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The Secretary
Govt. of India
Ministry of Health & F.W.
Deptt. of Health (AHS Section)
Nirman Bhawan
NEW DELHI – 110 011.

Sir

The Pharmacy Council of India (PCI) is a statutory body working under the Ministry of Health and Family Welfare, Government of India, New Delhi. It is constituted under the Pharmacy Act, 1948 to regulate pharmacy education and practice of profession in the country.

The Council, taking note of the Ministry seeking comments on the draft National Health Policy, 2015 on its website, discussed it in the Council and desires to place the following points for the consideration.

- At the outset, the PCI congratulates the Ministry of Health and Family Welfare, Govt. of India for preparing a very comprehensive and progressive National Health Policy that addresses preventive, curative and rehabilitative efforts required for developing a healthy India. It becomes more important when the targets set by the millennium development goals will be getting over in the year 2015.
- The Council is pleased to note that for the first time the Health Policy recognizes the significant role played by the pharmacists, pharmaceutical industry, pharmacy professionals and the capability of the country in producing quality medicines at low cost and making it available not only to India but globally. However, the Council feels that the points that are being mentioned herein may further strengthen the Health Policy proposed by the Govt. and may support the initiatives laid therein to provide health for all in our country.

Comments

2. Situation Analysis

2.12 Healthcare Industry

The volume of medicines manufactured in India which is to the tune of around Rs.1,20,000 crores and 50% of which is also being used for export may be included.

2.15 Human Resource Development

After the words nursing schools being set up, add “Similarly there has been an expansion of pharmacy education. There are 1114 number of institutions offering B.Pharm programme, 777 number of institutions offering D.Pharm programme and 190 number of institutions offering Pharm.D. programme in pharmacy.

The Pharm.D. programme which was started in 2008 requires the pharmacy institutions to set up Pharmacy Practice Department in a 300 bedded hospital and provides guidelines for rational use of medicines, patient counselling on medication, drug information to physicians and health care professionals and over all enhances the pharmaceutical care. The starting of the Pharm.D. programme and the availability of clinically trained pharmacists after 6 years of exhaustive study has positive impact on more than 45,000 patients who visit on daily basis atleast in more than 150 hospitals where the Pharm.D institutions have tied up and has resulted in the responsible use of medicines saving the cost to the patients and also the hospital management. This unique effort of the Govt. of India and the Ministry of Health and Family Welfare has set a new trend in the safe use of medicines. This has also resulted in strengthening the pharmacovigilance programme of the Govt. of India and has generated data-base of adverse drug events being reported and helps in generating policies for the continuity of the medicines based on its safety profile.

The PCI strongly supports this effort where the right use of medicines at right dose at right time can prevent the emergence of multi-drug resistance and save the ex-chequer.

4.3.1 Primary Care Services & Continuity of Care

4.3.1.7 The primary care services and continuity of care in the Para 4.3.1.7 has highlighted the role of nurse and para medical staff who with the suitable training should be able to provide the necessary care. For all chronic illness, a doctor or specialist may have to initiate the treatment and supervise it, but most elements of the continuity of care required for chronic illness can be provided locally by the primary care team, thus preventing overcrowding at the higher level and underutilization at the primary health centre level and saving the family enormous costs and sufferings. The use of ICT tools including tele-medicine would support the primary care teams.

The pharmacist who is an expert in medicines can play a significant role in this direction. The Ministry of Health and Family Welfare has recently approved the Pharmacy Practice Regulations highlighting the role and responsibilities of the pharmacists wherein the pharmacist can play a significant role in the continuity of the care and thus reducing the burden of large number of patients on the physicians besides ensuring the rational use of medicines thus reducing a huge burden on the Govt. which, in turn, can be utilized for other health care needs of the country.

National Health Programmes

National Health Programme plays an important role in reducing the disease burden of the country. The policy clearly highlights the role which various health professionals can play in the reproductive and Child Health Programmes, communicable diseases under National Disease Control Programmes, Mental Health, Emergency Care and Disaster preparedness, utilization of AYUSH and Tertiary Care Services. In all these areas, pharmacists trained at different levels can play a significant role in strengthening the health care efforts of the country.

4.3.7 Communicable Diseases under National Disease Control Programmes

4.3.7.3 Control of Tuberculosis

The awareness programme on DOTS particularly multi drug resistance and TB awareness carried out by the pharmacists in the states of Maharashtra, Karnataka and Tamil Nadu is well known. The role of clinical pharmacist with Pharm.D. qualification in preventing multi-drug resistance particularly against diseases like TB and HIV / AIDS can be of great use. The pharmacist as a “friend in need” has been proven nationally and globally in giving advice to the patients on safe use of medicines. The role of pharmacist in creating awareness on HIV / AIDS has several success stories and the health policy can include that pharmaceutical scientists and clinical pharmacists will play a significant role in development of newer drugs and ensure responsible use of medicines.

5. Human Resources for Health

Human Resources plays a critical role in success of any programme. The Pharmacy Council of India has been successfully producing well trained competent pharmacists to meet the different needs of the country in this sector. The Pharmacy Council of India has presently 777 number of diploma in pharmacy institutions producing 46520 number of diploma pharmacists who work in hospital pharmacy and community pharmacy (drug stores) throughout the country. It is estimated that more than 700 thousand pharmacists are working in more 600 thousand community pharmacies (drug store) and in about 100 thousand hospital pharmacies of the State and Central Govt. hospitals. The

pharmacy graduates and post-graduates (B.Pharm and M.Pharm) meet the needs of the country in the manufacturing of medicines. The PCI has approved 1114 number of institutions producing 73618 number of B.Pharm graduates per annum.

Presently the Ministry of Health has approved the B.Pharm Regulations and M.Pharm Regulations which will further enhance the quality of pharmacy graduates and post-graduates who would be strengthening the pharmaceutical industry both in manufacturing and discovery of new drugs. The Pharm.D programme of the country which was introduced in 2008 with a vision of the Ministry of Health and Family Welfare is a unique programme where we are bringing out professionally and clinically trained pharmacists who will ensure the safe and efficacious use of medicines.

The Ministry of Health and Family Welfare in its 11th and 12th Five Year Plan has set aside an amount of rupees around 500 crores for development of pharmacist workforce in the country. It is proposed that this will be spent on continuing education of the pharmacists and also for strengthening and upgradation of D.Pharm and B.Pharm institutions including financial assistance to Government medical colleges for starting pharmacy programmes. Besides, the PCI has also proposed to the Ministry of Health and Family Welfare for establishing a National School of Pharmacy with the objective of producing clinically trained pharmacists who will play a significant role in Pharmacovigilance in the country. Perhaps the pharmacy profession is the only profession which has trained the required number of professionals that are needed for the country and also continues to evolve the mechanism which suits the needs of the health professionals.

The PCI is proposing to maintain a live register of pharmacists on its data base which will have an accurate number of pharmacists working in the country thereby giving the availability of the human resource in different sectors-urban, rural, metropolis, private sector, Govt. sector etc.

- 5.11 The National School of Pharmacy and the Govt. Medical colleges need to start Pharm.D. Programme to strengthen the clinically trained pharmacists workforce in the country.

7. Regulatory Framework

- 7.5 To strengthen the efforts of the country in the manufacturing of medicines, the Govt. of India has proposed that it would -
- a) nurture the industry.
 - b) amend the Drugs and Cosmetics Act to bring a regulatory environment that would facilitate the directed growth of the industry. It is important to mention here that these amendments should focus that only the professionally trained and competent persons who have an extensive knowledge of pharmaceutical

sciences, clinical outcomes and utilization of medicines shall be involved in all the activities involving the discovery, development, manufacture, sales, distribution and use of medicines. The PCI for the said purposes has, with the approval of the Ministry of Health and Family Welfare, made the B.Pharm, M.Pharm and Pharm.D. course Regulations to ensure that competent workforce is available with the currency in their knowledge to meet all the above requirements. The engagement of professionally trained and competent pharmacists in all the above roles will reduce the embarrassment which country is presently facing in receiving dis-approval from various international drug regulatory agencies.

8. Medical Technologies

- 8.6 The Govt. of India has emphasized the need for Drug Innovation and New Drug Discovery and has also highlighted that the main constraints to innovation are funding, inadequate structure and functioning of regulatory institutional mechanisms. Besides the barriers to clinical and animal research, it has been proven globally that many of the innovations have come out of academic and industry partnerships. The Govt. of India, Ministry of Health and Family Welfare should lay emphasis on academic-industry partnership which PCI would be pleased to support through its regulatory mechanism with the provision for Industry Academic partnership cells which would nurture innovation in the drug industry. The other facet which mainly helps the country is the rational and responsible use of medicines. This initiative alone can save the Govt. exchequer in the form of savings to the tune of almost 50% of expenditure that is made in procurement of medicines.

The effective use of clinical pharmacists and a very robust pharmacovigilance programme under the clinical pharmacists would help the country to realize this objective. Hence there is need for establishment of pharmacovigilance centre in every district of the country under the supervision of the clinical pharmacists which shall be responsible for ensuring rational, responsible and safe use of medicines and will serve as a nodal centre for providing information on medicines to patients as well as health professionals.

10. Knowledge for Health

National Health Policy recognizes the key role that health research plays in the development of nation's health. The policy has expressed concern that 96% of the research publications in India emanated from as little as 9 medical colleges that reflect how little most of them are geared to the challenges of health research.

It is emphasized that the large number of publication in Journals of high impact factor are published by more than 500 pharmacy institutions which supply the research environment in the country. The PCI has aggressively promoted the scientific environment of the country in drug discovery and innovation. The Ministry in Para 10.3 may like to highlight the PCI role in promoting health research.

The PCI at its end would like to state that it will strongly partner with Govt. of India in all its initiatives towards realizing the goal of National Health Policy. The PCI is also pleased to make necessary contribution in the form of discussion, presentation, supporting documents etc. as may be required for finalization of the National Health Policy.

Yours faithfully

Sd/-

(ARCHNA MUDGAL)
Registrar-cum-Secretary