



# The Indian Pharmaceutical Association (IPA)

*Platinum Jubilee Year*

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## MISSION

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects

**2014-2016**

IPA/110/185

November 5, 2014

**President**

Rao V. S. V. Vadlamudi

To

**Dr. Harsh Vardhan**

Ministry of Health & Family Welfare

Department of Health & Family Welfare - Govt. of India

Room No. 348; 'A' Wing, Nirman Bhavan,

New Delhi-110011

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**Past President**

J. A. S. Giri

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**Subject: Recruitment rules for appointment of Drugs Controller, Joint Drugs Controllers, Deputy Drugs Controllers, Assistant Drug Controllers and Drug Inspectors.**

Honourable Sir,

Let me take this opportunity to introduce our organization, the Indian Pharmaceutical Association (IPA), which is a premier professional organization registered as a charitable trust, with an objective to promote the science and art of pharmacy in all aspects and impart suitable education and training to professionals working in the pharmacy profession. IPA is celebrating its platinum jubilee this year. As a member of the Drug Technical Advisory Board (DTAB), IPA is actively involved in advising the government on matters of Drug Regulation and drug industry. IPA is actively involved in healthcare activities in collaboration with international organizations like-WHO, PMNCH & FIP.

We came to know from reliable sources that a committee is working on an "amendment of the recruitment rules of Drugs Controller General of India and other officers".

This is to draw your kind attention to the fact that the Drugs Controller General of India is the Licensing and Controlling Authority and should have the qualification and experience as per Sec 49A & 50 A of the Drugs and Cosmetics Rules. In the said rules there are provisions for appointing a person who-

- (i) Is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law; and
- (ii) Has experience in the manufacture or testing of drugs or enforcement of the provision of the Act for a minimum period of five years.

Sir, though there are provisions for appointing both pharmaceutically qualified persons and qualified Medical persons, nobody can deny the fact that persons professionally qualified in the field of Pharmaceutical Sciences and Pharmaceutical Technology, and adequately experienced, who are complying the provisions of the law are appropriate for appointment as the Drugs Controller General of India. The post of DCGI should not be considered only in terms of qualifications required for Licensing Authority or Central License Approving Authority. Since the role of the incumbent of DCGI position is that of a guiding beacon to the pharmaceutical industry, the person should be adequately qualified and experienced for leading the Indian Pharmaceutical sector to its destined position in the global market. In the Pharmacy course every aspect of pharmaceutical sciences like -basics of pharmacy, all aspects of drug discovery, development and approval process, Manufacturing technology, quality control and quality assurance along with the regulatory requirements being taught and hands on training provided, which is absent in any other course curriculum including the MBBS course.



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Indian Pharmaceutical industry showed tremendous growth during the last few decades (Table- I) when Central Drugs Standard Control Organization (CDSCO) was headed mainly by pharmacists, for example, Dr. S.S. Gothoskar, Ph.D. (Pharmacy); Dr. Prem Kumar Gupta, M.Pharm., Ph.D.; Mr. Ashiwini Kumar, M.Pharm.; Dr. M.Venkateswaralu, M. Pharm. Ph.D.; Dr. G.N.Singh, M.Pharm., Ph.D. etc. (Table-II).

Presently India ranks 3<sup>rd</sup> in terms of volume and 14<sup>th</sup> in terms of value in production of drugs amongst the world. Now we are exporting drugs throughout the globe including developed countries. Our pharmaceutical industries are technically so sound that we have maximum numbers of FDA approved plants outside USA. India is now considered as the "Pharmacy of the globe".

**Table-I: Growth of Pharmaceutical Industry.**

	1947	1970	2000	2006	2009	2012
No. of Units	Approx. 100	Approx. 2000	Approx. 6000	Approx. 10000	Approx. 10563	Approx. 8000
Volume of Business						
Local	Approx. 10 crores	Approx. 900 crores	Approx. 22500 crores	Approx. 45000 crores	Approx. 60000 crores	Approx. 65000 crores
Export	Nil	Approx. 200 crores	Approx. 9000 crores	Approx. 24000 crores	Approx. 40000 crores	Approx. 65000 crores

**Table-II: Personnel heading the Central Drugs Control Organization**

Sl. No.	Name	Academic Qualification	Designation	Duration
1.	Dr. S.S.Gothoskar	Ph. D.	Drugs Controller of India	1974-1985
3.	Dr. Prem Kumar Gupta	M.Pharm., Ph.D	Drugs Controller of India	1986-1992
5.	Sri Ashiwini Kumar	M.Pharm.	Drugs Controller General of India	1999-2006
6.	Dr. M. Venkateswaralu	M.Pharm., Ph.D	Drugs Controller General of India	2006-2008
8.	Dr. G.N.Singh	M.Pharm., Ph.D	Drugs Controller General of India	2011- till date



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Self-sufficiency in drug production reduced disease burden and improved quality of life in Indian population over the decades.

The Indian Pharmaceutical market is expected to expand at a rate of 23.9 per cent to reach US \$ 55 billion by 2020 A.D. It will be the 6th largest in the world by then according to a major study by global management and consulting firm McKinsey and Company. The Pharmaceutical sector is highly knowledge based and its steady growth is positively affecting the Indian economy. Among the science-based industries, it is growing at the fastest rate. The organized nature of the Indian pharmaceutical industry is attracting several global companies that are finding it viable to increase their operation in the country.

We would like to bring to your kind notice, that, most of the officers of CDSCO and State Drugs Control organizations are pharmaceutically qualified, who have the required knowledge, training and experience to head the organization for the benefit of the human health. Moreover, there is no dearth of highly qualified and experienced pharmacists in the Drugs Control organizations and outside Drugs Control organization. Presently, there is a large pool of pharmacy Graduates, Post graduates, and Ph. D. holders in Pharmacy in India and a huge number is joining this pool every year from a large number of reputed institutions.

The Drug Controller General of India is a torch-bearer to the pharmaceutical industry. Considering the enormous responsibilities that this person has to shoulder, the DCGI should have the technical expertise in the pharmaceutical field rather than mere knowledge about clinical applications of pharmaceuticals to do justice to the post.

We strongly believe that a Post graduate & Ph.D. degree holder in Pharmacy with adequate experience is best suited for leading the CDSCO and request you to make provisions so that none other than a Post graduate & Ph.D. holder in Pharmacy can lead CDSCO as Drugs Controller General of India.

We also strongly believe that pharmacy qualified personnel are best suitable for the posts of Joint Drugs Controllers, Deputy Drugs Controllers, Assistant Drug Controllers and Drug Inspectors because of their specialized education & training and we request you to make provisions so that none other than a graduate/post graduate in Pharmacy can appointed for the post of Joint Drugs Controllers, Deputy Drugs Controllers, Assistant Drug Controllers and Drug Inspectors under CDSCO.

Hope you will consider our appeal for the sake of the health of the people.

With best regards.

Yours sincerely,

Kaushik Desai  
Hon. Gen. Secretary

Copy:

1. Secretary, Department of Health & Family Welfare, Govt. of India, Room No. 348; 'A' Wing, Nirman Bhavan, New Delhi-110011
2. Mr. Satyanand Mishra, Former Secretary (DOP), C-6/14, Vasant Vihar, New Delhi- 110057