Submission of Suggestions for Proposed Pharmaceutical Policy

[A representation submitted to the Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, New Delhi vide letter no. IPA / 110 / 30 dated April 24, 2017].

Sir,

At the outset, we would like to thank you immensely for seeking suggestions for drafting the proposed pharmaceutical policy. As desired, put below are our inputs on some of the critical points that you had listed out in the meeting on 21st April 2017:

Creation of MoP — Single window regulatory clearances and better synchronization of operations

The Government should look at creation of Ministry of Pharmaceuticals (MoP) to handle pharmaceuticals, bio-pharmaceuticals, devices & diagnostics, herbals & nutraceuticals, production & supply chain, sales, pricing, licensing & regulation, export promotion, dispensing, utilization of pharmaceuticals, pharmacovigilance, patient counseling & drug information, pharmaceutical care in community & clinics, pharmacy education, regulation & accreditation, NIPERs, and development & deployment of qualified human resources to improve national healthcare. This move would effectively bring in all regulatory and related activities of DCGI, IPC, PCI, NPPA, NIPER and Pharmexcil under one roof. Besides, it would also include the control of public sector pharma enterprises like IDPL, HAL, RDPL, KAPL and BCPL within its ambit.

All requisite permissions / approvals for setting up manufacturing / clinical research / contract research/ R&D / sales / distributor / retail units would then be obtained from a single window, under MoP, as against the multiple approvals currently required from different ministries and government departments for setting up a business venture in this very important sector. The reduced approval timelines with a single window regulatory clearance would contribute greatly to the ease of doing business and would bolster growth of the industry.

Accord infrastructure status to the pharmaceutical & biotech industry

The Indian pharma industry is expected to grow over 15 per cent per annum between 2015 and 2020, and is expected to outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same period. India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 11.44 per cent to US $12.91 billion in FY 2015-16, according to data from the Ministry of Commerce and Industry. In addition, Indian pharmaceutical exports are estimated to grow between 8-10 per cent in FY 2016-17. In order that the potential of this promising sector is maximized to the fullest extent possible, it is important that the pharmaceutical & biotech industry be accorded infrastructure status so that better finance options are made available and capital inflow into the industry is facilitated. Special designated zones / parks for encouraging production of APIs, critical intermediates and starting raw materials as-well-as finished pharmaceutical and biotech products should be created by the government to provide a fillip to this sector that has the potential to draft India's success story as global economic superpower.

Pharmacist as indispensible member of the healthcare team and the only qualified and eligible professional for drug regulatory, drug policy-making, drug handling and pharmacy education-related teams

Pharmacist is an indispensible member of the healthcare team and the only professional equipped and qualified to extend pharmaceutical care to the patients in the hospital and community setups. The pharmacists' role as the first-line provider of patient care ought to be highlighted in all pharma & health-related documents / notifications / policies announced by the government. With the government's thrust on physicians prescribing generic medicines, the role of pharmacist in the retail set-up becomes all the more crucial and critical, with the pharmacist alone having the professional competence to supply to the patient, the right drug product with the correct salt / polymorphic form of the drug molecule, in the prescribed dose and with the desired drug release attributes, as against generic prescription. The role of the pharmacist in prescription audits in the retail as-well-as hospital setups is something that needs to be developed if better and improved healthcare delivery has to be achieved.

Further, pharmacy graduate / post graduate degrees should be considered the most desired qualification for all positions at all levels in MoP, drug regulatory framework, drug policy making bodies, drug industry, pharmacy education-related teams, drug handling teams including drug distributors, wholesalers and stockists. Implementation of these measures would ensure building and maintenance of quality in all aspects pertaining to drugs and medicines.

Building quality human resources

The importance of quality and well-trained human resource in adequate numbers, in the growth of any sector cannot be emphasized enough. Pharmacy education in the country can be strengthened by increasing the government spend in terms of creating more NIPERs and providing increased support to state-funded and private educational institutes conducting quality research programs. The pharma industry support to the educational institutes is vital and industry should be encouraged to outsource activities like the mandatory BA / BE studies, preclinical research, drug development and scale-up projects (projects that do not entail serious confidentiality issues) to pharmacy academic institutes of repute.

Pharmacy / pharmaceutical sciences should be included as one of the subjects in the civil services examination so that pharmaceutical professionals who understand the needs and requirements of the pharmacy profession have a better opportunity to get involved in the civil services, thereby contributing in a more effective way towards pharma policy-making and implementation. In the years ahead, government can also look at introducing examination of Indian Pharmaceutical Services on similar lines as that of other civil service examinations which could be taken up by all those candidates keen on government service in MoP.

DPCO to move from price control of only scheduled drugs & devices, to price monitoring of all scheduled as-well-as non-scheduled drugs & devices

The ceiling price fixed by NPPA for scheduled drugs & devices is viewed by the industry as a complete dampener, with many of the scheduled drugs & devices either getting withdrawn from the market after price control or getting reformulated as a new drug product along with other non-scheduled drug molecules, most often as irrational, unjustified and sometimes unsafe drug combinations. On the other hand, there are a whole lot of non-scheduled drugs including cosmeceuticals and AYUSH medicines that are exorbitantly priced. A better approach towards ensuring drug accessibility and availability, therefore, would be to shift from excessive price control of only scheduled drugs and devices to the moderate price monitoring of all scheduled as-well-as non-scheduled drugs and devices. The move would be well-received and accepted by the pharma industry and would also ensure accessibility and availability of improved and updated drugs and innovations in medical devices to the public at large.

Kaushik Desai
(Mumbai) Hon. General Secretary-IPA ◆