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भारतीय आयुर्विज्ञान अनुसंधान परिषद

INDIAN COUNCIL OF MEDICAL RESEARCH

स्वास्थ्य अनुसंधान विभाग (स्वास्थ्य एवं परिवार कल्याण मंत्रालय)

DEPARTMENT OF HEALTH RESEARCH (MINISTRY OF HEALTH & FAMILY WELFARE)

वी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली-110 029

V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX-4911, NEW DELHI-110029

No.18/1/2015 Admn.II

Dated: 1.9.2015

To

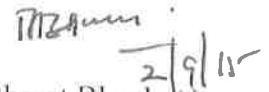
The Directors/Directors-in-Charge of all
Permanent Institutes/Centres of the Council

Subject: Meeting taken by the Joint Secretary to the Prime Minister reg. the challenges faced by the Indian Pharmaceutical sector in the international market reg.-

Sir/Madam

Please find enclosed herewith a Copy of the approved record of discussions on the subject mentioned above received from Prime Minister's Office, South Block New Delhi-110011 for information and taking further necessary action at your end.

Yours faithfully,



(Bharat Bhushan)

Administration Officer
for Director General

Encl : As above

PRIME MINISTER'S OFFICE

South Block,
New Delhi - 110 011

Please find enclosed, for further necessary action, a copy of the approved record of discussions of the meeting taken by Joint Secretary to Prime Minister on 13.08.2015 regarding the challenges faced by the Indian Pharmaceutical Sector in the International market.

OG 10/08/2015
171 PM


(Mayur Maheshwari)
Deputy Secretary
Tel: 2301 7676

- Foreign Secretary
- Secretary, D/o Commerce
- Secretary, D/o Pharmaceuticals
- Secretary, D/o Health & Family Welfare
- ✓ Secretary, D/o Health Research
- Secretary, D/o Biotechnology
- Secretary, M/o Environment, Forests & CC
- Drug Controller General of India

PMO ID No. 320/31/C/11/2015-ES.2

Dated 19.08.2015

*Director
Dr. K.P. Pandey Committee
AO (Admin II)*

Circulate To All Division Chiefs + JS (RPM) / Head of MS

Directors

26/8/15

MS. 211/12
Chand
27/8/15

DY. NO 969A-U
28/08/2015

3000776

Minutes of Meeting chaired by Joint Secretary to PM regarding the challenges faced by the Indian Pharmaceutical Sector in the International market on 13th August, 2015 at 11.00 am

Joint Secretary (AJ) took a meeting on 13.08.2015 at 11.00 am regarding the challenges faced by the Indian Pharmaceutical Sector in the International market. The list of participants is annexed.

2. The following roadmap was agreed upon:

(i) Gap analysis of the Indian GMP with WHO GMP be done on priority for improving/amending the relevant Schedule of the Drugs and Cosmetics Rules to bring it at par with the WHO GMP.

[Action: DCGI]

(ii) Examination and finalisation of the technology upgradation schemes for pharma sector be done and Cabinet Note be finalised by 15.09.2015.

[Action: D/o Pharmaceuticals]

(iii) Examination of the alternative mode of procurement of medicines, Pharmaceutical Pricing regime under NPPA be done. D/o Commerce to bring a proposal in consultation with MoHFW.

[Action: D/o Commerce]

(iv) National Institutes of Pharmaceutical Education and Research [NIPERs] should be strengthened. D/o pharma to bring up a proposal.

[Action: D/o Pharmaceutical]

(v) DoC to give a note on development of Pharma cluster for APIS.

[Action: D/o Commerce]

(vi) DoP should harness innovation in technology for drug discovery.

[Action: D/o Pharma and Department of Health Research]

(vii) CDSCO should submit a concept note on the following issues.

- a. Status of clinical research trials
- b. IPR Issues
- c. Restructuring of DCGI

(viii) The issue of timely approvals should be closely examined by DBI/MoH (GEAC) and MoHFW.

[Action: CDSCO, M/o Environment and Forests and D/o BT]

(ix) Higher degree of convergence is needed between various Ministries/Departments/institutions involved in matters relating to drug discovery, health research and related areas. DHR/ICMR should steer this convergence.

[Action: Department of Health Research]

(x) CDSCO component should be positioned in Indian Embassy in China. Replication in 3 other market from where sourcing is done by India be examined. Regulators' engagement with the EU, PMDA, ANVISA, TGA, MCC, ASEAN, Health Canada and USA, etc. should be stepped up.

[Action: MEA and CDSCO]

(xi) Output-input ratio for export of various bulk drugs and formulations for Indian Pharma Industry to be examined and report be submitted by 30.09.2015. Weekly meeting may be held, D/o Commerce and CDSCO will provide requisite assistance.

[Action: D/o Pharma, DoC, MoHFW]

(xii) Domestic laws and rules should not impede exports. Wherever required, the rules should be amended appropriately to empower CDSCO to give necessary clearances.

[Action: M/o HFW and CDSCO]

(xiii) Revision of Registration fee charges should be examined.

(xiv) CDSCO website should be updated. It should have Spanish, French, Russian, German versions. D/o Commerce to fund this activity.

[Action: CDSCO and D/o Commerce]

(xv) Explore the feasibility of getting Indian Pharmacopeia recognised by major pharma manufacturing countries.

[Action: Indian Pharmacopeia Commission]

Meeting to be chaired by Joint Secretary (A.J)
on 13.08.2015 at 11.00 am

List of Participants

1. Dr. G.N. Singh, Drug Controller General of India
2. Shri Sudhanshu Pandey, Joint Secretary, D/o Commerce
3. Dr. M. Ariz Ahmmed, Joint Secretary, D/o Pharmaceuticals
4. Shri K.L. Sharma, Joint Secretary, Department of Health & Family Welfare
5. Shri Nagaraj Naidu, Director, Ministry of External Affairs