DRUGS CONTROL OFFICERS (I) WELFARE ASSOCIATION

(Regd.No. 634 of 2022)

E-mail: dcoidcwa@gmail.com Website: www.dcoiwa.com

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President
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Organizing Secretary:
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Vice-Presidents:
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Date: 3rd Sep 2025
Place: Hyderabad

To,
Shri Jaya Prakash Nadda,
Hon'ble Union Health Minister,
Minister of Health and Family Welfare,
Room No. 402D, Nirman Bhavan,
New Delhi - 110 011
Email : india-hfm@gov.in

Detailed Draft Proposal (White Paper) that for submission to **MoHFW, CDSCO, and State Authorities** to formally push for systemic reforms:

Draft WHITE PAPER

Strengthening India's Drugs Regulatory Enforcement:

A National Proposal from the Drugs Control Officer India Welfare Association (DCOIWA)

Submitted by:

National President
Drugs Control Officer India Welfare Association (DCOIWA)

1. Executive Summary

India's pharmaceutical sector is a global leader, yet the increasing incidence of **spurious, adulterated, misbranded, and substandard (NSQ)** drugs poses a grave **public health and international reputation risk**. Drugs Control Officers (DCOs) serve as the **frontline enforcement arm** under the **Drugs & Cosmetics Act, 1940**.

However, across states, the DCO fraternity is **critically understaffed, under-equipped, and under-recognized**, leading to inadequate market surveillance, delayed prosecution, and low conviction rates.

DCOIWA calls for **urgent systemic reforms** to create a strong, well-trained, well-equipped drug enforcement network, backed by **dedicated manpower, infrastructure, and special courts**.

2. Current Challenges

Issue	Status	Impact
Severe Manpower Shortage	WHO recommends 1 Drug Inspector per 50 establishments; many states average 1:200+.	Low inspection frequency, poor surveillance.

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Issue	Status	Impact
Workload Explosion	NSQ, counterfeit medicines, unlicensed sales, online pharmacies, narcotic control, cosmetics regulation.	DCOs overburdened, reduced efficiency.
No Dedicated Enforcement Wing	Raids depend on local police; no permanent armed support.	Risky operations, delays in crackdown.
Lack of Special Courts	Prosecutions take years; conviction rates are low.	Weak deterrence for offenders.
Training Gaps	No central academy or regular forensic training.	Uneven enforcement standards.
Infrastructure Deficiency	Labs underfunded, shortage of mobile vans, no integrated digital surveillance.	Slow sample testing, poor intelligence sharing.

3. Proposed Reforms

A. Manpower Augmentation

- **Immediate creation of 5,000+ new inspector posts** across states.
- Establish a **National Drugs Regulatory Cadre** with uniform recruitment, training, and promotion structure.

B. Dedicated Drugs Enforcement Wing

- Create a **Special Enforcement Wing** in every state, modeled after Excise or Food Safety departments.
- Permanent attachment of trained police officers for raids and intelligence operations.
- Officers to be empowered under **Section 22 of D&C Act** with clear SOPs for enforcement.

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C. Special Fast-Track Drugs Courts

- Invoke **Section 36AB of D&C Act** to establish **exclusive Drugs Courts** in every division or state.
- Target case resolution **within 6 months** of charge sheet filing.

D. National Training & Research Academy

- Create a **Central Drugs Control Academy** under CDSCO for:
  - Induction training
  - Advanced forensic & cyber investigations
  - International collaboration (USFDA, WHO)
- Mandatory refresher courses every 3 years.

E. Digital Intelligence & Market Surveillance

- Implement **national QR/barcode-based track-and-trace** for all medicines.
- Establish a **National Drugs Surveillance Portal** (integrated with state-level inputs).
- AI-driven alerts for counterfeit medicines and unauthorized sales.

F. Infrastructure Upgrade

- Upgrade state drug labs to **NABL accreditation** level with increased staff.
- Deploy **mobile testing labs** in all districts.
- Funded through a mix of **Central Health Budget and State Allocation**.

G. Recognition & Welfare

- Introduce **commendation medals, risk allowance, and awards** for officers leading major enforcement actions.
- Ensure **psychological safety & legal backing** for officers facing threats from criminal networks.

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4. Implementation Roadmap

Phase	Actions	Timeline
Phase 1	White paper submission, stakeholder consultations with MoHFW, CDSCO, and Law Ministry.	3 months
Phase 2	Pilot projects in 3 states (UP, Maharashtra, Gujarat) for enforcement wings and drugs courts.	6-12 months
Phase 3	National rollout of enforcement wings, training academy, and mobile testing labs.	18-24 months
Phase 4	Fully operational **digital surveillance and track-and-trace system** nationwide.	3 years

5. Expected Outcomes

- **Faster Enforcement:** Raids and seizures become swift, efficient, and safe.
- **Higher Convictions:** Fast-track courts ensure deterrence.
- **Global Trust:** Improved drug quality reputation for Indian pharma.
- **Officer Morale:** Recognition programs and better infrastructure encourage proactive vigilance.

6. Conclusion

Strengthening India's Drugs Regulatory System is a **public health imperative**. DCOIWA urges the **Union Ministry of Health & Family Welfare, CDSCO, and State Governments** to adopt this roadmap to empower the Drugs Control Department as a **dedicated enforcement force**, equipped to safeguard citizens and uphold India's standing as the "Pharmacy of the World."

G. Koteshwar Rao
National President

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2. **Shri Rajeev Singh Raghuvanshi,**
   Drugs Control General of India, FDA Bhavan,
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   Email : dci@nic.in
3. **All state health ministers through concerned HOD s**

Enclosed : **Mashelker Committee Report**

REPORT

OF

THE EXPERT COMMITTEE

ON

A COMPREHENSIVE EXAMINATION OF DRUG REGULATORY ISSUES, INCLUDING THE PROBLEM OF SPURIOUS DRUGS

MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA

NOVEMBER 2003

EXECUTIVE SUMMARY

1. There has been a wide-ranging national concern about spurious / counterfeit / substandard drugs. The Supreme Court of India, the National Human Rights Commission and the Members of Parliament have time and again expressed a concern about improving the drug regulatory system in the country. The Drugs and Cosmetics Act has not been reviewed in a comprehensive manner since its inception although the Rules have been amended from time to time. The Government of India, in the past, had constituted several Committees, which had examined the issues and had made many recommendations. These recommendations have been implemented by the Government to some extent, but the core issues have remained unresolved.

2. The Government of India decided to constitute an Expert Committee under the chairmanship of Dr. R.A. Mashelkar to examine all the aspects regarding the regulatory infrastructure and the extent and problem of spurious/substandard drugs in the country. The Committee was asked to make recommendations and suggest a roadmap for implementation of the recommended measures so that this problem could be solved in its entirety. The Committee had an eminent scientist, an eminent lawyer, and former police commissioners as its members. Officials representing key Ministries/Departments/States/ drug manufacturers, trade, consumer and professional associations were also inducted as members. Drugs Controller General (India) acted as the Member Secretary.

3. The Committee examined the broader issues by looking at the recommendations of earlier committees, the extent of progress made and the bottlenecks in implementation of the recommendations. The Committee noted that while some measures had been initiated by the Central Government, much more needed to be done to improve the regulatory system. Further, the response to these issues at the State Government level was a matter of special concern.

4. The Committee noted that although the Drugs and Cosmetics Act has been in force for the past 56 years, the level of enforcement in many States has been far from satisfactory. The non-uniformity in the interpretation of the provisions of laws and their implementation and the varying levels of competence of the regulatory officials were the main reasons for this less than satisfactory performance**.**

5. The Committee noted that in the light of the assessment and the recommendations of several committees, the Ministry of Health & Family Welfare had made proposals for expansion and upgradation of CDSCO. Several posts to strengthen port offices, zonal offices and testing laboratories were also created. These posts could not be filled due to some administrative complexities. The posts have since lapsed. The committee understands that efforts were made to revive these posts but actual filling of the posts has not been done yet.

6. In 1999, the Pharmaceutical Research & Development Committee (PRDC) had recommended comprehensive strengthening of CDSCO to enable it to carry out the multifarious activities that the Department was expected to perform. The Committee noted, however, that in spite of the fact that three years had lapsed from the acceptance of the PRDC report by the Government, no infrastructural improvement in respect of manpower had occurred in CDSCO.

7. The idea of setting up of National Drug Authority (NDA) starting with the Hathi Committee Report (1975) was reiterated by Drug Policy (1986), and Drug Policy (1994). However, it was not implemented.

8. The Committee concluded that the problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

9. The Committee concluded that the existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. The Committee felt that creating another authority will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA) was the most appropriate solution. A detailed proposal to create such a structure and strengthen the State level regulatory apparatus with complementary roles of the Centre and the States, while at the same time ensuring uniform and effective implementation, has been considered and recommended by the Committee.

10. The Committee noted that the onus of monitoring drug manufacturing standards, drawing and testing of samples, taking legal action against infringers rested primarily with State Drug Regulatory agencies. Hence for any effective intervention, it was essential that the State Governments strengthen and support their Drug Control Organizations. This will include provision of additional personnel, with top class technical and investigative skills, appropriate infrastructure and adequate resources. Despite several directions from the Central Government, many State Governments were yet to upgrade the drug testing facilities and the competence of their regulatory infrastructure was not at the desired level.

11. The information collected from the States in response to a questionnaire sent by the Committee revealed serious inadequacies of the regulatory apparatus. Out of the information received from 31 States/UTs, only 17 drug-testing laboratories were found to be functioning. Out of 17 States having their testing laboratories, only 7 were reasonably equipped/staffed, while the others were poorly staffed and did not even have the bare minimum equipment.

12. The Committee further observed that right from the time of Hathi Committee Report (1975), the States had been repeatedly requested to set up an intelligence cum legal cell but so far only 10 States had reported to have set up such cells. It was not clear as to how many of these are really functioning actively and effectively.

13. The Committee was able to obtain detailed information regarding different categories of manufacturing units licenced by the State authorities. It was found that as against the frequently quoted figure of about 20,000 manufacturing units. The actual number of drug manufacturing licenses issued was - bulk drugs (1333), formulations (4534), large volume parenterals (134) and vaccines (56). Thus, the total number of manufacturing units engaged in the production of bulk drugs and formulations is not more than 5877. Besides there are 199 medical devices units, 638 surgical dressings and 272 disinfectant units, 4645 loan licences and 318 repacking units, 1806 blood banks, 2228 cosmetics units and 287other units not covered in the above categories.

14. The Committee examined the various reports and statistics presented at various fora and the media by diverse individuals, associations and agencies concerning the extent of menace of spurious drugs. The reported extent ranged widely between 0.5% (based on the cases analysed by State regulatory authorities reported in this Report) to 35% (ascribed to WHO Studies). However, WHO itself has written in response to a query from the Indian Government that 'There is no actual study by WHO, which concludes that 35% of World's spurious drugs are produced in India'. Some estimation of the quantum of spurious drugs in the market quoted is available based on the cases detected in selected pockets and regions in the country. Validation of the claims made by several agencies was not available as concrete and authenticated evidence even at the time of the submission of this final report.

15. The Committee has concluded that it is absolutely essential to evaluate systematically and scientifically the extent of the problem. For this purpose, several approaches including the model proposed by the Delhi Pharmaceutical Trust were considered by the Committee. It is recommended that a scientifically and statistically valid methodology should be used to evaluate and quantify the extent of the problem of spurious drugs at various levels in the supply chain at the Regional and National levels. The Committee, in its interim report had recommended that the Government should provide funds for this study. The Government has since agreed to provide adequate funds for undertaking the study.

16. The Committee has come to the conclusion that while the present Drugs And Cosmetics Act contains various provisions for effective punitive action against manufacturers and distributors of spurious drugs, more deterrent measures were needed. Although in the overall context of legal system, the offences having penalty of more than 3 years are construed to be cognisable, there is a need to make a distinct provision in the Drugs and Cosmetics Act itself declaring all offences related to spurious drugs as

cognisable and non-bailable. Apart from penalties of stiff fines and imprisonment for life, specifically in those cases, which had resulted in grievous body harm or loss of life, death penalty was required to be provided.

17. The Committee noted with dismay that most of the prosecution cases pertaining to offences related to spurious drugs remain undecided for years. There is no greater deterrent than a 'severe', 'sure' and 'swift' punishment. This problem needs to be solved squarely by making a separate provision for speedy trials of such offences.

18. For effective and successful implementation of the penal steps, it is necessary to involve the Police authorities in addition to the Drugs inspectorates, at an early stage, by authorising them to file prosecutions for spurious drug offences under the Drugs & Cosmetics Acts. It may be necessary to invoke changes in the related statutory provisions including fresh legislations for effective implementation of the steps needed to be taken for both punitive and deterrent punishments to those involved in criminal acts of manufacture and distribution of drugs, which may lead to mortality or serious threat to life of innocent consumers.

19. The Committee recommends that Drugs and Cosmetics Act should be suitably amended and the maximum penalty for sale and manufacture of spurious drugs causing grievous hurt or death should be enhanced from life imprisonment to death. Likewise, the Government should make the penalties more deterrent for other related offences.

20. While the prevailing penalties are decided by the courts following normal legal procedures, it is imperative that there should be an effective deterrence against such offenders at the investigation level itself. The Committee, therefore, recommends a specific provision in the Drugs and Cosmetics Act that will allow persons indulging in spurious drug offences to be detained for a minimum period.

21. Specific recommendations for amending the provisions of existing Drugs & Cosmetics Act 1940 to give effect to the recommendations in 14-19 above have been made by the Committee. The details can be seen in **Annexure-13** of the Report.

22. The Committee is of the view that the responsibility for effective management of the issue of spurious drugs, their manufacture and distribution lies not only with the Drug Regulatory Agencies at the Centre and in the States and the Police, but also with all the other stake holders, namely, the medical and para-medical professionals, pharmaceutical companies, distributors and retail trade, patients, the media, the NGOs and the public at large. This is largely because these components of the healthcare system are the most affected and in many cases are the first contacts in the supply chain.

23. The Committee feels that, while, many of the stake holders, such as the regulatory agencies and the pharmaceutical companies have sufficient

expertise to detect and analyse spurious drugs, others need to be made aware of the problems involved, the potential grievous harm which can be caused and the initiatives they could and should take in tackling this menace. The Committee suggests that the industry and trade associations should play a more active and collaborative role as has recently been done by Indian Pharmaceutical Alliance (IPA) to arrest the menace of spurious drugs in the country. Specific recommendations concerning the way ahead have been made in the Interim Report.

24. The report of the Committee has been divided in part A and part B according to the terms of reference of the Committee. Part A deals comprehensively with the issue of implementation of all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and the way to bring them up to international standards. It provides the design of Central Drug Administration (CDA), its size, functions and the sharing of the responsibilities vis-à-vis the States including directions for licensing of manufacturing units by a central authority. It also deals with the regulatory health food/dietary supplements/therapeutic foods, Indian system of medicines and herbal products, over the counter drugs, medicines & diagnostics. It addresses the issue of drug development and clinical research in India with special reference to the drug regulatory agency including modern biotechnology. Part B covers the problem concerning spurious and substandard drugs in the country and the measures to deal with it.

SUMMARY OF RECOMMENDATIONS

A. COMPREHENSIVE EXAMINATION OF DRUG REGULATORY ISSUES

1. Recommend a new structure for the Drug Regulatory System in the country including the setting up of a National Drug Authority

1.1 The Committee concluded that the problems in the regulatory system in the country are primarily due to:

- inadequate or weak drug control infrastructure at the State and Central level;
- inadequate testing facilities;
- shortage of drug inspectors;
- non-uniformity of enforcement;
- lack of specially trained cadres for specific regulatory areas;
- non existence of data bank; and
- non- availability of accurate information.

1.2 The existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as a National Drug Authority (NDA) will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped, empowered, independent and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA) reporting directly to Ministry of Health would be the most appropriate solution.

2. Recommend measures to strengthen the drug regulatory infrastructure in Centre and States

2.1 The restructured CDA should have 10 main Divisions at the headquarters manned by adequately trained manpower. Each of these divisions may have several sections depending upon the scope of the activities of the respective division. These divisions could be named as:

1. Division for Regulatory Affairs & Enforcement
2. Division for New Drugs & Clinical Trials
3. Division for Biological & Biotechnology Products*
4. Division for Pharmacovigilance
5. Division for Medical Devices and Diagnostics
6. Division for Imports
7. Division for Organizational Services
8. Division for Training and Empowerment
9. Division for Quality Control Affairs
10. Division for Legal and Consumer Affairs

2.2 The Committee recommends that the Central Drug Administration should be made into an independent office under the Ministry of Health and Family Welfare as is the case in most of the countries. The proposed overall organization is shown in **Fig.1**.

2.3 The above changes will require Government's commitment and a strong political will. In particular, the following measures would be required for the implementation of the above proposal:

- Expansion of zonal and sub-zonal offices;
- Creation of additional infrastructure for new offices in states;
- Creation of considerable number of additional senior level and supporting posts;
- Need of additional funds to set up a world class Central Drug Administration.

2.4 The proposed structure of CDA at the headquarters, zonal, sub zonal offices and state offices (for Phase I central licensing to begin by 1st January 2005, see 2.8.2 below for explanation) will need the following additional posts:

- Joint Drugs Controllers – 3;
- Deputy Drugs Controllers – 2;
- Assistant Drugs Controllers – 6;
- Drugs Inspectors – 50;
- Technical Experts – 5;
  - Pharmaceutical chemist
  - Pharmaceutist
  - Pharmacologist
  - Toxicologist
  - Statistician
- Administrative Officer – 1;
- Accounts Officer – 1;
- Computer Operators – 15; & adequate supportive staff.

2.5 The functions of central regulatory agency being multi-disciplinary in nature, considerable sourcing of expertise from external experts and institutions will be required. It is necessary that such consultations are managed speedily, since drug development activities are very cost and time sensitive. This would require provision of sufficient funds at the disposal of office of DCG(I) to support sourcing of external expertise and an easy mechanism to make payments of honorarium and travel expenses without delay, as per the systems available with CSIR and ICMR.

2.6 The committee observed that the issue of non-uniformity of enforcement at the state level was serious and needs to be addressed immediately. In particular, the Committee noted the repeated pleas made by National Human Rights Commission, Hathi Committee Report, Estimates

Committee of Seventh Lok Sabha, etc. for Central Government to assume the responsibility of granting manufacturing licenses. The guiding principle driving this suggestion has been aptly summarised in para 33 of the Hathi Commmittee Report *'quality control of products manufactured anywhere in India was not solely the responsibility of the state in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one state was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other states. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country'*.

2.7 In the light of the above the Committee recommends that the grant of manufacturing licenses should be given by Central Drug Administration. However, the Committee noted that a time table for change will have to be created, since the present CDSCO is ill equipped (due to shortage of manpower, etc.) to take up this function immediately. The take over has to be synchronised with the conversion of CDSCO into a full fledged CDA.

2.8 The following is the **Proposed Roadmap** for CDA to undertake functions of licensing of Drug Manufacturing units

Categories of States/UTs

2.8.1 After analysing the information received from the states and union territories, the Committee noted that more than 75 % drug manufacturing licenses are in 7 states, namely, Maharashtra, Gujarat, Tamilnadu, Andhra Pradesh, Karnataka, West Bengal and Goa. 10 states namely Bihar, Delhi, Goa, Haryana, Kerala, Madhya Pradesh, Orissa, Punjab, Rajasthan and Uttar Pradesh account for about 20 % of drug manufacturing licenses. The remaining 18 states and union territories have only 5 % of the licenses. It was felt that for the purpose of licensing, the states and UTs can be divided into 2 categories, depending upon the quantum of manufacturing licenses.

Category 1 – Maharashtra, Gujarat, Tamilnadu, Andhra Pradesh, Karnataka, West Bengal and Goa;

Category 2 – Bihar, Delhi, Haryana, Kerala, M.P, Orissa, Punjab, Rajasthan, U.P., Andaman & Nicobar Islands, Arunachal Pradesh, Assam, Chandigarh, Chattisgarh, Dadar & Nagara Haveli, Daman & Diu, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Lakshadweep, Manipur, Meghalaya, Mizoram, Nagaland, Pondicherry, Sikkim, Tripura and Uttaranchal.

2.8.2 The switch over to Central licensing of drug manufacturing units could be considered in 3 phases.

Phase – I (to be completed by 31 December 2004)

During this phase, it is expected that manpower and infrastructure of the proposed CDA would be in place by 31st December 2004. The manpower requirements of proposed CDA can also be met partially by absorbing some of the experienced and willing regulatory officers from the States for the purpose of inspection and licensing.

Phase – II (1st January 2005 onwards)

From 1st January, 2005 onwards, the licensing functions of Category 2 states and UTs will be taken over by the proposed CDA.

CDA will operate from the following new offices for performing the new functions:

Sub zonal offices of East Zone office at Guwahati for licensing of units of NE states/union territories, at Bhuvaneshwar for Orissa and at Patna for Bihar.

The North Zone office at Ghaziabad will be reorganized to take up the licensing functions of UP, Delhi and Uttaranchal.

Sub zonal offices of North zone office at Chandigarh for licensing of units of J &K, HP, Punjab, Haryana and Chandigarh and at Jaipur for Rajasthan.

The West Zone office at Mumbai and the port office at Ahmedabad will be re organized to take up the licensing functions of units at Daman & Diu, Dadar, Nagar and Haveli.

Sub zonal office of West Zone Office at Indore for units of M.P and Chhattisgarh.

The South Zone office will take care of units at Pondicherry, Kerala, Lakshadweep and Andamans & Nicobar Islands.

Phase - III (1st January 2006-onwards)

The licensing of manufacturing units of Category 1 states will be undertaken by CDA from 1st January, 2006 onwards by opening new offices and reorganizing the structure of existing zonal, sub zonal and state offices to make sure that all the areas are appropriately covered.

2.9 In summary, the Committee concludes that:

- The process of establishing CDA should be completed by 31st December 2004 and the State/UT Regulatory Systems should be suitably strengthened;

- Guidelines and directions issued to the State/UT Drug Regulatory Authorities on regulatory policies should be strictly and uniformly complied with failing which action may be taken against the concerned regulatory officials;

- Based on the accepted performance indicators of a good regulatory agency, the functioning of drug control agencies may be audited by a panel of independent experts. This activity should be funded by the central government. If the performance of any state DRA is found to be below par and/or not in accordance with the provisions of the Act and the Rules, the Central government shall have the powers to take suitable action; and

- Accordingly, the Drugs and Cosmetics Act and the Rules may be amended to assume such powers.

2.10 A sub-Committee of Drugs Consultative Committee (DCC) may be set up to specifically examine the following and recommendations made thereon may be used to modify the Drugs and Cosmetics Act.

- *The Drugs and Cosmetics Rules provide that the manufacturers as well as wholesalers and retailers have to obtain separate licenses based on categorization of drugs classified as C & C1 and those other than C & C1. These provisions have been in place since inception and they need to be reviewed to further rationalize the licensing and regulatory procedures keeping with the contemporary developments*

- *Schedule H gives list of drugs that are required to be sold only on prescription of a Medical Practitioner. There is a need to review and revise the present Schedule H.*

- *Section 33 P of Drugs and Cosmetics Act may be amended to give powers to DCG(I) to issue directives to state licensing authorities, to review the orders passed by them and if necessary, to revoke the product permission granted by them.*

2.11. The Committee recommends that the State Drug Control Organisations should be urgently strengthened with competent and trained manpower and with adequate budgets. The following are the specific recommendations:

a) State Governments should strengthen the drug regulatory system in their states. There is a need to augment the number of Drug Inspectors in many states, especially in category 1 states (para 2.8.1), where the majority of the manufacturing & sales units are located.

b) The capability & skill of state enforcement staff should be continuously upgraded by adequate training in specific regulatory areas of inspection and investigation.

c) State Governments should provide adequate infrastructure for the office of state DRA and the field officers including sufficient funds for vehicles and purchase of samples.

d) Structured mechanisms should be set-up to enable interstate exchange of regulatory officials to bring about better understanding of processes adopted in different states. This would help in harmonising the enforcement practices and would bring an improved uniformity.

2.12 The specific actions recommended for State Drug Control Organizations are as follows:

a. Strengthen the State Drug Control Organization with additional manpower, infrastructure, technical capabilities and financial sources.

b. Set up Intelligence cum legal cell under the supervision of trained senior nodal officers. The State Government should put in place efficient mechanism for timely police help to these officers.

c. Establish a proper surveillance system for keeping a watch over suspected persons. Watchers should be employed and secret funds may be made available for intelligence activities.

d. Set up efficient communication networking for sharing and exchanging information in cases involving inter-state movement of spurious drugs.

e. Request the government to identify designated courts for speedy trial of spurious drug cases.

f. Set up an adequate testing laboratory according to the need to ensure that the suspected samples are tested expeditiously.

g. Monitor the sources of purchase and quality of drugs stocked by dispensing medical practitioners and institutions.

h. Provide a toll free number to receive public complaints/ information, etc.

i. The condition of license for sale of drugs should be strictly enforced.

3. Other Related Drug Regulatory Issues

3.1 Health Food/Dietary Supplements/Therapeutic Foods

- Create new categories for covering dietary supplements and functional foods.

- These should be regulated under the PFA or any other emergent mechanism/infrastructure.

- Products that claim or are intended to diagnose, cure, prevent or treat a disease should be classified as drugs as is the current rule.

- The particular products (1) that are formulated with the intent to supplement the diet with nutrients, or (2) have had a scientifically proven ingredient- disease relationship, and (3) marketed with health claims, should be brought under the purview of food laws.

- It should be made mandatory that for the ingredients used in products, bibliographic evidence of safety, or evidence of traditional and prolonged usage, or scientific toxicity evidence should be provided.

As regards the manufacturing practices, the Committee recommends that these products should to be regulated in respect of their quality & safety by incorporating a special provision and corresponding procedures under the relevant food law. The products with distinct medicinal claims would have to qualify as drugs as per the prescribed procedures.

3.2 ISM, Herbal Products and Drugs of Natural Origin

3.2.1 There is a need to review and update the list of books included in Schedule I. A high-powered expert body should be appointed for this purpose. This body should carefully review and approve only the authoritative books for such a purpose.

3.2.2 The definition given under 3(h) of the Drugs and Cosmetics Act uses the term “Patent or Proprietary (P&P) Medicine”. The meaning of the term ‘patent’ in the present day context is totally different and has other legal implications. Hence this definition should be amended to drop the words “Patent or”.

3.2.3 The licensing requirements need to be updated to include requirement of data related to confirmatory evidence of efficacy claims of the product. Additional safety data should be provided if long-term safety data on its usage are not available. Through the provision of these data, one will ensure that the new combinations of ingredients are scientifically proven for their safety and efficacy.

3.2.4 The conditions for licensing should be amended to demand rationale for the P or P medicine either on ISM basis or on the basis of the data that are generated by adopting a current scientific methodology. If such data justify a new usage for ISM ingredients and combinations not mentioned in the official books, then they should be allowed in the law.

3.2.5 In order to manufacture modern dosage forms, use of all the approved inert pharmaceutical excipients must be accepted and legally permitted, wherever required. No restrictions except for the safety concerns should be placed in this context.

3.2.6 Use of ethyl alcohol (alone or in combination with water) should be approved for extraction of herbs and the same should be incorporated in one of the schedules under the Drugs &Cosmetics Rules.

3.2.7 For promoting excellent recipes of ISM in both domestic and international markets, a new category, which could be defined as ***Ayurvedic Cosmetics,*** should be introduced.

3.2.8 If herbs from outside India are adequately researched using research methodology of ISM and their characteristics are evaluated on ISM guidelines (like *Rasa, Guna, Veerya*, *Vipaka, Prabhava*, etc) adoption of such herbs in the ISM system could be permitted. This would encourage herbs from other countries to be evaluated adopting ISM philosophies and principles.

3.2.9 Such permissions should be granted only after due evaluation by an expert body of ISM. A high level ISM expert committee may be

appointed to critically evaluate this issue and make recommendations concerning the practices to be adopted for this purpose.

3.2.10 Methods for the extraction and preparation of marker compounds, their identity and quality also needs to be published for guidance to the industry. Such work cannot be left to the industry alone.

3.2.11 Standard monographs of important and most commonly used medicinal plants and their standardised extracts be prepared and published.

3.3 Over The Counter Drugs (OTC)

3.3.1 Schedule K should be reviewed comprehensively. Products, which by virtue of their long usage and/or nature of their application (e.g. substances used for household cleaning and disinfectants generally used in a diluted form and not meant for direct application on human skin) could be considered for inclusion in the exempted category under schedule K to further facilitate their easier access to the public at large.

3.3.2 Schedule H should be reviewed on an ongoing basis to add or delete products from the schedule depending upon their usage and safety profile.

3.3.3 A mechanism should be set up to review the list on a periodical basis. This should enable bringing in sufficient flexibility in the system on one hand and promoting sales and distribution of desirable products without in any way compromising on quality of the product on the other hand.

3.4 Medical Devices and Diagnostics

3.4.1 The ‘Medical Devices’ should be specifically defined under section 3 of the Drugs and Cosmetics Act and relevant Rules and guidelines framed for their proper regulation.

3.4.2 A specific Medical Devices Division should be set-up in the office of newly restructured CDA for proper management of approval, certification and quality of medical devices.

3.4.3 An appropriate regulatory mechanism should be set up by CDA for certification, quality assurance and post-marketing surveillance of imported as well as locally made medical devices.

3.5 Drug Development including Clinical Research

3.5.1 The safety of Indian study subjects is of paramount importance. All policies and regulatory systems will have to be so tailored that protection is given to an Indian Citizen at any cost. There has to be a sharing of responsibility by all the stakeholders in clinical research viz.

investigators, sponsors, ethics committees as well as regulators to ensure this.

3.5.2 The Committee noted that many stakeholders – sponsors and investigators alike – are not fully aware of GCP fundamentals, ethics, written SOPs, documentation, ADR management, internal audits as well as regulatory inspections. It is **absolutely essential** to institutionalize Good Clinical Practices (GCP) to achieve credibility for the data generated in India.

3.5.3 The regulatory agency is required to develop adequate capacity to undertake routine inspections of the clinical trial sites. For this purpose, assistance of external experts would be availed. It should have a recourse to the need based therapeutic advisory groups for review of applications. Regulatory officials must be kept up-to-date so that they are adequately trained with the latest global trends in data evaluation, including electronic submissions, etc. Adequate funds should be made available to support all these activities

3.5.4 In order to ensure an enabling environment the regulatory division dealing with the applications concerning new drugs and clinical trials would be required to develop suitable mechanisms to ensure confidentiality of the submissions.

3.5.5 The Committee examined a suggestion that the Indian regulatory agency may consider approval of clinical trial applications of INDs on the basis of approvals accorded by the regulatory authorities of US FDA or western European agencies who, being ICH (International Conference on Harmonisation) signatory countries, have elaborate and strict review processes. The committee, observed that the draft notification of the revised Schedule Y published by Ministry of Health stipulates (para 4.1) that for new drug substances discovered in countries other than India. Phase-I data generated out side India has to be submitted to the licensing authority and permission may thereafter be granted to repeat Phase-I studies. The Committee concurs with this provision under Schedule Y.

3.5.6 The regulatory agencies in India, however, could consider expedited approvals for Phase-II and III clinical trials on the basis of approvals accorded by ICH signatory countries. This is in view of the fact that the ICH signatory countries undertake strict reviews as per ICH guidelines, which aim for a common technical document for mutual acceptance of data.

3.5.7 A single window clearance mechanism for approval of various applications concerning drug research and approval, including research materials etc, should be created within CDA.

3.5.8 The policies and procedures presently applicable in the country for animal experiments need to be rationalised so that research projects are not unduly delayed or shifted out of the country.

3.5.9 Institutional ethics review committees in India need a lot of support in terms of development of their systems including the systems of their constitution. Appropriately constituted and functioning Ethics Committees will need to ensure that Indian public too builds confidence in the process of clinical research. It should be the responsibility of the Indian Council for Medical Research (ICMR) to keep a watch over the systems and methodologies of various Ethics Committees to ensure GCP compliance.

3.6 Storage and Distribution

3.6.1 State Licensing Authorities should devise suitable standard operating procedures to restrict excessive concentration of retail/wholesale outlets.

3.6.2 The drug manufacturers should follow good storage practices for their products during transport as well as their depots.

3.6.3 The drug manufacturers should have limited number of main stockists. Only these main stockists should sell to the retailers or hospitals.

3.6.4 The manufacturers should ensure that retail and wholesale chemists are aware of proper storage conditions of their products.

B. PROBLEM OF SPURIOUS AND SUBSTANDARD DRUGS

4. Evaluate the Extent of Spurious and Sub-Standard Drugs and Recommend Measures Required to Deal with the Problem

4.1 The Committee came to the conclusion, after examining all the data and reports at hand, that there was an absence of a scientifically and statistically designed investigation, which could give a realistic estimate of the menace of spurious drugs.

4.2 The model for such an evaluation presented to the Committee by the Delhi Pharmaceutical Trust appears to be one, which had a rational approach to achieve this objective. The Committee recommends that the Central Government should provide assistance to undertake such scientific and statistically significant study in order to have a clear picture about the exact extent of spurious drugs in the country.

4.3 The gist of the recommendations to tackle the spurious drugs problem is as follows:

- Creation of effective interaction between the stakeholders i.e. industry and regulators, industry and consumers, trade and regulators and medical professional and regulators.
- Creation of intelligence cum legal cells in State and Central offices.

- Discouragement of proliferation of drug distribution outlets.
- Making changes in law to provide enhanced penalties, making the offences cognisable and non-bailable in the light of similar provisions in Narcotic Drugs and Psychotropic Substances Act.
- Designation of special courts to try the cases of spurious drugs.
- Preparation of dossiers of suspected dealers and manufactures.
- Provision of secret funds and incentives to informers.
- Creating effective networking system between States
- Checking on drug supplies to practitioners who buy and supply drugs to their patients.
- Creation by the industry of its counterfeit drug strategies, better surveillance and efficient complaint handling system.
- Creation of better surveillance system by the Trade Association on defaulting members and to take strict action against them.
- Creation of better awareness amongst consumers.

4.4 The Committee noted that there is non-uniformity in the action taken on substandard drugs, especially when the manufacturer of substandard drugs is located in a different state. The Committee recommends that:

a) The DCC should deliberate on the issue of action to be taken on substandard drugs and review the existing guidelines. It should analyse the nature of substandard reports and status of concerned manufacturing units as well as the system of distribution; and

b) The existing classification by DCC of defects found in substandard drugs into category A and category B and the action to be taken on each category of defects needs to be reviewed and updated.

4.5 The Committee noted that majority of the States are not either adequately staffed or technically equipped to monitor the quality of drugs manufactured and sold in their State. There is a strong need to strengthen the organizations with competent and trained manpower and with adequate budgets. This will enable them to detect, investigate and take quick action in spurious/counterfeit drug cases.

4.6. The officers needed to be specially trained for the purpose. The Committee recommends that:

a. The drug control organizations in States should be adequately strengthened. Additional manpower, infrastructure, technical capabilities and financial resources should be made available to the organization. They should

have continuous vigilance facilities and strategies to implement an effective system to monitor and control the manufacture and distribution of spurious drugs.

b. States should set up Intelligence cum legal cells under the supervision of trained senior officer. State Governments should put in place efficient mechanism for timely police help to these officers.

c. States should establish a proper surveillance system for keeping a watch over suspected individuals. Watchers should be employed to purchase samples from suspected persons without disclosing their identity. Secret funds should be made available for intelligence activities.

d. States, which have a large number of drug distribution outlets, should set-up a well-equipped testing laboratory to enable them to test all categories of drugs in shortest possible time. All States should plan to take more samples to check the quality of drugs manufactured and sold in the market. Those States, where it was not technically and economically viable to support their own drug testing facilities, needed to make use of facilities of other States and Central laboratories or even the private approved laboratories for testing of suspected samples.

e. States should set up an efficient communication network system between the Center and other States in order to facilitate exchange of information and rapid investigation in cases involving inter-state movement.

f. States should also monitor the source of purchase and quality of drugs stocked by dispensing registered medical practitioners through their drugs inspectors.

4.7 As regards the improvement of the drug testing laboratories, the committee recommends the following:

a) Drugs and Cosmetics Rules should be amended to include GLP norms as statutory requirement for approved testing labs and also the in house testing labs of manufacturers.

b) Accreditation with NABL should be made mandatory for all testing laboratories including the Government laboratories.

c) The Central Government should initiate a programme to have coded samples of the same product tested at different central and state labs from time to time and have the results assessed by experts for their proficiency testing.

d) The state testing labs should be frequently audited by a team of experts to ensure their proper functioning.

e) A separate Division needs to be established under CDA to oversee the overall working of drug testing laboratories in the country.

4.8 The Committee noted that specific penalties in Drugs and Cosmetic Act were provided in 1982 for offences concerning manufacture and sale of spurious drugs. However, the penal provisions have not acted as adequate deterrents and have not instilled the desired extent of fear among the offenders. It was, therefore, felt that the penalties for all offences related to spurious/counterfeit drugs should be further enhanced.

4.9 The Committee, more specifically, recommends that:

a. The penalty for sale and manufacture of spurious drug that causes grievous hurt or death should be enhanced from life imprisonment to death. Even the penalty for manufacture and sale of spurious drugs that do not cause grievous hurt or death should also be made more severe (Annexure 13, 27a and 27aa).

b. The offences related to spurious drugs should be made cognisable and non-bailable. The bail, if considered by the court should be granted only after a period of three months (Annexure 13, 32b).

c. The penalty for not disclosing the source of purchase of drugs by a dealer should be made stringent (Annexure 13, 28a).

d. A provision should be included in the Drugs and Cosmetics Act to enable the Central and State Governments to designate special courts for speedy trial of spurious drugs cases (Annexure 13, 32(2))

e. A provision for compounding of offences should be included in the Drugs and Cosmetics Act (Annexure 13, 32(c)).

f. Under Drugs and Cosmetics Act, besides the Drug Inspectors, Police should also be authorized to file prosecution for offences related to spurious drugs (Annexure 13, 32(1(a))

Recommended steps to be taken by the Pharmaceutical Industry and Pharmacy Association to tackle the Problem of Spurious Drugs.

4.10 Recommended Action for Pharma industry

a. Use their well-developed marketing network to identify distribution channel and persons involved in spurious drug trade.
b. Assist, through its associations in detection and unearthing of spurious/counterfeit drugs by cooperating with the regulatory and/or police authorities.
c. Prepare, through its associations, a checklist for the guidance of manufacturers, wholesalers and retail sellers to identify and distinguish between the spurious and genuine products.
d. Formulate its own spurious/counterfeit drugs policy and a surveillance strategy to tackle the problem of spurious drugs.
e. Establish a close interaction with regulatory authorities and extend full cooperation to eliminate the menace of spurious drugs.
f. Streamline their supply chain and distribution network.
g. Ensure proper storage of products during transit as well as at places of distribution.

4.11 Recommended Action for the Pharma Trade Association

a. Play a proactive and visible role to contain the menace of spurious/counterfeit drugs
b. Develop its mechanism in identifying the persons directly or indirectly involved in abetting the distribution of spurious, counterfeit or questionable quality drugs
c. Prepare a checklist for the guidance of members and widely publicize it for information of all members
d. Sub Rule 3 of Rule 65 (4) of Drugs & Cosmetics Rules requires that the supply by retail of any drug shall be made against a cash/credit memo. This condition of license should be strictly adhered to by all retail licensees.
e. Every chemist/pharmacist to act as a watchdog to prevent entry of any spurious/doubtful quality drugs or those purchased from unauthorized sources or without proper bills in the supply chain.

4.12 **Recommended Action by the Consumer and other Professional Associations**

There is an urgent need for an awareness campaign to educate the consumers and the medical and paramedical professionals. The Committee, in particular, recommends that the Consumers and health professional/associates should play an active and visible role to create awareness about the hazards of spurious drugs. They should undertake campaigns at the national level to educate the public on the ways and means of detecting spurious drugs and the advantages of purchasing from licensed sources with valid cash memos.

1.0 INTRODUCTION

1.1 The Ministry of Health and Family Welfare, Government of India constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, Director General of CSIR to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs on January 27, 2003. The terms of reference of the Expert Committee were as follows:

1. Recommend a new structure for the Drug Regulatory System in the country including the setting up of a National Drug Authority.

2. Recommend measures to strengthen the drug regulatory infrastructure in Centre and States.

3. Evaluate the extent of the problem of spurious and sub-standard drugs and recommend measures required to deal with this problem effectively.

4. Recommend changes required in the Drugs and Cosmetics Act, 1940 as well as in judicial procedures related to offences committed under this Act.

5. Recommend steps to be taken by the pharmaceutical industry and pharmacy association to tackle the problem of spurious drugs.

6. Consider and advise on any other issue incidental to the above

7. Devise road maps for implementation of all recommended measures.

A copy of the Government order giving composition of the Committee and other details is at **(Annexure 1).**

2.0 APPROACH ADOPTED BY THE COMMITTEE

2.1 The Committee held four meetings, the first on February 26, the second on July 17, 2003, the third on August 11, 2003 and the fourth on October 21, 2003. In the first meeting, after discussing the various terms of reference, it was decided to constitute two sub-committees to examine specific and distinct terms of reference. The composition and specific terms of reference drawn for each of the sub-committees is given in **(Annexure 2 & 2A).** Dr. Prem K. Gupta, former Drugs Controller (India) was co-opted as a member of the Expert Committee in April 2003 **(Annexure 1A).**

2.2 The two sub-committees met on April 29, 2003 and April 30, 2003, respectively. The members had a discussion on all aspects of the specific terms of reference and gave their views and recommendations.

2.3 The present Committee also took into consideration several reports of the Committees, which were set up by the Government of India from time to time. The Committee also considered several submissions that were made by citizens, institutions and organizations, representing different interests and interest groups. The Committee also considered two major policy statements approved by the central government, namely, the National Health Policy 2001 and the National Pharmaceutical Policy 2002.

2.4 A working document in the form of a preliminary draft report of the Committee in 2 parts (A and B) was created on the basis of the studies undertaken and conclusions drawn by the two sub-committees. This report, circulated to all the members, formed the basis of discussion of the meeting on July 17, 2003. A few eminent scientists drawn from diverse sectors, namely, Dr. Nityanand, Dr. Ranjit Roy Choudhary, Dr. D.B. Narayana of drug industry were invited to make presentations concerning the terms of reference. Further, representatives of organizations namely, Indian Medical Association (IMA), Delhi Pharmaceutical Trust (DPT), Consumer Education and Research Centre (CREC) Ahmedabad and Confederation of Indian Industry (CII) were also invited to present their views. The details of those, which either deposed before the committee, or sent in written views, are given in **(Annexure 3)**.

2.5 The Committee was required to submit its report within six months after its formation, i.e., before July 27, 2003. Since it was not possible to complete the entire report with all its terms of reference within this period, the Government extended the term of the Committee accordingly by three months **(Annexure 4)**.

2.6 The interim report containing Committee's views and recommendations in regard to the extent of problem of spurious drugs, changes required in the law to deal with the problem etc. was submitted to the Government on August 12, 2003.

2.7 The Committee decided to constitute three sub-Groups to further examine various issues related to its remaining terms of reference. The composition and the specific terms of reference drawn for each of the three sub-Groups are given in **(Annexure 2A).**

2.8 This final report is a consolidated document, which incorporates the final recommendations made in the light of the overall terms of reference of the Committee.

2.9 The Committee considered it appropriate to make the report in two distinct parts. Part A would deal with general regulatory issues whereas part B would cover the issues concerning spurious and sub-standard drugs and the changes that are required in the law, etc.

PART A

3. DRUG REGULATORY SYSTEM: ROLES AND RESPONSBILITIES

3.1 The Committee was asked to:

1. Recommend a new structure for the Drug Regulatory System in the country including the setting up of a National Drug Authority,
2. Recommend measures to strengthen the drug regulatory infrastructure in Centre and states
3. Consider and advise on any other issue incidental to the above.

3.2 The drug regulatory system is responsible for protecting the public health by assuring the safety, efficacy and quality of human and veterinary drugs, biological products, medical devices, diagnostics & cosmetics. The drug regulatory system is also responsible for advancing the public health by keeping its systems contemporary and by helping to speed innovations that make pharmacotherapy safer and more effective. The regulatory system also helps in the consumers getting accurate and adequate information concerning the appropriate use of medicines and related products.

3.3 The vision of a model drug regulatory system would be to protect public health by ensuring provision of safe, effective and quality drugs & pharmaceuticals based on scientific excellence and best possible regulatory practices. Development and deployment of qualified and trained professionals can alone provide nationwide enforcement, which is uniform, consistent and of a high quality.

3.4 The following values and creeds are important to attain the envisioned levels of appropriateness and excellence:

- Professionalism through integrity, diligence, objectivity, excellence, commitment and consistency;

- Accountability through open and transparent operations;

- Achievement through professionalism and effective, efficient and timely work practices, which are focused on outcomes;

- Open and effective communication with all stakeholders.

3.5 It is logical that in order to achieve such a vision, the following critical requirements are met:

- Strategies, structures and processes, which are clear and aligned to meet the laid down objectives, policies and priorities;

- Staff with adequate professional and operational skills and competence to meet the evolving role and all functions of the drug regulatory policies and enforcement strategies;

- A capacity to gather and use information for achieving and managing improved outcomes and performance standards;

- Leadership in strategic planning & management ;

- Clear communication and effective consultation with staff, state regulatory authorities and stakeholders;

- Effective research, information gathering and analysis;

- Skills to consider innovative solutions;

- Maintenance and enhancement of the organisational skill base and expertise;

- Effective participation in the international fora;

- Specific strategies to address the timely implementation of the Government's policy changes in health and industry matters;

- Continuous improvement of regulatory operational systems;

- Effective partnerships with other relevant Ministries and other Departments, regulators and research bodies;

- Professional and timely response to communications;

4.0 CURRENT DRUG REGULATORY SYSTEM IN INDIA

Various regulatory aspects related to import, manufacture, sale and advertisements related to drugs are covered under three separate enactments, namely, Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945, The Pharmacy Act 1948 and the Drugs & Magic Remedies (Objectionable Advertisements) Act 1954.

4.1 Drugs & Cosmetics Act

4.1.1 The Drugs and Cosmetics Act 1940 is a central legislation, which regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious and conform to prescribed quality standards and the cosmetics marketed are safe for use.

4.1.2 The Drugs Act was enacted in 1940 in pursuance of the recommendations of Chopra Committee constituted in 1930 by the Government of India. The Act received the assent of the Governor General on 10th April 1940 and thus became a statute. The Drugs Rules were promulgated in December 1945 and the enforcement of these statutes started in 1947. The Drugs Act, as enacted in 1940, has since

been amended several times and is now titled as Drugs and Cosmetics Act. The Rules have also been amended from time to time to meet the needs of the times and to make good any deficiencies noticed during the implementation. The very definition of 'Drug' under the Drugs & Cosmetics Act covers a wide variety of therapeutic substances, diagnostics and medical devices. It thus requires an adequate multidisciplinary expertise, which should be available with regulatory agencies, especially at the central level. Moreover, the standards of safety, efficacy and quality of therapeutic products are becoming ever demanding. Therefore, regulatory capacity has to become world class. Under the Constitution of India, 'Drugs' being a concurrent subject, the responsibility of enforcing the various provisions of the Act vests with the Central Government and the State/UT Governments. The roles of Central & State Governments are well defined.

4.2 The Central Drug Standard Control Organisation (CDSCO)

4.2.1 The Central Drugs Standard Control Organisation (CDSCO) headed by the Drugs Controller General (India) (DCGI) discharges the functions allocated to Central Government. The CDSCO is attached to the office of the Director General of Health Services in the Ministry of Health and Family Welfare. The DCGI is a statutory authority under the Act and has port offices, zonal offices and drug testing laboratories functioning under him.

4.2.2 The main functions of the Central Government are:

a. Approval of new drugs to be introduced in the country;
b. Permission to conduct clinical trials;
c. Registration and control on the quality of imported drugs;
d. Laying down regulatory measures and amendment of Acts and Rules;
e. Laying down standards for drugs, cosmetics, diagnostics and devices and updating Indian Pharmacopoeia;
f. Approval of Licenses as Central License Approving Authority for manufacture of large volume parenterals, vaccines and biotechnology products and operation of blood banks and also of such other drugs as may be notified by Government from time to time;
g. Coordinating the activities of the States and advising them on matters relating to uniform administration of the Act and Rules in the country.

4.2.3 The State Governments are responsible for :

a. Licensing of manufacturing establishments and sales premises;
b. Carrying out inspections of licensed premises for ensuring compliance to conditions of licenses;
c. Drawing samples for test and monitoring the quality of drugs and cosmetics moving in the State;
d. Taking appropriate actions like suspension/cancellation of licenses;

e. Surveillance over sale of spurious / adulterated drugs;
f. Instituting legal action, wherever needed, as provided in the Act and Rules; and
g. To monitor objectionable advertisements pertaining to drugs.

4.2.4 The State Drug Controllers exercise these functions through State Drugs Inspectors. The organizational set up varies widely from State to State. While in some States, a full time technical person heads the drug control organisation; the others have administration or medical persons as ex-officio Drugs Controllers or heads of offices. Only a few States have well-equipped testing laboratories, while others have either no laboratory or a very small one, with scant testing facilities. The States have not taken action to provide full-fledged testing facilities, despite the rapid increase in the number of sales premises. The number of drug inspectors in the States as also their skills are observed to be generally not commensurate with the load of work of inspections and monitoring of quality of drugs. A detailed study conducted by the present Committee concerning this aspect and its conclusions are provided later in this report.

4.3 Past Recommendations for Strengthening Drug Regulatory Infrastructure

4.3.1 The Drugs and Cosmetics Act has been in force for the past 56 years but the level of enforcement in many States has been far from satisfactory. The non-uniformity in the interpretation of the provisions of laws and their implementation and the varying levels of competence of regulatory officials are the main reasons for this less than satisfactory performance.

4.3.2 Several committees have studied the enforcement problems of the States and have given recommendations. As early as 1975, Hathi Committee gave a comprehensive report and recommended measures for strengthening and streamlining the Central and State Drug Control organisations. Some of the recommendations of Hathi Committee have been implemented at the Central level. The States have not been able to strengthen their organisations as per the recommendations.

4.3.3 In June 1982, Government of India appointed a Task Force with Additional Secretary, Ministry of Health & Family Welfare as its Chairman. The Task Force in its report had made several recommendations for action to be taken by the Central Government as well as the State Governments. Among their several recommendations, one was that the number of drug inspectors in the States should be increased in keeping with the number of manufacturing and selling premises licensed. It was suggested that the number should be on the basis of one drug inspector for 25 manufacturing units and one for 100 sales premises. Most of the States have not been able to augment their inspectorate staff as per this recommendation.

4.3.4 In addition, the Estimates Committee of Lok Sabha (1983 –1984) had also studied the problem and given its views as well as recommendations on the problem of drug standards, testing laboratories and organizational set up, etc.

4.3.5 The Committee was informed that in the light of the assessment made and the recommendations of all these committees, the Ministry of Health & Family Welfare had made proposals for expansion of CDSCO. The Government, in 1992, had created several new posts. Realizing the additional load of work, many group A posts were sanctioned for the head quarter to assist the DCGI. Several posts to strengthen port offices, zonal offices and testing laboratories were also created. These posts could not be filled due to the administrative complexities and got lapsed. The Committee was informed that efforts were made to revive these posts, but actual filling of the posts never took place.

4.4 PRDC (1999) Recommendations on CDSCO

4.4.1 In 1999, the Pharmaceutical Research & Development Committee (PRDC) headed by Dr. R.A. Mashelkar had recommended comprehensive strengthening of CDSCO to enable it to carry out the multifarious activities that the Department was expected to perform, especially in the context of post 2005 scenario, when the Indian drug industry would have to rise to entirely new set of challenges.

4.4.2 The report had emphasized -

"In the backdrop of strong trend towards globalisation of regulatory and scientific requirement pertaining to safety, efficacy and quality issue, the committee has recommended a professionally managed and efficient regulatory mechanism under the CDSCO. Several specific measures have been suggested to facilitate creation of a new structure for CDSCO".

- Full-time experts in key areas with adequate scientific and medical expertise and back-up support should be made available to the DCGI.

- A time schedule for processing of application for different stages of clinical trials should be developed and made known by the DCGI along with the fees to be charged for different stages.

- Units of the DCGI may be assisted by expert panels for each activity disease–wise for drafting of the testing protocols.

- The fees at each stage of trial should be charged for processing an application.

- A strict programme schedule should be adhered to, that could be: (i) IND Phase I – within 3 months, (ii) IND Phase II – within 6 months, and (iii) marketing approval within 3 months.

- The responsibilities of post marketing surveillance should also be with the regulatory authorities and not with the R & D institutions or pharmaceutical companies.

- Adverse Drug Reaction (ADR) monitoring should be of high quality done through a special unit manned by experts and this should be made available to the CDSCO office.

- On a priority basis, the office of the DCGI should be provided with electronic networking nationally and internationally to facilitate and expedite decisions.

- An advisory Board may be set-up to advise the DCGI regarding the protocols for drug testing and for policy development in order to strengthen the knowledge base of this office.

- A GMP on the lines of US FDA to recognize quality manufacturing practices needs to be instituted by DCGI.

4.4.3 To facilitate the above, a new structure for CDSCO was envisaged. A detailed note for strengthening Central Drug Regulatory Agency along with the Organizational Chart of CDSCO as recommended by the Committee is shown (**Annexure 5 & 5 (A).**

4.5 Initiatives taken by the Central Government for strengthening CDSCO

4.5.1 The Committee was informed that the Government had already taken a number of initiatives in the light of the recommendations of Pharma Research and Development Committee (PRDC). These included:

- Time schedule for processing of applications for different stages of clinical trials has been laid down i.e. 90 days for Phase-I, 45 days for Phase- II and 45 days for Phase-III;

- Expert panel for evaluation of new molecules developed in India has been created and is headed by DG, ICMR;

- Separate expert panel for evaluation of r-DNA based drugs has also been created;

- Application fee ranging from Rs15,000 to Rs.50,000 for new drug applications and clinical trials has been prescribed;

- Rules have been amended to prescribe post marketing surveillance as a mandatory condition for drugs approved in India;

- A comprehensive Adverse Drug Reactions (ADRs) Pharmaco-vigilance monitoring programme has been formulated and is to be implemented under Capacity Building Project;

- Computerization networking at national level has been initiated;

- Schedule M has been revised to bring the Good Manufacturing Practice requirements in consonance with international guidelines;

- Comprehensive revision of Schedule Y that prescribes requirements of clinical trials has been undertaken in order to harness country's potential to participate in global multi-centric clinical trials;

- Good clinical practice guidelines have been formulated;

- A strict regulatory process for registration of imported drugs has been introduced. Fees of 1500 US dollars for registration of overseas manufacturers and of 1000 US dollars for imported drugs have been prescribed;

- A comprehensive and dynamic web-site (www.cdsco.nic.in) has been made available; and

- GLP Accreditation and monitoring authority has been constituted under the Ministry of Science & Technology in respect of establishments involved in pre-clinical studies.

4.5.2 The Committee noted, however, that in spite of the fact that three years had lapsed from the acceptance of the PRDC report by the Government, no infrastructural improvement whatsoever in respect of personnel has occurred in CDSCO.

4.6 Gap Analysis:

The Committee examined in detail the existing drug regulatory scenario in the country as well as the prevailing systems in a number of other countries and performed a gap analysis vis-à-vis the envisioned situation. The Committee came to the conclusion that it would be necessary to revamp the existing drug regulatory structure and practices to achieve a world-class system in the country. This will also be in consonance with the goals defined in the National Pharmaceutical Policy 2002.

4.6.1 The major gap areas were identified as:

- Inadequacy of trained and skilled personnel and infrastructural support at Central as well as State levels commensurate with their respective specialized roles and responsibilities and emerging challenges;

- Non-uniformity in implementation of existing regulatory requirements and policies;

- Variation in the quality of enforcement;

- Inadequate and disjointed drug testing laboratories scenario;

- Lack of performance management of systems;

- Inadequate administrative, professional and financial support, which hindered the opportunity of availing expertise from outside specialists, particularly in the field of new regulatory areas;

- Lack of data base of drug products licensed by various State authorities in the country.

5.0 NATIONAL DRUG AUTHORITY

5.1 Hathi Committee Report

The idea of setting up of National Drug Authority (NDA) started with the Hathi committee report, which, under Chapter IV stated that :

> *"The committee believes that health care has a direct relationship with socio economic growth of the country and a welfare state should treat production, procurement and distribution of essential drugs, as a social responsibility just as import as ensuring supply of food and shelter. With a view to tackling the problem of large scale production and distribution of drugs, the Committee recommends the creation of a Statutory Body which may be called the National Drug Authority of India (NDA)".*

The report had mentioned several functions for NDA. The Government of India, however, did not accept this recommendation and no action was taken for creating NDA. Thus the Drug Policy formulated by Government of India for the first time in 1978 did not include the concept of NDA.

5.2 Drug Policy 1986

The concept of NDA was again included in the Policy Document of 1986, titled "Measures for Rationalization, Quality Control and Growth of Drugs

and Pharmaceutical Industry in India". In this document, in Part –III, under the main heading "Rational use of Drugs" with sub-heading, 3.1 "Registration of new formulations, Rationalization of Existing Formulations and Creation of the National Drug Authority", it is stated –

> *"New formulations based on Drugs already approved for use in the country would not be allowed to be manufactured unless their therapeutic efficacy and rationality are adequately tested and proved. A machinery called the National Drug and Pharmaceutical Authority would be established at the Central level, with a permanent secretariat".*

The nomenclature used here is National Drug and Pharmaceutical Authority (NDPA). It may be seen that the concept of NDPA as described above did not define its functions & responsibilities with clarity. It is the responsibility of DCGI to ensure that new formulations are allowed to be manufactured only after their safety, efficacy and rationality are established. It was not made clear as to whether the functions of DCGI were to be transferred to the proposed NDPA or whether DCGI was to be re-designated as NDPA.

5.3 Drug Policy 1994

5.3.1 The Drug Policy announced in 1994 once again envisaged setting up of an independent body called NDA (and not NDPA). It was to be set up by an Act of Parliament for providing a more efficient mechanism for ensuring quality control and rational use of medicines.

5.3.2 The NDA was envisaged to be an autonomous body, to be set up by an Act of Parliament. The main objective of constituting the NDA is to create an independent empowered body that could function with a higher degree of independence, to strengthen the drug control system in the country and to enforce appropriate quality standards of medicines and Good Manufacturing Practices (GMPs), with conviction and intent. It would regulate all matters relating to introduction and rational use of drugs, in particular, the registration of new formulations and rationalization of existing formulations. It would also be assigned the specific function of quality control and quality assurance with a predominantly inspectoral role to ensure adherence to standards, specifications and manufacturing capabilities and practices.

5.3.3 The main functions to be performed by the National Drug Authority were:

1. To develop and define basic appropriate standards relating to the manufacture, import, supply, promotion and use of drugs.

2. To enforce effectively appropriate quality standards of medicines and Good Manufacturing Practices, throughout the country, having full regard to the needs of public health and standardize dosage strengths and pack sizes of formulations with a view to check proliferation.

3. To approve and register pharmaceutical products for use in the country only if:

   a. it meets real medical need;
   b. it is therapeutically effective; and
   c. it is acceptably safe.

4. To monitor standard practices in drug promotion and use and to clearly identify those, which are acceptable and prohibit those, which are unethical and against the consumers' interest.

   1. To monitor standard practices and to evaluate their appropriateness for the purpose of guiding the medical profession and for achieving the aim of rational prescribing.

   2. To ensure that appropriate information about the registered pharmaceuticals is made available for the guidance of consumers having regard to :

      a. the adverse consequences of non-compliance by patients particularly in case of antibiotics, steroids etc.;
      b. the dangers of self medication; and
      c. the need to involve consumers as partners in the health care system.

   3. To prepare and publish a national formulary and formularies relevant to various levels (like district hospital, community center, primary health center) for the guidance of consumers as well as doctors.

5.3.4 The Committee noted that most of the above functions, if not all, were already being performed by CDSCO and the State Drug Controllers, except some, which were not within the domain of the regulatory system. This means that the NDA was actually intended to perform all the statutory functions of the existing Central and State Licensing Authorities.

5.4 Examination of NDA as considered by MOH&FW

5.4.1 The Committee was informed that MOH&FW did consider the matter of setting up of NDA and its funding by levying a cess as proposed. The Department of Legal Affairs, however, advised that the taxation measures be separated from the other issues and that there should be separate Bill for cess. There were also a number of other issues, where there was a lack of clarity. These included the structure of proposed NDA, its role, its source of funding, etc.

5.4.2 In 1999, the Ministry appointed a consultant to examine the existing legal and operational framework of drug control system in India, and to suggest available options for the organizational structure of the

proposed NDA. Earlier, the Ministry had also prepared a draft NDA Bill and had it examined by a legal consultant. A lot of work has been done to take this concept forward but no real progress seems to have been made for several reasons.

5.4.3 Some of the observations made by the consultant were as follows:

1."The present infrastructure in CDSCO is grossly inadequate to meet the actual requirements. With substantial increase in the scope of work of CDSCO, following its reconstitution as NDA, the technical manpower will need to be augmented suitably. Additional posts of JDCs, DDCs, ADCs and DIs etc. will be needed both for the headquarters and the field offices. Some structural changes by way of re-organization of the present set up may also be necessary for functions such as inter-state commerce, regulatory affairs and surveillance and monitoring etc."

2."In order to have a policy of uniform implementation of various drug laws in all the States and Union Territories, the question of withdrawing State Governments powers in these areas and vesting the same in NDA, needs to be given a serious consideration".

5.4.4 For reasons of complexities involved, the Government was not able to set up NDA during the period 1994–2000.

5.5 The Pharmaceutical Policy 2002

In the Policy document of 2002, the Government indicated its preference in the following terms-
The Ministry of Health & Family Welfare would *"set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcements administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals".*

Thus, the Pharmaceutical Policy 2002 opted for a world class CDSCO, rather than NDA.

5.6 Views of the States on the formation of NDA

5.6.1 A questionnaire was sent to all the State Drug Controllers in order to get all relevant information about their set up, the inspectorate staff and testing facilities etc. **(Annexure 7).** Additional information regarding category wise number of manufacturing licences and requirement of additional staff including budget was invited from Drugs Controllers of all State/Uts**).** Information has been received from most of the States **(Annexure 8)**. A comparative picture of the number of sale licenses, manufacture licenses and Drug Inspectors in 2003 as compared to 1975 (Ref. Hathi Committee Report) is available (**Annexure (B),** to**, 8(E)**).

5.6.2 One of the questions asked was as to whether NDA should be created and if so, whether it should perform the statutory licensing functions. Also if the CDSCO (CDA) was to be strengthened, then would there be still a need for NDA. 19 out of 31 states (with 4 no comments) stated (**Annexure 8**) that there is a definite need to strengthen the central administration and if CDSCO (CDA) can perform the statutory functions efficiently, there is certainly no need of NDA.

5.6.3 Most States have opined that once the CDSCO (CDA) gets its desired strength it should also take care of the following areas that at present are not being regulated as is the case in most developed countries or as is very relevant to country's needs.

- Post marketing surveillance
- Control on medical devices
- Control on diagnostics
- Control on neutraceuticals, feed supplements and herbal products
- Guidelines for promotional literature
- Promotion of rational use of drugs
- Guidelines for self medication
- Monitoring of clinical trials and bio equivalence studies
- Monitoring of ADRs
- Interaction with consumers and handling of complaints
- Central nodal intelligence cum legal cell to coordinate the inter-state activities
- Training of regulatory and laboratory personnel

5.6.4 In the meeting of the sub-committee (Group II) which was mandated to examine the issue of NDA, most members opined that the need for NDA was felt only because of the inherent problems of non-uniformity of enforcement and inability of State Governments to provide better regulatory infrastructure, etc. The members felt that if creating a world-class Central Drug Administration (CDA) can solve these problems, then there will be no need to set up NDA.

5.7 Conclusions on NDA

5.7.1 The Committee concluded that there were several complex operational, legal, constitutional and political issues that are involved in setting up NDA. The question as to whether NDA should be an autonomous body or a wing of the Ministry, whether it should take over all the statutory functions of DCGI and state authorities, whether it should be on the lines of US FDA (which is Food and Drug Administration) or an Authority etc. needed a careful consideration.

5.7.2 The Committee concluded that the problems in the regulatory system in the country are primarily due to :

- inadequate or weak drug control infrastructure at the State and Central level;
- inadequate testing facilities;
- shortage of drug inspectors;
- non-uniformity of enforcement;
- lack of specially trained cadres for specific regulatory areas;
- non existence of data bank; and
- non- availability of accurate information.

5.7.3 The existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as a National Drug Authority (NDA) will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped, empowered, independent and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA) reporting directly to Ministry of Health would be the most appropriate solution.

5.7.4 The Committee concluded that strengthening of CDSCO, in the manner described in 4.4.2 was absolutely essential. For this, it was particularly important that a structure as envisaged and described in PRDC report **(Annexure 5A)** should be established.

5.7.5 A strong CDA would require significant and adequately qualified and skilled human capital. It would, of course, need the creation of certain minimum number of additional posts at the headquarters and at the field offices. It would also involve the commitment of the Government for additional funds. In addition, if the CDA has to perform the licensing of all manufacturing units in the country, it would need to set up offices in many States, where there is a concentration of drug manufacturers, and on a regional basis in States, where the drug manufacturing activity is less significant. This means enhanced deployment of technical manpower in the proposed CDA.

5.8 International Experience

5.8.1 A recent WHO Publication entitled “An Effective Drug Regulation, a multi-country study” defines the broad contours of an effective Drug Regulatory System regardless of the development status of the country concerned. It mentions among other things, that based on the multi-country study, a drug legislation must:

- define the categories of the medicinal products and activities to be regulated;

- state the missions and goals of drug regulation;

- create the administrative bodies necessary for implementing drug regulation and define the structural and functional relationships;

- state the roles, responsibilities, rights and functions of all parties involved in drug regulation, including those of the regulators and the regulated;

- define the qualifications and standards required for those handling drugs;

- create mechanisms to ensure that all responsible parties are licensed and inspected, and ensure compliance with drug legislation and with the standards and specifications laid down for persons, premises and practices;

- define the norms, standards and specification unnecessary for ensuring the safety, efficacy and quality of drugs products as well as the appropriateness and accuracy of product information;

- state the terms and conditions for suspending, revoking or cancelling licenses to import, manufacture, export, distribute, sell supply or promote drugs;

- establish the administrative measures and legal sanctions that will be applied if drug legislation provisions are violated;

- create a mechanism for ensuring the transparency and accountability of drug regulatory authorities to the Government, the public and consumers; and

- create mechanisms for ensuring Government oversight.

5.8.2 The Committee noted that India has reasonably well drafted legislations, namely, Drugs and Cosmetics Act, which was enacted in 1940 and Drugs and Cosmetics Rules, which were drafted in 1945. These legislations define most of the above-mentioned functions but it is the **enforcement** at several levels that has not been consistent and uniform because of the multiplicity as well as the variable quality of enforcement authorities.

5.8.3 WHO report also states that in many countries, all functions related to drug regulation come under the jurisdiction of a single agency, which has a full authority in command and control of these functions. It also bears the responsibility for their effectiveness. In some countries, Drug Regulatory functions are assigned to two or more agencies, at either the same or different level of Government. Fragmentation and uncoordinated delegation of powers can impede the regulatory effectiveness of a country. Ideally, drug regulatory systems should be designed in such a way that the central coordinating body has overall responsibility and is accountable for all aspects of drug regulation for the

entire country. A system with formal channels of coordination and information flow should be created to support drug regulatory decision-making at the national level.

5.8.4 Among the various recommendations incorporated in the WHO report, the following are relevant :

- drug laws should be sufficiently comprehensive, covering all activities involving drug products and information and updated regularly;

- one central agency should be accountable for the overall effectiveness of drug regulation;

- personnel engaged in drug regulation should have integrity and be appropriately trained and qualified. Staff should have access to the latest scientific and technological information to facilitate their work;

- sustainable financing is essential to promote effective drug regulation;

- appropriate standards and guidelines should be developed and used as tools for the application of regulatory processes;

- the regulatory process should be systematically monitored in order to identify problems and determine whether actual activities match the intended actions; and

- drug regulatory agencies should communicate regularly with their clients. They should also acknowledge the right of citizens to be provided with accurate and appropriate information on drugs marketed in their county.

5.8.5 A study of drug regulatory systems and organizational set ups of 13 countries (Australia, Brazil, Canada, China, EU, Indonesia, Taiwan, Thailand, Mexico, South Korea and USA) was undertaken by the Committee. The study revealed that :

- Almost all countries indicated that the drug regulatory authority is centralized for the whole country; and

- The head of the regulatory authority in all the above mentioned countries reports directly to the Ministry of Health with the exception of South Africa.

5.8.6 The Committee noted the recommendations of WHO for effective drug regulation and the prevailing drug regulatory systems in number of countries. The Committee recognised a strong trend towards global harmonization of regulatory and scientific requirements pertaining to

safety, efficacy and quality issues. The Committee concluded that there was a need to have a strong, professionally managed and efficient regulatory mechanism under the MOH&FW, Govt of India, which may be structured as Central Drug Administration (CDA) and headed by DCG(I).

5.9 Structure of Central Drug Administration (CDA)

5.9.1 It was a unanimous decision of the Committee that the manpower position and the infrastructural facilities of the CDSCO, which deals with multi-disciplinary issues and a variety of responsibilities, needs immediate strengthening. Several Committees, in the past have recommended strongly that the Central Drug Administration should have qualified pharmaceutical and pharmacological scientists, legal and other competent officers at the headquarters, at the zonal offices and at the drug testing laboratories to perform their functions more effectively and expeditiously.

5.9.2 The restructured CDA should have 10 main Divisions at the headquarters manned by adequately trained manpower. Each of these divisions may have several sections depending upon the scope of the activities of the respective division. These divisions could be named as :

1. Division for Regulatory Affairs & Enforcement
2. Division for New Drugs & Clinical Trials
3. Division for Biological & Biotechnology Products
4. Division for Pharmacovigilance
5. Division for Medical Devices and Diagnostics
6. Division for Imports
7. Division for Organizational Services
8. Division for Training and Empowerment
9. Division for Quality Control Affairs
10. Division for Legal and Consumer Affairs

5.9.3 The role and scope of Divisions would be as follows:

1. Division for Regulatory Affairs & Enforcement

- Drug Consultative Committee issues
- Central Licensing
- Zonal / sub-Zonal and State Offices
- Inspections (domestic & international)
- Guidelines and directives
- Interstate issues
- Drug recalls
- Investigations
- Regulation of promotion of medicines & product information
- Legal affairs
- International cooperation
- Exports

2. Division for New Drugs & Clinical Trials

- Clinical Trials approvals (including regulation and
- registration of investigation sites, ethics committees & investigators)
- Regulatory inspections of clinical trial sites, sponsor sites and ethics committees
- Efficacy & safety evaluation of new drugs including INDs
- Pharmaceutical & quality evaluation
- Biostatistics
- Veterinary new drugs
- Issues related to border-line products
- Screening of existent drug formulations

3. Division for Biological & Biotechnology Products

- Vaccines & Sera (human & veterinary)
- Blood & blood products
- Recombinant and other biotechnology products

4. Division for Pharmacovigilance

- Safety monitoring of drugs and devices
- National Pharmacovigilance Advisory Committee

5. Division for Medical Devices and Diagnostics

- Devices' evaluation
- Diagnostics' evaluation
- Licensing & enforcement
- Imports

6. Division for Imports

- Registration of overseas manufacturing
- Overseas inspections
- Managing Port offices
- Import Licenses
- Quality monitoring of imported products

7. Division for Organizational Services

- Administrative matters
- Accounts
- Planning & Finance
- Information technology

8. Division for Training and Empowerment

- Planning & forecasting
- Training
- Evaluation and impact assessment

9. Division for Quality Control Affairs

- Managing Central drug laboratories
- Monitoring of State and private laboratories
- Audits (including proficiency testing) and accreditations
- Drug standards
- Indian Pharmacopoeia
- International harmonization

10. Division for Legal and Consumer Affairs
- Court cases
- Parliament affairs
- Consumer information (healthcare)
- Public complaints
- Licensee's information
- Website
- Press & public relations
- Publications
- Implementation of Drugs and Magic Remedies (DMR) Act

5.9.4 The Committee recommends that the Central Drug Administration should be made into an independent office under the Ministry of Health and Family Welfare as is the case in most of the countries. The Committee further observed that most of the States within the country have also moved towards independent drug control directorates under their respective Health Ministries. This step would be in keeping with the expanded role of proposed CDA.

5.9.5 The proposed structure of CDA at the headquarters, zonal, sub-zonal offices and state offices (for Phase I central licensing by 1st January 2005, see 6.2.2 below) will need the following additional posts:

- Joint Drugs Controllers - 3
- Deputy Drugs Controllers - 2
- Assistant Drugs Controllers – 6
- Drugs Inspectors - 50
- Technical Experts – 5
  - Pharmaceutical chemist
  - Pharmaceutist
  - Pharmacologist
  - Toxicologist
  - Statistician

- Administrative Officer – 1
- Accounts Officer – 1
- Computer Operators – 15 & adequate supportive staff

The approximate expenditure for the above mentioned additional posts will be Rs. 1.6 crores per annum. The expenses including contingencies for creation of 7 additional offices as mentioned in para 6.2.2. will be about 50 lakhs.

5.9.10 The functions of central regulatory agency being multi-disciplinary in nature, considerable sourcing of expertise from external experts and institutions will be required. It is necessary that such consultations are managed speedily, since drug development activities are very cost and time sensitive. This would require provision of sufficient funds at the disposal of office of DCG(I) to support sourcing of external expertise and an easy mechanism to make payments of honorarium and travel expenses without delay, as per the systems available with CSIR and ICMR.

The Organogram for the proposed Structure of CDA at the Headquarters is shown at **Annexure 15.**

6.0 LICENCING OF DRUG MANUFACTURING UNITS BY CENTRAL AUTHORITY

6.1 Analysis

6.1.1 Information gathered by the Committee about the regulatory systems in some developed and developing countries revealed that :

- The Drug Control Organization functions directly under the Ministry of Health;
- The registration of products and licensing of drug manufacturing units is generally overseen by a single authority at the central level;
- The Drug Policy emerging from the Health Policy is issued by the Ministry of Health; and
- In some countries, especially the developed ones, the licensing and control of retail pharmacies is done by professional bodies of pharmacist and not by FDAs. The focus is on the professional obligation and Good Pharmacy Practices of pharmacists.

6.1.2 The Committee observed that in India, because of numerous licensing authorities (State/UT's), the implementation of drugs laws has been weak and non-uniform even after 56 years of enforcement. It is well established that the regulatory infrastructure in many States is below par, while it is functioning better in some. This has resulted in lack of adequate confidence among the consumers and level playing field for industry. The Committee observed that the issue of non-uniformity of

enforcement at the state level was serious and needs to be addressed immediately. The Committee records that there should have been a single agency to regulate the manufacture and quality control of drugs in the country and that it should be done centrally.

6.1.3 The matter of licensing of manufacturing units by Central Government has been considered on several occasions in the past. During 1988-89, the reports of poor quality of I V fluids and substandard blood made the Central Government focus on the issue of having a stricter control on these products. This resulted in the amendment of Rules to provide for dual licensing mechanism in December 1992, the Central authority being the License Approving Authority (CLAA) and the States being the license giving authorities. The idea was to improve the quality and implement uniform norms but the experience has not been encouraging. The change, however, has not made the desired level of impact.

6.1.4 The National Human Rights Commission in their order of 1999 clearly stated that:

"the present dual system of control does not appear to have achieved desired effectiveness, therefore, Central Government must immediately take steps to examine the entire system of Licensing (including loan licensing), Certification and Complaint handling under effective Central Government control through CLAA or other suitable means"

6.1.5 The Committee noted that Government of India has in the past, often considered the question of non-uniformity of enforcement at the State level and had pondered over the idea of making licensing of all drug-manufacturing units by Central Authority. This can be seen from the following comments extracted from the Hathi Committee report (para 33)

"The Committee of Economic Secretaries of the Government of India had considered the existing conditions in drug control in India in a meeting held in January 1970 and it was agreed that quality control of products manufactured anywhere in India was not solely the responsibility of the State in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one State was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other states. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country and also supervise their wholesale distribution among the various States. Unfortunately, these decisions have not been given effect to with the vigour that was necessary mainly because of financial and administrative reasons. Augmentation of the staff and testing facilities in the CDSCO, it must be admitted has been slow".

6.1.6 This view was bolstered further by a comment made by the Estimates Committee of seventh Lok Sabha (1983 –84) is :

"This division of responsibilities fails to take into account the role of overall coordination of control that the Central Drug Control Organization should play. The Committee of Economic Secretaries of the Government of India recognized this shortcoming and stressed the importance of the Central Government assuming responsibility for (in addition to the present role of advising on) statutory enforcement and control over the manufacture of drugs all over the country".

6.1.7 The Committee was also informed about a statement of proposal mentioned in the EFC memorandum prepared by the ministry of Health and Family Welfare in 1994 for strengthening of Drug Control Organization in the Centre and States, which reads as follows:

"In order to ensure an equitable fair and uniform administration of the provisions of the Drugs and Cosmetics Act and Rules across the country it is necessary to have the manufacturers engaged in inter-state trade to be registered with the Drug Controller (India). This would enable enforcement of strict quality control of drugs as well as uniformity in dealing with inter-state commerce in drugs. It has, therefore, been decided to register all the drug manufacturing units which intend to market their drugs in the inter-state commerce, in public interest".

6.1.8 Apprehensions have been expressed, among others, by All India Drug Control Officers Confederation (AIDCOC), the Gujarat State Food & Drug Control Administration Gazetted Officers Association, and to some extent by IDMA, with regard to the proposed switch over to Centralized Licensing over drug manufacturing activities in the country. Majority of the State Drug Controllers are also not in favour of Centralized licensing. The perceived disadvantages and the problems that are likely to be faced by the industry as brought out in these representations were carefully examined by the Committee. Most of these appeared to be misplaced because they emanate from a mistaken impression that the licensing system under CDA would operate from Delhi only. In fact, what is envisaged is that the CDA would have its offices in most of the State capitals, where there is a significant drug manufacturing activity. A unified structure of CDA would be system based i.e., for every activity, there would be clear policy framework and efficient supervision to ensure a uniform implementation. This includes timely disposal of licence applications, endorsement of additional products, efficient communication with industry, renewals, transparency, and overall, a pro-active approach to enable healthy growth of industry, etc.

6.1.9 The Committee observed that if the CDA is required to perform the functions of licensing of all manufacturing units in the country, it would require the creation of significant additional posts at the head quarters and at the field offices and would involve the commitment of the Government for additional funds. It would also need to set up offices in

many States, where there is a concentration of drug manufactures and on zonal bases, where the drug manufacturing activity in concerned states is not significant. This means enhanced deployment of technical manpower in the proposed CDA.

It has been also argued that the existing system affords better control as the authority has to control one State only. This pre-supposes the existence of an efficient infrastructure and quality of enforcements in every State, which is, unfortunately, not the case as was evident to the Committee. It has also been argued that a central agency would not have a clear understanding of the regional situation as compared to the understanding that the local state organisation would have. In the overall view of the Committee, this issue does not appear to be significant as the objective of a national organisation would be countrywide uniformity of enforcement and of creating a level playing field. Though there may be some element of variation due to the differences in the skills and expertise of the concerned field officials, such variations can be checked and contained through built-in management systems that are efficient and effective.

6.1.10 It has been further argued that though there is a centralized licensing authority in countries like USA, Brazil, Australia, Malaysia, China and South Korea etc., there are vast differences in geographical, political, socio-economical and technological situations as compared to India. It would, however, be seen that these countries represent a cluster of highly industrialized nations as well as developing countries in South-East Asia. India has to belong to such a club, as it is doing today in several other areas.

6.1.11 It has also been argued that the fee for grant of licenses, product permission and various certificates are the only source of revenue for State Drug Departments and that centralization would cause loss of revenue to the State Drug Departments. However, the Committee noted that the fee collected under these provisions do not necessarily go to the concerned organisations. The budget for drug control organisations is provided by the State Governments and that in majority of the States, the fee collected through licences etc., is not adequate in itself to support the respective drug control organisations and drug testing laboratories. Furthermore, when it comes to the issue of protecting the health of the people of India as against protecting the revenues of the State (which in any case represent a very insignificant part of the State revenues), the emphasis has to be clearly on the regulatory systems that will provide for protecting the health of the people.

6.1.12 All the members of the Committee concurred with the suggestion of licensing of drug manufacturing units by a central authority, excepting for one member, namely the Commissioner, Food & Drug Administration, Government of Maharashtra, who gave a note of dissent. This was duly taken note of.

6.1.13 The Committee feels that it is important that the Government should have a long-term vision to establish a world-class regulatory system in the country, which can deal effectively with the health concerns of one sixth of humanity. The issue of administrative complexities, creation of additional posts, opening of new offices can be squarely tackled with an effective implementation team and starting. In what follows, the Committee has proposed a structure for Central Drug Administration, which will fully meet the national needs.

6.2 Proposed Roadmap for CDA to undertake Functions of Licensing of Drug Manufacturing units

6.2.1 Categories of States/UTs

After analysing the information received from the States and Union Territories, the Committee noted that more than 75 % drug manufacturing licenses are in 7 States, namely, Maharashtra, Gujarat, Tamilnadu, Andhra Pradesh, Karnataka, West Bengal and Goa. 10 states namely Bihar, Delhi, Goa, Haryana, Kerala, Madhya Pradesh, Orissa, Punjab, Rajasthan and Uttar Pradesh account for about 20 % of drug manufacturing licenses. The remaining 18 States and Union Territories have only 5 % of the licenses. It was felt that for the purpose of licensing, the States and UTs can be divided into 2 categories, depending upon the quantum of manufacturing licenses.

Category 1 – Maharashtra, Gujarat, Tamilnadu, Andhra Pradesh, Karnataka, West Bengal and Goa;

Category 2 – Bihar, Delhi, Haryana, Kerala, M.P, Orissa, Punjab, Rajasthan, U.P., Andaman & Nicobar Islands, Arunachal Pradesh, Assam, Chandigarh, Chattisgarh, Dadar & Nagara Haveli, Daman & Diu, Himachal Pradesh, Jammu & Kashmir, Jharkhand, Lakshadweep, Manipur, Meghalya, Mizoram, Nagaland, Pondicherry, Sikkim, Tripura and Uttaranchal.

6.2.2 The switch over to Central licensing of drug manufacturing units could be considered in 3 phases.

Phase – I (to be completed by 31 December 2004)

During this phase, it is expected that manpower and infrastructure of the proposed CDA would be in place by 31st December 2004. The manpower requirements of proposed CDA can also be met partially by absorbing some of the experienced and willing regulatory officers from the States for the purpose of inspection and licensing.

Phase – II (1st January 2005 onwards)

From 1st January, 2005 onwards, the licensing functions of Category 2 states and UTs will be taken over by the proposed CDA.

CDA will operate from the following new offices for performing the new functions:

Sub-zonal offices of East Zone at Guwahati for licensing of units of NE states/union territories, at Bhuvaneshwar for Orissa and at Patna for Bihar.

The North Zone office at Ghaziabad will be reorganized to take up the licensing functions of UP, Delhi and Uttranchal.

Sub-zonal offices of North zone at Chandigarh for licensing of units of J & K, HP, Punjab, Haryana and Chandigarh and at Jaipur for Rajasthan.

The West Zone office at Mumbai and the port office at Ahmedabad will be reorganized to take up the licensing functions of units at Daman & Diu, Dadar, Nagar and Haveli.

Sub zonal office of West Zone at Indore for units of M.P and Chhatisgarh.

The South Zone office will take care of units at Pondicherry, Kerala, Lakshadweep and Andamans & Nicobar Islands.

Phase - III (1st January 2006-onwards)

The licensing of manufacturing units of Category 1 states will be undertaken by CDA from 1st January, 2006 onwards by opening new offices and reorganizing the structure of existing zonal, sub-zonal and State offices to make sure that all the areas are appropriately covered.

6.2.3 The above changes will require Government's commitment and a strong political will. The following measures would be required for implementation of the above proposal:

- Expansion of zonal and sub-zonal offices;
- Creation of additional infrastructure for new offices in States;
- Creation of considerable number of additional senior level and supporting posts; and
- Need of additional funds to set up a world class Central Drug Administration.

6.2.4 The Committee clearly sees the following advantages ensuing from these changes:

- Will bring accountability and responsibility of action under one Authority;
- Will bring uniformity in interpretation of laws and of enforcement of various provisions;
- Will have uniform compliance of GMP, GLP, GCP norms;
- Will eliminate irrational combinations;
- Will make easy acceptability of information about the number of licenses issued and the products permitted for manufacture;
- Will establish much better control on the quality of production of drugs ;
- Will ensure effective follow up actions against the defaulting manufacturers;
- Will position the Indian Regulatory System at par with other developed countries; and
- Will fulfil the repeated recommendations for such an action done by several bodies over the past two decades.

6.2.5 In summary, the Committee concludes that:

- The process of establishing CDA should be completed by 31st December 2004 and the State/UT Regulatory Systems should be suitably strengthened;

- Guidelines and directions issued to the State/UT Drug Regulatory Authorities on regulatory policies should be strictly and uniformly complied with, failing which action may be taken against the concerned regulatory officials;

- Based on the accepted performance indicators of a good regulatory agency, the functioning of drug control agencies may be audited by a panel of independent experts. This activity should be funded by the Central Government. If the performance of any State DRA is found to be below par and/or not in accordance with the provisions of the Act and the Rules, the Central government shall have the powers to take suitable action; and

- Accordingly, the Drugs and Cosmetics Act and the Rules may be amended to assume such powers.

6.3 Regulatory Systems at States/ UTs

6.3.1 The responsibilities and functions of State regulatory authorities are mentioned above in para 4.2.3 and 4.2.4.

6.3.2 A questionnaire was sent to all States/UTs, asking them to furnish their requirement of manpower, infrastructure facilities and finance. Most of the States have indicated that they are short of manpower, specially the

Drug Inspectorate staff. Earlier, the norms suggested were 1 drug inspector for 25 manufacturing units and 1 drug inspector for 100 sales units. In view of the amended requirement of statutory inspections (only once a year instead of twice a year and five year's validity of licence instead of two years), the requirement of appropriate inspectorate staff could now be considered as 1 inspector for 50 manufacturing units and 1 inspector for 200 sales units.

6.3.3 From the information conveyed by the States, it is observed that there are 418411 total number of sales licenses including 253666 retail licenses and 145447 wholesale licenses and a combined figure of 19298 retail and wholesale licences given by Karnataka. This total number is not absolute because majority of the sales units have both retail as well as wholesales licenses. Currently, there are 935 Drug Inspectors in all States/UT's in the country put together. Presuming that the number of sales units to be inspected will be approximately 300,000, the number of Drugs Inspectors required is estimated to be 1500.

6.3.4 The total number of manufacturing licences reported by the States is 19,203 which includes licensees for bulk drugs, formulations, vaccines, LVPs, blood banks, medical devices, disinfectants, surgical dressings, repacking and loan licenses etc. The states were asked to furnish category-wise information separately for each type of licence. The information received from 25 States/Uts is as follows **{Annexure 8 (8-A)}**:

Bulk drugs	1333
Formulations	4354
Large Volume Parenterals	134
Vaccines	56
Blood Banks	1806
Surgical Dressings	638
Disinfectants	272
Repacking	318
Loan Licences	4645
Medical Devices	199
Cosmetics	2228
Homeopathic	966
Miscellaneous (not covered by above)	287

From the above information, it may be seen that the total number of units in bulk drugs, formulations, LVPs and vaccines categories, which need intensive inspection is about 5877 and not 20,000 has been cited all the time. This would require about 120 Drugs inspectors and the remaining categories may perhaps need another 100 Drugs inspectors. Thus the total number of Drug Inspectors required for inspection of manufacturing units in the country is 220. This plus the figure of 1500 Drugs Inspectors required for inspection of sales units brings the total requirement to 1720.

6.3.5 The State enforcement system has to develop a strong capacity in the areas of inspection of sales premises, inspection of manufacturing units and surveillance / investigations concerning the movement of spurious / counterfeit and adulterated drugs. It is important to see that these enforcement activities are of a uniform nature throughout the country and the enforcement staff delegated for specific tasks have adequate training and skills suited to corresponding regulatory areas.

6.4 Review of Drugs and cosmetics Act and Rules

The Committee had considered the suggestions and the views received from several sources. Some of these observations pertaining to changes required to be made in the Drugs and Cosmetics Act and Rules there under are as follows:

1. The Drugs and Cosmetics Rules provide that the manufacturers as well as wholesalers and retailers have to obtain separate licences based on categorization of drugs classified as C & C1 and those other than C & C1. These provisions have been in place since inception and they need to be reviewed to further rationalize the licencing and regulatory procedures keeping with the contemporary developments. The Committee is of the view that DCC may undertake a review of these provisions;

2. Schedule H gives list of drugs that are required to be sold only on prescription of a Medical Practitioner. It is the view of many that the Schedule contains some drugs which are in use for many years and are known to be safe and perhaps do not need prescription any more. Moreover, many new drugs that should be sold on prescription are not included in the list. The Committee feels that there is a need to review and revise the present Schedule H;

3. Schedule K that lists products that are exempted from the provisions of chapter IV of the Act and the Rules made there under to the extent and subject to specified conditions, needs to be reviewed and amended;

4. Gujarat State FDA Gazetted Officers Association has made some observations. They have suggested that distribution channels of drugs of all manufacturers need to be predetermined and under control. The drugs sold by the manufacturer to their stockists/distributors are resold to several sub-stockists/distributors before it reaches the consumer and this leads to unhealthy competition in the market. The Association has made many suggestions, which need to be looked into;

5. The All India Drugs Control Officers' Confederation (AIDCOC) has suggested that section 33 P of Drugs and Cosmetics Act may be amended to give powers to DCG(I) to issue directives to State licensing authorities, to review the orders passed by them and if necessary, to revoke the product permission granted by them.

The Committee noted that the above mentioned suggestions regarding the changes required in the existing provisions of the Drugs and Cosmetics Act and Rules and recommends that a sub-committee of DCC should review and examine all such suggestions, and based on their report, necessary amendments may be made.

6.5 Recommendations

The Committee makes the following recommendations:

2. For Central Government

a) Central Government should take immediate steps to fill the existing sanctioned posts, which are lying vacant for a number of years.
b) Central Government should create additional posts and augment the infrastructure facilities of Central Drug Administration as proposed.
c) Central Government should seriously consider all aspects of Committee's recommendations of licencing of manufacturing units by central authority in phases, as proposed.
d) Central Government should establish a mechanism to audit the functions of State drug regulatory agencies (DRA) by a panel of independent experts. In case, the functioning of any State DRA is found below the accepted performance indicators, the Central Government should have powers to take suitable action.
e) Necessary amendment in Section 33P of Drugs and Cosmetics Act may be considered to empower Central Government to issue directions to State licensing authorities and to review the orders passed by them and if necessary, to revoke any permissions granted by them.

3. For State Governments

The Committee recommends that the State Drug Control Organisations should be urgently strengthened with competent and trained manpower and with adequate budgets. The following are the specific recommendations:

a) State Governments should strengthen the drug regulatory system in their States. There is a need to augment the number of Drug Inspectors in many states, especially in category 1 States (para 6.2.1), where the majority of the manufacturing and sales units are located.

b) The capability and skill of state enforcement staff should be continuously upgraded by adequate training in specific regulatory areas of inspection and investigation.

c) State Governments should provide adequate infrastructure for the office of state DRA and the field officers including sufficient funds for vehicles and purchase of samples.

d) Structured mechanisms should be set-up to enable interstate exchange of regulatory officials to bring about better understanding of processes adopted in different States. This would help in harmonising the enforcement practices and would bring an improved uniformity.

6.6 Other Related Drug Regulatory Issues

While examining various aspects of drug regulatory apparatus, other related crucial areas, which were relevant to the context of Committee's overall terms of reference were considered in the light of the reference of Committee, namely, (6). These include :

a. health foods / dietary supplements / therapeutic foods;
b. medical devices;
c. over the counter (OTC) medicines;
d. drugs of Indian System of Medicine (ISM);
e. regulatory capacities vis-à-vis drug development / clinical trial activities; and
f. drug distribution systems.

The sub-Groups constituted by the Committee undertook an in-depth examination of these areas in the context of contemporary national and global perspectives.

7.0 OTHER RELATED DRUG REGULATORY ISSUES

7.1 Health Food / Dietary Supplements / Therapeutic Foods

Background

7.1.1 This is a new and emerging category of ingredients and products across the world as well as in India. Since first introduced, the concept of a food product intended to provide a benefit that is other than nutritional or aesthetic has been referred to by several titles. These have included “designer food”, “pharmafood”, “phytoceutical”, functional food” and “nutraceutical”. All but the latter two have fallen into disuse. Nutraceutical is the broader of the two terms, because it has been applied to foods and food components in both conventional and non-conventional form (e.g. pills). "Functional food" has been referred primarily to products in the form of conventional food. Different countries have dealt with this category in different ways as regards the regulation. The use of these products, which are available mostly in the form of

capsules, tablets, powders or granules, has witnessed a dramatic upsurge, especially in developed countries during the last few years.

7.1.2 The increasing market for such supplements appears to relate to the desire of certain segments of population to become more directly responsible for their own health and well being through preventive or proactive life style and dietary techniques. Internationally, there is a trend of "going back to nature". Hence, there is an increasing acceptance of plant materials and herbals as well as biological extracts as potential health ingredients.

7.1.3 The use of botanicals as spices etc. has been unique to our dietary practices. In Ayurvedic principles, there is integration of food and medicines and, therefore, formulating foods as health products has been a well-accepted practice. However, keeping in view the growing commercialisation and global trades, there is a need for a better clarity in the regulatory policies in the interest of the consumer as well as the industry especially in view of a tendency on part of some players to make exaggerated medicinal claims for such products. There are also reports about the illegal use of some drugs to further enhance their publicised health benefits.

7.1.4 The Committee noted that there is no complete clarity with in regard to the regulatory policies and procedures concerning safety, quality, claims, labelling, classification etc. of products, which are not claimed or considered as medicines, but which are consumed and propagated for certain health benefits or nutritional advantages. These products do not even fit into the domain of conventional or regular foods, under the regulatory scheme of PFA, etc.

Position in other countries

7.1.5 The members took an overview of the regulatory systems prevailing in various countries in respect of class of products termed as "**Dietary supplements" (DS).** USA was the first country in the world to have created a new category and to have come out with its regulation. Dietary Supplements Health and Education Act (DSHEA) was enacted in 1994 in USA. This allows marketing of these products as a category separate from drug or conventional food. After several amendments, this act allowed the industry to make certain health benefit/disease claims.

7.1.6 Dietary Supplements [DS] are defined as those products that are used to supplement a diet and which contains (one or more) dietary ingredients such as vitamins/minerals, herbs or botanicals, amino acids, dietary substance to increase daily intake. They can be in the form of pills, capsules, tablets or liquids. DSHEA has also prescribed GMP's for their manufacture, provided for labelling conditions, provided for measures to prevent advertisements and regulate the same. United States Pharmacopoeia has come out recently with a detailed scheme for

Certification of Dietary Supplement with a logo, which can be affixed, on each container of products certified by USP.

7.1.7 The Committee noted that all the countries have not completed legislation in the category but recognise the “Supplement” category. EU (in its directive 2002/46/EC) had laid out the background for regulating this category with this directive covering vitamins and minerals in the first instance. “Food Supplement” as food stuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with nutritional or physiological effect, alone or in combination, marketed in dose forms such as capsules, pastilles, tablets etc. designed to be taken in measured small unit quantities. EU has yet to put into place regulations pertaining to functional foods, where health claims not amounting to medicinal claims are possible, as is being done under US FDA.

7.1.8 Functional Foods as a category is well regulated in Japan. It is probably the only country to put in place a regulatory system for functional foods through its “Foods for Specified Health Use” (FOSHU) in 1993. USA FDA considers these as ordinary foods with specified ingredients being approved as GRAS. The specific features of this category of foods are that they contain ingredients that have a physiological relationship with a disease and are permitted with health claims in an approved manner and text. Other requirements are:

1) It is presented in the form of a food and is derived from natural sources. It will not be in the form of capsules, powders etc;
2) It can be, and should be, consumed as part of a daily diet;
3) It has a particular health function when ingested as specified; and
4) They are foods with permitted health claims based on scientific evidence.

7.1.9 The Japanese have a wide variety of foods to choose from that have been approved by their health regulatory officials. Instead of using the term functional foods, the Japanese coined a term for this new category, calling it as Foods for Specific Health Use. (FOSHU). Since this system was put into place in 1993, over 69 foods have been approved, and they can carry the FOSHU label. This is based on a list of approved foods and ingredients that the Japanese Department of Health feels have enough scientific evidence to support the attendant health claims.

Current Position in India

7.1.10 India does not have any well-defined and clear regulations to cover a Dietary Supplement or a Food Supplement or even a FOSHU like product in strict terms. Indian Laws cover either the Food Regulations (namely PFA and FPO which define foods, fortified food, proprietary food, fruit and vegetable products like fruit juices, nectars, ready to serve fruit drinks squashes, pastes etc), or Drug Regulations. The Drugs and

Cosmetics Act and Rules include new drugs, a drug including medicines, Patent or Proprietary (P&P) medicines and cosmetics etc.

7.1.11 The Committee noted that due to the existing ambiguities, food supplement type of products are being introduced and sold either under "Proprietary Foods" or even licensed under P & P medicines category. For such products, it is not known as to whether or not enough safety and efficacy data are available. However, strong ingredient claims are being made, as a rigorous proof of functionality is not legally required in India.

7.1.12 The Committee also recognises that there is a growing belief in India that a good diet is essential for health. The Indian consumer is aware and wants to have access to better diet or dietary ingredients for maintaining one's health. Preference for natural or nature based ingredients is increasing. There is an influx of such products from abroad too. The Indian industry is also looking for growth and opportunities in this area, which can be triggered only by harmonized and rational regulations that will promote the use of safe and effective products keeping in mind the safety of the consumer.

7.1.13 This new category of food supplements has to be dealt in a way that is entirely different in all aspects on requires their regulation, manufacture, sale, marketing etc. and certainly different from the way the drugs or traditional medicines are dealt with.

7.1.14 Since these products cannot logically make any specific disease preventive or curative claims, there is no possibility of health foods being considered as drugs in the context of the provisions of Drugs & Cosmetics Act, 1940. The Committee recommends that in the overall context of the nature and use of the products under consideration, this category should be covered under laws regulating food products.

Earlier Efforts to Evolve Regulatory Framework

7.1.15 The Directorate General of Health Services (DGHS) had considered the above aspects in a meeting of experts to examine the regulatory issues concerning the classification and control over Dietary Supplement/Health Foods/Nutraceuticals on 30th May 2000. After detailed deliberations, this committee had felt that since introduction of separate regulatory measures within the existing legal framework of PFA Act may take a considerable time, the possibility of laying down specific regulatory provisions through an executive order passed by the Government may be necessary. The Committee had given specific overall recommendations including setting up of a tripartite committee consisting of representatives from the office of the DCG (I), PFA division, and Dept of ISM&H, to evaluate and decide on such products.

7.1.16 The Department of ISM&H, Government of India proposed a Draft "Bill on Health Food Supplement (HFS)" in August 2002. This Draft Bill was widely circulated to all stakeholders and industry, various Government

Departments, Ministries, nutrition associations, etc.

Recommendations

7.1.17 After deliberations, the Committee observed that, at present, there is lot of ambiguity regarding the regulations of dietary supplements, ISM & herbal products, ayurvedic cosmetics etc. The regulatory policies, rules and guidelines of these products are not clearly defined.

7.1.18 The Committee feels that there is a need to have separate regulations, defining dietary supplements, laying criteria for permissible limits of ingredients, a procedure for evaluation of safety and efficacy, information to consumers and provisions related to their advertisements. The regulations are also required to specifically cover combination products of botanicals, herbs (known in ISM) with other chemical based actives. Summarizing briefly :

a. Create new categories for covering dietary supplements, functional foods;

b. These should be regulated under the PFA or any other emergent mechanism/infrastructure;

c. Products that claim or are intended to diagnose, cure, prevent or treat a disease are to be classified as drugs as is the current rule;

d. The particular products (1) that are formulated with the intent to supplement the diet with nutrients, or (2) have had a scientifically proven ingredient- disease relationship, and (3) marketed with health claims, should be brought under the purview of food laws;

e. It should be made mandatory that for the ingredients used in products, bibliographic evidence of safety, or evidence of traditional and prolonged usage, or scientific toxicity evidence should be provided; and

f. As regards the manufacturing practices, the Committee recommends that these products should be regulated in respect of their quality & safety by incorporating a special provision and corresponding procedures under the relevant food law. The products with distinct medicinal claims would have to qualify as drugs as per the prescribed procedures.

Manufacturing Practices

7.1.19 The Committee recommends that these products should to be regulated in respect of their quality and safety by incorporating a special provision and corresponding procedures under the relevant food law. The

products with distinct medicinal claims would have to qualify as per prescribed procedures.

7.2 ISM and Herbal Products

Introduction

7.2.1 All Traditional medicines (like Ayurvedic, Unani and Siddha products) containing primarily one or more medicinal plant ingredients are governed under Chapter IV A of Drugs & Cosmetics Act., which was introduced in 1969. Before this amendment, definition of products containing herbs or herbal ingredients was non-existent in the Indian Drug laws. However, plant based products are also regulated under Chapter IV where adequate scientific data on safety, efficacy and quality are available. A few such plant-based medicines, which were well standardized and clinically tested, have been licensed as new drugs by DCG (I) recently.

7.2.2 As a part of this amendment, the definition for Ayurveda, Siddha and Unani medicines as well as Patent or Proprietary Medicines was incorporated in the Drugs & Cosmetic Act under section 3 (a) and 3 (h). For the purpose of these two definitions, Schedule 1 was introduced in the Act, which listed some books as official text books of Ayurveda, Siddha and Unani (referred to as ISM in rest of the text). These official books formed the basis for recognition of recipes of herbs, minerals and other ingredients and the processing methods, which became mandatory requirements for obtaining the license for the manufacture of ISM drugs.

7.2.3 The mandatory license covered not only the manufacture but also a permission to sell the same in the market. Recognizing the strength of ISM, long term usage experience and codified knowledge in these official books, the Government decided to have no separate sale license as a requirement (at either wholesale or retail level) to distribute, stock or sell ISM products.

Current position

7.2.4 There is a separate Department of ISM & H under the Ministry of Health & Family Welfare. The provisions of chapter IV A of Drugs and Cosmetics Act have been in existence for more than three decades. These have met with varied interpretations across the country, which are most often not uniform across the country. The licenses referred to above are issued at the State level for both classical and Patent or Proprietary (P & P) medicines. In some States, the Drugs Controller, who basically deals with allopathic medicines, issues licenses, whereas in several States, licenses are issued by Director of Ayurveda or on the advise of an Ayurvedic Technical Officer. Such practices form the real

cause of non-uniformity of interpretation with reference to the licensing system.

7.2.5 The conditionalities laid down for the issue of licenses do not provide for detailed mandatory requirements with regard to documentary evidence of safety, efficacy, standardization and quality control methods. Generation of scientific data on these aspects of ISM products or their raw materials is not required under the current law. The Committee felt that science based considerations in respect of standards, GMPs, safety evaluation and quality control should be similar for all drugs, irrespective of the system to which they may belong. *Therefore, the Committee recommends that the regulatory control of all drugs should be under the overall umbrella of one national agency, which may have separate divisions and experts for effective management*.

Recommendations

7.2.6 ISM products get compared with herbal products abroad. Lack of adequate scientific data has been seen as serious lacunae when such comparisons are made. There is a need for providing a strong impetus to promote research in ISM herbs and raw materials as well as finished products. In this context, the Committee noted that Central Councils for Research in ISM of the Government as well as a number of industrial houses have been undertaking research on different aspects of ISM drugs. The effectiveness, the quality and the rigour of such work is not entirely clear.

7.2.7 The Committee felt that there was a strong need for appropriate regulatory impetus by way of enabling provisions for research based data as a requirement for licensing so that such products could be promoted. Such regulatory provisions would drive research, and in turn the growth and acceptability of ISM products worldwide.

7.2.10 The Drugs & Cosmetics Act will need to be changed by incorporating major amendments in the Drugs & Cosmetic Act and the Rules. These are as follows:

a) Schedule I of the Drugs & Cosmetic Act, which provides the List of official books should be revised. Criteria for selection and inclusion of books in Schedule I have not been understood properly. There has been a regular demand that many important authoritative as well as old classical books form different parts of the country and in different languages have been left out for no apparent valid reason. Over the years, and especially in recent years, several national laboratories and ISM organisations have brought out research based compilation-involving experts of ISM and modern scientists, which have clarified anomalies and have provided interpretation of well known ISM books and recipes. There is a need to review and update the list of books included in Schedule I. A high-powered expert body should be appointed for

this purpose. This body should carefully review and approve only the authoritative books for such a purpose.

b) The definition given under 3(h) of the Drugs and Cosmetics Act uses the term “Patent or Proprietary (P&P) Medicine”. The meaning of the term ‘patent’ in the present day context is totally different and has other legal implications. Hence this definition should be amended to drop the words “Patent or”.

c) The legal aspects of Patent or Proprietary medicines is not very clearly understood by the consumer and there is an ambiguity with regards to terms like Ayurvedic medicine, Ayurvedic product, Herbal product, Ayurvedic ingredients, Herbal cosmetics, Ayurvedic cosmetics, etc. There has been a rapid growth of Ayurvedic medicines, much of which has been from different types of Ayurvedic products licensed as Patent or Proprietary Medicines category. While regulation is one of the important means of promoting growth of the industry, it is important that the regulatory framework should provide distinct categories, which are clear and uniformly interpretable. The current situation does not angur well in this context. Hence, suitable changes should be brought in the Drugs & Cosmetic Act to provide a clear demarcation so that only such products, which are used for medicinal purposes (prophylactic or therapeutic), are licensed and sold as Patent or Proprietary medicines.

d) The Current Indian law permits new combination of ingredients from different recipes from one or more authoritative books recognized in Schedule I, with out the need for any data on their safety and efficacy. The mere mention of these ingredients in the authoritative books is taken to provide enough rationale, while issuing a P & P license. There is an urgent need for emphasis on **safety and efficacy** of such new combination products. For this purpose, the licensing requirements need to be updated to include requirement of data related to confirmatory evidence of efficacy claims of the product. Additional safety data should be provided if long-term safety data on its usage are not available. Through the provision of these data, one will ensure that the new combinations of ingredients are scientifically proven for their safety and efficacy.

e) It has also been observed that therapeutic rationale for such products is insufficient in most cases. The law needs to be tightened to make it mandatory that the new combinations have sufficient therapeutic rationale even when analysed to meet the philosophy of ISM drugs like *Prakrut*i, effect on specific *Doshas,* etc. Such a rationale provided with license applications, can also meet different interpretations amongst Vaidyas or licensing authorities. It may be difficult to get uniform interpretations across

the country. Also such rationale should not restrict development of innovative and scientific combinations, if these can be justified on pharmacological/biological basis. Hence the conditions for licensing should be amended to demand rationale for the P or P medicine either on ISM basis or on the basis of the data that are generated by adopting a current scientific methodology. If such data justify a new usage for ISM ingredients and combinations not mentioned in the official books, then they should be allowed in law. In the long run, this will promote the role of ISM.

f) In order to promote ISM drugs and make them acceptable nationally as well as internationally, modern dosage and delivery forms need to be specifically included and permitted in the law. This area is currently left to the discretion of the licensing authority and leads to several problems for the industry. The manufacturers it must be allowed to modernise the dosage form using the latest technological advances, while retaining the basic directives prescribed by the ISM systems. In order to manufacture modern dosage forms, use of all the approved inert pharmaceutical excipients must be accepted and legally permitted, wherever required. No restrictions except for the safety concerns should be placed in this context.

g) An area of concern and controversy relates to the processing of herbs, gums and resins and other ingredients, with solvents other than just water for the manufacture of ISM drugs. Well recognised processes exist in Ayurveda, wherein self generated alcohol like in asavas, arishtas, etc. are known to provide improved extractions of the herbal ingredients leading to better quality and efficacy. Modern scientific evaluation has proven that hydro-alcoholic extracts provide better extracts that are rich in polar and non-polar compounds and that enhance the efficacy. Therefore, the use of ethyl alcohol (alone or in combination with water) should be approved for extraction of herbs and the same should be incorporated in one of the schedules under the Drugs & Cosmetics Rules. This change will help further promote ISM medicines and their acceptability in the international market.

Ayurvedic Cosmetics

7.2.7 A large number of herbal products are currently licensed as Patent or Proprietary Medicines but are primarily designed and meant to be used as Cosmetics for skin, hair, nails etc. Many such products are formulated by using modern dosage forms and contain ayurvedic ingredients. ISM wisdom and official books are replete with many recipes primarily for beautification purposes like many lepas, tailas etc. For lack of provision in Drugs & Cosmetic Act today, they are all licenced as Patent or Proprietary Medicines. It would be appropriate if such products are classified as a new category of cosmetics.

7.2.8 A major thrust can be given for promoting excellent recipes of ISM in both domestic and international markets, a new category, which could be defined as ***Ayurvedic Cosmetics*** should be introduced. It is understood that this issue has been discussed and debated in the past and was also approved in ISM Drug Technical Advisory Board but not implemented so far. Laws applicable to cosmetics category of products would govern this new category. Care has to be taken that the ayurvedic ingredient(s) used provides the appropriate cosmetics benefit in the product. The current policy of not allowing allopathic actives with ayurvedic ingredients should continue as at present. While creating this new category, a new set of standards based on performance and quality need to be evolved and adopted. Such products need to be evaluated for safety to build credibility, which can be enhanced by creating an ISI type marking system.

Drugs of Natural Origin

7.2.9 In addition to the medicinal plants, minerals, metals and animal based products, recognized and used in ISM drugs; the western herbs and ingredients also play an important role in the health care. Suitable legislation and criteria for their evaluation and approval for marketing need to be introduced. For this purpose, the following approaches are suggested:

7.2.10 Several regulatory authorities of the world like US FDA, Australian TGA have proposed guidelines for evaluation of Botanical drugs to be licensed as either OTC drugs or prescription drugs. (Refer-***www.fda.gov/cder/guidance/index.htm***). This can be considered for inclusion under the definition of New Drugs in Rule 122 E of Drugs & Cosmetic Act, with suitable amendments in Schedule Y.

7.2.11 If herbs from outside India are adequately researched using research methodology of ISM and their characteristics are evaluated on ISM guidelines (like *Rasa, Guna, Veerya*, *Vipaka, Prabhava*, etc) adoption of such herbs in the ISM system could be permitted. Such permissions should be granted only after due evaluation by an expert body of ISM. This would encourage herbs from other countries to be evaluated adopting ISM philosophies and principles. A high level ISM expert committee may be appointed to critically evaluate this issue and make recommendations concerning the practices to be adopted for this purpose.

7.2.12 The Drugs & Cosmetics Act currently provides detailed guidelines for approval of drugs and cosmetics not so far approved for marketing in the country and also for grant of their import permission/approvals. Such provisions do not exist clearly in the law pertaining to import and marketing of herbal products and cosmetics from other countries. However, many countries require registration of even herbal and cosmetic products, before they can be marketed in those countries, especially as safety is a matter of primary concern. Some manufacturers of cosmetics make therapeutic claims, which is not desirable. In order

to provide a level playing field, all such imported products need to be evaluated by Central Drug Administration, before granting permissions. Fresh rules for the same need to be framed.

7.2.13 It is recommended that standard monographs of important and most commonly used medicinal plants and their standardized extracts be prepared and published. In the absence of such standards, monitoring for quality becomes difficult. While Industrial Associations have taken some lead, the Standards developed by them need to be fitted in the regulatory framework and put in IP format. This work needs validation and making available reference standards of relevant marker compounds.

7.2.14 Methods for the extraction and preparation of marker compounds, their identity and quality also needs to be published for guidance to the industry. Such work cannot be left to the industry alone. The Health Ministry should make funds available for this important task, appoint expert committee to oversee this activity and also induct experts in this field into IP Committee. It is pertinent to mention that United States Pharmacopoeia and British Pharmacopoeia have included monographs on several medicinal plants in their recent editions.

7.3 Over The Counter Drugs (OTC)

7.3.1 As per the Drugs and Cosmetics Act and Rules, there is no separate category of drugs called OTC drugs. Currently those drugs, which are not covered under Schedule H, or G and their formulations (except their products for external applications) can be called as OTC drugs. However, all these need to be stocked, distributed and sold through premises licensed for sale, except for those, which have been specifically exempted by inclusion in Schedule K of D&C Rules. There is a need to improve the access to household medicines and products, which provide hygiene, to large masses in the interest of preventive health.

Recommendations:

7.3.2 The Committee recommends the following:

a) Schedule K should be reviewed comprehensively. Products, which by virtue of their long usage and/or nature of their application (e.g. substances used for household cleaning and disinfectants generally used in a diluted form and not meant for direct application on human skin) could be considered for inclusion in the exempted category under schedule K to further facilitate their easier access to the public at large. Other categories / drugs, which have been reviewed by an expert, sub-committee of DTAB and recommended for inclusion in Schedule K are calcium preparations without vitamins, antiseptic lotions, medicated mouth washes/rinses, psyllium and its preparations, cough and cold preparations without antihistamines and drugs included under NDPS Act.

b) Schedule H should be reviewed on an ongoing basis to add or delete products from the schedule depending upon their usage and safety profile.

c) A mechanism should be set up to review the list on a periodical basis. This should enable bringing in sufficient flexibility in the system on one hand and promoting sales and distribution of desirable products without in any way compromising on quality of the product on the other hand.

7.4 Medical devices & Diagnostics

Background

7.4.1 Medical and Health Care Technology has undergone rapid transformation in the recent past. Technological innovation has revolutionized the preventive, diagnostic, rehabilitative and therapeutic capabilities of these devices. Several innovative medical devices have emerged on the market.

7.4.2 Medical devices have generally been defined by the regulatory agencies of some countries as instruments, apparatuses, implements, machines, appliances, materials, implants, reagents, calibrators and other similar articles intended to be used in human beings or animals, for the purpose of diagnosis, prevention, monitoring, treatment, mitigation or alleviation of disease/disorder or for replacement, modification or supporting the structure or physiological process of the body. Typically, a device does not achieve its principal intended purpose by pharmacological, chemical, immunological or metabolic means although it may be assisted in its function by such means.

7.4.3 The Committee is of the view that it would be more appropriate to provide a separate and specific definition of a medical device under Section 3 of the Act and provide for relevant rules, regulations & procedures under the Rules.

Regulation of Medical Devices in India

7.4.4 There is presently no specific organization to oversee certification / approval or monitoring of medical devices in general. However, a few of such products are regulated by central and state drug control agencies under the provision of Drugs & Cosmetics Act. The definition of 'drug' under section 3(b) was extended in the year 1982 to include:

All medicines for internal or external use of human or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

7.4.5 There is an ever increasing number of medical devices being used by the practitioners, out of which the following have so far been notified under the provision for Drugs and Cosmetics Act:

- Disposable hypodermic syringes
- Disposable hypodermic needles
- Disposable perfusion sets
- Copper T
- Tubule ring
- Condoms

7.4.6 These devices require a license to manufacture, sell and distribute. Any devices, other than those mentioned above, whether imported or manufactured in the country, are not regulated at present. The Bureau of Indian Standards (BIS) certifies and regulates few other low technology devices. However, the current procedures are not adequate to assure the quality of high technology medical devices. The imported high technology devices, approved by the country of the origin or by the FDA of USA, are permitted for marketing in India. Currently, no regulatory mechanism exists for certification, quality assurance and post marketing surveillance of imported and locally made medical devices except for the notified devices and diagnostics. Many of these devices are sterilized using various techniques, efficacy of which need to be validated.

Regulation of Diagnostic Kits/Reagents

7.4.7 The diagnostic kits and reagents have been classified as ‘critical’ and ‘non-critical’. Kits for HIV, HBSAg, HCV & Blood grouping are defined as critical kits and all others are known as ‘non-critical’ kits. For licensing of critical kits, the applicant has to submit a Product dossier along with details about the manufacturing facility. The manufacturing facility is inspected for GMPs and the product is evaluated at NIB before license to manufacture is granted. In vitro blood grouping sera & in vitro diagnostic devices for HIV, HBSAg, HCV have been notified in schedule C-1 of Drugs & Cosmetics Act. This is an encouraging initiative, which lead to an improved regulatory control over diagnostics.

Regulatory Scenario

7.4.8 There is varying degree of control over medical devices and enforcement procedures in different countries. However, the regulatory responsibilities and modalities are seen to be mostly managed by the

respective Drug Administrations through dedicated divisions under their overall set-up.

7.4.9 The regulatory policies are seen to be framed around the categories of devices which is based on their *in vitro* - *in vivo* use, functional objectives etc. Many products like sutures, surgical dressings, X-ray contrast media, etc are also classified as medical devices in some countries, whereas in India, these products have been regulated as drugs under the provision of Drugs and Cosmetics Rules.

7.4.10 The Committee is of the view that there is an urgent need to provide for a certifying/approval mechanism for medical devices developed in the country in order to ensure their acceptance by medical community both at national and international level.

Need for Regulatory Control

7.4.11 It is the responsibility of the Government to regulate and assure the quality of any product marketed in the country. In the case of medical devices, which have potential health risks, this responsibility becomes even greater. The main reason for less regulatory control on medical devices has been the lack of adequate manpower, infrastructure facilities, and also a focus in the office of CDSCO.

7.4.12 The Committee noted the current regulatory status of medical devices. It recommends that a suitable policy and a proper mechanism should be established in the office of DCGI to regulate and control the quality of medical devices available in the country.

7.4.13 The Committee was informed that the Society for Biomedical Technology (SBMT) has framed a proposal to set up Indian Medical Devices Regulatory Authority (IMDRA). This authority proposes to lay down a mechanism for (a) essential certification of high-risk devices and (b) preferred certification for moderate devices by assessing the safety and efficacy data and also monitoring the post marketing surveillance. However, keeping in view the fact that a countrywide regulatory infrastructure is already available through Central and State Drug Administrations (which are also regulating many devices), and the fact that in most of the countries Drug Administrations enforce quality and safety parameters over medical devices, the Committee is of the view that the proposed CDA should aim for adequate enforcement over medical devices in general, by increasing the existing capacity through formation of a separate division. The proposed division should have adequate in-house expertise as well as a networking with external experts and institutions.

7.4.14 The Committee noted that the Pharmaceutical Research and Development Committee in its report of 1999 had also recommended the creation of a specific Medical Devices Division within the CDSCO.

Recommendations

7.4.15 The Committee makes the following recommendations:

a. The 'Medical Devices' should be specifically defined under section 3 of the Drugs and Cosmetics Act and relevant Rules and guidelines framed for their proper regulation;
b. A specific Medical Devices Division should be set-up in the office of newly structured CDA for proper management of approval, certification and quality of medical devices; and
c. An appropriate regulatory mechanism should be set up by CDA for certification, quality assurance and post-marketing surveillance of imported as well as locally made medical devices.

7.5 Drug Development including Clinical Research in India

Background

7.5.1 Pharmaceutical R&D is expensive *per se*. Clinical research constitutes about 70% of the time and money in taking a new molecule to the market. These costs are expected to grow by more than 10% during the next five years in conjunction with global requirements for more detailed and larger patient-based trials.

7.5.2 India has some inherent and natural advantages in clinical research. India's highly skilled medical fraternity, many world-class medical institutions and a large treatment-naive population has given a hope that India's potential as a global hub for clinical research can be reached sooner rather than later. Cost competitiveness will enable Indian industries and research institutions to contribute to global drug development in a significant way since the technology infrastructure required to support clinical trials will surely give a India definite advantage over other countries.

7.5.3 Mashelkar Committee (1999) report on Pharmaceutical R&D had identified clinical research as an area with immense growth potential in the country. This Committee had stated that "citing the unique opportunity for India to become a leading centre for clinical trials, the Committee has called for basic changes in the legislation allowing import of animals, contract research and a legal status for institutional ethics committees. Furthermore, establishment and operationalization of a cGMP, GLP and GCP monitoring authority has been also recommended."

7.5.4 In consonance with these recommendations, CDSCO planned a strategic intervention to improve the situation. One of its first measures was to release the Indian GCP guidelines. Together with ICMR's "Ethical Guidelines for Biomedical Research on Human Subjects" the basic framework for appropriate regulatory intervention in clinical research has also started shaping up. A completely overhauled Schedule Y, of which

the draft has since been published by the Ministry of Health in August 2003, will bring Indian clinical research regulations at par with contemporary global levels. Revision of Indian GCP guidelines based on the amended Schedule Y and initiation of National Pharmacovigilance Programme will complete a major phase of Government's initiative in this regard.

7.5.5 It is **absolutely essential** to institutionalize Good Clinical Practices (GCP) to achieve credibility for the data generated in India. Most stakeholders – sponsors and investigators alike – are not fully aware of GCP fundamentals, ethics, written SOPs, documentation, ADR management, internal audits as well as regulatory inspections. These are some of the critical areas that will have to be addressed in India.

7.5.6 There has to be a sharing of responsibility by all the stakeholders in clinical research viz. investigators, sponsors, ethics committees as well as regulators to ensure this. Even far more important is ensuring complete protection of the Indian study subjects.

7.5.7 The Committee critically analysed the contemporary scenario, the emerging challenges and opportunities. Various suggestions made by the stake holders as well as the recommendations of the PRDC report were also considered. The Committee also noted the suggestions received from CII which were the outcome of an international conference organized by them on 'Clinical Research – Road Map for India' at New Delhi in September 2003.

7.6 The Role of Drug Regulatory Agency

7.6.1 In order to manage the increasing regulatory responsibilities in this field and to respond to the expected growth in clinical trials in India, the chasm in regulatory capacity would need to be appropriately addressed. This will ensure that clinical data generated in India attains credibility and world-wide acceptance, including by the regulatory agencies of ICH participating countries.

7.6.2 The Committee observed that evaluation of data pertaining to new drugs and clinical trial approvals is necessarily multi-disciplinary in nature and it would always be imperative to seek advice and inputs from other institutions and external experts. The regulatory authority must ensure that such consultations are managed efficiently, within a fairly short and well-defined time frames. The Committee observed that the present cumbersome system of providing financial compensation (honorarium as well as TA/DA payment) is a major hindrance in taking recourse to external expertise. The Committee recommends that the compensation mechanism must be substantially eased and brought in line with the system followed by CSIR, ICMR etc. This would significantly facilitate the involvement and commitment of experts.

7.6.3 It is imperative to have well defined regulatory processes besides an adequate infrastructure, which should not only regulate the drug development and clinical trial activities but also provide an enabling environment for drug research. The regulatory agency is required to develop adequate capacity to undertake routine inspections of the clinical trial sites. For this purpose, assistance of external experts would be availed. Adequate funds should be made available to support these activities.

7.6.4 The regulatory organization must be professionally and technically abreast with the global contemporary review standards and must provide high quality reviews, within optimal time lines which are fundamentally important for drug discovery research.

7.6.5 In order to ensure an enabling environment, the regulatory division dealing with the applications concerning new drugs and clinical trials would be required to develop suitable mechanisms to ensure confidentiality of the submissions. It should have a recourse to the need based therapeutic advisory groups for review of applications. Regulatory officials must be kept up-to-date so that they are adequately trained with the latest global trends in data evaluation, including electronic submissions, etc. Adequate funds should be made available to support all these activities.

7.6.6 The Committee examined a suggestion that the Indian regulatory agency may consider approval of clinical trial applications of INDs on the basis of approvals accorded by the regulatory authorities of US FDA or western European agencies who, being ICH (International conference on Harmonization) signatory countries, have elaborate and strict review processes. The Committee observed that the draft notification of the revised schedule Y published by Ministry of Health stipulates (para 4.1) that for new drug substances discovered in countries other than India. Phase-I data generated outside India has to be submitted to the licensing authority and permission may thereafter be granted to repeat Phase-I studies. The Committee concurs with this provision under Schedule Y.

7.6.7 The Committee supports the suggestion by the stakeholders for single window clearance mechanism for approval of various applications concerning drug research and approval, including research materials etc. within CDA.

7.6.8 The pre-clinical study involving animal experimentations is an integral component of drug development research. In order to provide an enabling environment to research based pharmaceutical industries and the national laboratories. The Committee is of strong view that the policies and procedures presently applicable in the country for animal experiments need to be rationalised so that research projects are not unduly delayed or shifted out of country.

7.6.9 A substantially enhanced evaluation capability must reside within the office of DCG(I). To attain this capability, experts with the following specializations needs to be provided:

i) Pharmacology
ii) Toxicology
iii) Statistics
iv) Pharmaceutics
v) Pharmaceutical chemistry

7.6.10 It is imperative that all the scientific experts dealing with new drug data appraisals, including external ones, are familiarized with the regulatory aspects of data evaluation.

7.7. Responsibilities of Ethics Committees

7.7.1 World wide, Ethics Committees share a major role in clinical research. The Committee observed that the proposed Schedule Y draft has elaborated the constitution and functional requirements of ethics committees. A provision for Independent Ethics Committees (IECs) has also been made to facilitate research in institutions where internal ethics committees are not GCP compliant. Presently, most institutional ethics review committees in India need a lot of support in terms of development of their systems including the systems of their constitution. Appropriately constituted and functioning Ethics Committees will also ensure that Indian public too builds confidence in the process of clinical research. It should be the responsibility of the Indian Council for Medical Research (ICMR) to keep a watch over the systems and methodologies of various Ethics Committees to ensure GCP compliance.

7.8 Responsibilities of Investigators

7.8.1 Clinicians are usually hard-pressed for time. They will be able to do justice to the trials only after they are adequately trained for GCPs. Further, they should be willing to take time for extensive documentation needed for clinical research. Investigator sites as well as clinical laboratories need to have SOPs. Furthermore, investigators will have to appreciate the critical importance of compliance with GCP requirements in general and the professional importance of obtaining informed consent, in particular. This points to the need for appropriate training of clinicians desiring to work as clinical trial investigators – not only in scientific methodology but also in the principles and finer nuances of GCP and this is where they will need continuous professional up gradation.

7.9. Responsibilities of Sponsors

7.9.1 Sponsors of clinical trials will need to demonstrate that they have appropriate systems in place to discharge their duties as per GCP and to

verify that their systems work. This will mean that a comprehensive set of written SOPs to comply with GCP must be put in place.

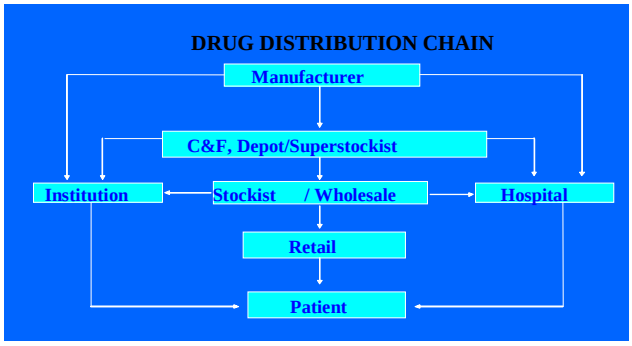
7.9.2 Sponsors will have to consciously select appropriately trained investigators and to ensure that they are aware of and comply with their responsibilities under GCP and applicable regulatory requirements.

7.9.3 The regulatory authority needs to have a register of Institutional Review Boards / Independent Ethics Committees as well as Investigators.

7.9.4 While the Government does have a regulatory role to perform in clinical research – GCP is clearly the minimum professional standard expected from medical professionals.

7.10. Drug Storage and Distribution

7.10.1 The significant and crucial role of the distribution channels of drugs & pharmaceuticals (wholesale as well as retail) can not be overemphasized. The Committee noted that medicines take a long winding and circuitous route before they reach the consumers.



7.10.2 Very often the products are bought and sold at five or six or even more times by C&F agents, whole-sellers, stockists, sub-stockists etc. before they reach a retail pharmacy and eventually the patient. Understandably, this secondary market is particularly vulnerable to unscrupulous endeavours of unethical traders and criminals. Illegally imported, stolen, spurious or adulterated drugs have an easier access to the distribution system through the secondary market.

7.10.3 The committee noted that transportation channels of drugs were also susceptible to be exploited by the unscrupulous elements to infiltrate their spurious products in the distribution channels. Therefore, it is imperative that the secondary market is more closely regulated to ensure compliance with Act and Rules, particularly with respect to proper documentation of the movement of products in the course of trade.

7.10.4 At the retail distribution level, the situation can be substantially improved by developing and fostering a professional culture among 'Qualified

Persons' engaged in retail distribution of drugs. While they are suitably qualified to manage dispensing of drugs – the Committee felt that there is a need to inculcate a climate of self-regulation among them. Enforcement of regulations by statutory authorities would always have its limitations in retail distribution scenario since retail sale of medicines is a professional activity involving moment to moment conformity with high standards of patient and drug management and a professional commitment. It is not tenable to enforce professionalism through one or two annual inspections by drugs inspectors.

7.10.5 Trade and professional associations, Pharmacy Council of India as well as State Pharmacy Councils need to play a much larger role to reform the drug management and patient interface practices in retail outlets.

7.10.6 In this regard, the Committee noted that the Government has made a very clear policy statement in the preamble of Pharmacy Act 1948 which states "it is expedient to make better provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils"

7.10.7 There is an urgent need to implement India specific Good Pharmacy Practices and Good Storage Practices that will improve the distribution system and will minimize the chances of spurious and sub-standard drugs entering the supply chain. Pharmacy Councils must perform a proactive role in bringing awareness about these concepts and should ensure that their knowledge is linked with the registration under the Pharmacy Act.

7.10.8 The Committee noted that in several countries the responsibility of regulating retail sale of drugs is entrusted with professional bodies or state boards that register pharmacists. Continuing education for renewal of registration as pharmacists is also mandatory in several countries. In India, the registration of pharmacists, under the Pharmacy Act, is done by the State Pharmacy Councils while the licensing of retail outlets where these pharmacists are deployed, is done by the Drugs Control Department under the Drugs & Cosmetics Act and Rules. There is a need to review this system and possibly integrate pharmacists and the pharmacy profession and make them more accountable for their roles in drug distribution. The concept of locum (stand-in or substitute) pharmacists may be introduced to further ensure that the drugs in supply chain are managed in an appropriate manner, till they reach the patients.

7.10.9 The enormously large number of retail outlets does appear to strain the economic viability of retailers as well as poses an overwhelming challenge to the regulatory system. The Committee noted that the present regulations are sufficient to deal with the situation and efficient implementation of the relevant provisions of the Rules would largely curb any tendency of fringe players and other unscrupulous elements to be tempted to deal in spurious medicines.

Recommendations

- State Licensing Authorities should devise suitable standard operating procedures to restrict excessive concentration of retail/wholesale outlets.
- The drug manufacturers should follow good storage practices for their products during transport as well as storage at wholesale and retail stores
- The drug manufacturers should have limited number of main stockisits
- Only these main stockists should sell to the retailers or hospitals
- The manufacturers should ensure that retail and wholesale chemists are aware of proper storage conditions of their products.

PART B

8.0 EXTENT OF SPURIOUS AND SUBSTANDARD DRUGS IN THE COUNTRY AND MEASURES TO DEAL WITH THE PROBLEM

8.1 Spurious /Counterfeit Drugs

8.1.1 There have been wide spread reports on the availability of Spurious / fake/counterfeit drugs in the country. Trade in counterfeit/ spurious drugs is prevalent internationally and affects both developing and developed countries. Despite Indian Pharmaceutical Industry having a domestic turnover, which is worth more than Rs. 20,000 crores, and exports worth over Rs. 10,000 crores, the shadow of spurious drugs is likely to raise apprehensions about the availability of safe and genuine drugs from India in general. It needs to be emphasized that counterfeiting of commercial products has been in existence since long.

8.1.2 The problem of spurious drugs is reported to be a global phenomenon and India is no exception. Although the problem of counterfeiting or fake goods has been reported in all parts of the world, especially in respect of popularly used consumer goods, it acquires more serious dimensions, when it involves medicines. In the case of drugs, the most serious issue is the adverse impact on human safety causing sometimes a grievous injury and even death, due to the failure of the intended pharmacological intervention. There is also the issue of economic loss to the manufacturing companies holding the rights for particular products. It is therefore imperative that the regulatory authorities, pharmaceutical industries, trade and consumers should work in unison and make all-out efforts to ensure that only genuine and good quality drugs are made available to the public at large.

8.1.3 Several possible factors contribute to proliferation of spurious drugs. Some of the prominent ones are:

a. Lack of enforcement of existing laws
b. Weak penal action
c. Very remunerative trade
d. Large scale sickness in small scale pharmaceutical industry
e. Availability of improved printing technology that helps in counterfeiting
f. Lack of coordination between various agencies
g. Too many retail & whole sale chemist outlets
h. Inadequate cooperation between stakeholders.
i. Lack of control by importing/exporting countries
j. Wide spread corruption and conflict of interests

In India, although appropriate legislation and regulatory systems exists, there is a considerable non-uniformity of enforcement standard followed by state drug control authorities.

8.2 Definitions of Spurious / Counterfeit Drugs

8.2.1 The definition of spurious drug was included in the Drugs and Cosmetics Act by the Amendment Act of 1982. Section 17-B defines that a drug shall be deemed to be spurious:-

a. if it I s manufactured under a name which belongs to another drug; or
b. if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
c. if the label or container bears the name of an individual or company purporting to be the manufacture of the drug, which individual or company is fictitious or does not exist; or
d. if it has been substituted wholly or in part by another drug or substance; or
e. if it purports to be the product of a manufacturer of whom it is not truly a product.

8.2.2 The Food and Drug Administration, USA defines counterfeit drug as :

"A drug which, or the container of which, or labelling of which, without authorization, bears the trademark, trade name, other identifying mark, imprint or device or any likeness, there of a drug manufacturer, processor, packer, or distributor other than the person, or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor."

8.2.3 According to WHO, a counterfeit medicine is one which, is deliberately and fraudulently mislabelled with respect to identity and/or source.

Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.

8.2.4 The term, 'counterfeit' that is commonly used worldwide for spurious drug does not appear in Drugs and Cosmetic Act but the above definition of spurious drug comprehensively covers counterfeit drug also.

The Drugs and Cosmetics Act also defines "Misbranded Drug", under Section 17 and "Adulterated Drug", under Section 17A.

A drug is considered "Not of standard Quality" or substandard if it fails to comply with any of the parameters of the overall standards laid down for it either in a recognized Pharmacopoeia or otherwise pre declared by the manufacturer.

8.3 Impact on Public Health and National Economy

8.3.1 Spurious/Counterfeit drugs harm the consumers, because they could cause serious injury or fatal consequences, if they do not contain active ingredients or contain harmful substances. Treatment with ineffective counterfeit drugs such as antibiotics or other life saving drugs may have deleterious effect. In most cases, such products are manufactured in the absence of quality control and assurance systems, which are subjected to normal regulatory control.

Furthermore, the Government revenue suffers, since the makers of spurious drugs do not pay any duties or taxes. These products would also have a negative impact on the growth of industry. There is a discernible trend of organized crime taking over manufacture and sale of spurious/counterfeit medicines.

8.3.2 There are examples of counterfeit drugs, which are the exact copies of known brands of established companies. These may contain all the ingredients as per claim. Such drugs are passed off at cheaper rates or to unwary customers. This is normally projected as more of a problem for the pharmaceutical industry but it is also a problem and challenge for the regulatory authorities. In such cases, the manufacturers can set up their own system of surveillance to tackle the problem but they should also partner closely with the Government. The Committee noted that the efforts made by Indian Pharmaceutical Alliance (IPA) in this direction have resulted in the successful unearthing of cases of manufacture of spurious/counterfeit drugs in recent years. The manufacturers should also have appropriate and effective systems of handling public complaints.

8.4 Assessment of the Extent of Spurious Drugs

8.4.1 The figures quoted in the media and by different sources about the extent of spurious drugs in the country have varied anywhere from 0.5% to 35 %.

8.4.2 Based on the samples tested by the State authorities, data were analysed for the period 1995-2003. These data are given in (**Annexure 9**). According to these data, the extent of sub-standard drugs varied from 8.19 to 10.64% and of spurious drugs varied between 0.24 % to 0.47%.

8.4.3 There were presentations made to the Committee on 17th July 2003 by CII representatives. Their conclusions were as follows:

a Revenue loss of over Rs. 4000 Crores to industry;
b 2001 production of total drugs : 22,887 crores. 18% spurious =>4112 crores;
c Government supplies-majority fail quality test;
d WHO statistics on spurious drugs – India leads with 35% of world production; and
e USA keeps India under watch list special 301

The Committee had requested CII to present whatever evidence it had to the Committee. It was agreed that it will be presented to the Committee in due course. The desired evidence in respect of alleged quality of spurious drugs and regarding majority of Government supplies failing in quality has, however, not been made available.

8.4.4 Media plays a very crucial role in projecting issues and problems of interest to society. The Committee studied the media reports. Some sample examples are given below :

"India Today", in an article in September 2, 2002 issue stated, *"The India Pharma Alliance (IPA) claims an annual damage of Rs. 4, 000 core to the pharmaceutical industry due to spurious drugs"*.

A meeting of the sub-committee (Group I) mandated specifically to look into the issue of spurious drugs was held on 29th April 2003. In this Committee, the IPA representative clarified that the figures extrapolated by them are a matter of general perception and may not be accurate. He also said that it is difficult to estimate the real extent of spurious drugs since it is an under cover activity.

8.4.5 WHO had been quoted to have given a figure of 35% of fake drugs produced in the world coming from India. (Reference Patralekha Chatterjee in Lancet 2001, 357 No. 9270; 1776, 2nd June and The Week May 18, 2003). For example, "The Week" published a detailed article titled "Flood of Fake Medicines". It quoted various sources and gave quantitative figures. For example it reported, *"According to the WHO, 35% of fake drugs produced in the world come from India, which has a*

Rs. 4,000 Crore spurious drug market. About 20% of medicines in the country are fake or sub-standard. Of these, 60 % do not contain any active ingredient, 19% contain wrong ingredients and 16 % have harmful and inappropriate ingredients".

8.4.6 Enquiries were made by the office of DCGI with WHO. WHO's response is reproduced in (**Annexure-10**). The WHO representative in India stated that "There is no actual study by WHO, which concludes that 35% of world's spurious drugs are produced in India." I have investigated this matter with our regional office, and they believe that the source is a commentary from 2001 by an Indian journalist in the Lancet. I will also try to seek the issuance of a clarification from our side, but this may take some time. It went on to add that 'The Indian pharmaceutical market, with annual sales ranging between US $ 7-8 billion, ranks third in the world, and the majority of the Indian pharmaceuticals are produced by large manufactures according to WHO Good Manufacturing Practices (GMP)'

8.4.7 In any event, the figures floating in the media, claimed as being WHO figures, remain unsubstantiated today. The above clarification from WHO was made available to the press on August 12, 2003 during the submission of the interim report to the Hon'ble Union Health Minister. It has, therefore, come as a surprise in spite of WHO's that clarification and the observations of this Committee in regard to the extent of problem in its interim report - which was made public on the above date – the media has continued to take an alarmist view by giving unsubstantiated figures about the alleged circulation of spurious drugs in the country. The committee specifically noted the cover story in a weekly newsmagazine 'Outlook' dated September 22, 2003 which claims that "30% of the world's fake drugs are made in India" and that "1 in every 4 medicinal drugs sold in India is spurious".

8.4.8 It is clear that the problem of spurious drugs certainly exists in the country. However, its exact extent is difficult to ascertain. It is, therefore, evident that a systematic and authentic study of the problem at hand is called for urgently.

8.5 A Need for Systematic Investigation of the Extent of Spurious/Counterfeit Drugs in the Country

8.5.1 The issue of spurious drugs justifiably gets debated with a lot of emotive content due to the understandable concern among the public at large. However, a systematic and thorough evaluation of the extent (in terms of number of units/brands/amount) and the nature (content is lower than claimed or is missing or content okay but misusing some other fast selling brand) of counterfeiting is called for.

8.5.2 In other words, any scientific exploration to comprehend and subsequently deal with the situation will call for a systematic collation of information, a logical model to analyse the collated data and then to

extrapolate the conclusion to get a clearer understanding of the extent of the problem across the country.

8.5.3 Delhi Pharmaceutical Trust (DPT) made a presentation to the Committee members and suggested a scheme to carry out a statistically validated and scientific study so that its final evidence based analysis will stand the test of scrutiny. An exact time and cost estimate can be worked out on the basis of a detailed protocol and a statistical model.

8.5.4 The proposal aims to identify a list of most commonly reported spurious/counterfeit drugs, to prepare a list of companies known to have faced counterfeit problems and to select certain areas in the country where these drugs are reported to be prevalent. Trained designated buyers will purchase 2 units of each of the identified drugs from each identified territory and sub-territory. Similarly samples will be taken from dispensing doctors and various dispensaries/Government institutions. The 2 units of drug will be segregated and one set forwarded to a designated laboratory, which, at the first instance will look for physical signs of counterfeiting. The laboratory will analyse 100% of suspected samples, 50% of probable suspects and 25% of not suspected samples. The complete project is likely to cost about Rs. 15 to 20 Lacs. It will take about 3 to 4 months to complete.

8.5.5 The Committee concluded that such a study, carried out scientifically, may provide a realistic picture about the extent of spurious drugs in the country.

8.5.6 The Committee in its interim report had recommended that the Government should arrange to undertake such a study so as to generate credible and authentic data as to the extent of spurious drugs in the country. The Committee was informed that the Government has since agreed to fund the study proposed by Delhi Pharmaceutical Trust.

8.5.7 The outline of the draft protocol as formulated by sub-group 3 is at Annexure 11.

8.6 Current Status of the Regulatory Apparatus at the Sate Government level

8.6.1 In India, the State Governments are solely responsible for :

a. Licensing of drug manufacturing establishments and sales premises;
b. Carrying out inspections of licensed premises for ensuring compliance to conditions of licenses;
c. Drawing samples for test and monitoring the quality of drugs and cosmetics moving in the State;
d. Taking appropriate action like suspension/cancellation of licenses; and
e. Instituting legal action wherever needed as provided under the

Act and Rules.

8.6.2 It is therefore, imperative that a uniform and competent enforcement infrastructure as well as uniform procedure should exist in all States. This is important because a drug manufactured in one State moves freely in inter-state commerce, as well as in export market. However, the infrastructure facilities, the number and quality of drug inspectors, testing facilities, support systems, etc. continue to vary significantly from State to State. Thus, while in some States the organization is headed by a full time technical person, the others have administrators, police or medical persons as heads of office.

8.6.3 The Drugs and Cosmetics Act has been in force for the past 56 years but the enforcement in many States has not yet reached the desired level. As early as 1975, Hathi Committee had also given a comprehensive report and recommended measures for strengthening and streamlining the Central and State Drug Control organisations.

8.6.4 The drugs testing facility has not kept pace with the progress made by the pharmaceutical industry and growth of trade in many States. As per the information received from 31 States/UTs, Only 17 drug testing laboratories are functioning **(Annexure 8).** Even among these laboratories, only 7 are reported to have the capacity to test all categories of drugs. Ten States/UTs have a very small laboratory with scant testing facilities. It is seen that some States having large population base have also not been able to establish viable testing facilities and have not cared to provide intelligence cells despite the rapid increase in the number of sales premises and the corresponding need for efficient monitoring in such States. The infirmities in regulatory environment are in all likelihood being taken advantage of by antisocial elements to push spurious/counterfeit or sub standard drugs.

8.7 Current status of the Regulatory Apparatus at the Central Government Level

8.7.1 The main functions of Central Government are:

a. Laying down regulatory measures and amendment of Act and Rules;
b. Approval of new drugs introduced in the country;
c. Permission to conduct clinical trials;
d. Registration and Control on the quality of imported drugs;
e. Laying down standards for drugs, cosmetics, diagnostics and devices and updating Indian Pharmacopoeia;
f. To approve licenses as Central License Approving Authority for manufacture of large volume parenterals and vaccines and operation of blood banks and such other drugs as may be notified by Government from time to time; and

g. Coordinating the activities of the States and advising them on matters relating to uniform administration of the Act and Rules in the country.

8.7.2 The Committee noted that in the recent years, the Central Government had made certain efforts to eradicate the menace of spurious drugs. As such, it had initiated several steps based on the recommendations of various committees. Some of the steps taken are summarised below :

a. The detailed guidelines on strategies to be adopted by State Authorities to fight the menace of spurious drugs have been provided to all concerned;

b. A comprehensive plan to upgrade the testing facilities in States under a capacity building project through World Bank assistance is soon to be taken up. This project involves financing of construction of 5 new state laboratories and renovation/extension of the building, equipment etc. of 14 States/UTs besides considerable assistance for purchase of costly equipments. This will not only increase the number of samples that can be tested but will also bring down the reporting time;

c. A Computerized Management Information System is being set up for quick availability of information/database and better coordination between the State and Centre by linking through the network of National Informatics Centre (NICNET). This project is likely to be complete by the end of 2003;

d. A specialized training programme for drug control officers of State Governments responsible for keeping surveillance over possible movement of spurious drugs has been initiated. The first such programme started in Mumbai in June this year in cooperation with FDA, Maharashtra;

e. Schedule M of Drugs Rules incorporating current Good Manufacturing practices to improve standards of production of Drugs has been amended and made stricter;

f. The validity period of licenses have been increased from 2 to 5 years so that the regulatory staff has more time for enforcement activities; and

g. Procedure for registration for all drugs imported into the country has been introduced in order to ensure better check over their quality and manufacturing standard.

8.8 Examination of the problem by DGHS Committee.

8.8.1 In July 2001, a Committee was constituted by the Union Ministry of Health & Family Welfare, Government of India under the chairmanship of Dr. S. P. Aggarwal, Director General of Health Services (DGHS), to

suggest remedial measures to combat menace of manufacture and sale of spurious drugs/fake medicines. The Committee was set up in view of serious concern expressed, in print as well as in electronic media, and in the Parliament about the availability of spurious drugs in various parts of the country.

8.8.2 The Committee examined in–depth, various issues concerning the manufacture and sale of spurious drugs and suggested certain remedial measures which needed to be taken to combat the menace of spurious drugs. The Committee felt that as the prime responsibility of providing quality drugs to the public is that of the Government, the State Drug Control authorities, which are empowered to regulate manufacture and sale of drugs and to monitor their quality, are required to gear up for making effective and continuous efforts in tracking down the persons indulging in clandestine manufacture and sale of spurious drugs. As the drugs manufactured in one State are sold in other States, the coordination among the States is of paramount importance in tracking down such clandestine and criminal activities. The Drugs Controller General (India) had circulated the recommendations of DGHS Committee to all State/UT Drugs Controllers in September 2002 for adoption and implementation.

8.8.3 The DGHS Committee suggested a number of measures for adoption by drug regulatory authorities, pharma industry and trade to help in combating & controlling the menace of spurious drugs. The present Committee fully endorses the recommendations made by the DGHS Committee.

8.9 Defining the Role of Chief Ministers

8.9.1 The Union Minister of Health and Family Welfare wrote to Chief Ministers of all States in October, 2002, on issues concerning spurious drugs '*seeking their personal intervention to ensure that adequate measures are taken to vigorously pursue the strategies needed to preclude any possibility of menace of spurious products so as to collectively ensure its total eradication in a manner that the word 'spurious or counterfeit drug' becomes a word of past in India'.*

8.10 Examination by State Health Ministers

8.10.1 The Union Minister for Health & Family Welfare convened a meeting of State Health Ministers in November 2002 to discuss measures to check manufacture and sale of spurious/fake medicines. In his address, the Minister stated that:

"surveillance and management of spurious/counterfeit drugs is a social responsibility. The regulatory agencies must initiate focused strategy for its stoppage by monitoring such criminal and illegal activities. There are reported to be more than 3.5 lakh sales outlets in the country and about 800-900 drugs inspectors for about 600 districts in the country. Only 17 States have drug testing facilities of which only 6 laboratories have

facilities for complete testing of all categories of drugs. In such a scenario, the problem cannot be effectively tackled in a routine manner by quality monitoring or licensing activities".

He further stated that :

'For any civilized society, it is an evil, which needed to be tackled with top most priority by involving all stakeholders and utilizing all possible resources'.

8.10.2 Health Ministers/Secretaries/Drug Controllers of States gave their views and highlighted the problems faced by them at the State level. Most of them stated that lack of funds was a major constraint for not being able to strengthen their regulatory infrastructures that they requested for a central support for this purpose.

8.10.3. The Committee was informed that the following suggestions and views emerged as outcome of discussion in the State Health Ministers Meeting in November 2002.

a. It was agreed that there is a basic need for uniformity in implementing various regulatory requirements by State Drug Control Organisation.
b. Nodal officers to be identified by all States for monitoring suspected manufacture and sale of spurious drugs and a special training programme for these officials to be conducted a FDA Maharashtra with the help of Central Government .
c. Amendment of Sec. 27 of the Act to be considered so that spurious/counterfeit drugs, which otherwise may not be considered harmful, may also attract a severe penalty of imprisonment of 5 year extending to life imprisonment. Offences related to spurious drug to be made cognisable.
d. State of Gujarat has used 'The Gujarat Prevention of Anti-social Activities Act, 1985' (PASA) for preventive detention of drug offenders for anti-social and dangerous activities prejudicial to the maintenance of public order. State Governments may examine this enactment for deterrent action against offenders.
e. Drug testing facilities in the States needs to be augmented and dug testing time needs to be brought down to one month, which, in many States extends to 6 months.
f. For efficient information exchanges, computerization and networking of all Central and State drug regulatory offices to be established.
g. Surveillance over distribution of drugs through medical practitioners is also needed.
h. Zonal offices of CDSCO needed to be more effectively involved in inter-state matters.
i. The Pharma industry needed to take adequate initiative in detection of counterfeit products and to coordinate with drug regulatory agencies.
j. In order to ensure speedy trials, the States Governments needed

to take up the matter with their High/Law Deptt. concerning setting up a special court.

k. A provision of toll free number, at Drug Control offices to be considered so that consumers or doctors can easily make their complaints.

8.11 Proposed Actions by the Stake Holders

In the light of the recommendations made in the DGHS Committee Report, the national level consultations referred to above and also the deliberations of the present Committee, it is recommended that action needs to be taken by several stake holders. This is summarized below:

8.11.1 Action for State Drug Control Organizations

a. Strengthen the State Drug Control Organization with additional manpower, infrastructure, technical capabilities and financial sources.

b. Set up Intelligence cum legal cell under the supervision of trained senior nodal officers. The State Government should put in place efficient mechanism for timely police help to these officers.

c. Establish a proper surveillance system for keeping a watch over suspected persons. Watchers should be employed and secret funds may be made available for intelligence activities.

d. Set up efficient communication networking for sharing and exchanging information in cases involving inter-state movement of spurious drugs.

e. Request the Government to identify designated courts for speedy trial of spurious drug cases.

f. Set up an adequate testing laboratory according to the need to ensure that the suspected samples are tested expeditiously.

g. Monitored the sources of purchase and quality of drugs stocked by dispensing medical practitioners and institutions.

h. Provide a toll free number to receive public complaints/ information etc. The condition of license for sale of drug should be strictly enforced.

8.11.2 Action for Pharma industry

a. Use their well-developed marketing network to identify distribution channel and persons involved in spurious drug trade.

b. Assist, through its associations in detection and unearthing of spurious/counterfeit drugs by cooperating with the regulatory and/or police authorities.

c. Prepare, through its associations, a checklist for the guidance of manufacturers, wholesalers and retail sellers to identify and

distinguish between the spurious and genuine products.

d. Formulate its own spurious/counterfeit drugs policy and a surveillance strategy to tackle the problem of spurious drugs.
e. Establish a close interaction with regulatory authorities and extent full cooperation to eliminate the menace of spurious drugs.
f. Streamline their supply chain and distribution network.
g. Ensure proper storage of products during transit as well as at places of distribution.

8.11.3 Action for the Pharma Trade Association (AIOCD)

a. Play a proactive and visible role to contain the menace of spurious/counterfeit drugs.
b. Develop its mechanism in identifying the persons directly or indirectly involved in abetting the distribution of spurious. counterfeit or questionable quality drugs
c. Prepare a checklist for the guidance of members and widely publicize it for information of all members.
d. Adopt highest professional standards in the interest of consumers.
e. Every chemist/pharmacist to act as a watchdog to prevent entry of any spurious/doubtful quality drugs or those purchased from unauthorized sources or without proper bills in the supply chain.

8.12 Role of Pharma Industry, Trade and other Professional Associations.

8.12.1 In the case of counterfeit drugs that are exact copies of the known brand, it is the industry that gets affected financially. It is observed that genuine manufactures often get a bad name, when the authorities detect a counterfeit drug, that is a copy of their brand and the news is flashed to the public through the media. It is felt that the industry should have its own surveillance strategy to tackle this problem. The industry has a well-developed marketing and distribution network and should use its manpower to detect cases of counterfeit drug trade. Indian Pharmaceutical Alliance has recently taken successful initiatives in unearthing cases of spurious drugs. The industry should streamline their supply chain and distribution network to effectively trace the movement of their products.

8.12.2 The Committee observed that initiatives taken by the industry associations, particularly Indian Pharmaceutical Alliance in the last few years have resulted in unearthing of some spurious cases. The industry should establish even a closer interaction with the regulatory authorities and work together to eliminate this menace.

8.12.3 It was reiterated that all India Organisation of Chemists and Druggists should play an active role to educate their members and to cooperate with the regulatory authorities to eliminate sale of spurious and

substandard drugs by their members. Any case of procurement by dealers from unauthorized sources should be dealt with severely.

8.12.4 There is a need for better awareness of the consumers and for this, the consumer and professional organizations should play a proactive and visible role.

8.12.5 The Committee appreciated the recommendations made by the DGHS Committee in this regard and agreed that in view of the current suggestions made by the member; those recommendations can be further supplemented. It also reiterated that sharing of responsibility by all stakeholders which includes enforcement agencies, pharma industry, trade, health professional and consumers etc. and cooperation between all the members of the society was essential for achieving success in containing the menace.

9. SUMMARY OF THE MEASURES TO DEAL WITH THE PROBLEM OF SPURIOUS / COUNTERFEIT DRUGS

9.1 The Committee endorsed the views expressed by the DGHS Committee and also the views that emerged as outcome of discussion at the meeting of State Health Ministers. The members re-emphasised several of these suggestions as remedial measures to eliminate/reduce the menace of spurious drugs in the country. In summary, the gist of the recommendations is:

- Effective interaction between the stakeholders i.e. industry and regulators, industry and consumers, trade and regulators and medical professional and regulators.
- Creation of intelligence cum legal cells in State and Central offices.
- Discouraging proliferation of drug distribution outlets.
- Changes in law to provide enhanced penalties, making the offences cognisable and non-bailable in the light of similar provisions in Narcotic Drugs and Psychotropic Substances Act.
- Designation of special courts to try the cases of spurious drugs.
- Preparation of dossiers of suspected dealers and manufactures.
- Provision of secret funds and incentives to informers.
- Effective networking system between States.
- Check on drug supplies to practitioners who buy and supply drugs to their patients.
- Industry to have its counterfeit drug strategies, better surveillance and efficient complaint handling system.
- Trade associations to have better surveillance on defaulting members and to take strict action against them.
- Creation of better awareness amongst consumers.

9.2 The Committee recommends that each State should have a designated officer trained in investigation of spurious counterfeit drugs and there should be a central nodal officer to establish a countrywide network. The

Central Government should assist in providing training to all the State intelligence cum legal officers.

9.3 The Committee observed that there is a considerable apprehension that many of the registered medical practitioners, who dispense drugs to their patients, do not always purchase their supplies from authorized sources. They are, thus, likely to be supplied with spurious/counterfeit and substandard drugs. This is corroborated by the fact that there are reports of manufacture and sale of drugs without proper documents. It is necessary to have a better control and monitoring of these supplies to practitioners.

9.4 In this regard the Committee noted that the present Schedule K provides exemption to registered medical practitioners, who supply drugs to their own patients from the provisions of the Act and Rules in that they do not have to take any sales license but this exemption is subject to certain conditions. These conditions include that the drugs should be purchased only from a licensed dealer or a manufacturer and records of such purchases showing the names and quantities of such drugs, together with batch numbers and the names and addresses of the source shall be maintained. The Drugs Inspectors are authorized to inspect the records, make enquiries and if necessary, take samples for test etc. There are no data to indicate as to whether drugs inspectors routinely go and check the records of purchase of these practitioners or not. The Committee recommended that the state authorities should implement this provision more stringently in order to ensure that the drugs purchased by these practitioners for dispensing to their patients are supported by proper purchase records and are of standard quality.

9.5 The Committee also felt that there should be some restriction for issuing retail and wholesale licenses, since agglomeration of chemist shops results in cutthroat competition and indulgence in possible purchase of drugs from unauthorized sources for economic reasons. The feasibility of this suggestion needs to be examined.

9.6 If a spurious drug is detected in one State, the source of its origin is usually from another State. By the time the concerned State drug authorities are contacted, the evidence normally is destroyed at the source. The real offender escapes detection and may keep on indulging in this trade. The actual supply of spurious drug remains untraceable and recoveries are not affected. It is, therefore, necessary that there should be a speedy information exchange mechanism. This will enable a functional coordination with all States in the count.

9.7 The Committee felt that there was a strong need for an effective communication system by means of computer networking in all States that would help in rapid investigation of spurious drugs. In this regard the Committee noted that the Central Government has already initiated a major project to provide state-wide computer interlinking.

10.0 CHANGES REQUIRED IN VARIOUS LAWS

10.1 The Committee reviewed the various legislative positions in different countries in the world with reference to offences connected with spurious/counterfeit drugs. **(Annexure 12**) provides the details.

10.2 By amendment of The Drugs and Cosmetics Act in 1982, the punishments for various offences were rationalized and life imprisonment was included as penalty for sale and manufacture of a spurious drug that causes grievous hurt or death. It was, however, noted that so far not a single prosecution has resulted in life imprisonment. While some members of the Committee suggested that for real fear among the possible offenders the penalty should now be enhanced from life imprisonment to death, some others were of the view that legal proceeding in cases involving death penalty may result in very complicated and lengthy trials. It was also agreed that even in cases of spurious drugs that are not likely to cause grievous hurt or death, the penalty should be enhanced with increased fine. The Committee recommends that the existing provisions under Section 27 of Drugs & Cosmetics Act need to be amended.

10.3.1 It was the general view of the Committee that these offences should be made cognisable and non-bailable. At present, the offenders usually get bails and the prosecutions normally take about 10 to 15 years for decision. In many cases, the offender may get away with minor punishment whereas in all likelihood, he continues to indulge in spurious drug trade/ manufacture during the period of trial. It is considered necessary that offences related to spurious drugs are made non-bailable.

10.4 The Committee noted that in Gujarat State, legislation called Prevention of Anti Social Activities Act. (PASA), which allows detection of suspected offenders, is being used in spurious drug offences. In Uttar Pradesh, provisions of National Security Act (NSA) to book habitual spurious drug offenders are reported to be used.

10.5 The Committee also examined the provisions of Narcotic Drugs and Psychotropic Substances Act where the offences are non-bailable and provide for detention of the accused. It was felt that similar provision should be included in the Drugs and Cosmetics Act so that the courts may consider applications for bail only after a period of 3 months.

10.6 The existing provisions, 274, 275 & 276 of I.P.C/ Cr.P.C related to drug offences are bailable and cognisable and are not in consonance with the provisions of Drugs and Cosmetics Act. There is no mention of spurious drug offence in the Cr.PC. Therefore, in order to ensure a uniform legislative intent reflecting upon the gravity of offences, it is essential to delete the existing provision from the statute.

10.7 The Committee also noted that sale of spurious drugs takes place almost always without bills and hence the penalty for dealers who are unable to produce authentic documents in support of their purchases should be made more stringent so that they exercise more diligence while procuring their drug supplies from unauthorized sources. The Committee felt that it was better to have a strong deterrence by making penalties more severe.

10.8 The Committee noted that currently the legal proceedings are far too complicated and lengthy; the process moves slowly and the conviction rate is low. At least in the core of spurious drug offences, quick disposal and immediate/appropriate punishment is called for, as it would act as a true deterrent. The Committee, therefore, recommends that a provision should be made under Drugs and Cosmetics Act to empower State and Central Government to constitute special courts for trial of offences under this Act.

10.9 The Committee felt that since the entire process of filing of prosecution to completion of trials is a lengthy process, it becomes an exercise in futility to prosecute licensees for minor offences. For example, for offences Under Drugs Price Control Order (DPCO), even if there is an over charge of ten paise, the only remedy provided is prosecution which is considered to be infructuous by the Drug Authorities. For this purpose ,it was suggested that a provision for compounding of offences may be included in Drugs and Cosmetics Act for commission of minor offences.

10.10 The Committee noted the functions of the officers of regulatory system are mostly of technical nature, whereas manufacture and sale of spurious drugs is a criminal activity that requires specialized training and skills as well as help of police. The Committee observed that under the present provisions of Drugs and Cosmetics Act, only Drugs Inspector is authorized to file prosecutions. It was felt that whenever a spurious drug case is detected and investigated by police, they should also have the power to prosecute independently. The Drugs and Cosmetics Act, therefore, needs to be amended to authorize the police also to file prosecutions.

10.11 A detailed proposal for the amendment of various provisions pertaining to drug offences for the consideration of the Government is submitted by the Committee (**Annexure 13**).

11.0 EXTENT OF SUB-STANDARD DRUGS

11.1 Standards of Quality

According to Section 16 of Drugs and Cosmetic Act 1940, “Standard Quality” means that the drug complies with the standards set out in the Second Schedule. The Second Schedule stipulates that all drugs imported or manufactured in the country have to comply with the standards laid down in the India Pharmacopoeia. The drugs that are not included in the Indian

Pharmacopoeia should comply with the standards specified in the official Pharmacopoeia of any other country. The patent or propriety medicines have to comply with the formula displayed on the label or otherwise pre-declared by the manufacturer.

A drug is considered not of standard quality, (NOSQ) or sub-standard, if it fails to comply with any of the parameters of the over all standards laid down for it either in a recognized Pharmacopoeia or otherwise stipulated by the manufacturer.

11.2 Problem of Sub-Standard Drugs

The problem of sub-standard drugs is confined mainly to licensed manufacturers. An analysis of number of samples of drugs tested by state drugs testing laboratories and the number of drugs found sub-standard during the last five years indicates a figure of about 10%. However, it would not be correct to conclude from these figures that 10% of the drugs moving in the market are sub-standard. The State Drugs Inspectors normally draw samples of drugs which are thermolabile and are close to expiry dates and which they suspect to be sub-standard, such as vitamins and antibiotic preparations. They also draw samples of preparations for which complaints have been received or those manufactured by less known manufactures. Due to paucity of funds for purchase of samples in many states, the Drugs Inspectors draw limited number of samples for test and pick up only such samples that are suspected to be substandard.

11.3 Reasons for Drugs becoming sub-standard

Sub-standard drugs can result mainly because of two reasons. One reason could be the inadequate pre-formulation development studies before the drug is marketed or lack of in-process controls exercised by the manufacturers during the process of manufacture. For example, if a drug is not formulated properly and the stability studies are not done before marketing the formulation, it is likely to deteriorate on storage and may fail in one or more parameters. Likewise, if adequate in-process controls are not exercised during manufacture of tablets, it is possible that the tablets produced may fail in the disintegration or in weight variation tests. Similarly, in case of vitamin and antibiotic preparations, if adequate stability studies not conducted, the preparations may deteriorate before their expiry dates. The second reason could be the improper conditions under which drugs are stored and transported. The drug preparations could become sub-standard if they are not stored or transported under proper conditions as stipulated on the label. Thus antibiotic, vitamin and other thermolabile preparations, if stored or transported at higher temperatures and/or humid conditions, could deteriorate and become sub-standard.

If the drug manufacturers follow Good Manufacturing Practices (GMPs), observe proper in-process controls, test all raw materials, packaging materials and the finished products, the possibility of their drugs becoming sub-standard would be much less.

11.4 Nature of defects in Sub-standard Drugs

It may be relevant to point out that a sub-standard drug may or may not be a harmful drug. Drugs may be declared sub-standard because of defects, which may not affect the therapeutic efficacy of the drug. For example, tablet preparations may be declared sub-standard because they do not conform to the standards for uniformity of weight, diameter or they are chipped, discoloured etc. Similarly, liquid preparations and injections could be declared sub-standard, because the quantity contained is found to be less than that stated on the label. There are however, certain defects which could affect the therapeutic efficacy of the product e.g. disintegration/dissolution test for tablets, sterility and pyrogen test for parenteral preparations and active content being much less than the claimed amount.

11.5 Action to be taken on Sub-standard Drugs

As samples of drugs are drawn by the State Drug Inspectors and sent for test, action on the sub-standard test reports has to be taken by the State Drug Control Authorities. The Committee was informed that action normally taken by them is both administrative and legal. Where the defects observed are not of serious nature, administrative action against the manufacturer is taken by way of warnings, suspension or cancellation of license. In case of serious offences or a manufacturer whose preparations have repeatedly found to be of sub-standard quality, prosecutions may be resorted to.

11.6 Guidelines for Action to be taken on Sub-standard Drugs

The Committee was informed that the matter regarding action to be taken on substandard drugs has been discussed several times in Drugs Consultative Committee (DCC) meetings and guidelines have been framed and circulated to all states. The defects found in sub-standard drugs have been categorized into Category A and Category B defects (Annexure 14). Category A defects are those, which are considered to be serious in nature and affect the quality of a drug (examples, active ingredient content below 70%; tablets failing in disintegration/dissolution tests and in content uniformity; liquid preparations showing presence of foreign matter or fungus and parenteral preparations failing in sterility or pyrogen test etc.). Category B defects are minor in nature (examples, broken or chipped tablets or presence of spots or discoloration; cracking of emulsion or liquid preparations showing sedimentation or change of colour and parenterals showing isolated cases of particulate matter or fungus growth etc.). The suggested action for category A defects is immediate recall of batch and stop further sale by the manufacturer. The regulatory authority is required to investigate the matter immediately and take appropriate action according to the results of the investigation.

The guidelines state that it should be left to the concerned state drug authorities to take action in their state or to refer the case to the drugs controller of the manufacturing state. Despite the guidelines issued, there is wide variation in the action taken by the state drugs authorities. In particular, cases where the sample is found sub-standard in one state and manufacturer is

located in another state, no uniform system is followed. The cases are referred to the concerned state drug controller but the response is usually delayed and complete details of every individual case is i.e. GMP status of concerned manufacturers, recall of products etc. is usually not available. In most cases, the test reports are received after six months or even a year and by that time the product is invariably consumed. Also, due to multi-layered distribution system, involving number of stockists, wholesalers, sub-wholesalers etc., the follow up on recall is difficult.

It has also been submitted to the Committee by stakeholders that efficiency and expertise of Government drug testing laboratories in the country needs to be ensured. A view has been expressed that it is likely that many sub-standard reports may in fact be a result of:

i. Improper methods of analysis;
ii. Use of improper chemicals/reagents;
iii. Incorrect interpretation of prescribed standards; and
iv. Improper storage conditions after a drug leaves the manufacturing premises.

The Committee feels that this is a complex issue and also another area of non-uniformity of action at the state level and suggests that adequate action should be taken against the manufactures of sub-standard drugs. If necessary, specific Rules should be framed for the purpose. The Committee is of the view that the Drugs Consultative Committee should extensively deliberate on this issue and review the existing guidelines, analyse the nature of sub-standard reports and status of concerned manufacturing firms as well as the distribution cycle etc.

Recommendations

11.7 The Committee noted that there is non-uniformity in the action taken on sub-standard drugs, especially when the manufacturer of sub-standard drugs is located in a different state. The Committee recommends that :

a) The DCC should deliberate on the issue of action to be taken on sub-standard drugs and review the existing guidelines. It should analyse the nature of sub-standard reports and status of concerned manufacturing units as well as the system of distribution; and
b) The existing classification by DCC of defects found in sub-standard drugs into category A and category B and the action to be taken on each category of defects needs to be reviewed and updated.

12.0 QUALITY ASSURANCE AND TESTING LABORATORIES

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

The primary responsibility of ensuring that quality drugs are manufactured and distributed is that of drug manufacturers. Under the Drugs and Cosmetics Rules every drug manufacturer must have his own in-house testing facilities for all drugs manufactured by him. He is required to test all the raw materials used in the manufacture and every batch of finished product. However, where testing requires sophisticated and expensive equipment, the rules provide for drug manufacturers to get their products tested in laboratories approved for the purpose by the state regulatory authorities. It is, however, the responsibility of the regulatory authority to randomly take samples and monitor the quality of drugs marketed in the country.

12.1 State drug Testing Laboratories

The major responsibility of administering and monitoring the manufacture, sale, distribution and storage of drugs is in the domain of States. Each State is required to provide arrangements to test the quality of drugs manufactured and sold in the State. Many State Governments have given less priority to this aspect and thus the Government's drugs quality control system has not kept pace with the progress made by the pharmaceutical industry. Only 17 States have drug testing and even among these laboratories, only about 7 have the capacity to test all classes of drugs. On an average, about 36,000 samples are tested annually, both in the Central and State drug testing laboratories. The number is, however, inadequate as compared to number of batches of thousands of formulations manufactured in the country. Because of less capacity to test, the time taken to complete the testing of drug samples is observed to be taking even a year. This does not serve any purpose. As a result, samples of less than 1 % of the batches of drugs manufactured in the country are exposed to scrutiny by the Government drug testing laboratories. The number of samples that are reported every year as not of standard quality by the Central and State Government laboratories are only indicative of lax quality assurance system in the manufacturer's quality control labs and are not representative of the actual situation in the country. The limitations in testing of drug samples in the government labs are related to the absence or lack of sophisticated instruments, lack of trained analysts, lack of commitment, lack of reagents, non-validated methods, shortage of funds, inadequate number of staff and in many cases a combination of more than one of these constraints.

12.2 Central Assistance to States

The Committee observed that the Central Government, in various five year plans and through WHO funds has provided assistance to States for setting up/upgrading their testing facilities but the progress has been far from satisfactory. For example, Bihar State had a building for its testing lab built about 20 years back but the funds provided by the State for its maintenance and upkeep have been woefully inadequate. There is no money even to buy glassware and reagents etc. Sophisticated equipment, like HPLC and Laminar Flow benches have been received through central assistance but the building does not have proper electricity load and suitable wiring for these instruments to be made functional. Likewise, many States with major consumer population have not been able to provide a full-fledged functional testing laboratory. These

States depend on the Central Laboratories to test their statutory samples.

12.3 Central Government Laboratories

The Central Government has 5 drug testing laboratories under its direct control. These are:

- Central Drugs Laboratory (CDL), Kolkata
- Central Indian Pharmacopoeia Laboratory (CIPL), Ghaziabad
- Central Drug Testing Laboratory (CDTL), Mumbai
- Central Drug Testing Laboratory (CDTL), Chennai
- Regional Drug Testing Laboratory (RDTL), Gauwhati

In addition, construction of a new RDTL building at Chandigarh is reported to be nearing completion.

CDL Kolkata is the oldest and the only statutory lab under the Act. It assists DCG(I) in testing of new drugs before these are approved for marketing in the country and maintains library of Reference Substances. The National Institute of Biological, Noida is being utilized for testing selected diagnostics and is expected to take over the testing of vaccines and blood products in due course. CDL Kolkata and CIPL, Ghaziabad tests statutory samples of drugs for many States which do not have their own facilities. CDL Kolkata also functions as an Appellate laboratory under the Drugs and Cosmetics Act in respect of all drugs with the exception of the following:

a. CRI, Kasauli exercises the power of CDL for sera and vaccines; CIPL, Ghaziabad, for condoms and CDTL, Mumbai for Copper-T and Tubal rings; and

b. Regional Drug Testing laboratory, Gauwhati was taken over recently from Government of Assam to cater to the requirements of North Eastern States. It has yet to start functioning and make its impact.

12.4 Capacity Building Project on Quality Control of Drugs through World Bank

The Committee noted with appreciation that the Government of India has taken a major initiative for comprehensive plan to provide new buildings and upgrade the existing testing facilities of Central and State testing laboratories under a capacity building project through World Bank assistance.

12.4.1 Assistance for Central Laboratories

It is proposed to construct a new building for central drug testing laboratory at Mumbai (building, equipment, lab supplies, furniture, manpower etc) and renovate/extend the existing building of CIPL at Ghaziabad. In addition, equipment, manpower, and lab supplies will be provided to other central drug testing laboratories.

12.4.2 Assistance for State Laboratories

The project would finance construction, renovation/extension of the building, equipment, supplies, furniture, operation and maintenance costs. Five new buildings will be built at Kolkata, Raipur, Ranchi, Rudrapur, and Panaji. Five existing laboratories at Baroda, Bhuvanehwar, Chennai, Agartala, and Lucknow will be renovated and 9 laboratories at Hyderabad, Vijaywada, Thiruvanthapuram, Bangalore, Bhopal, Baroda, Bhuvanashwar, Pondicherry and Khanda ghat will be further extended. It is hoped that the project when complete, will not only increase the capacity to test samples in Central and State laboratories but also reduce the testing and reporting time.

12.5 Private Testing Laboratories

The primary responsibility of quality assurance of drugs is of the drug manufacturer. The GMP norms prescribe adequate measures for quality assurance at every stage of manufacture. The Drugs and Cosmetic Rules, however, provide that the manufacturers can get their raw materials and finished products tested at the approved private testing laboratories where use of sophisticated instruments is involved. There are about 150 private testing labs approved by the State Drugs Control administrations in the country. Various institutes also use these laboratories to test drugs purchased by them. It is very important that these laboratories have adequate facilities and competent manpower of integrity to issue reports, which are authentic and correct. These labs are not inspected/audited regularly by the state authorities to verify and cross check whether the results of tests carried out by them are correct and reproducible.

12.6 Technical Audit of Testing Laboratories

The CDSCO had taken a laudable initiative to arrange technical audit programme to evaluate the performance of all Government and private testing laboratories during the year 2001. Expectedly, almost all the labs audited were found deficient in many respects. The major deficiencies observed related to infrastructure, absence of internal audit, training of chemists and non-existence of Standard Operating procedures (SOPs). The first round of technical audit has helped in creating an awareness of GLP norms in these laboratories.

The Committee noted that there is a strong need to have a system which makes the functioning of these labs totally quality oriented with no room for complacency and possible conflict of interest. The Committee felt that since the overall feedback on quality of drugs made available to the government and the consumer revolves around the performance and integrity of these labs, it is important that the labs should acquire efficiency, credibility and accreditation.

Since in India, State drug testing laboratories have varying degree of infrastructural support, training of technical staff, budget to procure consumables and maintenance of equipment, availability of reference standards and technical books / periodicals etc., there is a need to harmonize

the functions of State and Central laboratories. This would be ideally achieved by formation of a separate Division under the proposed CDA, which would oversee the activities of all drug-testing laboratories in the country.

Recommendations

12.7 The Committee recommends the following measures for this purpose:

a) Drugs and cosmetics Rules should be amended to include GLP norms as statutory requirement for approved testing labs and also the in house testing labs of manufacturers;

b) Accreditation with NABL should be made mandatory for all testing laboratories including the Government laboratories;

c) The Central Government should initiate a programme to have coded samples of the same product tested at different central and State labs from time to time and have the results assessed by experts for their proficiency testing;

d) The State testing labs should be frequently audited by a team of experts to ensure their proper functioning; and

e) A separate Division needs to be established under CDA to oversee the overall working of drug testing laboratories in the country.

13.0 FINAL RECOMMENDATIONS:

13.1 State Drug Control Organizations

The Committee noted that majority of the States are not either adequately staffed or technically equipped to monitor the quality of drugs manufactured and sold in their State. There is a strong need to strengthen the organizations with competent and trained manpower and with adequate budgets. This will enable them to detect, investigate and take quick action in spurious/counterfeit drug cases.

The officers needed to be specially trained for the purpose. The Committee recommends that:

a. The drug control organizations in States should be adequately strengthened. Additional manpower, infrastructure, technical capabilities and financial resources should be made available to the organization. They should have continuous vigilance facilities and strategies to implement an effective system to monitor and control the manufacture and distribution of spurious drugs;

b. States should set up Intelligence cum legal cells under the supervision of trained senior officer. State Governments should put in place efficient mechanism for timely police help to these officers;

c. States should establish a proper surveillance system for keeping a watch over suspected individuals. Watchers should be employed to purchase samples from suspected persons without disclosing their identity. Secret funds should be made available for intelligence activities;

d. States, which have a large number of drug distribution outlets should set-up a well-equipped testing laboratory to enable them to test all categories of drugs in shortest possible time. All States should plan to take more samples to check the quality of drugs manufactured and sold in the market. Those States, where it was not technically and economically viable to support their own drug testing facilities, needed to make use of facilities of other States and Central laboratories or even the private approved laboratories for testing of suspected samples;

e. States should set up an efficient communication network system between the Centre and other States in order to facilitate exchange of information and rapid investigation in cases involving inter-state movement; and

f. States should also monitor the source of purchase and quality of drugs stocked by dispensing registered medical practitioners through their drugs inspectors.

13.2 Central Drugs Control Organisation

13.2.1 The Committee noted that the Central Government has already initiated steps for upgrading of testing facilities and countrywide computer networking under a capacity building project through World Bank assistance. It is hoped that these projects, when completed, will be of great assistance to the States in arresting the menace of spurious drugs.

13.2.2 The Central Government should strengthen the infrastructure and provide world class Central Drug Administration as recommended earlier by the Pharma R & D Committee under the chairmanship of Dr. R.A. Mashelkar and as also announced in the Pharmaceutical Policy 2002. The Committee recommends that:

a. Central Government should initiate steps to strengthen the Central infrastructure in the light of these recommendations;
b. Central Government should continue to provide assistance to States for testing of drug samples specially the smaller states where it is technically and economically not viable to have a full fledged laboratory of their own;
c. Central Government should have a programme to train the intelligence cum legal officers identified by the States; and
d. Central Government should have a central nodal officer to coordinate with the intelligence cells set up by the State.

13.3 Extent of Spurious /Counterfeit Drugs in the Country

13.3.1 The Committee came to the conclusion after examining all the data and reports at hand. that there was an absence of a scientifically and statistically designed investigation, which could give a realistic estimate of the menace of spurious drugs. The model for such an evaluation presented by the Delhi Pharmaceutical Trust appears to be one, which had a rational approach to achieve this objective.

13.3.2 The Committee recommends that the Central Government should provide assistance to undertake such scientific and statistically significant study in order to have a clear picture about the exact extent of spurious drugs in the country.

13.4 Changes Required in the Act and Judicial Procedures

13.4.1 The Committee noted that the specific penalties in Drugs and Cosmetic Act were provided in 1982 for offences concerning manufacture and sale of spurious drugs. However, the penal provisions have not acted as adequate deterrents and have not instilled the desired extent of fear among the offenders. It was, therefore, felt that the penalties for all offences related to spurious/counterfeit drugs should be further enhanced.

13.4.2 The Committee, more specifically, recommends that:

a. The penalty for sale and manufacture of spurious drug that causes grievous hurt or death should be enhanced from life imprisonment to death. Even the penalty for manufacture and sales of spurious drugs that do not cause grievous hurt or death should also be made more severe (Annexure 13, 27a and 27aa);
b. The offences related to spurious drugs should be made cognisable and non-bailable. The bail, if considered by the court should be granted only after a period of three months (Annexure 13, 32b);
c. The penalty for not disclosing the source of purchase of drugs by a dealer should be made stringent (Annexure 13, 28a);
d. A provision should be included in the Drugs and Cosmetics Act to enable the Central and State Governments to designate special courts for speedy trial of spurious drugs cases [Annexure 13, 32(2)];
e. A provision for compounding of offences should be included in the Drugs and Cosmetics Act [(Annexure 13, 32(c)]; and
f. Under Drugs and Cosmetics Act, besides the Drug Inspectors, Police should also be authorized to file prosecution for offences related to spurious drugs [Annexure 13, 32(1(a)].

13.5 Action by the Pharmaceutical Industry

13.5.1 The Committee noted that industry has a well-developed marketing and distribution network. The industry can streamline their supply chain and make use of their manpower to detect the movement of spurious drugs.

13.5.2 The Committee recommends following actions for Pharma industry:

a. Use their well-developed marketing network to identify distribution channel and persons involved in spurious drug trade.

b. Assist, through its associations in detection and unearthing of spurious/counterfeit drugs by cooperating with the regulatory and/or police authorities.

c. Prepare, through its associations, a checklist for the guidance of manufacturers, wholesalers and retail sellers to identify and distinguish between the spurious and genuine products.

d. Formulate its own spurious/counterfeit drugs policy and a surveillance strategy to tackle the problem of spurious drugs.

e. Establish a close interaction with regulatory authorities and extend full cooperation to eliminate the menace of spurious drugs.

f. Streamline their supply chain and distribution network.

g. Ensure proper storage of products during transit as well as at places of distribution.

13.6 Action by the Pharma Trade

13.6.1 The Committee noted that the sale of spurious drugs invariably takes place through wholesalers and retailers and State Drugs Controllers should take a severe action against those, who are found indulging in this activity and are not able to produce valid purchase records.

13.6.2 The Committee recommends following actions for the Pharma Trade Association:

a. Play a proactive and visible role to contain the menace of spurious/counterfeit drugs;
b. Develop its mechanism in identifying the persons directly or indirectly involved in abetting the distribution of spurious, counterfeit or questionable quality drugs
c. Prepare a checklist for the guidance of members and widely publicize it for information of all members

d. Sub Rule 3 of Rule 65 (4) of Drugs & Cosmetics Rules requires that the supply by retail of any drug shall be made against a cash/credit memo. This condition of license should be strictly adhered to by all retail licensees.

e. Every chemist/pharmacist to act as a watchdog to prevent entry of any spurious/doubtful quality drugs or those purchased from unauthorized sources or without proper bills in the supply chain.

13.6.3 Action by the Consumer and other Professional Associations

There is an urgent need for an awareness campaign to educate the consumers and the medical and paramedical professionals. The Committee, in particular, recommends that the Consumers and health professional/associates should play an active and visible role to create awareness about the hazards of spurious drugs. They should undertake campaigns at the national level to educate the public on the ways and means of detecting spurious drugs and the advantages of purchasing from licensed sources with valid cash memos.

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Annexure - 1

No. Z.28015/112/2002-D/DMS&PFA
Government of India
Ministry of Health & Family Welfare
(Department of Health)

Nirman Bhavan, New Delhi
Dated : the 27th January, 2003

The Pharmaceutical industry represents one of the India's strength. It has been growing annually at the rate of over 10% for the last decade and currently occupies the fourth position in the world in terms of volume. The industry has moved from being an importer of every formulation in the fifties to one that has assumed prestige in terms of its exports today. As the number of drugs, as well as their volumes, keep increasing, the issue of quality will assume permanent importance. Across the globe, countries are adopting rigorous drugs quality control systems and enforcement mechanisms to avoid sub-standard/spurious drugs in their respective markets.

2. Supreme Court of India, the National Human Rights Commission and the Standing Committee of Parliament have time and again recommended improving the drug regulatory system. The new Pharmaceutical Policy approved by the Cabinet recently addresses these quality concerns. The Haathi Committee had earlier recommended the setting up of a National Drug Authority. The Mashelkar Committee on Pharmaceutical Research and Development had recommended the Establishment of a First Class Drug Regulatory infrastructure.

3. There has not been a comprehensive review of the Drugs & Cosmetics Act 1940 since its enactment, although Rules have been amended from time to time to keep them up to date. There is also a national concern regarding the problem of spurious drugs. It is important to see all the issues in an integrated manner.

4. The Government of India has, therefore, decided to set up an Expert Committee which will look into all these issues with the following Terms of Reference.

1. Recommend a new structure for the Drug Regulatory System in the country including the setting up of a National Drug Authority.

2. Recommend measures to strengthen the drug regulatory infrastructure in Centre and States.

3. Evaluate the extent of the problem of spurious and sub-standard drugs and recommend measures required to deal with this problem effectively.

4. Recommend changes required in the Drugs and Cosmetics Act, 1940 as well as in judicial procedure related to offences committed under this Act.

5. Recommend steps to be taken by the Pharmaceutical Industry and Pharmacy Association to tackle the problem of spurious drugs.
6. Consider and advise on any other issue incidental to the above.
7. Devise road maps for implementation of all recommended measures.

COMPOSITION OF EXPERT COMMITTEE

The composition of the Expert Committee will be as follows:

Chairman Dr. R. A. Mashelkar

Members

1. Dr. S.P. Agarwal, DGHS
2. *Representatives (JS Level officers) of Department of Chemicals & Petro Chemicals, Ministry of Home and Ministry of Law. Joint Secretary I/C drugs, Department of Health.*
3. *Health Secretaries / Drug controllers of the States of Karnataka, West Bengal, Maharashtra, Delhi, Bihar and Madhya Pradesh.*
4. *Presidents of the following Associations :*
   (i)Organisations of Pharmaceutical Producers of India (OPPI)
   (ii) Indian Drug Manufacturers Association (IDMA)
   (iii) India Pharmaceutical Alliance (IPA)
   (iv) All India Small Scale Drug Manufacturers Association(AISSDMA)
   (v) All India Organisation of Chemist & Druggist (AIOCD)
   (vi) Indian Pharmaceutical Association (IPA)

5.Eminent lawyer; Sri Amarendra Sharan, Sr. Adovcate, Supreme Court, 105 New Chamber Block, Supreme Court, Bhagwan Das Road, New Delhi

6. Shri Julius Rebeiro, Ex-Advisor to Governor.

7. Shri Vijay Karan, Ex Commissioner; Delhi Police

8. Representative of Consumers: Shri Bijon Mishra, Vice Chairman, Consumer Coordination Council.

9.Eminent Scientist – Dr. M.D. Nair

Member-Secretary Mr. Ashwini Kumar, DCG (I)

The Committee will have the freedom to co-opt 2-3 eminent scientist who can make contribution in this field. The committee may also invite anybody as a Special Invitee.

The Committee will also take into consideration reports of Committees set up earlier.

The Committee would also examine the best international practices which could be comparable to India.

The Committee should submit its report within six months.

TA/DA of official members will be borne by their respective offices. TA/DA to non-official members (S.No. 5 to 9 above), co-opted members and special invitees will be paid in accordance with SR 190 and further instructions as contained in Appendix – 2 to Part-II of FRSR.

The expenditure involved will be met out of the sanctioned budget under Demand No. 42, Major Head 2210, 08104-Drugs Control (Minor Head), 02 CDSCO (Plan) for the year 2002-03.

This issues with the concurrence of Finance Division vide Dy. No. C-721/IFD dated 27.1.2003

Sd/-

(NITA KEJREWAL)
UNDER SECRETARY TO THE GOVT. OF INDIA

Copy to :

1. Prime Minister's Office, New Delhi (Shri Jarnail Singh, JS).
2. Dr. R. A. Mashelkar, Director General, CSIR and Secretary to the Govt. of India, New Delhi.
3. Secretary, Department of Chemicals and Petro-Chemicals.
4. Secretary, Ministry of Home Affairs
5. Secretary, Ministry of Law
6. Chief Secretaries, Karnataka, West Bengal, Maharashtra, Delhi Bihar and Madhya Pradesh.
7. IFD, Ministry of Health and F.W.
8. All Members of the Committee

Copy also to :

1. PS to HFM/MOS (HFW)
2. PPS to Secretary (Health)/DGHS

Annexure-1A

ASHWINI KUMAR
DRUGS CONTROLLER GENERAL (INDIA)

DCGI/15-6/2003-D
Directorate General of Health Services,
Tele : 011-23018806
Fax : 011-23012648
Email :- dci@nb.nic.in
Web:-
www.cdsco.nic.in

Nirman Bhawan,New Delhi

Dated: 21st May 2003

Dear Dr. Gupta,

Govt. of India has constituted a Committee under the Chairmanship of Dr. R.A. Mashelkar, to examine the drug regulatory system in the country including the issue of spurious drugs.

In this connection, it has been decided with the approval of the Chairman of the Committee to co-opt you as a member of the Expect Committee.

You are requested to kindly make it convenient to attend to the meeting.

Kindly confirm your participation in advance.

Thanking you,

Yours faithfully,

(ASHWINI KUMAR)
Drugs Controller General (India)

To

Dr. Prem Kumar Gupta
Retired Drugs Controller (India)

Annexure - 2

Terms of Reference (T.O.R.) of Sub Committee (Group-I) and its Members

Terms of Reference

- To visit the recommendations and conclusions of earlier Committees on similar issues
- To study the specific progress, if any made and the bottlenecks experienced and conceptualize a relevant model so that the areas of national concerns can be converted to regulatory systems' sphere of influence
- Evaluate the extent of the problem of spurious medicines in the country
- Evaluate the problem of manufacture and sale of medicines without licenses, without invoices and people by who are not qualified
- To study the commercial, handling, storage, transportation practices and methodologies adopted by the commerce in distribution (including transit and transit storage) of medicines, besides business modalities adopted at major transit points
- Recommend measures and practices to be followed to ensure better distribution of medicines
- Recommend training context and outlines for regulatory officials
- Recommend changes required in existing legal provisions
- To recommend measures to ensure speedy trails in courts
- To review the role played by the industry and professional & trade associations in the gamut of drug manufacture & distribution
- To examine export related issues in the contest of substandard and counterfeit drugs
- Recommend surveillance mechanism to control and check and menace substandard and spurious medicines in the country.

Members

1. Sh. Vijay Karan, Ex. Commissioner, Delhi Police
2. Joint Secretary (Health) Ministry of Health & FW
3. Joint Secretary, Law
4. Commissioner, FDA, Maharashtra

5. Drugs Controller, Bihar
6. Drugs Controller, MP
7. Drugs Controller, NCT Delhi
8. Indian Drugs Manufacture Association (IDMA)
9. Indian Pharmaceutical Alliance (IPA)
10. Indian Pharmaceutical Association (IPA)
11. Organization of Pharmaceutical Producer of India (OPPI)
12. Consumer Organization (VOICE)
13. All India Organization of Chemists & Druggist
14. All India Small Scale Pharma Manufacturing Association
15. Drugs Controller General (India)

Terms of Reference (T.O.R.) of Sub Committee (Group-II) and its members

Terms of Reference

- To visit the recommendations and conclusions of earlier Committees on similar issues
- To study the specific progress, if any made and the bottlenecks experienced and conceptualize a relevant model so that the areas of national concerns can be converted to regulatory systems' sphere of influence
- To study the contemporary regulatory setups in other (developed as well as developing countries) e.g. China, Malaysia, Thailand, Indonesia, South Korea. Australia, UK, USA, Brazil, Mexico and South Africa.
- To define the scope, role and responsibilities of the proposed NDA
- Measures to strengthen regulatory infrastructure in the country to a truly world class set-up
- To study the working of some of the states in the country (e.g. UP, Bihar, Haryana, Gujarat, Tamil Nadu, Maharastra etc.) and objectively analyze the problem faced by them in implementing the drug regulations.
- Identify various functions requiring regulatory responsibilities and professional interface with industry, State Govt. and other national & International agencies and the corresponding capabilities which need to be available with national level drug regulatory office. Such functional areas other than medicines could be medical devices, diagnostics, promotional literatures, clinical research, pharmacovigilance, newer therapeutics, neutraceuticals etc. Record the systems that need to be established in the contemporary global context.
- Define possible structure and identify major processes of NDA and the changes which would be required in the existing legal dispensation.

Members

1. Director General of Health Services, Ministry of Health & FW
2. Dr. M.D. Nair
3. Joint Secretary (Health), Ministry of Health & FW
4. Joint Secretary (C&PC), D/o Chemicals & Petrochemicals
5. Indian Pharmaceutical Association
6. Indian Pharmaceutical Alliance
7. Joint Secretary (Law)
8. Sr. Amarendra Sharan, Sr. Advocate, Supreme Court

9. Drugs Controller, Karnataka
10. Drugs Controller, West Bengal/Health Secretary, West Bengal
11. Drugs Controller, NCT, Delhi
12. Commissioner, FDA Maharashtra
13. Drugs Controller General (India)

ANNEXURE – 2A

Directorate General of Health Services
Office of DCG(I)

In the context of the terms of reference of the Expert Committee constituted by the Ministry of Health and F.W. under the Chairmanship of Dr. R.A. Mashelkar, D.G., CSIR to examine supplemented to it, it has been decided to constitute following sub group to deliberate on specific issues and to recommend appropriate course of action etc.

I. Sub-group I

Restructuring of central and state regulatory system.

Members:

1. Dr. M.D. Nair
2. Representative of Indian Pharmaceutical Alliance
3. IPA – Mr. Praful Sheth
4. Dr. Prem Gupta
5. Representative of Delhi Drug Control
6. DCG(I); and
7. Dr. S.D> Seth, Chair in Clinical Pharmacology, ICMR – Co-opted.

Terms of Reference:

a) To recommend the design and structure of Central Drug Administration, its size and functions to enable speedy and effective performance of its enhanced role and responsibilities.

b) To examine logistic of licensing of drug manufacturing within the country by a central agency to ensure uniform standards of enforcement and quality of drugs manufactured and sold in the interstate commerce.
c) To suggest models for strengthening of state drug regulatory system in order to ensure uniformity of standards.
d) To suggest indicators for uniformity effective performance of drug regulatory agencies in states and their accountability.

Sub-group II

Regulatory system for Food/Nutritional supplements, ISM drugs, herbal products, OTC, medical devices etc.

Members:

1. Dr. M.D. Nair
2. Dr. D.B. Ananthnarayana
3. IDMA
4. DCG(I)
5. Dr. A.B. Vaidya
6. Director, CDRI
7. Representative from ICMR

Terms of Reference:

a) To recommend legislative measures to regulate products labeled as food/nutritional supplements and those derived from plant resources.

b) To recommend measures to regulate the performance of medical devices, diagnostics, prosthetics etc.

Sub-group III

Survey to undertake study on the extent of spurious/counterfeit drugs in the market.

Members:

1. Representative of OPPI
2. Shri D.G. Shah (IP Alliance)
3. Shri Brijesh Regal
4. Dr. Prem Gupta
5. DCG(I)
6. Stastistics expert from ICMR

Terms of Reference:

a) To examine and approve the protocol of study.

Annexure-3

II. Written comments/presentations made to the committee

NAME	DESIGNATION	ORGANISATION
Mr. S.S. Ahluwalia	Member Parliament	Rajya Sabha
Dr. Satya Agarwala		IDMA
Dr. Nityanand	Eminent Scientist	Former Director CDRI, Chairman I.P. Committee
Dr. Ranjit Roy Chowdhary	Eminent Scientist	Delhi Medical Council
Dr. Ashish Sabhrawal	Hon. Secretary	Indian Medical Association
Prof. Manubhai Shah	Chairman	Consumer Education & Research Society, Ahemdabad
Dr. D.B.A. Narayana	Eminent Scientist	Hindustan Lever Research Centre, Mumbai
Mr. Brijesh Regal	Consultant	Delhi Pharmaceutical Trust
Mr. Harinder S. Sikka	Sr. President	CII & Nicholas Piramal Private Ltd.
Mr. Ajit Singh	Chairman & M.D.	Associated Capsules Group
Mr. Ashok Chabra	Executive Director	Proctor & Gamble Hygiene & Health Care Ltd.
Mr. V.C. Sane	Ex- Commissioner	FDA, Maharashtra
Mr. D.B. Mody	Director	J.B. Chemicals & Pharmaceutical Ltd.
Dr. U.Y. Rege	Eminent Scientist	Mukta Technical Consultancy Services
Mr. S.S. Venkatakrishnan	Ex-Drugs Controller,	Kerala
Mr. Jagmohan Rai Agarwal	Chairman	M.P. Small Scale Drug Manufacturers' Association
Dr. Anil Bansal	President	Delhi Medical Association
Mrs. Sandhya Tiwari	Director	CII
Dr. Manjusha Rajarshi	Regulatory Affairs, Manager	Serdia Phama Ltd.
S. W. Deshpande	Secretary General	AIDCOC
M.R. Shastri	Director (Retd.)	DC Administartion, Gujarat
Arvind Kumar	Representing	Prahari, New Delhi
J.R. Agarwal	Chairman	M.P. Small Scale Drug Manufacturers Association
Harish Marwaha	C & MD	Marico Industries limited
Dr. Sudhir Krishna	Surgeon	Mool Chand hospita, New Delhi
Dr. Mira Shiva	Director WHD &RPD	VHAI
Dr. Subbi Reddy	Assistant Director	Drug Control Deptt., A.P.
Raj Vaidya	Chief Pharmacist	Hindu Pharmacy, Panaji, Goa

III. Annexure – 4

No. Z-28015/112-D/DMS&PFA
Government of India
Ministry of Health and Family Welfare

Nirman Bhavan, New Delhi
Dated the 1st August, 2003

OFFICE MEMORANDUM

Subject : Constitution of the Expert Committee under Dr. R. A. Mashelkar, DG, CSIR to review the drug regulatory system in the country and the problem of spurious drugs etc.

In continuation of this Department's O.M. of even no. dated 27.01.2003 on the above Mentioned subject, the undersigned is directed to say that the Government has decided to extend the term of the Expert Committee set up under Dr. R. A. Mashelkar, DG, CSIR to review the drug regulatory system in the country and the problem of spurious drugs etc by a further period of three months. The terms and conditions of the Committee remain the same as indicated in the O.M. dated 27.01.2003.

Sd/-
(NITA KEJREWAL)
Under Secretary to the Govt. of India

Copy to :

9. Prime Minister's Office, New Delhi (Shri Jarnail Singh, JS).
10. Dr. R. A. Mashelkar, Director General, CSIR and Secretary to the Govt. of India, New Delhi.
11. Secretary, Department of Chemicals and Petro-Chemicals.
12. Secretary, Ministry of Home Affairs
13. Secretary, Ministry of Law
14. Chief Secretaries, Karnataka, West Bengal, Maharashtra, Delhi Bihar and Madhya Pradesh.
15. IFD, Ministry of Health and F.W.
16. All Members of the Committee

Copy also to :

3. PS to HFM/MOS (HFW)
4. PPS to Secretary (Health)/DGHS

Annexure – 5

Strengthening Central Drug Regulatory Agency

1.0 Need for Strengthening of Central Drug Regulatory Agency

1.1 It is the basic responsibility of the Government to ensure that drugs to be used by the public meet the established standards of quality, safety, biodiversity and efficacy.

1.2 In India, the import, manufacture, sale and distribution of drugs and cosmetics in India is regulated under the Drugs and Cosmetics Act 1940, and Rules 1945 made thereunder, (hereinafter referred to as the Act and the Rules) respectively. Standards of identity, purity, freedom from toxicity and strength in respect of every medicine and related products used for diagnosis, prophylaxis and treatment of diseases in human beings or animals have to be specified. Under the Act, distinct statutory functions and responsibilities have been assigned to Central and State Governments. The Central Drug Standards Control Organisation (CADCO), Dte. General of Health Services, Ministry of Health &FW is entrusted with the enforcement of regulatory responsibility at the Government of India level. Some of the important activities of the CDSCO includes direct interface with R&D activities in pharmasector at National and International level and are discussed below from the point of view of providing an efficient regulatory framework. The fast-changing scenario in drug-related fields requires the CDSCO to become a vibrant and dynamic organisation.

2.0 Quality Control and Good Manufacture Practices (GMPs)

2.1 The pharmaceutical industry in India has made remarkable progress over the years. India is manufacturing most of its requirements of drugs and is also in a position to export a significant quantity of medicines of internationally acceptable quality to many countries including those of the developed world. The quality of drugs has to be closely monitored so that drugs of doubtful quality are not manufactured.

2.2 The Rules provide in Schedule ‘M’ the Good Manufacturing Practices (GMPs) which a manufacturer is obliged to follow. A drug is of acceptable quality under the Act not only if it meets the finished product specifications but also more importantly if it is manufactured in a plant complying with GMPs. The responsibility for enforcement of GMPs in respect of most drugs rests with the state drug control authorities but the level of enforcement and competence of auditing personnel does not appear to be uniform among states. In view of the serious problems encountered with certain categories of drugs like blood and blood products, large volume parenterals (LVPs), vaccines, etc, joint inspections are required to be carried out under Rule 68A of the Rules

by inspectors of the CDSCO and the concerned State Government before a licence for a manufacture of the notified drugs can be granted or renewed by the Central Licence Approving Authority (CLAA) appointed by the Central Government under the Act. This list is expected to be enlarged as other specialized items like medical devices including transfusion sets, sterile syringes, etc. are notified in this category. Even for this remedy, the infrastructural support has to keep pace with the work demand.

2.3 Though the Drugs Controllers of the states are empowered to licence the manufacture and sale of drugs in their respective states under the Act, the DCG(I) in order to ensure uniform implementation of Rules, is enjoined with the responsibility of coordinating their activities and decisions under the Drugs and Cosmetics through the Drugs Consultative Committee (DCC). In addition, the Drugs Technical Advisory Board (DTAB), a statutory body under the Act, is required to advise the Central Government and State Government on technical matter arising out of the administration of the Act.

2.4 For a manufacturer intending to export drugs, a GMP certificate under the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce is the generally accepted. The WHO Certification Scheme is a mechanism by which the importing country is in a position to ascertain whether it has been manufactured in accordance with internationally accepted GMPs. These certificates are issued after joint inspections by teams from the Central and State Governments. Many importing countries, however, lay down their own stringent procedures of inspection and approval of the plant, facilities, manpower, procedures, etc. before a drug manufactured by the applicant is allowed to be imported. We may consider to introduce similar procedures in respect of import drugs into India to safeguard the health of the citizens and to have level playing.

2.5 With the growth of the pharmaceutical industry, there has been considerable impetus to research and development activity on drugs. A number of medicines are now exported. This requires proper regulation so that safety, efficacy and quality issues are attended to in a globally accepted manner. This has become all the more important with the coming into existence of the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Health Use, commonly known as the International Conference on Harmonization (ICH), which promotes scientific and technical aspects of registration of pharmaceutical products.

3.0 Registration of drugs

3.1 Most countries of the world, including developing ones, have a well-organised system of registration of drugs permitted to be imported or manufactured. Thus, master files of products are submitted for evaluation by the regulatory agencies. It is only after the furnished data has been found adequate that the product

is registered in the country. No such certalised system exists in India. There is need for checking this deficiency by introduction of the registration procedures which will also help in elimination of irrational/sub-therapeutic products. Adequate machinery has to be created in the CDSCO for the purpose.

4.0 Quality control and registration of herbal drugs

A number of countries including Germany, France, Canada, USA, China, etc. are registering standardized plant extracts of proven clinical efficacy and safety obtained from natural sources as herbal drugs or dietary supplements. Inspite of the fact that India has a vast resource of drugs of natural origin, we are unable to exploit the vast world market because we have an unsatisfactory system of their quality control and registration. On account of the importance of herbal drugs and TSMs in India, it may be necessary to create a separate division in CDSCO to regulate the quality of such drugs, and to provide proper focus on all related aspects. A system of registration of TSMs with acceptable standards of quality control and GMP's need to be put in position.

5.0 Approval for new drugs

5.1 A new drug is defined in Rule 122 of the Rules as :

(a) a new substance of chemical, biological or biotechnological origin in bulk or as a prepared dosage form,
(b) a drug already approved by the licensing authority which is now proposed to be marketed with modified or new claims,
(c) a fixed-dose combination (FDC) of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined in a fixed ratio,
(d) all vaccines.

As the range of products which are classified as new drugs is wide and practically all pervading, we need expertise in specific areas of specialization to evaluate the proposals is necessary.

Schedule 'Y' to the Rules specifies the requirements and guidelines on clinical trials for import and manufacture of new drugs, It is a set of comprehensive procedures the primary objective of which is to safeguard the well-being of patients. Thus, there is need for a proper regulatory and marketing environment which encourages investment on research and development towards discovery of innovative medicines and promotes their expeditious introduction. The present set up of CDSCO has not kept pace with the increasing demands of multi-disciplinary drug evaluation needs. Applications submitted to the DCG(I) for permission for clinical trials in respect of new drug applications (NDA) and abbreviated new drug applications (ANDA) are

often referred to outside agencies like the Indian Council of Medical Research (ICMR) and the Department of Biotechnology, Government of India (DBT) for review. This arrangement often leaves very little control with regard to the time runs. In order that the applicant is enabled to complete the investigations in the shortest possible time, it is imperative that adequate infrastructure for fast track clearances is created in the CDSCO. The DCG(I) should have under his direct supervision a number of divisions/departments with officers and support staff adequate and competent for the job. Each division/department may avail of the expertise drawn from various organiations but the responsibility and accountability for the decisions and their timeliness must rest on the shoulders of the DCG(I) and/or the divisional or departmental heads. It has to be clearly understood that authority and responsibility must go hand in hand. This will be possible only if the right systems, expertise and infrastructure are created.

5.3 The process of evaluation and review of applications of new drugs needs close collaboration which may include the following :

- **Universities, hospitals and health care experts** : For evaluating clinical trial data and other relevant information.
- **Industry and industrial associations** : For assistance in evaluation of data of new drugs.
- **Professional bodies** : For clarifications on relevant professional issues affecting the quality of drugs.
- **Central and State Governments agencies** : For obtaining views of these agencies on matters relating to introduction of a new drug.
- **Consumers and consumer organisations** : For inputs from the consumer angle.
- **Foreign governments and international organisations** : This may include the US FDA, WHO, etc. with a view to harmonizing the requirements with the international standards of quality of drugs.

5.4 Thus, there should be chemists/pharmaceutical technologists/chemical engineers to review areas connected with manufacture, in-process control, packaging, stability, purity and similar parameters of the product. Biotechnology-based and genetically-engineered drugs are getting introduced with greater frequency. Many of these are proteinous molecules and need to be delivered by invasive/non-invasive routes requiring non-conventional delivery systems. We, therefore, need to associate experts in these areas in the evaluation process. Pharmacologists/toxicologists should be there to evaluate the short term and long terms effects, including teratogenic and carcinogenic effects, in laboratory animals. To evaluate the therapeutic effects the adverse drug reactions of a new drug, physicians must be associated in the review process. There should also be adequate number of competent regulatory experts to ensure that not only the requirements of the Act are taken care of effectively but also to guard against the possibility of an over-zealous approach and overshooting the mark. Many drugs have serious

bioavailability problems. Thus there should be bio-pharmaceutical scientists available to evaluate data on the rate and extent to which the active medicament in the preparation of actually available to the body as well as on the distribution, metabolism and excretion of the drug molecule. As the applications submitted are expected to contain considerable data statistically analysed by the applicants, statisticians capable of evaluating the design of statistical tests performed and the validity of statistical analyses would also be necessary. Associations of microbiologists will also be necessary for evaluation of information in case of applications for anti-microbial drugs. Similarly, persons with specalised knowledge in specific areas may have to be brought in for evaluation of the data presented by the applicant. For instance, veterinary vaccines and other veterinary products may have to be evaluated by veterinarians; blood and blood products would need help from blood transfusion experts and haematologists; radiopharmaceuticals will need expert evaluation by nuclear scientists. In this age of specializations and super-specialisations, there will always be need for taking help from experts in a particular field if we wish to achieve excellence.

The clinical trial centre and Bioequivalence laboratories also need to be audited from time to time.

5.5 India has accepted the responsibilities under the TWO regime. With the Government of India approving the EMR route for implementing provisions of the new patent regime, applications for marketing approval will start being received. CDSCO must get ready to meet the situation well in time by creating adequate infrastructure for the critical role it will have to play as a regulatory authority for development of the pharmaceutical sector.

5.6 Pharmacovigilence activities which includes Post marketing suveillence, Adverse Drug Reaction Monitoring etc. is also a critical functioning of Drug Regulatory Agency. For this, a participative system involving Medical Community, Pharmacists and the Industry needs to be developed. This area appear to have remain neglected.

5.7 Provision of charging fees from applicants for drug evaluation activities also needs to be introduced. This amount can be utilized to meet the expenses incurred in utilizing the services of external experts.

6.0 Continuing education and training

6.1 We need to review the continuing education programmes so that all categories of staff from the Grade A officers down to the technical assistants get opportunities to upgrade their knowledge by suitable in-service training courses. This is particularly important because pharmaceutical sciences and technology are amongst the areas of fastest growth and development. Benefits from investment in this activity will be intangible in the initial stages but the improvement in the quality of work will ultimately give a sense of satisfaction. It is common

practice in regulatory agencies abroad and by pharmaceutical manufacturers of good standing to organize regular training and continuing education programmes for their staff.

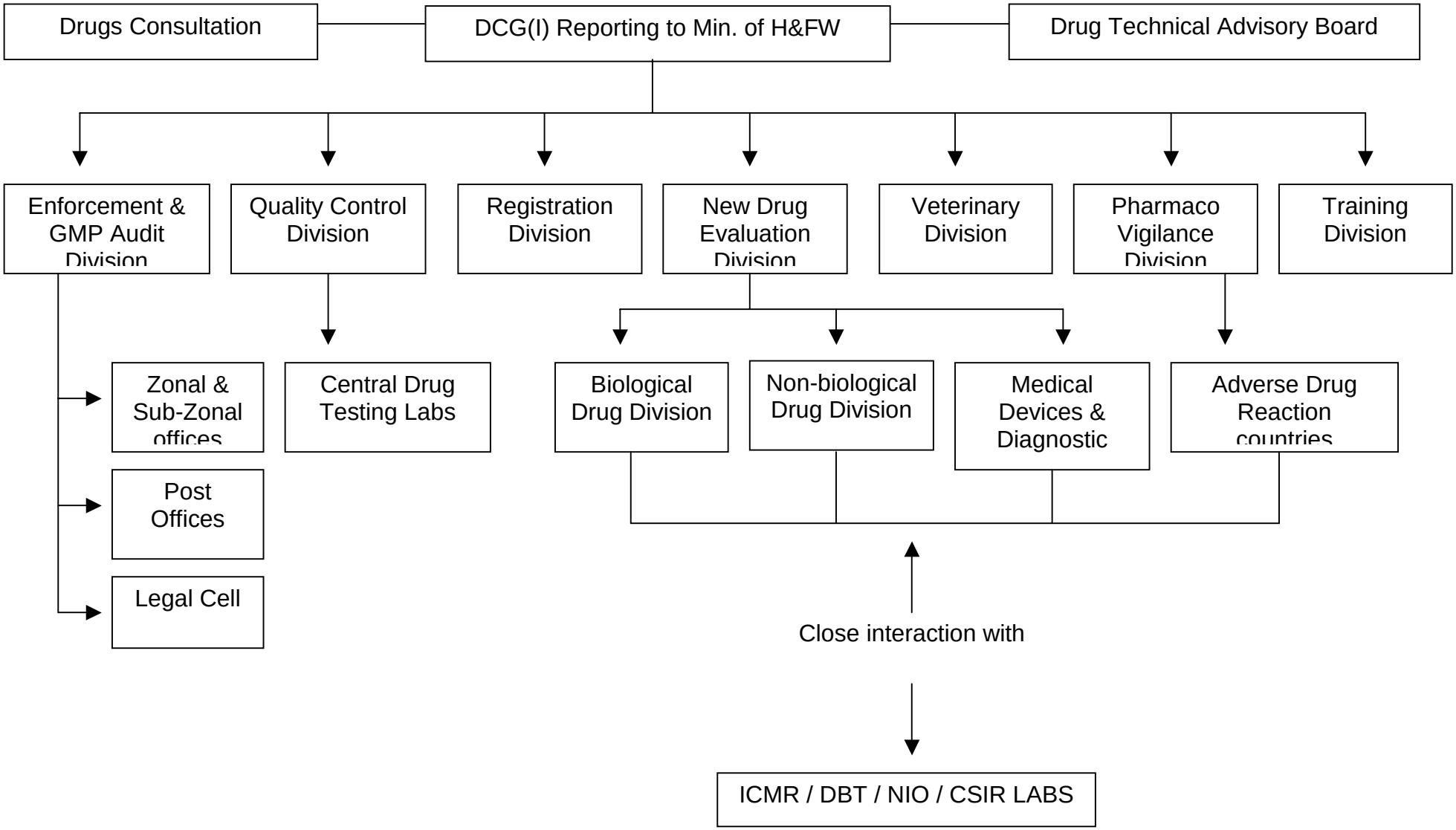
7.0 Infrastructure creation

7.1 It would thus be seen that CDSCO, needs to be given an independent status as available to National Drug Regulatory agencies in most countries. This agency is required to carry out multifarious functions but expertise in technical, administrative and vigilance functions is not sufficient. Full-time experts must be there with CDSCO for timely evaluation of the papers submitted by the parties.

7.2 The Committee, therefore, recommends : -

I. To create adequate infrastructure for efficient management of various activities listed above
II. To reorganize the CDSCO in such a manner that it is in a position to provide effective regulatory safeguards to ensure that the patient is protected from the hazards to health by poor quality and counterfeit medicines by comprehensive regulatory procedures and effective inspection and enforcement arrangements..
III. To ensure uniform standards of drug productions as well as the regulatory systems throughout the country.
IV. To provide adequate autonomy to manage the various activities in accordance with the requirements of the Act and the mandates of the Ministry.

ORGANISATIONAL CHART OF CDSC0



Annexure - 6

SURVEY OF SELECTED DRUG REGULATORY AUTHORITIES

	USA	CANADA	BRAZIL	AUSTRALIA	THAILAND	MALAYSIA	CHINA	SOUTH KOREA	SOUTH AFRICA	INDIA
1. Title of the country's drug regulatory authority	FDA Commissioner	Director General	President Director	Therapeutic Good Administration TGA - Director	Director-Thai Food & Drugs Administration	Director, Drug Control Authority	Director-SDA	Director – Korea Food & Drugs Administration	Registrar – Medicines Control Council which is an independent body appointed by the Minister for Health.	DCG(I) at Center and State Drugs Controllers at States
2. To whom does the head of regulatory authority report ?	Secretary of Health	Deputy Minister	Ministry/Dept. of Health	Secretary of Health	Ministry/Dept. of Health	Director General of Health Services	Vice-Premier who is responsible for Health, Food and Drugs	Ministry/Dept. of Health (President National Assembly)	Director General of Health Services	Director General of Health Services
3. Is Drug Regulatory Authority centralized for the whole country ?	Central	Central	Central/State	Central	Central	Central	Central	Central/State	Central	Central/State
4. Licensing of Drug manufacturers	Central	-	Central	Central	Central	Central	Central	Central	-	State

Annexure – 7

SURVEY ON
STATE DRUG REGULATORY AUTHORITIES IN INDIA

YOUR PARTICULARS

Name : _____

Title/Position : _____

State : _____

Postal Address : _____

_____

Telephone (with codes): _____ **Fax:** _____

E-mail : _____

SECTION A:
STATE DEMOGRAPHICS

1. Population _____

2. Annual budget of Drug control Department during the last three years

   a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

3. Is the budget adequate for efficient functioning of your department?

   YES ☐ NO ☐

4. Number of districts _____

SECTION B:
DRUG CONTROL INFRASTRUCTURE

I. ENFORCEMENT

5. Number of Drug inspectors _____

6. Number of supervisory officers

   a. Assistant drugs controllers / assistant commissioners _____

   b. Deputy drugs controllers/deputy commissioners _____

   c. Joint drugs controllers/joint commissioners _____

d. Number of non-technical staff _____

7. Trend of total manpower increase during last three years

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

II. TESTING

8. Do you have a separate full-fledged testing laboratory?

YES ☐ NO ☐

9. Has additional space been added during last five years?

YES ☐ NO ☐

10. Annual budget during last three years

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

11. Number of technical staff _____

12. Number of non-technical staff _____

13. Trend in manpower increase during last three years

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

14. Number of drug samples tested during last three years

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

15. Number of samples found not of standard quality

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

16. Action taken on not of standard quality drugs

a) Licenses suspended _____ b) licenses cancelled _____

c) Prosecutions launched _____ d) Convictions, if any _____

17. Number of private testing laboratories _____

SECTION C:
STATUS ON DRUG PRODUCTION

18. Local production in value _____

19. Total number of drug manufacture licenses _____

a) Bulk drugs_____

b) Drug formulations _____

i) Large volume parenterals _____

ii) Vaccines _____

iii) Surgical dressings _____

c) Cosmetics _____

d) Loan licenses _____

e) Miscellaneous _____

SECTION D:
Status on Drug Distribution

20. Number of retail licenses _____

21. Number of wholesale licenses _____

22. Number of registered pharmacists _____

SECTION E:
POLICY ON SPURIOUS DRUGS

I. EXTENT OF SPURIOUS DRUGS

23. Number of cases of spurious drugs detected during last three years:

a. 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

24. Give breakup of where they were detected:

i) Retail outlets _____

ii) Wholesale outlets _____

iii) Manufacturing units _____

iv) Hospitals/practitioners _____ v) Unlicensed premises _____

25. Was the detection of spurious cases based on information through:

i) Your own intelligence or surveillance YES ☐ NO ☐

ii) Trade YES ☐ NO ☐

iii) Drug manufacturer YES ☐ NO ☐

iv) Public YES ☐ NO ☐

v) Any other source _____

26. Do you think the definition of 'spurious drug' given in Drugs and Cosmetics Act is adequate?

YES ☐ NO ☐

27. If no, any suggestions for modifications _____

_____

II. RESULTS OF TESTING

28. Whether active ingredient was:

a) Present _____ b) Absent _____ c) Deficient _____

29. Whether the sample was a copy of:

a) A known brand with active ingredient _____ or without active ingredient _____

III. ACTION TAKEN AND RESULTS THERE OF

30. Number of cases prosecuted _____

31. Number of cases convicted _____

32. Give details of conviction

a) Simple imprisonment _____ b) Imprisonment with fine _____ **or** without fine _____

33. Under trial _____

Cases pending for more than: Three years ☐ Five years ☐ Ten years ☐

34. Average time taken to complete the trial _____

35. For elimination/reduction of the menace of spurious/counterfeit drugs, please give your suggestions/recommendations in respect of:

i) Improving the system of distribution:

ii) Speedy trials in courts _____

iii) Role played by industry _____

iv) Role played by trade _____

v) Role played by the professional associations _____

vi) Changes required in existing legal provisions _____

vii) Training of regulatory officials _____

viii) Seeking cooperation of police _____

ix) Surveillance mechanism _____

IV. SETTING UP OF INTELLIGENCE-CUM-LEGAL CELL

36. Have you setup intelligence-cum-legal cell and anti spurious squad?

YES ☐ NO ☐

37. If yes, give composition of the cell and name of the officer in-charge _____

38. Whether the police officials are attached exclusively to the cell?

YES ☐ NO ☐

39. Whether experienced law officer attached to the cell?

YES ☐ NO ☐

V. WATCHERS ACTIVITY

40. Have you employed watchers for test purchase of drug samples?

YES ☐ NO ☐

41. Whether there is availability of secret funds? YES ☐ NO ☐

VI. TRAINING OF PERSONNEL

42. Whether officers have undergone any special training for detection and investigation of spurious drugs?

YES ☐ NO ☐

43. If yes, please state where the training was taken?

In-house ☐ Elsewhere ☐

44. Do you think there is a need for a specialized training programme by central government?

YES ☐ NO ☐

SECTION F:
NETWORKING

45. Whether state drug control administration has efficient communication networking with -

a) Other state departments including police in your state?

YES ☐ NO ☐

b) With CDSCO?

YES ☐ NO ☐

c) With state drug control departments in other states?

YES ☐ NO ☐

d) If no, what action is being taken? _____

SECTION G:
SURVEY ON QUALITY OF DRUGS

46. Do you have any survey program? YES ☐ NO ☐

47. If yes, number of such surveys undertaken during last three years

a). 2000-2001 _____ b) 2001-2002 _____ c) 2002-2003 _____

48. Number of samples tested: a)_____b)_____c) _____

Tested at: a) Own facility _____ b) Elsewhere _____

49. Time taken to analyze survey samples

Two weeks ☐ Four weeks ☐ More than that ☐

50. Give summary of the results of such survey:_____

_____

_____

SECTION H:
SURVEILLANCE OVER DISTRIBUTION

51. Whether there is any mechanism to identify dealers/wholesalers suspected to be indulging in sale of spurious drugs? YES ☐ NO ☐

52. If yes, the number of such dealers identified _____

SECTION I:
SETTING UP OF DESIGNATED COURTS FOR SPURIOUS DRUGS

53. Whether special courts have been designated for summary trials?
YES ☐ NO ☐

54. If no, has the process been initiated with the state government?
YES ☐ NO ☐

SECTION J:
REACTIVATION OF STATE DRUG ADVISORY COMMITTEE

55. Have you setup or reactivated state drug advisory committee?
YES ☐ NO ☐

56. If yes, do they meet regularly? YES ☐ NO ☐

SECTION K:
Strengthening of regulatory infrastructure

57. Please list the problems faced by you for effective enforcement

i) _____

ii) _____

iii) _____

iv) _____

58. In your perception, is the enforcement of Drugs and Cosmetics Act and Rules uniform throughout the country?
YES ☐ NO ☐

59. Do you support licensing of drug manufacturing units in the country by a Central Authority?
YES ☐ NO ☐

60. If no, give reasons

i) _____

ii) _____

iii) _____

iv) _____

SECTION L:
DRUG POLICY AND CREATION OF NATIONAL DRUG AUTHORITY (NDA)

61. Are you aware of the recommendation in Drug Policy in 1994 for creation of NDA?

YES ☐ NO ☐

62. If yes, in your view which of the following functions should NDA perform?

a) Licensing of Manufacturing units YES ☐ NO ☐

b) Registration/approval of new drugs

i) Modern drugs YES ☐ NO ☐

ii) Traditional drugs YES ☐ NO ☐

iii) r-DNA based drugs YES ☐ NO ☐

iv) Neutraceuticals YES ☐ NO ☐

c) Monitoring of Clinical trials YES ☐ NO ☐

d) Monitoring of Bioequivalence studies YES ☐ NO ☐

e) Monitoring of Adverse Drug Reactions YES ☐ NO ☐

f) Post marketing surveillance YES ☐ NO ☐

g) Product recalls YES ☐ NO ☐

h) Market complaint handling YES ☐ NO ☐

i) Managing training centers for:

i) Drugs inspectors YES ☐ NO ☐

ii) Quality control analysts YES ☐ NO ☐

iii) Other regulatory staff YES ☐ NO ☐

j) Animal toxicity studies of new drugs YES ☐ NO ☐

k) Regulation of diagnostic aids YES ☐ NO ☐

l) Regulation of medical devices YES ☐ NO ☐

m) Regulation of medial equipment YES ☐ NO ☐

n) Control on the manufacture and sale of Neutraceuticals

YES ☐ NO ☐

o) Guidelines for promotional literature for consumers

YES ☐ NO ☐

p) Guidelines for self-medication YES ☐ NO ☐

q) National antibiotic policy YES ☐ NO ☐

r) Internal audit / validation of country's regulatory operations / systems

YES ☐ NO ☐

s) Banning of drugs YES ☐ NO ☐

t) Promotion of rational use of drugs YES ☐ NO ☐

u) Compilation of Essential Drugs List YES ☐ NO ☐

v) Controlling the prices of drugs YES ☐ NO ☐

63. Are you aware of Drug Policy 2002 regarding setting up of world class CDSCO?

YES ☐ NO ☐

64. Do you think there is no need to have NDA, if Central Drug Administration (CDA) is strengthened to a world class level,

YES ☐ NO ☐

65. If yes, do you think the Central Drug Administration should perform the above activities given in **SECTION L**?

YES ☐ NO ☐

Please provide any **additional comments** that you have: _____

_____

_____

_____

THANK YOU VERY MUCH
FOR TAKING THE TIME TO COMPLETE THIS SURVEY.

Annexure-B

INFORMATION FROM STATE DRUG REGULATORY AUTHORITIES IN INDIA

Name of State	No. of District	No. of tech. Staff		Testing Labs	Tech. Staff in the Lab.	No. Samples tested	Found not of Std. Qty.	No. of Spurious Drugs	prose-cutions Launched	Drug Prod. (Rs. Cr.)	No. of Mfg. Lics.	No. of Retail Lics.	Whol-esales Lics.	Intel. cum - legal cell	Net-working	Whether mfg. Lic. by Center	Whether CDA	Whether NDA
		Dis	Other															
ANDHRA PRADESH	23	55	11	Yes	28	3976	149	8	22	5000	1509	22600	8515	No	Yes	No	Yes	No
ARUNACHAL PRADESH	15	6	1	No	Nil	7	Nil	Nil	3	0.25	2	500	141	No	No	Yes	No comments	
ASSAM	23	23	3	Yes	Nil	437	55	Nil	107	170	70	12696	4082	No.	Yes	No	No	Yes
BIHAR	37	41	2	Yes	3	630	20	3	3	15	250	16370	6659	No	No	No	Yes	No
CHANDIGRAH #																		
CHATTISHGARH	16	5	2	No	Nil	923	43	Nil	3	4,68,13235	45	2635	1213	No	Yes	No	No comments	
DADER & NAGAR HAVELI #																		
DAMAN & DUE	2	1	0	No	Nil	43	Nil	Nil	Nil	Nil	140	21	55	No	No	No	Yes	No
DELHI	9	29	8	Yes	14	1977	105	10	17	600	131	3678	4224	Yes	No	No	Yes	No
GOA	2	5	4	Yes	3	172	Nil	Nil	Nil	2000	301	444	260	No	No	No	Yes	No
GUJRAT	25	29	28	Yes	155	3342	495	5	4	10495	3251	11358	9054	Yes	Yes	No	Yes	No
HARYANA	19	30	4	Yes	10	769	311	13	173	575	362	5132	2813	Yes	No	No	No	Yes
HIMACHAL PRADESH	12	12	1	No	7	508	19	1	Nil	1045	98	1944	1655	No	No	No	Yes	No
JAMMU & KASHMIR #	14	23	6	Yes	24	1232	86	1	YES	NA	32	2028	2396	No	No	No	Yes	No
KARANATAKA	27	46	38	Yes	55	3648	285	1	4	2000	667	19298*		Yes	Yes	No	No	Yes
KERALA	14	60	10	Yes	58	3359	124	Nil	NA	200	103	8605	2710	Yes	Yes	No	No	Yes
MADHYA PRADESH	45	54	2	Yes	22	1936	90	Nil	10	Nil	904	8406	5990	No	No	No	Yes	No
MAHARASTRA	35	159	65	Yes	91	5860	690	21	205	NA	6001	36236	16322	Yes	Yes	No	Yes	No
MANIPUR #	9	10	0	No	NA	NA	NA	NA	NA	NA	Nil	2419	367	No	No	Yes	Yes	No
MEGHALYA	7	9	1	No	NA	NA	NA	Nil	NA	Nil	6	902	138	No	Yes	No	Yes	No
NAGALAND	8	8	2	No	NA	NA	NA	1	Nil	NA	1	1124	74	No	Yes	No Comments		
ORISA	30	24	8	Yes	41	1509	69	1	1	10 Cr.	235	10413	5306	No	Yes	No	Yes	No
PANDICHERRY	1	4	1	No	Nil	Nil	Nil	Nil	Nil	NA	106	331	152	No	No	No	Yes	No
PANJAB	17	9	2	No	3	1768	242	16	NA	Nil	310	13615	6341	No	No	Yes	No	Yes
RAJASTHAN	32	42	11	No	13	1067	184	7	34	200 Cr	366	14155	7694	Yes	Yes	No	No	Yes
SIKKIM	4	1	1	No	Nil	Nil	Nil	Nil	Nil	NA	4	117	17	No	Yes	No	No	Yes
TAMIL NADU	29	84	18	Yes	66	3806	338	8	20	1700	1687	24419	8985	Yes	Yes	No	Yes	No
TRIPURA	4	10	1	Yes	3	481	9	Nil	Nil	6.2	5	1011	309	Yes	No	Yes	No	Yes
UTTER PRADESH	71	49	8	Yes	7	1073	210	30	3	NA	585	25678	28587	Yes	No	No	Yes	No
WEST BENGAL	18	99	44	No**	Nil	Nil	NA	Nil	9	NA	1998	23197	19141	No	No	No	No	Yes

* No. of retail & wholesales outlets

** Testing labortory not under DC deptt.

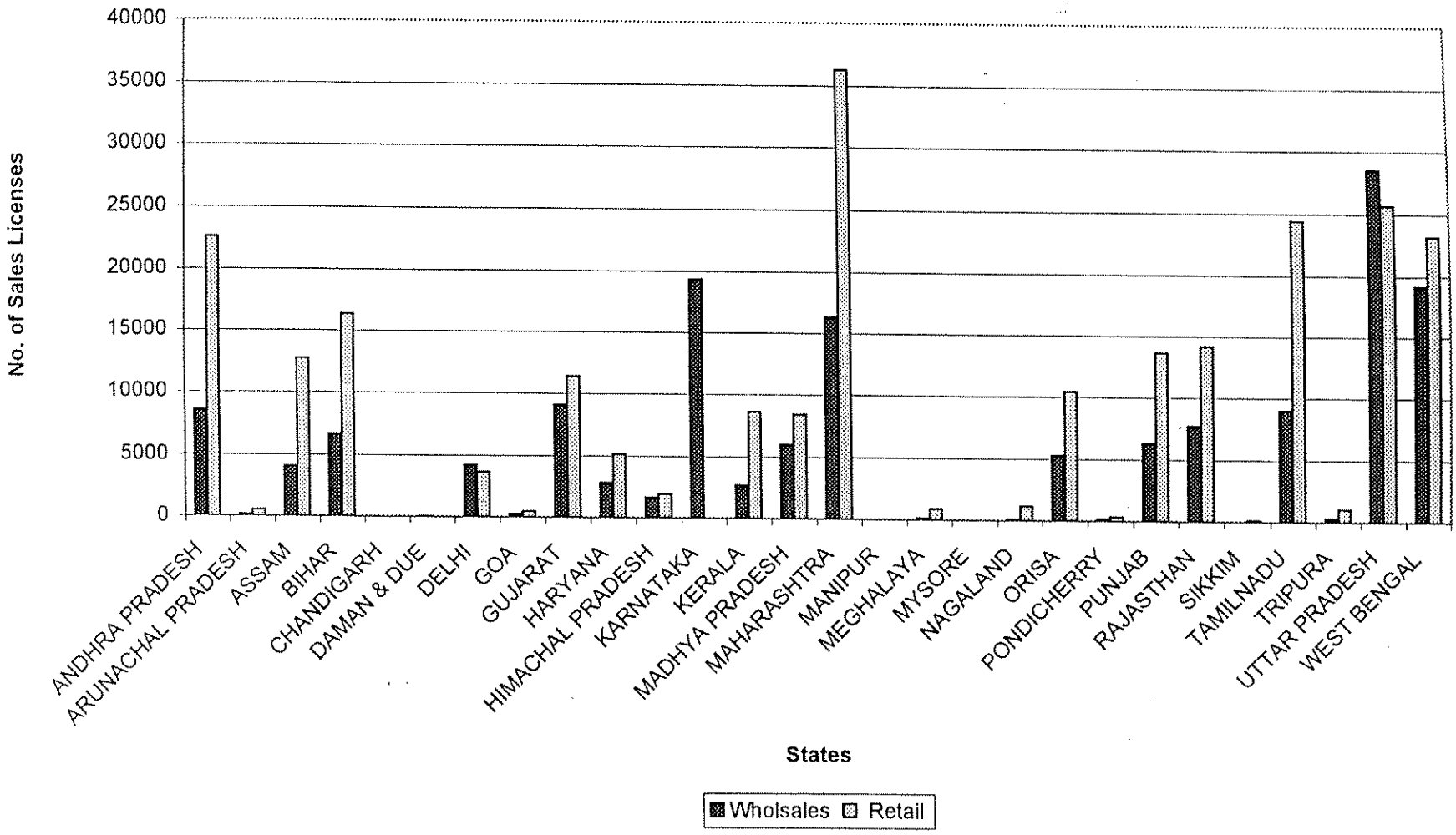
Information not yet received.

CATEGORIES WISE NO. OF MANUFACTURING LICENSES IN STATES

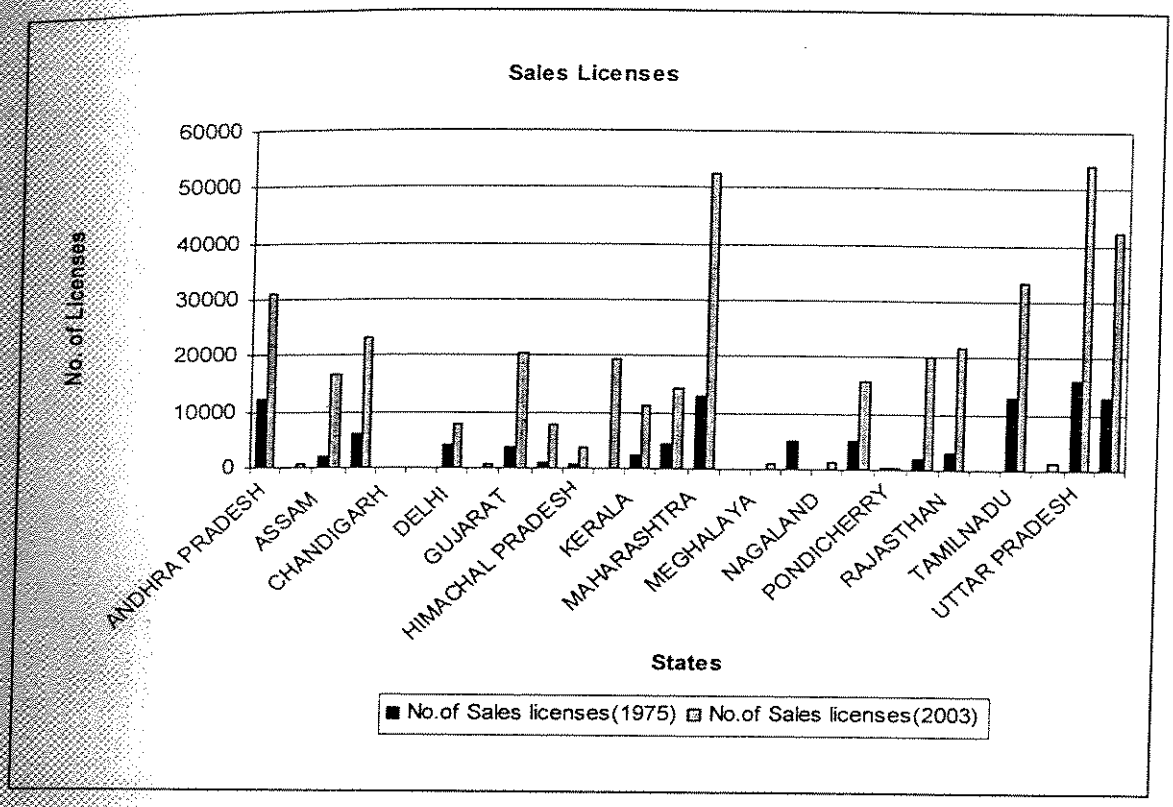
SL	States	Bulk Drugs	Formulation	Large Volume Parenter	Vaccines	Blood Banks	Surgical Dressings	Disinfectants	Repacking	Loan License	Medical Devices	Cosmetics	Ayurvedic, Unani Siddha	Homeopathic	Miscellaneous not covered
1	ANDHRA PRADESH	200	416	5	14	179	21		27	620		59			31
2	ASSAM	2	19	2		51	15	12	3		1	10	38	1	6
3	ARUNACHAL PRADESH		2			3									
4	BIHAR		236	3	1	38	included in 236			7		7	240	26	2
5	CHANDIGRAGH	1	13			3		4				2	3		
	CHATTISGARH	2	37			1	7	7		2	4	5	44	2	
	DADRA NAGAR HAVELI	5	56					1	2	47		54	15		
6	DELHI	4	90		1	42	28	4	1	89	1	499		69	
7	GOA	5	88	2		7	1	1	2	186	1	16	6		
8	GUJRAT	430	526	18	6	159	52	19	15	644	117	324	930	11	
9	HARYANA	23	230	6	2	42	65	8	6	13	4	39		10	
10	JAMMU & KASHMIR	3	15		1	14	5	2			1	1	10		
11	KARNATAKA	57	84	2	2	135	21	32	9	291	3	74			33
12	KERALA	4	60	10	1	125	2	2	6	15	4	11	800	17	
13	MAHARASTRA	347	693	17	9	245	38	29	49	1931	19	513	655	25	68
14	M. PRADESH	54	435	12	1	101	44	20	43	263	4	56	539	17	15
15	MEGHALAYA		2		1	4						3			
16	MIZORAM		1			5	1								
17	ORISSA	4	43		2	63	19	30	31	14		39		25	6
18	PONDICHERY	7	34			8		3	3	12	3	52	51	7	2
19	PUNJAB	9	187	3	2	72	13			12		71		3	13
20	RAJASTHAN	19	85	2	1	60	48	10	9	68	5	24		4	31
21	SIKKIM		1			3						3	1	1	
22	T. NADU	62	436	15	5	192	103	21	20	325	12	175	531	7	58
23	TRIPURA		4			6	1						1		
24	UTTARANCHAL	10	8	1	1	18	7	1	1	6	1	3		1	
25	U. PRADESH	44	329	9	3	126	115	30	53	16	12	51		40	12
26	W. BENGAL	46	280	27	3	104	32	30	40	131	7	191	850	700	10
	TOTAL	1338	4410	134	56	1806	638	273	320	4692	199	2282	4714	966	287

Annexure-8(8B)

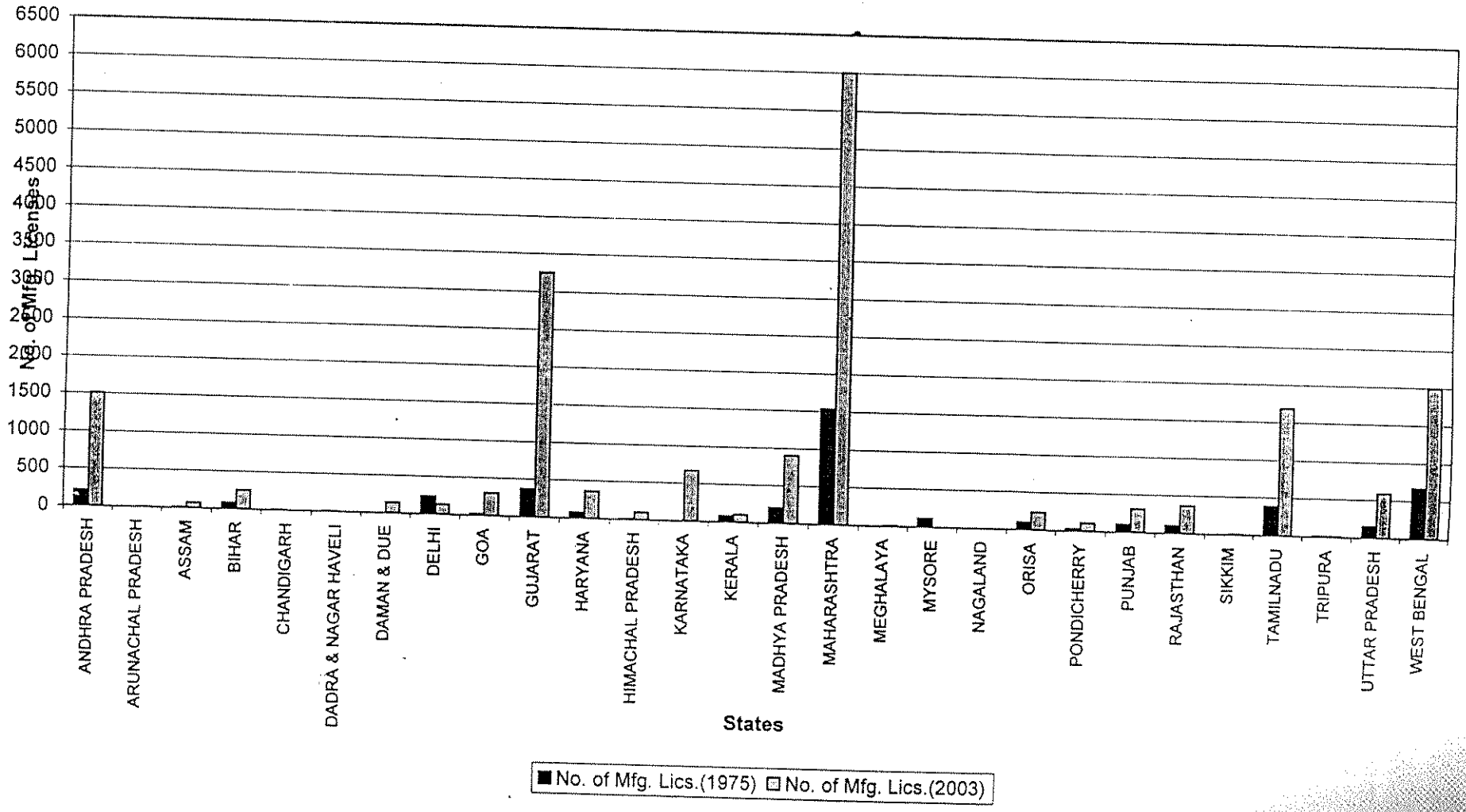
Comparison of Wholsale & Retail Sales Licenses (2003)



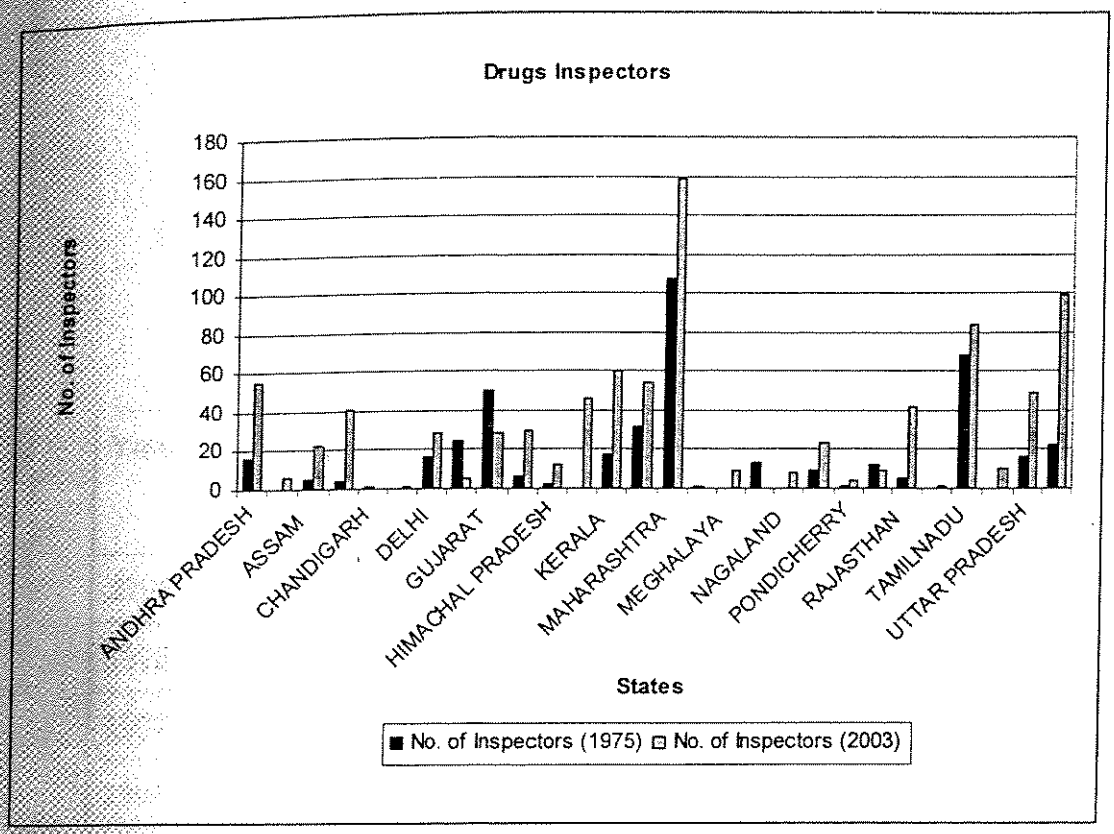
Annexure-8(8C)



Manufacturing Licenses



Annexure-8(8E)



Annexure - 9

A STATEMENT INDICATING NUMBERS OF SAMPLES TESTED, FOUND SUB-STANDARD/ SPURIOUS DURING THE PERIOD OF 1995-2003

Year	Tested	Not of Sub-Standard Quality	Spurious	Not of Sub-Standard Quality %	Spurious %
1995-1996	32770	3490	100	10.64	0.30
1996-1997	38936	3189	94	8.19	0.24
1997-1998	32936	2979	157	9.04	0.47
1998-1999	38936	3189	94	8.19	0.24
1999-2000	35570	3666	115	10.31	0.32
2000-2001	36947	3088	112	8.36	0.30
2001-2002	38824	3458	96	8.96	0.25
2002-2003	36314	3395	125	9.34	0.34

Annexure-11

Proposal for Scientific study of the extent of the spurious drugs moving in the market – Delhi Pharmaceutical Trust, New Delhi

The issue of spurious drugs keeps getting debated with a lot more emotive content than factual understanding of the situation. The very fact that it is a matter of serious concern – particularly since it relates to ailing section of the society – it calls for a scientific evaluation of the extent (in terms of number of units/brands/amount) and nature (content lower than claimed or missing or content okay but misusing some other fast selling brand) of counterfeiting.

Any scientific exploration to comprehend and subsequently deal with the situation will call for a scientific collation of situational information, a logical model to analyze the collated data and then to extrapolate the conclusion to get a clearer understanding of the extent of the problem across the country.

1) A preview of the study process

   Prepare a list of companies:
   a) Known to have faced counterfeiting problems
   b) Selling fast moving products which are prone to counterfeiting
   c) Selling high value products which are prone to counterfeiting

2) Identify products to be studied
   a) Fast moving products of not a very high value
   b) Slow moving products of high value

3) Sub-classify products with
   a) secure (for eg. with holograms seals) packs or
   b) standard packs

4) Determine approximate percentage of sales of each of those products in the following four sections
   a) Through retail pharmacies (promoted by retailers)
   b) Through retail pharmacies (on prescription)
   c) Government purchase system (supplied through distributors)
   d) Through dispensing medical practitioners

5) Determine the sample quantity for each drug based on the total number of units sold through each of the above four channels – spreading the figures across various major territories (spurious drug operators may not be active in all the territories)

6) Classify territories
   a) A Territories (strong enforcement)
   b) B Territories (average enforcement – prone to spurious drug manufacturing OR trade)

c) C Territories (below average enforcement - highly prone to trade AND manufacture of spurious drugs)

Distribution table may be made covering

A – Metros
B – Suburbs
C – Rural Areas
D – Micro Interior Areas.

Trained designated buyers have to purchase two units of each of the identified drugs from each of the identified territory (and sub territory). They will ask for the bill but not insist on it. Similarly, procurement will be made from dispensing doctors, by volunteers posing as patients or pre-identified patients and specimens will also be obtained from various dispensaries/government institutions which are known to procure medicines through distributors rather than directly from manufacturers.

The buyers will subsequently fill a simple report form for each drug procured and forward both the samples to a coordinator in their territory. The two units will be segregated and one set forwarded to a designated lab.

At the first instance the designated lab will look for physical signs of counterfeiting. The lab will analyze 100% of suspected samples, 50% of probable suspects and 25% of not suspected specimens. The samples will be analyzed for:

a) Identification of active ingredients
b) Content of active ingredients
c) Sterility (if applicable)

The samples will be double blinded through a coding system before they are sent for analysis.

Data obtained will be collated and extrapolated over each particular product's total sale across respective territory as well as across the entire country. For obtaining a larger picture the data will be pooled and extrapolated over country's over all volume of pharmaceutical products. Data may be stratified to obtain desirable information perspective.

It is estimated that an expenditure of about Rs. 15 Lakhs will have to be incurred on this project.

Annexure –12

Penalties for spurious drug offences provided in different countries

Country	Penalty Recommended in the different countries for the offence of counterfeit / spurious drugs
IV. Austria	Fine of max. 7260 Euro, Max fine of 14,530 in case of recurrence
V. Czech R	Imprisonment for the distributor ranging from 3-10 years
VI. Estonia	Imprisonment for the distributor ranging from 3-10 years
VII. Ireland	1) A fine not exceeding 127,000 Euro (or to imprisonment for a term not exceeding 10 years or to both 2) In case of a second or subsequent offence to a fine not exceeding 300,000 Euro or to imprisonment for a term not exceeding 10 years or to both
VIII. Latvia	Imprisonment for the distributor ranging from 3-10 years
IX. Lithuania	Imprisonment for the distributor ranging from 3-10 years
X. Slovak R	Imprisonment for the distributor ranging from 3-10 years
XI. Spain (Joan Escofet)	Minimum 5-10 years imprisonment
XII. Brazil	Jail term, compensation for the families of the dead people is expected to be paid
XIII. France	Subject to imprisonment
XIV. Vietnam	"Execution: i.e. death penalty
XV. Myanmar	Imprisonment
XVI. Peru	Jail for about 4 years or more
XVII. Mexico	Punishment could be from 3-7 years in jail
XVIII. UAE, Oman, Bahrain, Kuwait and Qatar	The legal punishment is mostly Death or Life term
XIX. China	For a counterfeit drug, illegal income from its manufacture or sale shall be confiscated, a fine imposed between 2-5 times the value of the illegally manufactured or sold drugs. Violations of criminal law shall be prosecuted.
XX. Egypt	Financial penalty around EGP 50000. Sentenced to be jailed for maximum 3 years
XXI. USA	Maximum criminal penalty of 3 years, depending upon the seriousness of the case, this could be up to 10 years.

XXII. Annexure -13

Proposed Amendments to Drugs & Cosmetics Act, 1940

Existing	Proposed
"**27. Penalty for manufacturer, sale, etc., of drugs in contravention of this Chapter.—** Whoever ,himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,-	[**27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.—** Whoever ,himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,-
(a) any drug deemed to be adulterated under Section 17A or spurious under Section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code (45 of 1860), solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less then five years but which may extend to a term of life and with fine which shall not be less then ten thousand rupees;	(a) any drug deemed to be adulterated under Section 17-A or spurious under Section 17-B **and** which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code (45 of 1860), solely on account of such drug being adulterated or spurious, as the case may be, **shall be punishable with death penalty or imprisonment for a term of life or imprisonment for a term which shall not be less than ten years and with fine of rupees one lakh or up to three times the value of the goods seized, whichever is higher.**
(b) any drug-	**aa**) **Where fine is realized, it shall be paid to the victim or next of his kin**.
(i) deemed to be adulterated under Section 17-A, but not being a drug referred to in clause (a), or (ii) without a valid licence as required under cause (c) of	(b) any drug-

Section 18, shall be punishable with imprisonment for a term which shall not be less then one year but which may extend to three years and with fine which shall not be less then five thousand rupees; Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less then one year and of fine of less then five thousand rupees; (c) any drug deemed to be spurious under Section 17-B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for term which shall not be less then three years but which may extend to five years and with fine which shall not be less then five thousand rupees: Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less then three years but not less then one year; (d) any drug, other then a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made there under, shall be punishable with imprisonment for a term which shall not be less then one year but which may extend to two ears	(i) deemed to be adulterated under Section 17-A, but not being a drug referred to in clause (a), or (ii) without a valid licence as required under cause (c) of Section 18,shall be punishable with imprisonment for a term which shall not be less then **three years** but which may **extend to five years and with fine which shall not be less then fifty thousand rupees;** Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, **impose a sentence of imprisonment for a term of less then three years and with fine which shall not be less than fifty thousand rupees;** (c) **Any drug deemed to be spurious under Section 17-B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less then seven years but which may extend to term of life and with fine of fifty thousand rupees or upto three times the value of the goods seized, whichever is higher.** Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, **impose a sentence of imprisonment for a term of less then seven years but not less than three years; and with a fine which shall not be less than fifty thousand rupees.**

and with fine ; Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less then one year". **Sec [28 . Penalty for non-disclosure of the name of the manufacturer, etc.-** Whoever contravenes the provisions of Section 18-A or Section 24 shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to One Thousand rupees, or with both. **Sec [28-A. Penalty for not keeping documents , etc., and for non-disclosure of information-** Whoever with out reasonable cause or excuse, contravenes the provisions of Section 18-B shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to One Thousand Rupees or with both. **Sec [30. Penalty for subsequent offences –** (1) Whoever having been convicted of an offence – a. under clause (b) of Section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees: Provided that the Court may, for any adequate and special	(d) any drug, other then a drug referred to in clause (a) or clause (b) or clause (c) in contravention of any other provision of this Chapter or any rule made there under, shall be punishable with imprisonment for term which shall not be less then One year but which may extend to Two years and with fine of **ten thousand rupees**. Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less then One year. **Sec. 28 . Penalty for non-disclosure of the name of the manufacturer, etc.-** Whoever contravenes the provisions of Section 18-A or Section 24 shall be punishable with imprisonment for a term which may extend to one year or with fine which is not less than **ten thousand rupees or with both.** **Sec. 28-A. Penalty for not keeping documents , etc., and for non-disclosure of information-** Whoever with out reasonable cause or excuse, contravenes the provisions of Section 18-B shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to **ten thousand rupees** or with both. **Sec [30. Penalty for subsequent offences –** (1) Whoever having been convicted of an offence – (a) under clause (b) of Section 27 is again convicted of an

reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than ten thousand rupees; b. under clause (c) of Section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees; c. under clause (d) of Section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than five thousand rupees, or with both]	offence under that clause, shall be punishable with imprisonment for a term which shall not be less than **seven years** but which may extend to **ten years** and with a fine which shall not be less than **one lakh** rupees: Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of **not** less than **five years** and of fine of not less than **one lakh** rupees; (b) under clause (c) of Section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than **ten years** but which may extend to life term and with fine which shall not be less than **one lakh** rupees;
[(1-A) Whoever, having been convicted of an offence under Section 27-A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years or with fine which may extend to two thousand rupees or with both]	**(c) Deleted**
(2) Whoever, having been convicted of an offence under Section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to ten years or with fine or with both.]	[(1-A) Whoever, having been convicted of an offence under Section 27-A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years or with fine which may extend to two thousand rupees or with both] (2) **Deleted**
Sec [32 Cognizance of offences.- (1) No prosecution under this chapter	

shall be instituted except by an Inspector or by the person aggrieved or by a recognized consumer association whether such person is a member of the association or not.	**Section 32 Cognizance of offences** (1) (a) No prosecution under this chapter shall be instituted except by an Inspector or by the person aggrieved or by a recognized consumer association whether such person is a member of that association or not.
(2) No Court inferior to that of [Metropolitan Magistrate or of a Judicial Magistrate of the first class] shall try an offence punishable under this Chapter.	**Provided that prosecution in respect of offences committed under Section 17-B, which are cognizable and non-bailable, may also be instituted by any police officer not below the rank of sub inspector or a CBI officer not below the rank of sub inspector.** 2) **No Court inferior to that of a Court of Session Judge shall try an offence punishable under Section 17-B of this Chapter. Special Court shall be constituted by the Central Government or State Government for trial of other offences under this act.** 3) Nothing contained in this chapter shall be deemed to prevent any person from being prosecuted under any law for any act or omission which constitutes an offence against this chapter. ***32-B Special provisions :-*** **No bail will be granted to an accused charged with an offence punishable under section 27 (a) or charged under section 17-B within the first three months of his detention unless the court is of the opinion that prima facie offence has not been made out.**

	32-C Power to compound offences :- **2) The Central Government or the State Government or any person authorised on this behalf by general or special order of the Central Government or the State Govt., may either before or after the institution of any proceeding under this Act, compound any offence punishable under this section where punishment is 2 years or less under this Act by payment of an amount not less than Ten thousand rupees.** 3) **Where an offence has been compounded, the offender whether in custody or not shall be discharged and no further proceeding shall be taken against him in respect of the offence so compounded.** 39. Amendment of Act 45 of 1860 – The Indian Penal Code shall be amended in the manner specified in the third Schedule to this Act. **THE THIRD SCHEDULE** **(See Section 91)** **AMENDMENT TO THE INDIAN PENAL CODE** **(45 OF 1860)** 1) The provision of Section 274, 275 and 276 of Indian Penal Code are hereby deleted.

DCC GUIDELINES ON NOT OF STANDARD QUALITY (NSQ) DRUGS

XXIV. CATEGORY B DEFECTS

TABLET

i) Presence of spot/discoloration
ii) Lump formations in few containers due to moisture
iii) Failing in uniformity of weight
iv) Picking
v) Chipping
vi) Capping
vii) Rough surface
viii) Brittle tablets
ix) Non uniformity in diameter
x) Uneven coating
xi) Non declaration of colour used on the label
xii) Failing in limit test (e.g. free salicylic acid)
xiii) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
xiv) Failing in particle size (Griseofulvin tablets)
xv) Net content

CAPSULES

i) Presence of spots / discoloration
ii) Lump formation in container due to moisture
iii) Failing in uniformity of weight
iv) Cake / lump formation of content of capsule
v) Failing in limit tests (e.g. Analgin and Nifedin capsules)
vi) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
vii) Net content

LIQUID ORALS (Syrups/elixirs/solutions/suspensions/emulsions/mixtures etc.)

i) Presence of foreign matter
ii) Change of colour
iii) Presence of suspended matter
iv) Cracking of emulsion
v) Sedimentation
vi) Dispersible cake / lump formation

vii) Net content
viii) Non declaration of colour on label
ix) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products
x) Minor variation in pH

EXTERNAL PREPARATIONS (ointment / solutions / cream / liniment / lotions / emulsions / like preparations)

i) Separation of phases
ii) Foreign matter
iii) Consistency / homogenecity
iv) Extrudation of content from tube (outside the nozzle/cap)
v) Limit test (e.g. Kinetic viscosity)
vi) Weight / ml.
vii) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.

OPHTHALMIC PREPARATIONS (Eye-ointment/drops/solutions etc.)

i) Presence of particulate matter
ii) Odour
iii) Clarity
iv) Extrudation of content from tube container
v) Consistency
vi) Particle size
vii) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
viii) Minor variation in pH

POWDERS (oral use)

i) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
ii) Formation of mass/lump/cake) due to moisture.

INJECTABLES, INCLUDING TRANSFUSION FLUIDS

i) Presence of particulate matter/glass pieces/precipitation
ii) Change of colour/description
iii) Extractable volume
iv) Uniformity of weight (for dry powders)
v) Particle size
vi) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
vii) Isolated case of fungus growth

COSMETICS

i) Net content
ii) Not conforming to any other standard as mentioned in IS except for heavy metal test.

BULK DRUGS

i) Description
ii) Solubility
iii) Any other test specified in monograph not mentioned in Category A.

AEROSOLS/INHALATIONS

i) Assay – 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products.
ii) Number of deliveries per container / water content, deposition of omitted dose (limit)
iii) Particulate matter
iv) Pressure testing
v) Delivery rate
vi) Tests such as total acids

MECHANICAL CONTRACEPTIVES (Condoms)

i) Description
ii) Air inflation test
iii) Dimensions
iv) Colour fastness

INTRAUTERIAL CONTRACEPTIVE DEVICES

i) Description
ii) Full test
iii) Flexibility

XXV. CATEGORY A DEFECTS

TABLETS

i) **Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.**
ii) Disintegration (except for marginal variation to be viewed on case to case basis)
iii) Dissolution (--- do ---)
iv) Contamination with foreign matters
v) Most of the tablets observed in powder form inside the strip pouches
vi) Content uniformity
vii) Addition of permitted colour when not recommended in Pharmacopoeia

CAPSULES

i) **Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.**
ii) Disintegration (except for marginal variation to be viewed on case to case basis)
iii) Dissolution (--- do ---)
iv) Content uniformity

LIQUID ORALS

i) **Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.**
ii) Presence of foreign matter such as fly/insect
iii) Fungus growth
iv) Non dispersible cake/lump formation.
v) Addition of non-permissible colours.

EXTERNAL PREPARATIONS

i) **Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products**
ii) Phenol coefficient (RWC) less than label claim

Grade I	: less tan 16
Grade II	: less than 8
Grade III	: less than 4

For other soluble disinfectants : below 80% of the required limit

iii) Fungal growth

OPHTHALMIC PREPARATIONS

i) Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.
ii) Foreign matter
iii) Metal particles
iv) Fungal growth
v) Fails in sterility

POWDERS (oral use)

i) Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
ii) Fungal growth

POWDERS (external use)

i) Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.
ii) Fungal growth

INJECTIONS INCLUDING TRANSFUSION FLUIDS

i) Sterility
ii) Pyrogen test
iii) Toxicity
iv) Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
v) Fails in any other biological test
vi) Fungal growth in different samples from different sources of same batches.

STERILE DISPOSABLE PERFUSION SETS

i) Sterility
ii) Pyrogen test
iii) Toxicity

STERILE DISPOSABLE HYPODERMIC SYRINGES

i) Sterility
ii) Pyrogen test
iii) Toxicity

STERILE DISPOSABLE HYPODERMIC NEEDLES

i) Sterility
ii) Pyrogen test
iii) Toxicity

BULK DRUGS

i) Assay – less than permitted limits
ii) Heavy metal test/arsenic test
iii) Sterility
iv) Toxicity
v) Microbial limit test

AEROSOLS / INHALATIONS

i) Assay – below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.
ii) Leak test

SERA / VACCINE

i) Toxicity
ii) Sterility
iii) Potency

SUTURES / CATGUTS

i) Sterility
ii) Tensile strength

MECHANICAL CONTRACEPTIVES

i) Water leakage test
ii) Tensile properties

INTRAUTERINE CONTRACEPTIVE DEVICES

i) Memory test
ii) Ash content
iii) Sterility
iv) Implantation test

COSMETICS

i) Use of non permitted colours/dyes
ii) Presence of heavy metal

ACTION TO BE TAKEN ON CATEGORY B DEFECTS

1. **Stoppage of further sale and recall of batch of the drugs from the market.**
2. Manufacturer to be asked to intimate stock and distribution details etc. of the particular batch.
3. Calling of explanation from the manufacturer.
4. After receipt of explanation or investigation report, if any carried out, further appropriate action may be taken by issuing show cause notice etc. if so required.

ACTION TO BE TAKEN ON CATEGORY A DEFECTS

1. **To enquire in the matter immediately.**
2. Issue instructions for immediate recall of batch from the market and to stop further sale.
3. To ask for particulars of stock, distribution and production and test records.
4. Calling of explanation from the manufacturer by issuing a show cause notice as to why license for the product / entire license should not be suspended/cancelled.
5. After receipt of explanation and/or investigation report, further appropriate action may be taken.

PRINCIPLES FOR INSTITUTION OF PROSECUTION UNDER DRUGS & COSMETICS ACT:

The weapon for prosecution should be used sparingly and judiciously but due regard to merits of the case be given as a prudent measure. Prosecution should be launched where administrative measures have failed to have desired effects. However, while deciding to prosecute, due regard should be given to the nature of contraventions.

The persistent defaulter should be prosecuted but _____ omissions may not form the basis of prosecution. Administrative action should be initiated wherever possible to ensure preventive measures to safeguard public health.

A broad classification of cases where prosecutions should be launched is given below:

1. Where a spurious drug or drug falling within the meaning of adulterated/spurious/misbranded under Section 17(C), 17(A), 17(B) and 17(D) of Drugs and Cosmetics Act is manufactured, sold or stocked or exhibited for sale or is distributed.

2. Cosmetic falling within the meaning of spurious drugs under Section 17(D) and misbranded under Section 17(C) (A) and 17(C).
3. Where drugs/cosmetics are manufactured without license.
4. Where a parenteral preparation is reported by the Government Analyst to be non-sterile, pyrogenic or toxic and provided on investigation is found to be substandard due to lack of adequate quality control and adherence to the provisions of GMP in the manufacturing processes.
5. Where a drug is found grossly sub-standard repeatedly.

PROSECUTIONS ARE NOT ORDINARILY WARRANTED IN THE FOLLOWING CASES:

The sub-committee feels that it is not necessary to specify the matters where prosecutions are not warranted as guidelines have already been suggested about the cases where prosecutions could not be considered.

INTERSTATE COORDINATION ON MATTERS REFERRED TO STATE DRUGS CONTROLLER:

The sub-committee examined this specific issue and after detailed deliberations came to the conclusion that it may not be pragmatic to stipulate that a prosecution may be launched only by the Drugs Controller in whose state the sample has been drawn or by the Drugs Controller in whose state the manufacturer is situated.

It should be left at the discretion of he concerned Drugs Controller to file a prosecution in his state or to refer the case to the Drugs Controller of the manufacturing state as circumstances warranted. Every Drugs Controller should invariably supply the information sought by other Drugs Controller in case the prosecution is contemplated. However, due regard should be given to the factual position or opinion supplied, if any, by the Drugs Controller of the state where the manufacturer is situated.

NOTE:

A. The above are broad guidelines for the guidance of state Drugs Control authorities. Cases not specifically covered by these guidelines or specific cases where a more serious/lenient view has to be taken, appropriate view can be taken by the state authorities, depending on circumstances of the case.

B. It is expected that final action after receipt of a note of standard quality report is taken within three months by the licensing authority / controlling authority and the same is informed to all concerned.

C. Repeated observance of Category B defects of a particular manufacturer should call for thorough inspection of manufacturing practices and facilities. If found deficient, it should be viewed seriously and stringent action is to be taken.