamil Nadu is discussed in section 8.
- 3.14. Large companies, producing high quality drugs, are not interested in government procurement because prices are too low and the regulatory process needs to be strengthened. The challenge, however, is to attract licensed companies to bid. One stakeholder proposed that the government should incentivise branded and follow-on products by securing them levels of market share: a branded company, for example could receive 50% market share, and the follow-ons would account for the other 50% with differential pricing.
- 3.15. It seems that not all drugs of high quality are being procured. As a result, even if prices are low, patients in public facilities may be dispensed medicines of low quality. This is because in practice, licenses are issued to manufacturers even if they have not met quality standards. This is discussed in section 4.

### **Quality of medicines offered from donors**

- 3.16. International agencies that procure medicines provide an important service to developing countries. In principle, these organisations should have clear processes for tendering and quality control.
- 3.17. One international aid agency which has high standards of quality is Médecins Sans Frontières (MSF). MSF is an international humanitarian aid organisation that provides emergency medical assistance in over 70 countries worldwide. MSF operates in different parts of India including Jammu and Kashmir, Assam and Maharashtra.
- 3.18. The agency's procurement operation for its programmes worldwide is run out of France and Belgium (MSF 2006). MSF has a strict quality assurance system. Quality must be approved by all 5 sector pharmacists. MSF carries out its own GMP audit to approve vendors. This list is mutually recognised the approved list of vendors of the United Nations Children's Fund (UNICEF), the International Committee of the Red Cross (ICRC) and WHO. This means that a manufacturer approved by UNICEF will be allowed to apply to a MSF tender because the manufacturer meets the mutually recognised quality assurance system.

- 3.19. The manufacturer must complete a questionnaire and a rating is given to the manufacturer based on six criteria. The manufacturer's site of operation must be approved. Once the manufacturer is approved, the company is allowed to apply to a tender.
- 3.20. The tendering process is an open tender system. MSF is able to procure low priced medicines because it tends to purchase generics. Medicines are bought in bulk and MSF will directly negotiate with the supplier. MSF's system of procurement is first based on quality and second on price. MSF has taken a proactive approach with firms in the types of molecule combinations that can be produced. The organisation found that there are firms that welcome its input in this area.
- 3.21. Concerns have been raised that not all large international NGOs and agencies have clear quality assurance systems in place. There are concerns that these approaches may sacrifice the medicine's quality (MSF, personal communication).

### **Health insurance schemes**

- 3.22. Less than 10% of the population in India have some form of health insurance (Garg CC 2005). This is illustrated by the low level of household expenditure on premiums of 1.5% (US\$ 231 million) of total household expenditure (US\$ 15 billion) (WHO 2005).<sup>7</sup> Health insurance schemes run by public sector bodies and private companies are in operation (Tripathi, Dey et al. 2004).
- 3.23. Government employees have health care coverage under the central government health scheme. Respective ministries have hospitals for their employees: police, military, railways and other central government employees. Government employees have free care at the state hospital. In the central government's budget, 37% (\$US 526 billion) out of (\$US 1.4 trillion) provides medical benefits to central government employees (WHO 2005). At the state level, 4% (US\$ 133 million) out of US\$ 3.6 billion is spent on providing medical benefits to state employees (WHO 2005).
- 3.24. Employees of private companies have access to the Employee State Insurance Corporation, which is a social insurance scheme that collects contributions from employers and employees. Contributions of employers was 4.75 % of the employee's wage, and the employee's contribution was 1.75% of the employee's wage (ESIC 2008). The state governments share the cost of the provision of medical care. For the past 5 years, the income of the ESIC has grown but benefits paid and total expenditure have grown at a slower rate and remained less than total income. In 2005-06, income was US\$ 542 billion; benefit expenditure was US\$ 214 billion and total expenditure was US\$ 288 billion (ESIC 2008).
- 3.25. An increasing number of general insurance companies are in operation. Private insurance companies accounted for 58% (US\$ 685 million) of total expenditure by firms (but this is still small fraction of total health expenditure (US\$ 22 billion); public sector enterprises and banks accounted for 40.6% (US\$ 481 million) (MOHFW 2005). The remaining was due to donations by private firms to NGOs (1.6%). Most of the private insurance companies are joint ventures with recognised foreign players across the globe.
- 3.26. According to the Insurance Regulatory and Development Authority (IRDA), out of the 17 general insurance companies, 6 are public sector and 11 are private sector (IRAD 2006). There are estimated to be 10 companies that offer health insurance: four from the public sector

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<sup>7</sup> The average annual exchange rate is taken from International Financial Statistics (IMF, 2008) and corresponds with the year the data were collected.

and six from the private sector.<sup>8</sup> In the private sector, there is one stand alone health insurance company and a second one was granted a license in 2007 to begin operations.<sup>9</sup>

- 3.27. MEDICLAIM, a public sector scheme run by New India Assurance Co. Limited is one of the largest in operation. Medicines part of public health programmes and NEML are covered (Tripathi, Dey et al. 2004). Reimbursement of treatment cost which includes medicines is covered for selected diseases/disorders subject to a ceiling that depends on the premium paid. Patients 65 or 70 years over are exempt and those with certain disorders may be exempt. About 5% are covered under such schemes.
- 3.28. The IRDA reported that liberalisation of the insurance sector as well as the increasing demand for health insurance, especially from the middle class, have fuelled growth in health insurance products; it is the fastest growing segment in the non-life insurance industry. In 2006-07, health insurance premiums stood at more than US\$ 722 billion (Rs.32 billion) and reported an increase of 35%.
- 3.29. The IRDA reports it is supportive to increase health insurance coverage and to support micro-insurance for the poor. Different products are being offered. One insurer recently introduced a stand-alone policy covering HIV. The IRDA has created a separate health department to respond to the number of queries it receives. The IRDA predicts that there will be more entries of health insurance companies. The IRDA established a National Health Insurance Working Group in 2003 as a platform for the industry to discuss product and regulatory matters.

### **Increasing insurance coverage**

- 3.30. A national health insurance scheme will come into effect on April 1, 2008. The Ministry of Labour has put this forward with support from the International Labour Organization (ILO). The scheme will be implemented in the unorganised sector and families will receive Rs. 30,000 on an annual basis. Qualified families will be issued a card. Three quarters will be paid from the central government and 25% from the state government. The government plans to roll out the programme across the country over a five year period. Previously a small scale effort in 2003 aimed to provide universal insurance Rs 200-300 but was not very successful.
- 3.31. The National Rural Health Initiative plans to provide insurance mechanism to rural areas. The health ministry has designed the scheme. Goals of the scheme involve outreach delivery of services, integrated access to primary care, reduction in high infant and maternal mortality rates, and coverage of medicine expenditure (Deolalikar, Jamison et al. 2007). To date the government has invested Rs 120 million.
- 3.32. Some stakeholders representing the industry were supportive of the government to make medicines affordable but were less clear on whether the industry should have a role. A managed care model similar to Medicare in the US is being studied by the government and insurance companies (OPPI. 2007).

## **Conclusion**

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<sup>8</sup> This is based on reported product information (IRAD, 2006). The public companies include: National Insurance, New India, Oriental and United India. The private companies include: Bajaj Allianz, HDFC, Reliance, Royal Sundaram, Star Health and TATA AIG.

<sup>9</sup> Apollo DK received its license in 2007 (IRAD, 2006).

3.33. Even though there are different sources of funding for pharmaceutical expenditure, a disproportionate share falls on the household. Steps to improve the insurance availability for low income families is a welcome step but more coordination between government and the private sector will be needed as the private insurance industry grows. Government financing of pharmaceuticals provides medicines for free or at a nominal cost but the findings suggest that the system of procurement is weak. A related issue to government procurement is whether medicines procured are of good quality. One important topic raised in the discussions confirmed literature findings that the system of licensing and quality control of medicines needs strengthening. These issues are discussed in the following section.

## 4. LICENSING OF MEDICINES AND QUALITY CONTROL

4.1. Licensing of medicines is a component of pharmaceutical regulation. A review of the literature and discussions with stakeholders suggests that this area requires significant strengthening to improve the process, quality of medicines and address lax regulatory rules. These issues are further developed in this section.

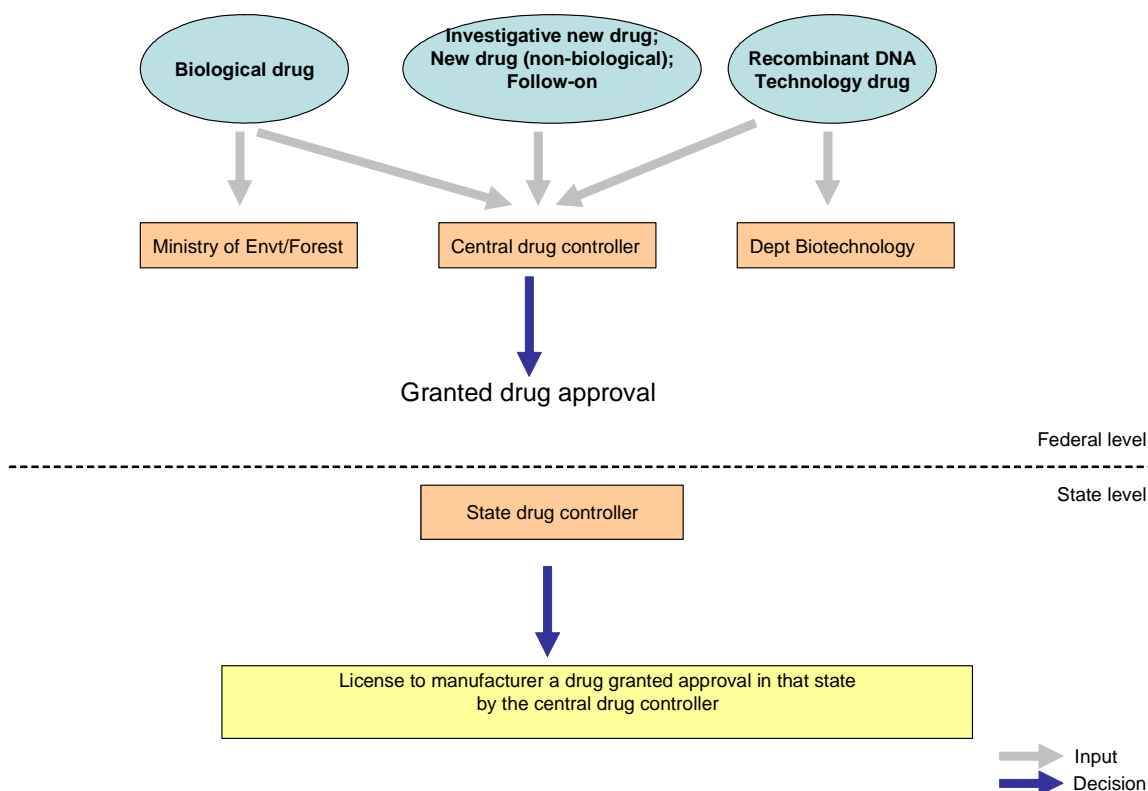
### Overview of licensing

4.2. Under the MOHFW, the DCGI is responsible for licensing and standards according to the Indian Drugs and Cosmetics Act, 1940. There is a division of authority between the central drug controller and the state level drug controllers.

4.3. The central authority is responsible for approval of new drugs, provision of standards, clinical trials in the country, quality control over imported drugs, coordination of activities of state drug authorities and supplying advice over the uniformity of the Drugs and Cosmetics Act (WHO 2004).

4.4. States have their own system of licensure for the manufacture, sale, and distribution of approved drugs and are responsible for the approved drug's quality. For domestic consumption, the states issue licenses for drugs that have already received approval from the central authority.<sup>10</sup> The diagram below describes the separation in responsibility.

**Figure 4.0: Licensing of pharmaceuticals**



Source: Author's analysis

<sup>10</sup> For exports, the state level controllers are responsible to issue a license to a manufacturer. This will also apply to products that are not approved for domestic use by the DCGI. Unapproved products are prohibited to be sold for domestic use.

## Central authority involvement in licensing

- 4.5. The Central Drug Controller grants market authorisation to three categories of drugs: investigative new drug; new drug and follow-on products.<sup>11</sup> Market authorisation grants a license but there is no explicit policy on periodic license reviews.
- 4.6. As Figure 4.0 illustrates, an investigative new drug, a new drug that is not a biological product or a follow-on product is approved only by the DCGI.
- 4.7. For a biological drug, the Ministry of Environment and Forests reviews the environmental impact assessment of the production process to ensure that safety procedures are in place for a biological drug.<sup>12</sup> The Genetic Engineering Approval Committee is responsible to review applications that involve medicines using biotechnology. The protocol is found in Schedule Y of the Indian Drugs and Cosmetics Rules, 1945 (CDSCO 2005). The procedure to be followed is outlined in five categories of protocols, whichever is applicable.
- 4.8. For a drug that uses recombinant DNA technology, the Department of Biotechnology within the Ministry of Science and Technology is involved. The Department of Biotechnology is approves pre-clinical studies and recommends human clinical trials to the DCGI. This is carried out on case-by-case basis. The procedure to be followed is outlined in five categories of protocols (Schedule Y, Indian Drugs and Cosmetics Rules, 1945), whichever is applicable.
- 4.9. Stakeholders estimated that decision times can be short (in less than a year) or range from 1 to 3 years. There is no explicit policy on the length of time to approve a drug.

### Clinical trials

- 4.10. Drug approval by the DCGI requires data from clinical trials. The DCGI permits phase I, II and III trials.<sup>13</sup> For new drugs discovered in India, it is mandatory to conduct Phase 1-III clinical trials as required under Schedule Y of Indian Drugs and Cosmetics Rules, 1945 (CDSCO 2005).
- 4.11. For drugs discovered in other countries, it is mandatory requirement for submission of phase I data from the other countries. Once the phase I data is submitted for review to the DCGI, the DCGI gives permission to repeat phase I and/or conduct phase II trials. A firm may use phase III data from another country but it is mandatory to still conduct phase III trials in India. Phase III trials may take place concurrently with other global trials for that drug (Corporate Law Group 2008). For a follow-on or generic product, bioequivalence tests are required.

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<sup>11</sup> The definitions are defined in the Drugs and Cosmetics Rules, 1945. 'Investigative new drug' is referred as a new chemical entity or a product having therapeutic indication but have never been earlier tested on human beings. 'New drug' has not been used in the country and has not been recognized as effective and safe; or it is already approved but the application is for a new indication, dosage form (including sustained release dosage form) and route of administration; or it is a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio. The full set of definitions is found in Annexure C.

<sup>12</sup> A drug using biotechnology refers to the application of knowledge about living organisms and their components to industrial products and processes (OFT, 2007).

<sup>13</sup> Phase I trials are the first stage of testing in human subjects to test the safety, tolerability and efficacy of the drug. At least 2 subjects are used for each dose at one or two centres. Phase II includes a larger sample of 10-12 patients at each dose in 3-4 centres. Phase III should be tested on at least 100 patients in 3-4 centres. Phase IV refers to studies performed after marketing of the pharmaceutical product. (CDSCO, 2005). Phase IV or post-marketing surveillance also refers to spontaneous reporting from health professionals and patients if adverse reactions to the drug occur.

- 4.12. The industry would welcome if data from another country could be accepted to prove the medicine's safety and efficacy and if the duplications of repeating trials were removed.
- 4.13. As part of the policy review to set up an equivalent FDA, proposals are being considered to improve policies on clinical trials (CDSCO 2005).<sup>14</sup> Harmonisation of regulatory procedures that draw on international practices would assist policy development.

### **State role in licensing**

- 4.14. The states issue a license to manufacture a drug that has already been granted market authorisation by the central drug controller. It is reported that quality of production is not uniform and that some state controller's are lax in adhering to GMP guidelines. This is discussed later in this section and in section 8.

### **Current regulatory environment**

- 4.15. The current arrangement between the DCGI, Ministry of Environment and the Ministry of Science and Technology is separate and is carried out on a case-by-case basis. The regulatory bodies do not appear to coordinate their processes well and more coordination would improve the drug approval process.
- 4.16. The process would benefit from explicit timelines, improved documentation and clear rules on the treatment of biological drugs. The drug controller's notifies the firm of its decision but does not provide a description about the decision. More transparency in the process is needed. For instance, once stakeholder noted that explanatory notes on the drug controller's decision would help.
- 4.17. The industry has become more proactive with the government authorities. Firms are pushing the government to be clearer with the regulatory process.

### **Quality control mechanisms**

- 4.18. The DCGI located in Delhi manages the aspect of drug quality in India. Actual administration, however, is handled by state controllers. Processes vary across states. Discussions with stakeholders confirmed literature findings that efficiency of state level operations varies.
- 4.19. There are differences in state capacity. Gujarat, Maharashtra, Southern states have stronger regulatory authorities than the north and eastern states (e.g. Himachal, Uttarakhand, Sikkim) where regulatory systems are lax.
- 4.20. Once the drug is on the market, phase IV (pharmacovigilance) studies are mandatory but discussions suggest it is not well enforced. Not all stakeholders were aware that it is mandatory. Post marketing surveillance is a challenge in high and low income settings, but in developing countries there tends to be little post-marketing safety monitoring (Edwards 1997; Lindquist and Edwards 2001).

### **Problems with quality assurance**

- 4.21. The two main problems with quality control relate to regulatory capacity and laboratory capacity. First, most of the state quality control agencies require more staff and better training.

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<sup>14</sup> In the 2007 USTR report, India will be on its priority watch list due to inadequate data protection for clinical trial data (USTR, 2007).

- 4.22. Second, quality testing takes place in government laboratories but facilities need to be better equipped to conduct tests. The World Bank reported that out of the 19 state drug testing laboratories, only 7 could perform the full range of tests (World Bank 2002).
- 4.23. Even though GMP came into force in June 2006 (Schedule M of the Drugs and Cosmetics Act, 1940), it has not been applied and implemented across the board.<sup>15</sup> There are different levels of quality and that the DCGI should coordinate standardising quality systems across the country.
- 4.24. For domestic consumption, quality control is not enforced. In practice, a small to medium sized company may receive a license to manufacture without having to meet the required quality standards, which exacerbates the problem of counterfeit medicines and appropriate packaging standards in the Indian market. This incentive may encourage the states to offer tenders to firms that do not produce quality medicines but offer a low price.
- 4.25. The Indian Drug Manufacturers' Association (IDMA), which represents small and medium sized Indian companies, was critical of GMP standards. IDMA felt that this may adversely affect firms that produce good quality medicines to exit the market because investing in GMP standards could be costly (Naidu 2007). Stakeholders indicated that government policy should support the development of small scale companies.
- 4.26. The discussions suggest that drugs for export to more regulated markets such as the US and Europe are required to meet the importing country's standards, which are higher than domestic quality standards.

#### *Counterfeit medicines*

- 4.27. One area of poor quality control involves counterfeit medicines, which continue to be a pressing global public health challenge. The WHO defines them as medicines that are deliberately and fraudulently mislabelled with respect to identity or source (WHO 2006). They may comply with quality standards while imitating popular brands (also known as spurious) or manufactured below established standards that are dangerous to a patient's health and ineffective in the treatment of disease.<sup>16</sup> The range of counterfeits is estimated to be 1% in developed countries to over 10% in developing countries.
- 4.28. There have been mounting concerns about the penetration of fake drugs from developing countries such as India into the global market (Shrivastava 2007). A related concern is that if a counterfeit medicine is sent to a country where there is no patent law, the medicine could be leaked out into other markets in developed and developing countries (USTR 2007).
- 4.29. These concerns have led to proposals to combat counterfeit medicines in western countries. In Europe, the European Commission presented a proposal for a directive and a Council framework decision aimed at introducing criminal sanctions for copyright infringements in respect of drugs.<sup>17</sup> Currently, the Directorate-General Enterprise and Industry is consulting all

<sup>15</sup> Good Manufacturing Practices (GMP) aims to minimise the following risks: unexpected contamination, incorrect labelling, incorrect active ingredient concentration (WHO, 2004)

<sup>16</sup> Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients (WHO, 2006). An industry source noted that the US and EU criticise that counterfeits from India and China also apply to those that infringe a patent.

<sup>17</sup> The proposal was amended by Parliament in April 2006. The draft foresees the introduction of a number of measures to curb the violation of intellectual property rights, including custodial sentences, fines, destruction of fake goods,

stakeholders and interested parties on key ideas for amending the regulatory framework for medicinal products in an effort to combat the counterfeiting of medicinal products (European Commission 2008).

- 4.30. In India, different estimates make it hard to ascertain the level of counterfeit medicines. Estimates for India have ranged from 0.5% to as high as 30% (Shrivastava 2007). The Indian government's own estimates between 1995-2003 found that substandard medicines ranged from 8 to 10% and spurious drugs ranged from 0.2 to 0.5% (Government Expert Committee 2003).
- 4.31. In response, a national survey was commissioned by the WHO, which found that 3% of drugs were counterfeit and about 0.3% were incorrectly labeled or spurious (Sheth, Reddy et al. 2007). The survey drew from 10,000 samples of 56 top selling drugs. The study only sampled those used for domestic consumption and not for export. The DCGI carried out a report that found most counterfeit medicines met most standards (DFID, personal communication). These studies deserve closer analysis given the acknowledged weaknesses in regulation. Some stakeholders and industry experts felt that the level is much higher (Shrivastava 2007).
- 4.32. Furthermore, there are no precise estimates on the number of companies producing counterfeit medicines in India. A government quoted figure from the Central Laboratory, Science and Technology estimated it to be 4,000. The Corporate Law Group calculated a higher estimate of 10,500 (Corporate Law Group, personal communication).
- 4.33. The DCGI is awaiting approval from the government to undertake a national survey to investigate 100,000 samples that will focus on a smaller number of brands (Shrivastava 2007). Presently, a bill is under consideration on how to address counterfeits and will call for stringent punishment for those engaged in the manufacture and sale of counterfeit medicines (Industry source).

#### *Lax regulatory environment*

- 4.34. Poor quality of medicines puts patients at risk. Lax regulatory standards have exacerbated the problem of falsification of quality standards. This is discussed in the box below.

#### **Box 4.0 – Falsification of manufacturing licenses**

The World Bank (WB) had invested in a project to strengthen the quality of food and drug supply in India (World Bank 2002). Results are mixed but the study found that sound regulatory practices were not followed. The purpose was to train analysts to promote GMP through the Department of Chemicals and Fertilizers and NIPER. Even in Tamil Nadu, a state which is considered to have strong regulatory practices, 30-40% of posts were vacant. The project found that laboratories did not have adequate staffing. Samples collected were 3,000-4,000 and nationally, 40,000. The project aim was to carry out testing of 100,000 samples.

The WB also found that incorrect procurement processes were followed by government officials. Furthermore, there were firms that received falsification of a certificate to manufacture medicines. Certificates were issued by local authorities for externally aided projects.

In response, the WB asked for the following conditions:

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closure of establishments used to commit an offence, bans on engaging in commercial activities, or bans on access to public assistance or subsidies (EAASM, 2008).

- the government should disclose all who have GMP on the MOHFW's website
- additional audits are needed before a contract is awarded;
- a technical notes checklist should be used to assist with the inspection which was prepared by the WB and the government authorities.

### **Current environment and proposals**

4.35. In some cases, the approach to quality is largely due to a firm's initiative. For instance, if a company suspects that there is a counterfeiter selling their product, the firm is likely to inform the authorities rather than vice versa.

4.36. A key issue for policy makers is that quality control needs improvement. To address this problem, the drug controller needs to have capacity to assess quality. A national drug authority similar to the FDA has been proposed to fall under the DCGI. It would lay out standards for medicines and cosmetics. A move towards establishing an FDA equivalent agency is welcome but it remains to be seen how effective this new institution will be. The FDA itself is considering establishing an office in India to speed up drug approvals for firms stationed there and may assist the Indian drug authorities with technical assistance (Edney 2008).

### **Conclusion**

4.37. Licensing and quality control is a key policy challenge for the Indian government. Recent proposals to improve the regulatory environment are welcome. Industry support for greater quality control should also encourage this process. The new drug standard body (equivalent to the FDA) has raised people's expectations. Government makers need to be aware of these pressures as they develop this new institution. The current government arrangement separates the responsibility of licensing and quality control from pricing policies in different ministries. This is the other main area of pharmaceutical regulation and is discussed in the following section.

## 5. PRICING POLICIES

5.1. This section discusses government policy to influence the prices of medicines. Two authorities are involved in this. The NPPA directly regulates the prices of selected medicines before taxes are applied and the Ministry of Finance, through its policies on tax and import duties affects the final retail price of the medicine. Most low and middle-income countries, however, do not regulate prices of medicines.

### Direct price controls

5.2. In India, pricing policy and industry regulation is the responsibility of the Department of Chemicals and Petrochemicals within the Ministry of Chemicals and Fertilizers. Within the Department, the NPPA is the charged with regulating medicine prices. The NPPA was established in 1997.

5.3. NPPA is responsible for the following (NPPA 2002):

- to implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- to deal with all legal matters arising out of the decisions of the authority;
- to monitor the availability of drugs, identify shortages, if any, and to take remedial steps;
- to collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations<sup>18</sup>;
- to undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals;
- to render advice to the Central Government on changes/ revisions in the drug policy; and assist the Central Government in parliamentary matters relating to the drug pricing

5.4. Price control over medicines was introduced in India in 1962 and has continued through the Drug Price Control Order (DPCO). The order sets out the procedures and methods of implementation for price fixation and penalties for contravention.

5.5. In 1978, there were selective price controls based on prevalence and disease burden. The list of prices controlled has decreased over time: around 80% of the market was under price control in 1979 (342 drugs); 142 drugs in 1987 and 74 in 1995. The current DPCO in operation was issued in 1995 under Section 3 of the Essential Commodities Act, 1995 (Patel et al., 2004). Drugs that are under price control are also referred to as scheduled drugs. The guiding principle for price regulation is based on two components: whether the medicine has mass consumption and there is absence of sufficient competition for the medicine. Drugs with high sales and a market share of more than 50% are targeted.<sup>19</sup>

5.6. The NPPA regulates prices of Active Pharmaceutical Ingredients (APIs), also referred to as bulk drugs, which are used as such as or as an ingredient in any formulation. A formulation is processed out of an API.

5.7. Currently, the NPPA regulates the prices of 74 APIs that are commonly used according to a standard formula. These medicines constitute less than 20% of the market and include imports or domestically manufactured products. Please see Annexe D for a complete list. Just under

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<sup>18</sup> The NPPA defines an API or bulk drug as any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation (Ministry of Chemicals and Fertilizers, 1995).

<sup>19</sup> The drugs considered for price regulation from the basket of drugs for selection will be those if the annual value is more than Rs. 250 million and the percentage share is 50% or more; or if the drug's annual value is more than Rs. 100 million but less than Rs. 250 million with a percentage share of 90% or more. (NPPA, 2002).

half of these, however, are not on India's list of essential medicines. The MOHFW would prefer more medicines to fall under price control (MOHFW 2005).

5.8. The NPPA sets the maximum retail price (exclusive of local taxes). The formula is

$$RP = (MC+CC+PM+PC) * (1+MAPE/100) +ED^{20}$$

- RP= retail price
- MC= material cost (includes API)
- CC=conversion cost
- PM=packing materials cost
- PC=packing charges
- MAPE= maximum allowable post-manufacturing expenses
- ED=excise duty charged by the central government

5.9. In 2002, the department's pharmaceutical policy proposed reducing the number of medicines under price control. Public interest groups filed a case with the Karnataka high court against the department's proposal. The supreme court told the government to draw out a list of essential medicines and to provide appropriate information on its decision. No policy decision has been made to date.

5.10. The Department's 2006 policy has been drafted and is now with cabinet. The proposal recommends including the entire NEML but there would be exceptions. The implications for the size market under price control are less clear. One estimate would move the market size from 20% to 12%.The Department feels that this policy will provide stability to the market.

### **Regulation of margins**

5.11. According to the NPPA, margins are fixed only for scheduled medicines: the wholesale margin is 8% and the retail margin is 16% (NPPA, personal communication). Some industry stakeholders pointed out that there are low margins for medicines part of the schedule and this discourages firms to enter the market.

5.12. An NPPA study, however, showed much higher margins. The study found that retailer margins could be as high as 300% for scheduled and non-schedule medicines (NPPA, personal communication). Three medicines were surveyed and margins varied from 100-500%.

### **Medicines outside price control**

5.13. For drugs not under price control, firms are free to set the maximum retail price (MRP). The NPPA will intervene if drugs have significant sales and where the annual price increases by more than 10%.This level was recently changed (in April 1, 2007). In the past, the NPPA would intervene if the annual price increases were more than 20%. About 10,000-20,000 manufacturers are monitored.

5.14. When price increases occur beyond the allowable limit, the NPPA will issue notices and if required, fix a price. The law permits NPPA to step in, but this action was infrequent during

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<sup>20</sup>The NPPA defines each component of the formula. These definitions are found in Annexe D. Proposals are underway to change the pricing formula pending Cabinet approval. These include increasing the number of APIs from 20% to 32%, MAPE to be increased for most products from 100% to 150%; R&D intensive companies will receive 200% MAPE (Kotwani and Levison, 2007).

the first nine years of the NPPA's existence. As of November 2007, about 54,000 medicine packs were being monitored. Prices are based on information given in the monthly retail store audit report from 4000 stockists. The database used for monitoring has undergone improvements. The database draws from Intercontinental Medical Statistics (IMS).<sup>21</sup> This data is based on embedded software, but not all pharmacies are equipped with this.

### **Reaction to price controls**

- 5.15. Support for the role of the NPPA was mixed. Some supported stronger government support and more price regulation while others expressed that the NPPA should focus on monitoring and not on price regulation.
- 5.16. One study suggests that the competitive market environment has kept price increases low. The Organisation of Pharmaceutical Producers of India (OPPI) estimates that between 2004 and 2006, there was an average annual decrease of 2.3% for scheduled drugs; for medicines not under price control there was an average increase of 1.3% (ORG-IMS 2006).<sup>22</sup> Evidence from the retail level suggests that there are wide variations in prices of different brands of the same drug in a market that has high product differentiation (over 60,000 different formulations) (Kotwani, Ewen et al. 2006; Kotwani and Levison 2007). More research is needed on how competitive the market environment is. This issue will be explored in the second report (please see section 10).

### **Taxes and import duties**

- 5.17. Policies that set the level of taxes and tariffs will affect the medicine's final price. Studies show that taxes, duties, and markups contributed more to the final retail price than the manufacturer's price (Levison 2003; WHO 2006).
- 5.18. The Central Board of Excise and Customs (CBEC) is a part of the Department of Revenue under the Ministry of Finance, Government of India. It deals with the tasks of formulation of policy concerning levy and collection of Customs and Central Excise duties, prevention of smuggling and administration of matters relating to Customs, Central Excise and Narcotics to the extent under CBEC's purview. The Board is the administrative authority for its subordinate organizations, including Custom Houses, Central Excise Commissionerates and the Central Revenues Control Laboratory.<sup>23</sup>
- 5.19. Its initiatives are aimed to address the following policy issues:<sup>24</sup>
- realising the revenues in a fair, equitable and efficient manner
  - administering the Government's economic, tariff and trade policies with a practical and pragmatic approach
  - facilitating trade and industry by streamlining and simplifying Customs and Excise processes and helping Indian business to enhance its competitiveness
  - creating a climate for voluntary compliance by providing guidance and building mutual trust
  - combating revenue evasion, commercial frauds and social menace in an effective manner

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<sup>21</sup> IMS is a for profit organisation that collects industrial retail and hospital data. Stakeholders noted that pharmacists issue a prescription even though this is not allowed. These sales are not captured in IMS data.

<sup>22</sup>The data for the year 2006 showed that for scheduled medicines prices decreased by -2% and drugs not under price control increased by 3%.

<sup>23</sup> (<http://www.cbec.gov.in/whoware/whoware.htm>).

<sup>24</sup> (<http://www.cbec.gov.in/whoware/vision-mainpg.htm>).

5.20. There had been lobbying efforts to reduce government tariffs on drugs. In the government's 2008 budget, the government responded to these efforts. The countervailing duty applied to pharmaceutical imported products for retail purposes dropped from 16% to 8%. The 16% duty is applied to a proportion of the MRP. Please see table 5.0.

**Table 5.0: Total Custom Duty Pre and post-budget 2008**

	Pre-budget Rs	Post-budget Rs.
MRP	500	
Assessable value	100	
Basic duty (10%)	10	10
Countervailing duty (CVD) of MRP (16% dropped to 8%)	46	25.8
3% tax on CVD	1.38	0.77
3% tax on total customs duty	1.72	1.10
4% special additional duty	6.36	5.51
<b>Total Customs Duty</b>	<b>65.47</b>	<b>43.19</b>

Source: Corporate Law Group (2008)

Note: For exposition, these numbers assume a MRP of Rs. 500 and Rs. assessable value of 100. Rates are applied to assessable value and MRP where appropriate. CVD pre-budget was 16% of 57.5% of MRP; post-budget it became 8% of 64.5% of MRP.

5.21. Table 5.0 shows that total customs duty was 36% and post-budget it has come down to 28%. Using pre-budget rates, the CVD was calculated on 57.5% of the MRP, but now it applies to 64.5% of MRP, which implies that the abatement allowed on MRP has fallen. The effective reduction is not as high as 8% but actually around 4-5% (Corporate Law Group, personal communication). There is a 4% VAT charged on all medicines in the public and private sector (Kotwani and Levison 2007).

## Conclusion

5.22. This section discussed pricing policies and the systems in place for price regulation. Industry stakeholders, however, support less price regulation. They argue that the industry is characterised by a competitive market environment which encourages price competition. Hence there is no need for price regulation. These issues are further explored in section 6 which discusses the Indian pharmaceutical industry.

## 6. INDIAN PHARMACEUTICAL INDUSTRY

- 6.1. The previous sections have described key aspects of the pharmaceutical system of regulation. The discussion now turns to the supply side issues concerning the pharmaceutical industry and the system of pharmaceutical supply.

### Overview

- 6.2. Patented drugs are more widely consumed in wealthy countries (about two thirds) and account for one third in low income countries (WHO 2004). The WHO (2004) notes that generic sales accounted for 60% in low and middle income countries and branded generics were more widely sold than unbranded generics. This is the case in the Indian market where branded generics dominate the market.
- 6.3. The Indian pharmaceutical market experienced significant growth at the start of the 1990s as a major supplier to the global generics market. India's pharmaceutical market is characterised by branded generics, unbranded generics and patented originator products. India is a net exporter and was ranked fourth according to volume and 14<sup>th</sup> according to value (IDMA, 2007). The market consists of 20,000 companies which is higher than in the U.S (Kripalani 2008).
- 6.4. In 2006, the total market by value was US\$ 13 billion (domestic was US\$ 7.9 billion and exports were US\$ 5.3 billion) (OPPI 2007). The government figure for exports was estimated to be a higher at US\$ 6.3 billion (Department of Chemicals and Petrochemicals 2008). According to OPPI, in 2006, the industry registered a growth of about 18%, which was the first time in 5 years that the industry registered double digit growth (OPPI 2007).
- 6.5. The industry argues that because of high competition in the market, prices remain competitive. Therefore, price control policies are not needed. Firms are aggressive and push their products on the retailer and wholesaler. For any given molecule, there will be many competitors. An example of the level of the competitors is found in published documents on medicine prices that indicate the number of competitors for any given drug. This information can be found in the following sources: Current Index of Medical Specialties (CIMS), Monthly Index of Medical Specialties (MIMS), and Drug Today. For any given drug there will be a number of competitors. For one medicine check, there were 30 competitors (IDMA, personal communication).
- 6.6. There are three main industry associations representing the different segments of the market. The Indian Drug Manufacturer's Association (IDMA) represents the domestic producers and has 650 members. Companies which produce APIs account for 250 and the rest are formulators (400).
- 6.7. The Organisation of Pharmaceutical Producers of India (OPPI) is an association of research based international and large pharmaceutical companies in India and is also a scientific and professional body represents. It has a membership of 77.
- 6.8. The Indian Pharmaceutical Alliance (IPA) is a lobby group of large Indian large generic producers. IPA consists of 13 members. It is part of the International Generic Pharmaceutical Alliance which consists of the generic companies in Europe, Canada, the US and Japan.

## Market environment

- 6.9. The success of the Indian pharmaceutical industry is mainly due the absence of product patent protection before 2005 when process patents were in place (Shah 2007). India had abolished product patents in 1971. This was prompted by the dominance of foreign companies that were charging very high prices: they would not part with their technology or significantly lower prices for public health concerns (Shah 2007).
- 6.10. A policy of process patents came into effect in the 1970s when the government provided significant public sector support to establish government facilities for the production of APIs. Many of the known Indian pharmaceutical companies today were started by staff that first worked in government facilities. The government pushed a cost-based price control system which encouraged firms to improve their efficiency (Shah, 2007).<sup>25</sup> This system created conditions for the industry to develop strong skills in patenting processes (i.e. reverse-engineering) in pharmaceutical production.
- 6.11. These policies affected the speed at which the market developed. In the 1980s, the industry attracted a number of entrepreneurs. The industry was characterised as having little barriers to entry. Development financial institutions had special schemes for funding start up investments (Chaudhuri 2005)
- 6.12. Until 1987-88, India was a net importer of pharmaceutical products. Since 1988-89, India, however, India has been a net exporter of pharmaceutical products. Please see table below.

**Table 6.0: India's exports 1998-2007**

Year	Rs. (billions)
1998-1999	62
1999-2000	72
2000-2001	87
2001-2002	97
2002-2003	128
2003-2004	152
2004-2005	178
2005-2006	225
2006-2007	249

Source: Department of Chemicals and Petrochemicals (2008)

Note: Nominal annual data for most recent years available.

- 6.13. India signed the TRIPS agreement in 1995 to come into effect in 2005. This policy decision triggered changes in the industry. More companies began to engage in R&D and shift from process development to innovation. R&D spend between 1995 and 2005 grew by 1223% in real terms. Please see table below.

<sup>25</sup> Other key government policies include required every firm in the organised sector had to invest in or undertake production of APIs, use a specified share of indigenous materials as against imported materials and involuntary dilution of equity holding by foreign companies (Shah, 2007).

**Table 6.1: R&D Spend of Pharmaceutical Industry, 1995-2005**

Year	US\$ Constant (billions)	% Real increase
1995	31.1	
2000	71.1	129
2005	411.6	479

Source: Shah (2007)

Note: Annual data expressed in constant dollars. (Ex. Rate \$1=INR 45).

6.14. Recent trends show Indian companies are becoming increasingly export oriented. The growth of the industry has followed from production for the domestic market to export production. Most firms export to markets with little regulation. Most of the Indian companies operate at the lower end of the market where products are at the later stages of the product cycle. Barriers are less and the number of competitors is more.

6.15. Almost half of the increase in exports between 1999-2000 and 2002-2003 was attributed to the exports of the top three exporters, Ranbaxy, Dr. Reddy's and Cipla. Indian companies export formulations in their own brands (branded generics) (Chaudhuri, 2005).

6.16. India's exports to Asia, Africa and East Europe accounted for 50% in 2004-05 (Shah, 2007). The majority of exporters focus on these markets which have little regulation (i.e. with little registration and inspection requirements). The majority of exports comes from formulations 71% (Chaudhuri 2005). Please see table below.

**Table 6.2: Pharmaceutical exports by region, 2003-2005**

Market	2003-2004	2004-2005	Share in %	Real annual growth
	US\$ (millions)	US\$ (millions)	2004-2005	%
Asia	1010.2	1062.6	28.7	5.2
West Europe	759.7	805.8	21.8	6.1
North America	594.3	681.7	18.4	14.7
Africa	405.6	443.6	12.0	9.4
East Europe	309.4	399.9	10.8	29.3
Other American countries	294.4	303	8.2	2.9
Total	3373.4	3696.6	100.0	

Source: Shah (2007))

Note: Annual data expressed in constant dollars. (Ex. Rate \$1=INR 45).

6.17. In markets with little regulation, exporters sell through traders not directly to actual users. Price competition exists to gain a share of the market. Data from IDMA indicate that the unit prices of half of the top 50 selling drugs declined for some by 30% between 1999-2000 and 2001-2002 (Chaudhuri, 2005). In some cases, prices were reported to be below domestic prices.

6.18. Exports to regulated markets (North America and West Europe) have grown and in 2004-05, they accounted for 40% of total exports (Table 6.2). About 50% of API exports go to regulated markets (Chaudhuri, 2005). In 2002, the US was India's largest trade partner in both API (16.7%) and formulations (13.7%) (Chadhuri, 2005).

6.19. Most Indian companies have opted for safer strategies which involve forming alliances and partnerships with the multinational companies (MNCs) (e.g. by being a supplier in the export market and a marketing partner in the domestic market). Another strategy by Cipla is to form alliances not with MNCs but with generic companies.

### **Western market penetration**

6.20. Firms keen to penetrate the US market will require sufficient resources to file an application with the FDA and enough resources for possible litigation costs. To file an Abbreviated New Drug Application (ANDA), the company must meet FDA requirements. An ANDA application may cost up to US\$1 million and may take up to five years (Chaudhuri, 2005). Processing of ANDA requires various types of review, which includes inspection of the manufacturing plants and facilities. According to Chadhuri (2005), the cost to meet US FDA requirements is almost 6 times the cost of a plant that does not follow GMP, 3 times the cost of one that does follow GMP and one third more than the cost of meeting EU guidelines.

6.21. At present, a minority of companies have the resources to target western markets. Most of the Indian companies which have set up such facilities have invested at least US\$10 million. The majority of Indian exporters only have Drug Master File (DMF is required for export to the US) in their names but ANDAs are in the names of their marketing partners. Companies provide data on active pharmaceutical ingredients through drug master file submissions. Indian companies filed 30 percent of new drug master files as of September 2007, surpassing leading contenders Italy (18%) and China (11%) (Edney 2008).

6.22. Dr. Reddy's and Ranbaxy also target the high value added segments of the market. They were successful in being granted the 180-day market exclusivity in the US market.<sup>26</sup> Dr. Reddy's was the first India company to market fluoxetine in 2001 and Ranbaxy obtained exclusivity for ibuprofen (Chaudhuri and Das 2006).

6.23. In 2002, Ranbaxy had the largest number of approved ANDA's among the Indian companies and the largest number of DMFs (Chadhuri, 2005). In the same year, it was the sixth largest generic company in the USA. In 2002, it filed the largest number of ANDS among all generic companies. Chaudhuri (2005) reports that in 2002, Dr. Reddy's had the second largest ANDAs and the US was its second largest market after India at 36% of total sales.

6.24. The top Indian companies have also developed partnerships with western pharmaceutical companies. Targeting regulated markets also resulted in opportunities for strategic alliances such as Ranbaxy-GlaxoSmithKline, Dr. Reddy's Laboratories-Novartis, Torrent-AstraZeneca (Shah, 2007).

### **Promotional activities**

6.25. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 lists disease categories for which advertisements cannot target consumers. The Act does not distinguish whether the drug is over-the-counter (OTC) or a prescription drug. Advertising to a registered medical practitioner is permitted if it is carried out in a confidential manner according to the Act.

6.26. There is intense competition to gain market share. The MOHFW is responsible to monitor industry marketing activities but enforcement needs to be strengthened.

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<sup>26</sup> One generic firm has market exclusivity for 180 days once the originator's patent expires.

- 6.27. A study on drug marketing found that firms sometimes engage in aggressive marketing tactics, including showering physicians, pharmacists, and wholesale distributors with expensive gifts (Roy, Madhiwalla et al. 2007). Gifts range from jewellery and consumer electronics goods to automobiles. Physicians in small towns are also targeted and receive more expensive gifts the more tablets they prescribe (e.g. 1,000 tablets per month will give the doctor a cell phone; 5,000 tablets are worth an air-conditioner; 10,000 tablets are worth a motorcycle). This implies that doctors may prescribe drugs based on company incentives rather than the needs of patients and are targeted very early in their careers (Kripalani 2008).
- 6.28. The industry recognises that more effective self-regulation is necessary. In January 2008, the OPPI published a Voluntary Code on Marketing Practices. The code calls for maintaining strict ethical standards. That is, no financial benefit or benefit-in-kind should have an inappropriate influence on the professional's prescribing practices (OPPI. 2007). OPPI received only two complaints about aggressive marketing practices in the past year—partly because doctors and patients were generally reluctant to speak out, but OPPI would like the code turned into law (Kripalani 2008).

### **Traditional medicine**

- 6.29. In the area of traditional medicine, volume data is unavailable on firms, which process herbs and medicinal plants for use in traditional medicine (WHO 2004). Furthermore, there is little monitoring of quality control. The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) should implement GMP to ensure proper shelf life of medicines and more regulatory intervention is necessary.
- 6.30. One stakeholder noted that one of its products includes an extract which comes from traditional medicine sources. The company has filed in Germany and the US and has launched in India. The company's view is that a firm needs to be very lucky to discover the right formulation to use traditional medicine. Few firms are attracted to this market and would require fiscal incentives to carry out research in this area.

### **Long term prospects**

- 6.31. A study by Chaudhuri (2005) assessed that under the new patent system, small exporters will likely suffer and exit the market. It is assumed that the Indian generics export market will compensate for the shrinkage in the domestic market (Chaudhuri, 2005). Cipla has the largest share of the domestic market and its CEO noted that it will be hard for companies to continue to expand if they do not have growth in the domestic market (Grace 2005).
- 6.32. India also feels the impact of China's presence in the pharmaceutical market. To take an example, the Department of Chemicals and Petrochemicals estimates that China's supply of penicillin as either final product or as an intermediate has taken away the market share previously held by Indian producers. Prices fluctuate considerably (from \$6 to \$20) which make it difficult for Indian producers to compete, and plan production (\$10-12 is the break even point for India producers) (Department of Chemicals and Petrochemicals, personal communication).
- 6.33. A McKinsey study reports that India will be ranked 10<sup>th</sup> with respect to value and its market will be worth \$US 20 billion by 2015 (McKinsey 2007). Some stakeholders predicted research should focus on innovation and that robust patent and data protection will be a positive step for the industry.

## **Conclusion**

6.34. This section described the pharmaceutical industry and changes in the market environment since the early 1990s. The industry is predicted to experience significant growth in the coming decade. There are conflicting policy priorities with respect to pharmaceutical policy. One section of government views pharmaceutical policy as health policy while the other considers it in the context of industrial policy. Government industrial policies are discussed in the next section.

## 7. INDUSTRIAL POLICY

7.1. There is considerable government support for the pharmaceutical industry. This section will discuss current policies in place that relate to fiscal instruments and the implication of intellectual property rights (IPRs) to stimulate growth. Views were divided on how the government should implement its policies; some preferred less regulation while others welcomed greater government involvement. These issues are discussed below.

### Policies to encourage industry growth

7.2. Industrial policy development is lead by the Department of Chemicals and Petrochemicals and the Ministry of Commerce and Industry. The Department of Chemicals and Petrochemicals is responsible to develop policies to stimulate industry growth. The Ministry of Commerce and Industry supports the industry on issues concerning exports, trade and patents. These issues are discussed in turn below.

### Fiscal measures

7.3. The objectives of the Department of Chemicals and Petrochemicals' policies are to ensure that there is abundant availability of good quality essential medicines at reasonable prices and to strengthen domestic capability for cost effective quality production of medicines. The Department has recently made a proposal to provide funds to the industry and to engage in R&D, particularly in diseases prevalent in India. The policies are aimed to encourage firms to employ a certain number of scientists, carry out R&D, acquire drug approval in western markets and file a certain number of patents each year. A summary of key policies waiting cabinet approval are presented below (Department of Chemicals and Petrochemicals, personal communication):

- **Fiscal incentive to boost R&D.** The proposal will deduct 150% of a firm's costs which are outsourced. Under the current arrangement there is no incentive for outsourcing but companies can deduct 125% of their costs if they occur domestically.
- **Government collaboration:** Drug and Pharmaceutical Research Programme handled by the Department of Science and Technology will offer a soft loan of 3% interest to firms that collaborate with a government research facility.
- **Neglected disease:** A firm is entitled to a grant for R&D which involves clinical research in phase I, II, or III in the area of neglected disease.
- **R&D:** Companies engaging in R&D will receive higher margins by being allowed to set higher prices for their drugs. The Department notes that companies spend about 5% of their turnover on R&D.
- **Free pricing:** Any drug developed with a product patent based on an indigenous process via a new drug delivery system will be exempted from price control.

7.4. Presently, the Department has a Pharmaceutical Advisory Forum which was established in 2004. The forum has members from the Department, central and state health ministers, the NPPA, central and state drug controllers, consumer and industry representatives. Three meetings have been held to date: two in 2006 and one in 2007. The Department found the meetings useful and steps are being taken to move forward with suggestions presented at the meetings. This is an important step in better regulatory coordination but it remains to be seen whether this will further strengthen the institutional environment.

## **Supporting export growth**

- 7.5. The Ministry of Commerce and Industry set up the Pharmaceutical Export Promotion Council (Pharmexcil) having its headquarters in Hyderabad and Regional Offices in Mumbai and Delhi in 2004. The Council's objectives are to extend assistance to the industry which involves delegations to various countries, business meetings, and funding support for export activities.<sup>27</sup>
- 7.6. Pharmexcil issues registration and membership certificates for Pharmaceutical Exports. The activities of the Council are administered by committee consisting of government officials and representatives from major pharmaceutical firms.
- 7.7. Stakeholders had mixed views on the extent to which government should support the industry. Some felt the industry has much potential to develop on its own while others had varying approaches to government intervention.
- 7.8. Some stakeholders were supportive of fiscal instruments and that government should focus on stimulating R&D for small sized companies. One proposed scheme would consist of 10-15 year bonds issued in favours equaled to R&D expenditure. For instance, if a firm had spent \$25 million on R&D, a five year amount of \$125 million could be issued for the firm to pay back to the government (NDTV 2008).
- 7.9. Others felt that the perception of India is more negative and that the advances the industry makes should be better communicated internationally. For instance, India has dramatically improved the availability of low cost good quality medicines to developing countries (MSF 2007).

## **Regulation for drugs for export**

- 7.10. To export a drug from India, a firm is required to show the order form to the Directorate General of Foreign Trade. A license is not required for export. A license is needed for manufacturing the product which is issued from the drugs controller. There are no other regulatory requirements under the law. The firm, however, is required to follow the importing country's conditions.
- 7.11. Exports to countries with more regulated markets will contribute to ensuring high quality goods are exported. For instance, a drug that receives FDA approval has high quality checks. FDA standards are very thorough: the inspectors go through the plant, collection information on the quality control procedure, and carry out audits once in 2 years. Once a site is approved, subsequent medicines produced there can be exported.
- 7.12. These conditions indicate that the criteria for exporting a product will not necessarily have the same rules for domestic consumption. Quality control for export to regulated markets is likely higher than for domestic consumption, which implies the need for better domestic quality control (discussed in section 4).

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<sup>27</sup>Various pharmaceutical items like Bulk Drugs and its intermediates, Formulations, herbal, ayurvedic, unani and homeopathic medicines, biotech and biological products, diagnostics, surgicals, neutraceuticals, and pharma industry related services, collaborative research, contract manufacturing, clinical trials and consultancy etc come under the purview of Pharmexcil. (<http://www.pharmexcil.com/V1/asp/AboutUs.aspx>)

## **Intellectual property rights**

- 7.13. Another important area that will have implications for industry growth and industrial policy relates to IPRs. This section will discuss some of the current issues that have risen due to India's adoption of TRIPS. A comprehensive assessment is outside the terms of reference for this report. Presently, DFID has commissioned a report to provide an update on IP issues and patents in India.
- 7.14. India became TRIPS compliant on January 1, 2005. The main features of the India Patent Ordinance are that it will limit patents granted to 'me-too' products, it will permit challenging a patent under review (pre-grant opposition), and exports should meet the rules of Paragraph 6 of the TRIPS agreement, but the procedures to issue a compulsory license (CL) were not streamlined (Grace 2005).<sup>28</sup> Parallel imports, however, are permitted.
- 7.15. The Department of Industrial Policy and Promotion is the agency responsible for IPRS and issues relating to patents. According to the Patent Law, TRIPS will apply to patents from January 1, 2005 but not before 1995. The contentious area is for patents granted between 1995 and 2005. In this case, a firm that produced a generic version can continue to produce its drug as long as it made significant investments. If this occurs, the generic firm is required to pay reasonable royalties to the originator firm. Alternatively, if a generic firm did not wish to pay the royalties, it could challenge the patent application under review (pre-grant opposition).
- 7.16. The main issue of contention will be to set a reasonable level of royalty payments because this is not defined (Corporate Law Group, personal communication). According to the Corporate Law group, this issue has not yet risen but the firm felt that it is unlikely that proving significant investment will become controversial.
- 7.17. The extent to which patents will affect access to affordable medicines is matter of ongoing debate. Some estimates show that medicines that account for 10-15% of value share will be affected; whereas as cardiovascular and pain drugs are less likely to be affected because there is a high level of therapeutic competition and substitution (Grace 2005). Diseases such as HIV/AIDS and resistant strains of TB and malaria will require new drugs and as a result patents will have implications for their affordability in developing countries (Grace 2005).

## **Conclusion**

- 7.18. The previous chapters have described the system of pharmaceutical regulation. The discussion highlights that in the current division of pharmaceutical regulation, more coordination between the authorities is needed. The Department of Chemicals and Petrochemicals also noted that it has very little interaction with the DCGI. The Department, however, does some work with the MOHFW.
- 7.19. There is structural problem with the institutional design of regulation because pharmaceutical policy is separated between different ministries: namely the MOHFW and the Ministry of Chemicals and Fertilizers. As the industry continues to target western markets, there will be a greater need to harmonise practices and to draw on international practices to improve the institutional environment.

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<sup>28</sup> Grace (2005) provides an overview of the implications of 2005 Indian Patent Law.

7.20. This report's purpose was to provide an overview of pharmaceutical issues at the central level. For illustration purposes, and to draw on issues raised in the previous sections, examples from state practices of pharmaceutical regulation are presented in the next section.

## **8. STATE CASE STUDIES**

- 8.1. Three case studies on drug policy implementation are presented below. They were carried out in Uttar Pradesh (Banaras Hindu University 2000), Karnataka (JSS College of Pharmacy 2000) and Tamil Nadu (Kilpauk Medical College 2000). The findings suggest that the rules for procurement are well designed but lack proper enforcement mechanisms for implementation. Quality assurance systems also need to be strengthened.

### **State Level - UP case study**

#### **Procurement and quality control**

- 8.2. Procurement had well defined procedures through screening at multiple levels by various committees. Estimations of drug requirements were based on previous year's consumption and estimates of drugs not dispensed (but prescribed) were based on record analysis of drug registers which was not comprehensive.
- 8.3. The public analyst's laboratory had a capacity to test 900 samples but they received more than 4,000. About 75% were tested after collection. Storage systems were not adequate but cold storage conditions existed.
- 8.4. The number of drugs from a basket of drugs available measured that private outlets had 89% and public was a bit lower at 83%. Availability was lower the further away the outlet was located from the district headquarters. Drugs were labeled in private facilities but not in all public facilities.

#### **Study observations**

- 8.5. The authors note that a greater system of coordination between the Central Medical Supplies Directorate and the Medical Stores, and between the drug controller and the drug inspector was needed. More staff should be trained to carry out inspections and knowledge of drug prices at the drug inspector level should be improved.
- 8.6. The study also recommended the implementation of a management information systems, and continuing education policies to improve rational drug use.

### **State Level – Tamil Nadu case study**

#### **Procurement and quality control**

- 8.7. Procurement was by two part tender system: technical tender used standard procedures whereas a commercial bid was through negotiation. Companies were black listed if quality failure was noticed and vendor rating was carried out. Hospitals' budget allotment was based on past utilisation levels.
- 8.8. There were 23 warehouses and all had internet capabilities to distribute drugs from warehouses to hospitals. Hospitals were informed about their date of order which helped in the smooth functioning of the system. The TNMSC reviewed the stock and supply of drugs every day. Availability of medicines in hospitals was evaluated as very good but not at the primary care level.

8.9. All EDL supplied through TNMSC were tested for quality. Samples were collected from all warehouses and hospitals and sent to various government and private laboratories selected through a tender system. The drug committee reviewed the list every year.

### **Study observations**

8.10. Legislation and regulation was structured well but the process did not work. Enforcement was weak due to lack of manpower; in particular activities in the private sector were difficult to implement.

8.11. Overall the strengths were low cost of good quality drugs, a good procurement and IT system, good drug distribution and quality control. Weaknesses include the system of ordering resulted in stock outs, stock management had not improved at the primary care level, procurement was not based on quantification of needs, and regular monitoring and evaluation was not done. Furthermore, the budget estimates should consider morbidities, and policies should strengthen education on rational drug use.

### **State level – Karnataka study**

#### **Procurement and quality control**

8.12. The state had a centralised, and well defined procurement system. All drugs were procured by tender. A therapeutic committee screened the list of drugs needed on an annual basis. The state had 8 approved laboratories. There were violations against the quality regulations: in 1999 there were 233 plus a similar amount whose decisions were pending due to judicial delays. Random sampling was done at the central warehouse but not all warehouses.

### **Study observations**

8.13. The strengths included adequate infrastructure, government machinery, diagnostic equipments, and staff. The authors found, however, that there was poor regulatory control in manufacturing, distribution and sale of drugs. The study suggests that stock availability should be improved, record maintenance should be strengthened, sales of drugs without prescription should not be permitted, and stronger rules on industry advertising should be put in place. Furthermore, training on rational drug use should be implemented and public facilities should be inspected on a more regular basis.

## 9. DISCUSSION AND CONCLUSION (OF PART ONE)

9.1. This report provides an overview of the regulatory environment of pharmaceutical regulation in India. Discussions in India provided useful insight into the institutional framework.

### Improve regulation

9.2. **Better coordination:** The report highlights that even though there are reforms underway, the government will need to continue to be proactive in the development of policy that strengthens key institutions—namely the MOHFW, and the DCGI. Steps for a central drug authority are welcome but the government will need to secure the support and interest among state level controllers to assist in greater coordination between the centre and the states to improve quality control. Furthermore, measures to improve transparency in the licensing of manufacturers and procurement of medicines are necessary.

9.3. A broader approach to pharmaceutical policy making is necessary that considers reform measures from a health systems perspective. This implies a different approach to existing institutional arrangements. There is a need for greater coordination between government bodies, such as MOHFW, the DCGI and the Department of Chemicals and Petrochemicals to meet on a regular basis to coordinate their efforts. This could be achieved through joint budgeting arrangements so each institution has a greater incentive in implementation. Such measures should be supported by law with a clear accountability framework.

9.4. **Private sector medicine distribution:** The large unregulated private sector will require greater government attention to regulate markups and put monitoring systems in place. Recent price surveys found that the private sector had better distribution systems. There will be a need for the government to increase its collaboration with the private sector and to take advantage of its distribution networks to supply medicines. This will be further discussed in the second report.

9.5. **Harmonise regulation:** The industry is very proactive with the government. Interestingly, its efforts have proposed measures to improve regulation of quality control. Harmonisation of practices which strengthen the institutional environment are important steps and more effort is needed in this area.

### Strengthen information

9.6. **Data sources:** Reliable data on the large pharmaceutical markets in the world's most populous countries, China and India are in short supply (WHO 2004).<sup>29</sup> Inpatient data records are available but outpatient data are lacking. Surrogate surveillance is how current research and analysis are carried out. There will be health system pressures such as an increase in consumption and sales among the middle class, and expansion of the private health insurance market, which will require a greater system of tracking information and coordination between various bodies that collect data.

9.7. The NPPA has price data as which has much potential for more research and analysis. Its industry data largely comes from ORG-IMS, which has its limitations but it is a source of information. The government should encourage greater use of its data sources from the various bodies, and strengthen its data collection systems.

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<sup>29</sup> Data on trade, production, expenditure and consumption come from different sources. Monetary value are reported rather than volume which does not reflect the scale of consumption (traditional, low-priced generics, branded and non-branded).

- 9.8. **Pharmacoeconomics:** The concept of pharmacoeconomics has not come to India because competition has mainly been between generics. As more patented drugs enter the markets, one will have to establish value, which will require some method of pharmacoeconomic analysis. These approaches are widely used in developed country settings where there is a trend to use information on the benefits that drugs bring to patients to inform pricing decisions (OFT 2007; Mossialos and Srivastava 2008). Most stakeholders were not aware or familiar with the concept.

### **Improve market competition**

- 9.9. The growing industry will bring much benefit to the Indian economy but the implications for the poor are less clear. A segment of the industry will be outward looking to penetrate western markets. Clear incentives and fiscal instruments will require that the government improve its regulation of quality control for domestic consumption (i.e. issue licenses that follow GMP and prove quality) and for the exportation of medicines to countries in the developing world as well.
- 9.10. Only 3% of medicines in the Indian market do not have substitutes (ORG-IMS 2007).<sup>30</sup> A McKinsey study projects that in 2015, the market will be worth \$20 billion; 10% of the market will consist of patented drugs and 90% will be generic (McKinsey 2007). The high number of competitors may encourage price competition. In the current environment, however markups are not well regulated which results in high private sector retail prices. This implies that affordability will continue to be problem for low income individuals unless regulation is improved, and well designed insurance schemes are put in place. Policy measures should improve regulation and monitoring of the pharmaceutical supply chain distribution, monitor pharmaceutical marketing practices, and encourage/incentivise physicians and pharmacists to dispense rationally (e.g. promote generic prescribing). These issues will be further explored in the second report.

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<sup>30</sup> The level of substitution could not be confirmed. It is likely that this refers to substitutes at the chemical level.

## **10. NEXT STEPS: OUTLINE OF SECOND REPORT**

- 10.1. The scope of this report was to provide a country level report of the pharmaceutical sector in India. The country report is separated into two parts. This report covered the first part which discussed the system of regulation of pharmaceuticals at the federal level in India.
- 10.2. The second part will take the discussion further on medicines, financial flows and discuss how the pharmaceutical sector operates. Issues covered will involve information on the pharmaceutical industry such as consumption trends and price trends, the pharmaceutical supply chain (wholesalers, and retail pharmacies), policies on delivery mechanisms that influence providers at primary care to prescribe cost effective medicines, and the patient's ability to purchase medicines.
- 10.3. A brief introduction to these issues is discussed below and will be further explored in the second report. These two reports will provide a comprehensive assessment of the pharmaceutical sector in India as part of the MeTA initiative to understand the pharmaceutical policy environment in developing countries.

### **Pharmaceutical supply chain**

- 10.4. Meetings with stakeholders suggest that manufacturers have different models of distribution. Some will engage in direct marketing (API marketed directly to a company); while others will sell through an agent. Selling through an agent involves selling to a wholesaler or a cost and freight agent (CNF). For example, the API is manufactured and sold to a pharmaceutical company which sells to a CNF and wholesaler. In every state there are areas known as distribution hubs which serve districts via stockists in that state to supply a retailer (Industry source, personal communication). Currently there are moves to vertically integrate distribution with manufacturers operating their own pharmacies, which will have implications for wholesalers and independent pharmacies (Kotwani and Levison 2007).
- 10.5. In developing countries, studies have shown that markups along the distribution chain will also affect the final price of the medicine (Levison 2003; WHO 2006; Kotwani and Levison 2007). Few countries attempt to regulate domestic markups. Studies appear to suggest that regulation of margins in the distribution chain are needed. Evidence from India suggests that public, NGO and private dispensaries had expired stock but the private sector had better distribution systems (WHO 2004). The distribution system and implications for the stock of medicines in retail pharmacies will be further explored in the second report.

### **Retail pharmacy market**

- 10.6. Pharmacists are required to have a diploma which is a 2 year degree to work in a public facility or be an owner of a private facility. In a pharmacy, there may be 4 or 5 employees but not all of them will necessary hold a diploma. Retail chemists are given a license to operate from the state drug controller. There are 700,000 (Industry source) registered chemists and about 13,000 registered retail chemist shops (Dr. Kotwani, personal communication).
- 10.7. Pharmacists are not allowed to issue a prescription but this is reported to take place. Issues around provider incentives and the retail pharmacy market will be researched in the second report.

### **Rational use of medicines**

- 10.8. Accurate dispensing and prescribing are key components to rational use of medicines. Many studies show inappropriate prescribing in primary and secondary care (Bapna, Tekur et al. 1992; Dharnidharka and Kandoth 1999; Das, Sarkar et al. 2006). Furthermore, there are high levels of self-medication and inadequate compliance of over the counter (OTC) sale of antibiotics (Ray, Mukhopadhyay et al. 2003). Other studies show that the use of guidelines lead to improved rational prescribing in the use of antihyperintensives (Malhotra, Karan et al. 2001; Kotwani, Gupta et al. 2002) and among sexually transmitted diseases (Rewari, Tekur et al. 2000) but less effective for asthma (Kotwani, Gupta et al. 2004)
- 10.9. Physicians lack incentives to rationally prescribe because they are aggressively targeted by sales and marketing representatives (see section 6). This trend, however, is changing. Efforts are underway to educate health professionals with seminars being led by academics and practitioners (India-Drug. 2008). This information is important to understand the supply chain of medicine distribution, how it affects patient access and whether they receive appropriate medicine treatment. These issues will be explored in the second report.

### **Consumption at the retail level**

- 10.10. The retail price of a medicine is a function of supply chain distribution system and will reflect the various supply chain markups (e.g. import tariffs, taxes, wholesale and retail markups). A pilot study was carried out on whether medicine prices paid by a patient are the same as the prices collected by data collection (Auton, Kotwani, 2006). The study found that priced paid by simulated clients were on average 8% less for innovator brands. Surprisingly, generic prices were 24% more expensive (mainly due to high prices for ciproflaxin) than the reported lowest priced generic collected by data collectors. Pharmacies surveyed were reluctant to offer generic substitution
- 10.11. Households account for 72% of total health care expenditure (WHO, 2005). Information about a patient's ability to pay is important and will affect access. Household survey data will be used to explore issues of ability to pay and patient access to medicines in the next report.

## **Annexe A: Terms of Reference**

### **Technical and financial proposal for consultancy services to draft a country level report on the pharmaceutical sector in India**

#### **The Objective**

The objective is to prepare a country level report on the national regulation of pharmaceutical policy in India. This report will inform DFID's policies on access to medicines and its work in the Medicines Transparency Alliance (MeTA), which is an initiative to increase access to high quality medicines in developing countries.

#### **The Scope**

The country level report will provide a policy review and will cover four main aspects of the pharmaceutical sector in India: policy and regulation; expenditure on medicines; the pharmaceutical market; and delivery mechanisms.

This will involve completion of a report only on policy and regulation by end of March 2008. The remaining three aspects will be completed in a subsequent contract.

Policy and regulation will discuss key institutions, legislation, licensing of pharmaceuticals, pricing and reimbursement, and public/private financing of pharmaceuticals. Expenditure on medicines will cover expenditure trends, consumption trends (e.g. in the top disease areas) and price trends. The pharmaceutical market will analyse the market at different stages of supply: manufacturers, wholesalers; and pharmacies. Policies on delivery mechanisms will cover demand side policies that influence providers in primary health centres.

The report will focus on federal policies and will draw on relevant data where available for analysis. Regional information on the National Capital Territory of Delhi will be used if federal information is unavailable.

#### **The Method**

The consultant will draw on existing analysis and information from international and national documents and data sources where relevant for analysis. Fieldwork to India will involve two trips to meet with policy makers and researchers to supplement information and data gaps.

A draft interim report will be produced and following comments with the DFID office in London, a final report will be produced. The consultant will retain authorship for her work and will be appropriately acknowledged. The consultant will be allowed to use the research conducted for this project in any future academic published work with appropriate acknowledgement given to DFID after termination of the contract.

## Annexe B: stakeholders contacted

Stakeholders met	Name
<b>Academic</b> University of Delhi	Dr. Anita Kotwani
<b>Donor Agencies</b> DFID Delhi	Health Advisory Team <ul style="list-style-type: none"><li>▪ Billy Stewart; Pankaj Jain; Peter Evans; Jenny Amery; Rashmi Kukreja; Jyoti Tewari; Gopi Menon, Pete Vowles</li></ul>
World Bank	Dr. Venugopal <ul style="list-style-type: none"><li>▪ Pharmaceutical Expert</li></ul>
World Bank	Dr. Ramana <ul style="list-style-type: none"><li>▪ Public Health Specialist</li></ul>
<b>Government</b> NPPA (National Pharmaceutical Pricing Authority)	Mr. Arun Jha <ul style="list-style-type: none"><li>▪ Member Secretary</li></ul>
Department of Chemicals and Fertilizers	Mr. Singh Sandhu <ul style="list-style-type: none"><li>▪ Joint Secretary</li></ul>
<b>Industry</b> IDMA (Indian Drug Manufacturers' Association)	Mr. Wakankar <ul style="list-style-type: none"><li>▪ Executive Director</li></ul>
OPPI (Organisation of Pharmaceutical Producers of India)	Mr. Tapan Ray <ul style="list-style-type: none"><li>▪ Director General</li></ul>
ARA Healthcare	Dr. Rama Mukherjee <ul style="list-style-type: none"><li>▪ Managing Director</li></ul>
Panacea Biotech	Mr. Rajesh Jain <ul style="list-style-type: none"><li>▪ Joint Managing Director</li></ul>
Unimark Remedies	Mr. Mehul Parekh <ul style="list-style-type: none"><li>▪ Executive Director</li></ul>
<b>Legal Experts</b> Corporate Law Group	Ms. Krishna Sarma <ul style="list-style-type: none"><li>▪ Managing Partner</li></ul>
<b>Civil Society</b> Centre for Trade and Development	Mr. K.M. Gopakumar <ul style="list-style-type: none"><li>▪ Research Officer</li></ul>
Médecins Sans Frontières (MSF)	Ms. Leena Menghaney, Ms. Elodie Jambert <ul style="list-style-type: none"><li>▪ Access to Essential Medicines</li></ul>

The following were contacted but were unable to meet me:  
Drug Controller General of India, MOHFW, Ministry of Commerce and Industry, Ministry of Finance, WHO, Indian Pharmaceutical Alliance

## Annexe C: Definitions of drugs for market authorisation

'Investigative New Drug' - Under Drugs and Cosmetics Rules, 1945, an "investigative new drug" is referred as a new chemical entity or a product having therapeutic indication but have never been earlier tested on human beings.

'New Drug' - Under Section 122E of Drugs and Cosmetics Rules, 1945, a 'new drug' shall mean and include-

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labeling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration.

*Explanation.-* For the purpose of this rule-

(i) all vaccines shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) (ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

Source: (CDSCO 2005) and (Corporate Law Group 2008).

## Annexe D: List of price controlled medicines

### THE FIRST SCHEDULE

#### List of Price Controlled Drugs (DPCO 1995)

[ See Paragraphs [2](#) and [3](#) ]

##### BULK DRUGS

- |                             |                                  |
|-----------------------------|----------------------------------|
| 1. SULPHAMETHOXAZOLE        | 39. GRISEOFULVIN                 |
| 2. PENICILLINS              | 40. GENTAMICIN                   |
| 3. TETRACYCLINE             | 41. DEXTROPROPOXYPHENE           |
| 4. RIFAMPICIN               | 42. HALOGENATED HYDROXYQUINOLINE |
| 5. STREPTOMYCIN             | 43. PENTAZOCINE                  |
| 6. RANITIDINE               | 44. CAPTOPRIL                    |
| 7. VITAMIN C                | 45. NAPROXEN                     |
| 8. BETAMETHASONE            | 46. PYRENTAL                     |
| 9. METRONIDAZOLE            | 47. SULPHADOXINE                 |
| 10. CHLOROQUINE             | 48. NORFLOXACIN                  |
| 11. INSULIN                 | 49. CEFADROXYL                   |
| 12. ERYTHROMYCIN            | 50. PANTHONATES & PANTHENOLS     |
| 13. VITAMIN A               | 51. FURAZOLIDONE                 |
| 14. OXYTETRACYCLINE         | 52. PYRITHIOXINE                 |
| 15. PREDNISOLONE            | 53. SULPHADIAZINE                |
| 16. CEPHAZOLIN              | 54. FRAMYCETIN                   |
| 17. METHYLDOPA              | 55. VERAPAMIL                    |
| 18. ASPIRIN                 | 56. AMIKACIN SULPHATE *          |
| 19. TRIMETHOPRIM            | 57. GLIPIZIDE                    |
| 20. CLOXACILLIN             | 58. SPIRONOLACTONE               |
| 21. SULPHADIMIDINE          | 59. PENTOXIFYLLINE               |
| 22. SALBUTAMOL              | 60. AMODIAQUIN                   |
| 23. FAMOTIDINE              | 61. SULPHAMOXYLE                 |
| 24. IBUPROFEN               | 62. FRUSEMIDE                    |
| 25. METAMIZOL (ANALGIN)     | 63. PHENIRAMINE MALEATE          |
| 26. DOXYCYCLINE             | 64. CHLOROXYLENOLS               |
| 27. CIPROFLOXACIN           | 65. BECAMPICILLIN                |
| 28. CEFOTAXIME              | 66. LINCOMYCIN                   |
| 29. DEXAMETHASONE           | 67. CHLORPROPAMIDE               |
| 30. EPHEDRINE               | 68. MEBHYDROLINE                 |
| 31. VITAMIN B1 (THIAMINE)   | 69. CHLORPROMAZINE               |
| 32. CARBAMAZEPINE           | 70. METHENDIENONE                |
| 33. VITAMIN B2 (RIBOFLAVIN) | 71. PHENYL BUTAZONE              |
| 34. THEOPHYLLINE            | 72. LYNESTRANOL                  |
| 35. LEVODOPA                | 73. SALAZOSULPHAPYRINE           |
| 36. TOLNAFTATE              | 74. DIOSMINE                     |
| 37. VITAMIN E               | 75. TRIMIPRAMINE                 |
| 38. NALIDIXIC ACID          |                                  |

Source: (Ministry of Chemicals and Fertilizers 1995)

The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely:

$R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED.$  where

- "R.P." means retail price;
- "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf;
- "C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf;

"P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;

"E.D." means excise duty:

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty percent of the landed cost.

Explanation - For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

Source: (CDSCO 1995)

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