Editorial

Deregulation of allopathic prescription and medical practice in India: Benefits and pitfalls

Abstract

In the background of debates on Universal Health Coverage, skill transfer from the medical practice license holders to other health-care providers such as nurse practitioner has become a global norm. In India, where the world's largest numbers of medical graduates are produced, this discussion is expanding to extremes and serious suggestions are coming forward for the development of legal framework for allowing dentists, homeopaths, pharmacists, and half duration trained doctors; permission to issue allopathic prescription. It is noteworthy that this discussion only pertains to the pharmaceutical products retailed through "allopathic medical prescriptions." A prescription is not only advice for patient's recovery but it also is a legitimate order for the sale of controlled drugs and pharmaceutical product; thereby functions as a regulatory tool for consumption of pharmaceutical products at retail level. Who is ultimately going to benefit from this prescription deregulation? This editorial explores benefits and pitfalls of prescription and medical practice deregulation.

Keywords: Health policy, industry, medical profession, prescription deregulation, primary care, universal health coverage

Universal Health Coverage and Prescription Deregulation: Background

Within the cotemporary health policy discussions, the broadening of the scope of practice and skill transfer for various groups of health-care workers is a debate in vogue. Expanding the framework of legal permission to issue medical prescription by nonlicensed providers to public at large has become a part of this broad process. A word of caution is required for developing economies, where medical practice regulation is still not sufficiently evolved or has been rendered noneffective due to various reasons. While the popular argument in the support of prescription deregulation is the "nonavailability of licensed medical doctors," a reality check is required on the account of capacity and intent of public/private health system to engage qualified medical practitioners.

Indiscriminate and illogical deregulation also has a flip side, and the debate is apparently moving toward a regulation-free distribution of curative medical services within the public health sector. The new employment contracts, remunerations, and recruitment policies of public health systems are indicative of prohibitive barriers toward entry and sustenance for licensed medical practitioners as resource regulators at the level of primary care curative services. In the well-regulated environment of developing countries, primary care often means the essential presence of licensed medical practitioners, who provide effective gatekeeping services in terms of provision of comprehensive medical care and public health expenditure. Whereas, the same "primary care" is often translated into several dysfunctional and fragmented vertical programs in the developing nations.

Prescription deregulation is especially important for countries which are contemplating upon implementation of Universal Health Coverage (UHC). Without an effective mechanism of regulatory mechanism within public health systems, more so in the case of curative medical services, the benefit of health-care subsidy of UHC is likely to be transferred to the industry or leaked to corruption instead of the intended purpose of palliating and preventing population morbidity and mortality. Public health resources must be protected from inherent fallacies of willful wasteful public health expenditure and crony corporate designs.

Allopathic Prescription

Prescription often refers to a health-care provider's written authorization for a patient to purchase a prescription drug from a pharmacist. Prescription by a Registered Allopathic Physician is the form of instructions that govern the plan of care for an individual patient. Prescribing entails the following four steps: Gathering patient history, assessing appropriateness of the medications, communicating the therapy to other health-care professionals, and monitoring patient's drug regimen.[1] Even though the process of prescribing seems simple, choosing the most appropriate medication therapy for the patient often requires a sound judgment on the part of the health-care provider.[2] Thus, a prescription is not only advice for patient's recovery but it is also a legitimate order for the sale of controlled drugs and pharmaceutical product; thereby functions as a regulatory tool for consumption of pharmaceutical products at retail level.

Deregulation of Allopathic Prescription: Caution Required

Recently a section of health policy experts is pushing for deregularizing the allopathic prescription in India. There have been conscious efforts to develop a legal framework to allow

nonlicensed providers, legitimacy to issues medical prescriptions. Deregulation of allopathic prescription requires a cautious consideration since it is a grave concern in the context of delivering safe and quality medical care to 125 crore citizen of India. It is often stated that India's health-care delivery is suffering mainly due to the acute shortages of allopathic doctors. It is also a common perception that allopathic doctors seldom prefer rural service. Let us examine these common perceptions in the background of available data.

Scarcity of Allopathic Doctors: Myths and Reality

India produces more than 50,000 allopathic doctors per year, but the public health system has only 100,000 existing posts for (total posts) employment of doctors. There is a deficiency of only a few thousand doctors within the public health systems at Primary Health Centers (PHCs), but as a country, India is producing several times more doctors. Shortage of doctors for primary health care has been overstated. As per Rural Health Statistics-2015 published by Ministry of Health and Family Welfare (MOHFW), Government of India, the number of allopathic doctors at PHCs has increased from 20,308 in 2005 to 27,421 in the year 2015, which is about 35.0% increase and shortfall of allopathic doctors in PHCs was 11.9% of the total requirement for existing infrastructure.[3]

To be more specific, all over India only 3002 allopathic doctors are shortfall in PHC and in that too only in nine states.[4] Of these vacancies, a proportion is due to nonrecruitment rather than nonavailability of doctors. Data showed that each year, about 100,000 doctors took postgraduate medical entrance examinations across the country. However, only around 25,000 made it and the rest were available for service as MBBS doctors for the public health system.[4] In fact, states like Maharashtra are now producing surplus MBBS doctors. The Government of Maharashtra has, therefore, decided to scrap the service bond to serve rural sector, which was earlier compulsory for all medical students qualifying from government medical colleges.[5] The requirements (advertised posts) have not changed for last several decades in India but the populations as almost doubled.

For any number of regular government medical officer posts advertised, there are far more applicants. The recent order to move retirement age from 60 to 65 years effectively means that there will be no urge for new recruitments for 5 more years. These additional senior doctors, who would have been looking after administrative responsibilities till now, are less likely to see patients in coming 5 years. Therefore, no change is expected in addressing community-based morbidity. The real problem is not nonavailability of MBBS doctors but recruiting them and giving an atmosphere to retain them. According to OPPI KPMG report on healthcare access initiatives, "the country faces acute shortage of infrastructure at the primary, secondary, and tertiary levels, which is further hampered by inadequately trained health-care professionals and staff."[6] The problem is underdeveloped infrastructure and rather than a shortage of workforce.

Who is Pushing for Prescription Deregulation?

Under the pretext of deficiency of doctors, the pharmaceutical industry is pushing further deregulation of allopathic prescription. Several pharmaceutical groups already run allopathic educational programs in the name of continuous professional development for nonlicensed practitioners. Legalizing cross pathy and creating an opportunity for back door entry for Homeopathy or Yoga graduates to practice Allopathy in the name of meeting shortage of allopathic doctors in rural India will only compound and complicate medical problems. One can prefer and adopt shortcut, short-sighted sightless, "stitch and suture" policy, i.e., cross pathy (engaging institutionally qualified ISM vaidyas to substitute the need of allopathic doctors) and can fill up the gap. But by legalizing cross pathy by deregulating allopathic prescription is likely to severely impact the prescription patterns at public health (government) health centers. The pharmaceutical industry is ultimately going to benefit from the deregularization of allopathic prescription.

Legal Boundaries of Medical Prescription in India

At the heart of medication therapy, lies the prescription; a legal document governed by the following laws: The Indian Medical Council Act, 1956; The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002; The Drugs and Cosmetics Act, 1940, and Rules 1945; The Pharmacy Act, 1948; The Narcotic Drugs and Psychotropic Substances Act, 1985, and Rules 1987; Drugs (Price Control) Order, 1995; and The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and Rules 1955.[7]

Judicial Protection of Prescription Rules: Legal Angle

In a landmark judgment, the High Court of Delhi on April 8, 2016, vide W.P.(C) No. 7865/2010 stated that practitioner of Indian System of Medicine or of Homeopathic Medicine practitioners cannot prescribe allopathic medicines. Delhi Medical Association, under Article 226 of the Constitution of India, had filed as a Public Interest Litigation, inter alia seeking directions from the honorable court.[8]

The matter regarding qualified practitioners of Ayurveda, Unani, Siddha, and Homeopathy systems prescribing allopathic medicines have been examined in depth by the Honorable Supreme Court of India in Civil Appeal No. 89 of 1987 Dr. Mukhtiar Chand *et al.* versus State of Punjab and others. Drugs can be sold and supplied by a pharmacist or a druggist only on a prescription of a Registered Medical Practitioner and who can also store them for the treatment of patients.

According to Section 2 (ee) of the Drugs and Cosmetics Rules, 1995, Registered Medical Practitioner means a person:

i. Holding a qualification granted by an authority specified or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or
ii. Registered or eligible for registration in a medical register of a state meant for the registration of persons practicing the modern scientific system of medicine (excluding the Homeopathy system of medicine); or
iii. Registered in a medical register (other than a register for the registration of homeopathic practitioners) of a state, who although not falling within subclause (i) or subclause (ii) is declared by a general or special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this Act.

Honorable Supreme Court of India upheld the validity of Rule 2 (ee) (iii), as well as the notifications issued by various State Governments there under allowing Ayurveda, Siddha, Unani, and Homeopathy practitioners to prescribe allopathic medicines.[9] In view of the above judgment, Ayurveda, Siddha, Unani, and Homeopathy practitioners can prescribe allopathic medicines under Rule 2 (ee) (iii) only in those states where they are authorized to do so by a general or special order made by the concerned State Government in that regard. Practitioners of Indian Medicine holding the degrees in integrated courses can also prescribe allopathic medicines if any State Act in the state in which they are practicing recognizes their qualification as sufficient for registration in the State Medical Register.[9]

The recent judgment of High Court of Delhi further rules out ambiguity. It states "That a harmonious reading of Section 15 of MCI Act and Section 17 of the Indian Medicine Act leads to the conclusion that there is no scope for a person enrolled on the State Register of Indian Medicine or Central Register of Indian Medicine to practice modern scientific medicine in any of its branches unless that person is also enrolled on a State Medical Register within the meaning of the MCI Act. That the right to practice modern scientific medicine or Indian system of medicine cannot be based on the provisions of the drugs rules and declaration made there under by State Governments."[8]

Earlier the High Court of Gujarat vide order dated June12, 2001, in Special Civil Application No. 511/1983 titled Gujarat State Branch of Indian Medical Association versus State of Gujarat has observed that diploma holders in nature cure and hygiene cannot be treated as "medical practitioners" and cannot be allowed to practice in the Allopathic System of Medicine.[8] High Court of Allahabad also in order dated September 6, 2001, in W.P.(C) No. 5896/2000 titled Dr. Mehboob Alam versus State of Uttar Pradesh has observed that Allopathic System of Medicine is not included in the definition of Indian System of Medicine and that a person holding a qualification recognized under the Indian Medicine Act in the system of Indian Medicine commonly known as Ashtang Ayurveda, Siddha, or Unani Tibb is entitled to practice only in the discipline in which he has acquired qualification and not authorized to practice in Allopathic System of Medicine. High Court of Allahabad vide order dated April 27, 2004, in Special Appeal No. 320/2004 has also directed the State Government to ensure that the right to health of citizens is not affected by the practice of unauthorized medical practitioners.[8]

The High Court of Madras vide order dated February 12, 2010, in W.P.(C) No. 2907/2002 titled Dr. K. Abdul Muneer versus State of Tamil Nadu had ordered that it is not open to medical practitioners of other systems of medicine to claim right to practice in modern medicine without qualification in the said system and that the practitioners of Indian System of Medicine though entitled to practice Indian System of Medicine cannot practice modern system of medicine.[8]

From these verdicts, the legal stand becomes very clear, i.e., medical practitioners who are not qualified and licensed to practice Allopathy cannot issue an allopathic prescription, which seems valid, logical, and scientific too.

Promotion of Ayurveda, Yoga, Unani, Siddha, and Homeopathy versus Demand for Deregulation of Allopathic Prescription

Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) systems of medical therapies have traditionally received support from the Government of India. To promote AYUSH, a new ministry was formed on November 9, 2014, earlier it had a status of department under MOHFW. A section of AYUSH practitioners, few of the public health organizations and a section of public health policy makers, have been advocating for legal permissions to allow practice of Allopathy by AYUSH practitioners.

It is understandable that by prescribing allopathic medicine their income and employment opportunities would improve dramatically. However, if allowed such a situation would defeat the purpose of the Government of Indian policy of promoting AYUSH. The viewpoint titled "Can a Homeopath Practice Allopathy?" published in National Journal of Homeopathy highly criticized those half-baked homeopaths desirous of Allopathy practice.[10] The article further states that "a very few homeopathic colleges send their students to learn surgery, midwifery and gynecology, and other allied sciences. What is taught in the Homeopathic Hospital is very cursory and is taught by doctors who have not had any opportunity of allopathic training."[10]

Therefore, argument for legal permission to allow AYUSH practitioners to issue allopathic prescription is not only paradoxical but also appears to be a noxious design which is being apparently pushed by the pharmaceutical industry and against the spirit of development of real AYUSH. The intention of promotion of sales of pharmaceutical allopathic products in the name of promotion of AYUSH is overtly clear.

Prescription Deregulation: Global Trends

There is a global trend to encourage developing economies toward bulk purchase of medical and pharmaceutical products through government funds and push it down through public health systems. The issue of deregulation of allopathic medicine is especially important at primary care level where the public interface exists. Primary care should function as efficient gatekeeping of health-care expenditure; however in countries like India, as discussed above, a design of nonrecruitment of licensed doctors is being encouraged. However, same is being propagated as deficiency of doctors for public consumption. Therefore, a legal framework is being developed to allow free distribution of pharmaceutical products through bulk purchase (through public funds) by deregulating allopathic prescription. Hence, all types of innovative proposals are being pushed forward such as (a) permission to allow allopathic drugs by hakims, Ayurvedic vaidyas, and homeopathic practitioners; (b) medical practice by pharmacists although over the counter sale of controlled drugs is rampant; almost everything is available in India without prescription except for narcotics at most of the places; and (c) bridge courses for dentists to be able to function as prescribers of allopathic medication for general medical problems.

The basic intention is to ease out and push the pharmaceutical products by nonqualified doctors through private and public health services.

Prescription Deregulation: Societal Loss

It will be interesting to go through the Consumer Protection Act Judgments: National Consumer Disputes Redressal Commission New Delhi Original Petition No. 214 Of 1997 stated that "*when a patient is admitted in a hospital, it is done with the belief that the treatment given in the hospital is being given by qualified doctors under the Indian Medical Council Act, 1956. It is not within the knowledge of the relatives of the patient that the patient is being treated by a Unani Specialist. We hold that it is clear deficiency in service and negligence by the hospital for leaving the patient in the hands of Unani doctor. As laid down by Apex Court in the above case (Jacob Mathew case), we feel it is high time that hospital authorities realize that the practice of employing nonmedical practitioners such as doctors specialized in Unani system and who do not possess the required skill and competence to give allopathic treatment and to let an emergency patient be treated in their hands is a gross negligence. We do not wish to attribute negligence on the part of Dr. Rehan alone, while the patient was in his charge in terms of directing to pay compensation but solely on the hospital authorities for leaving the patient in his complete care knowing he is not qualified to treat such cases*".[11]

Sadly, the attempt to deregulate allopathic prescription will elicit similar situation in public health scenario, i.e., leaving the patient in the complete care of nonlicensed practitioners under the perception of qualified practitioners.

Conclusion

Destabilizing and deregulating the existing legal framework of sale of pharmaceutical products is likely to have serious implications on the healthcare expenditure both in the public and private sector. Over the counter sale of controlled prescription items by private pharmacies is already a known challenge in India and almost everything including "antibiotics" is available for sale without presenting a legal order of a medical prescription. Further indiscriminate deregulation of prescription laws is likely to have a catastrophic impact on the public health curative expenditure.

After such a deregulation, there would be no need for doctors as professional (neutral) regulators of resources except at hospital as "procedurists" and "medical interventionalists" but without any autonomy or regulatory role. Professional regulatory pillar within the health services will be lost forever. There also seems to exist a tussle for control of regulatory powers over health-care resources between "medical professionals" and "administrators".

Amidst chaotic health-care ecosystem, there is an attempt for a hostile takeover of "medical profession" by the "industry" on the pretext of public health necessities. Political and thought leaders must deeply ponder over such interventions and move ahead with great caution. Moreover, there is an urgent need to develop a "National Health Agenda" instead of chasing and perennially lagging behind the "International Health Goals" decades after decades; India's last national health policy was released almost 15 years back in the year 2002.

Raman Kumar[1,2], Pritam Roy[3]

[1]President, Academy of Family Physicians of India, [2]Chief Editor, Journal of Family Medicine and Primary Care, [3]Chairperson, Primary Care and Public Health Policy Forum, Academy of Family Physicians of India

Address for correspondence: Dr. Raman Kumar, 049, Crema Tower, Mahagun Mascot, Crossing Republic, Ghaziabad, Uttar Pradesh - 201 016, India.
E-mail: dr_raman@hotmail.com

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