

No. I&M-3(25)/2006
Government of India
Planning Commission
(Industry Division)

Yojana Bhawan, Sansad Marg
New Delhi the 18th May, 2006

ORDER

Subject : Constitution of a Working Group on Drugs & Pharmaceuticals for Eleventh Five Year Plan (2007-12)

In the context of formulation of the Eleventh Five Year Plan (2007-12), it has been decided to set up a Working Group on Drugs & Pharmaceuticals. The Terms of Reference and Composition of the Working Group are: -

I. Terms of Reference

1. To review the status of the industry Tenth Plan targets, vis-à-vis achievements, in terms of production as well as exports, identify the reasons for major deviations, if any, bring out areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.
2. To assess the structure and capability of the domestic drugs & Pharmaceutical industry in the light of the new IPR regime, identify emerging areas having specific potential for growth and competitiveness and suggest measures for putting the indigenous industry on sound footing.
3. To assess the present status of WHO-GMP (World Health Organisation – Good Manufacturing Practice) certification and suggest measures for Schedule M compliance by manufacturers of drugs and Pharmaceutical products in the country.
4. To assess the present R&D status of the Drugs & Pharmaceuticals Industry and to suggest measures for increasing the role of the industry in R&D effort, Industry-Institutional linkages, investment (including foreign) by Industry to make the drugs and Pharmaceuticals industry internationally competitive and meet the emerging challenges arising out of the WTO regime.

5. To assess the requirements of equipment / machinery and indigenous capability for fabrication of internationally competitive equipment and suggest measures for augmentation of capabilities, where necessary.
6. To assess the present employment and likely employment that will be created in the Drugs & Pharmaceuticals Industry during the Eleventh Plan period and in the perspective of 15 years.
7. To assess the present education and training facilities and infrastructure for human resource development pertaining to Drugs and Pharmaceuticals sector and to suggest measures including institutional mechanisms to strengthen it, where required.
8. To assess the existing infrastructure for Pharmaceutical industry and to suggest measures to strengthen it including investment and source of investment alongwith option of revival of Pharmaceutical Public Sector Undertakings.
9. To assess the present regulatory mechanism and assess need for an apex authority to control price, quality and supply of drugs.
10. To review the present Drugs & Cosmetics Act and to suggest amendments to it including for ensuring GMP.
11. To review the present structure of the Indian Drugs Industry and suggest measures for improving the quality of drugs, particularly for tackling the menace of spurious drugs.
12. To benchmark the Indian Drugs and Pharmaceuticals industry against the international Drugs and Pharmaceutical industry and to suggest appropriate measures for bringing it up to international levels.
13. To make such other recommendations as are considered appropriate to make the drugs and Pharmaceuticals industry internationally competitive at the earliest
14. To suggest measures towards improvement of accessibility of essential medicines for the common man particularly the poorer sections of the population and availability of drugs for BPL families.
15. To identify steps required for facilitating implementation of the National Health Policy.

II. Composition of Working Group

- | | |
|--|--------------------|
| 1. Secretary, Department of Chemicals & Petrochemicals (DCPC) | Chairman |
| 2. Secretary, Deptt. of Scientific & Industrial Research/DG, Council of Scientific & Industrial Research or his Representative | Member |
| 3. Principal Adviser (Dev.Policy), Planning Commission | Member |
| 4. Principal Adviser / Adviser (Health), Planning Commission | Member |
| 5. Additional Secretary & Financial Adviser, Deptt. of C&PC (DCPC) | Member |
| 6. Joint Secretary (PI), Deptt. of C&PC | Member – Secretary |
| 7. Adviser (I&VSE) Planning Commission | Member |
| 8. Chairman, National Pharmaceutical Pricing Authority | Member |
| 9. Representative of Ministry of Health & Family Welfare | Member |
| 10. Representative of Deptt. of Science & Technology | Member |
| 11. Representative of Department of Bio-Technology | Member |
| 12. Director, Central Drugs Research Institute, Lucknow | Member |
| 13. Director, National Institute of Pharmaceutical Education & Research Mohali, Punjab | Member |
| 14. Representative, Pharmaceuticals Export Promotion Council, 101, Aditya Trade Centre, Ameerpet, Hyderabad – 500 038 | Member |
| 15. Representative, Indian Drugs Manufacturers Association 102B, Poonam Chambers, Dr. A.B. Road, Worli, Mumbai – 400 018 | Member |

16.	Representative of Confederation of Indian Pharmaceuticals Industry, A-3/314, 1 st Floor Paschim Vihar, New Delhi – 110 063	Member
17.	Representative of Indian Pharmaceuticals Alliance, 201, Darvesh Chambers, 743 P.D. Hinduja Road, Khar, Mumbai – 400 052	Member
18.	Representative of Organisation of Pharmaceuticals Producers of India Peninsula Chambers, Ground Floor, Ganpatrao Kadam Mary, Lower Parel, Mumbai – 400 013	Member
19.	Representative of Bulk Drug Manufacturers Association. C-25, Industrial Estate, Sanathnagar, Hyderabad – 500 038	Member
20.	Chairman, Dr. Reddy's Laboratories Ltd. 7-1-27, Ameerpet, Hyderabad – 500 016	Member
21.	Chairman, Ranbaxy Laboratories Limited Plot No.90, Sector 32, Gurgaon – 122011 Haryana.	Member
22.	Chairman, CIPLA Limited Mumbai Central, Mumbai – 400 008	Member
23.	Dr. Jai Prakash Narain, Lok Satta 401-402, Nirmal Tower, Punja Gutta, Hyderabad	Member
24.	Dr. Ahmed Masood, Ex-Adviser (PAMD) C2/994, Scottish Villa, Palam Vihar, Gurgaon – 122 017.	Member

2. The Chairman of the Working Group may include additional Term(s) of Reference in consultation with the Chairman of the Steering Committee.

3. The Chairman of the Working Group may co-opt any other Experts as Members of this Working Group, if considered necessary.

4. The Working Group will submit its report within three months of the date of this order to the Chairman of the Steering Committee on Industry. The Working Group will be serviced by the Department of Chemicals & Petrochemicals.

5. The expenditure on TA/DA of official members in connection with the meetings of the Working Group will be borne by the parent Department / Ministry to which the official belongs as per the rules of entitlement applicable to them. The non-official members of the Working Group will be entitled to TA/DA as permissible to Grade I officers of the Government of India under SR190 (a) and this expenditure will be borne by the Planning Commission.

6. Shri D. Banerjee, Dy. Adviser (CI), Planning Commission (Room No. 319A, Yojana Bhawan, Ph. 23096710) will asst as the Nodal Officer and any further communication in this regard may be made with the Nodal Officer.

Sd/-

(K.K. Chhabra)

Under Secretary to the Govt. of India

To

Chairman and all the Members (including Convenor) of the Working Group.

Copy to

PS to DCH / MOS (Planning)/ Members / Member Secretary, Planning Commission All Principal Advisers / Advisers / HODs in Planning Commission

Prime Minister's Office, South Block, New Delhi

Cabinet Secretariat, Rashtrapati Bhawan, New Delhi

Information Officer, Planning Commission, New Delhi.

Joint Secretary (Administration), Department of Chemicals & Petrochemicals

Controller of Accounts, Department of Chemicals & Petrochemicals

Sd/-

(K.K. Chhabra)

Under Secretary to the Govt. of India

Appendix II

MOST IMMEDIATE
TIME BOUND

No. 12025/21/2006-PI.III
Government of India
Ministry of Chemicals & Fertilizers
Department of Chemicals & Petrochemicals

Shastri Bhavan, New Delhi
Dated 27th June, 2005

OFFICE MEMORANDUM

Subject: Working Group on Drugs & Pharmaceuticals for Eleventh Five-Year Plan (2007-12) – Constitution of Sub-Groups.

The undersigned is directed to say that Planning Commission vide order No. I&M-3(25)/2006 dated 18th May, 2006 (copy enclosed) has constituted a Working Group on Drugs & Pharmaceuticals under the Chairmanship of Secretary (Chemicals & Petrochemicals). Since the Working Group has to submit its report within three months of the order issued by Planning Commission i.e. by mid August, 2006 to the Chairman of the Steering Committee, the following three Sub Groups have been formed in this Department with the approval of Secretary (Chemicals & Petrochemicals) to facilitate discussions and preparation of report :-

Sub-Group I

Regulatory mechanism (Item number 3,9,10, 11&13) of the terms of reference of the Working Group). Sub-Group-I has been formed as under: -

Joint Secretary (PI),	-	Chairperson
Representative of Deptt. of Biotechnology	-	Member
Representative of Deptt. of Indian System of Medicines	-	Member
Representative of Planning Commission (Health Division)	-	Member
DCGI, Ministry of Health and Family Welfare	-	Member
Executive Director, Pharmaceutical Export Promotion Council	-	Member
Managing Director, Rajasthan Drugs and Pharmaceuticals Ltd.	-	Member
Representative of Indian Drug Manufacturers Association	-	Member
Representative of Bulk Drug Manufacturers Association	-	Member
Representative of Organisation of Pharmaceutical Producers of India	-	Member
Director (PI), Department of Chemicals & Petrochemicals	-	Convener

Sub-Group II

Status and structure of the Pharmaceutical Industry (Item no. 1,2,8,12,13,14 & 15 of the terms of reference of the Working Group) Sub Group-II has been formed as under :-

Chairman, National Pharmaceutical Pricing Authority (NPPA)	- Chairperson
Member Secretary, NPPA	- Member
Senior Representative of Planning Commission	- Member
Managing Director, Hindustan Antibiotics Ltd. (HAL)	- Member
Representative of Pharmaceutical Export Promotion Council (Pharmexcil)	- Member
Deputy Secretary (PSU), Deptt. of C&PC	- Member
Senior Representative of Dr. Reddy's Lab.	- Member
Senior Representative of Ranbaxy Laboratories	- Member
Senior Representative of Organisation of Pharmaceutical Products of India	- Member
Representative of Indian Drug Manufacturers Association (IDMA)	- Member
Representative of Bulk Drug Manufacturers Association (BDMA)	- Member
Sh. Lalit Mohan Kaushal, Director, NPPA	- Convener

Sub-Group III

R&D, Training and Development Infrastructure, Employment generation etc. (Item no. 4,5,6&7 of the terms of reference of the Working Group) Sub Group III has been formed as under: -

Director, National Institute of Pharmaceutical Education & Research	- Chairperson
Representative of Department of Scientific & Industrial Research	- Member
Representative of Deptt. of Science & Technology (DST)	- Member
Representative of Deptt. of Biotechnology (DBT)	- Member
Representative of Indian Institute of Chemical Technology, Hyderabad	- Member
Director/Representative of Central Drug Research Institute, Lucknow	- Member
Director/Representative of Pharmexcil	- Member
Representative of Indian Drugs Manufacturers Associations (IDMA)	- Member
Representative of Bulk Drug Manufacturers Association (BDMA)	- Member
Representative of Organisation of Pharmaceutical Products of India(OPPI)	- Member
Representative of Indian Pharmaceuticals Alliance(IPA)	- Member
Shri P.U.M. Rao, Addl Industrial Adviser, (C&PC)	- Convener

State Drug Controllers and other experts may, however, be invited as Special Invitees for the meetings of all the above mentioned three Sub-Groups.

Meetings of the sub-groups may be convened immediately to take stock of the issues that have been allocated to each sub-group. **Each sub-group is required to prepare a report on the allocated subject and submit the same by 25th July 2006 positively.** Thereafter these reports would be put up before the Working Group, which would make the final recommendations.

A base Paper for the Working Group has been prepared to facilitate discussions by the Sub-Groups. A copy of the same is being enclosed herewith.

Sd/-

(Ram Chander)

Under Secretary to the Govt. of India
Tel No. 23384086 / Fax No. 23383392

To

Secretary, Department of Bio-Technology
Secretary, Department of Indian System of Medicines
Adviser, Planning Commission (Industry Division)
DCGI, Ministry of Health & Family Welfare
Secretary, Department of Scientific and Industrial Research
Secretary, Department of Science and Technology
Member Secretary, National Pharmaceutical Pricing Authority
Director, National Institute of Pharmaceutical Education & Research (NIPER)
Managing Director, Rajasthan Drug & Pharmaceutical Limited (RDPL)
Managing Director, Hindustan Antibiotics Ltd. (HAL)
Director, Indian Institute of Chemical Technology (IICT), Hyderabad
Director, Central Drugs Research Institute, Lucknow
Executive Director, Pharmaceutical Export Promotion Council, Hyderabad
Dr. Reddy's Lab.
Ranbaxy Laboratories
IDMA/BDMA/OPPI/IPA

Copy to: -

PS to Secretary(C&PC)/JS(PI)/Chairman(NPPA)/MS(NPPA)/Director(NIPER),
DS(PI)/DS(PSU)/AIA(R)

Copy also to: Adviser (I&VSE), Shri R.C. Jhamtani,
Planning Commission, Yojana Bhavan, New Delhi