EDITORIAL

Ethics regulation by National Medical Commission: No reason for hope

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Over the last three decades, medical councils in India have come under fire for rampant corruption and failure in the governance of medical education and practice. In fact, this journal itself grew out of the disquiet felt by a section of medical professionals at the barefaced corruption they witnessed in electoral practices, when contesting elections to the Maharashtra Medical Council in 1992 [1]. That experience triggered a movement of doctors and non-medical individuals for reform in the governance of healthcare, resulting in the birth of this journal in 1993. This also helped advance the disciplines of bioethics and healthcare ethics and humanities in India.

Much has been written in this journal and elsewhere to show the total disenchantment of good doctors and other healthcare workers with the medical councils. They were joined by some parliamentarians, who made it clear in the 92nd Parliamentary Standing Committee (PSC) Report, 2016, on "The Functioning of Medical Council of India", that "the MCI cannot be remedied according to the existing provisions of the Indian Medical Council Act, 1956 which is certainly outdated. If we try to amend or modify the existing Act, ten years down the line we will still be grappling with the same problems that we are facing today" [2: p 83]. In their paper in 2020, Keshri et al have summarised the recommendations of different committees over the last decade [3]. Interestingly, the reports cited in Keshri expressed strong reservations about the medical regulator being controlled solely by doctors, and declared the method of electing doctors to be a failure. Almost all the reports recommended representation from diverse, including non-medical, backgrounds.

Thus, on July 29, 2019, when Parliament passed the National Medical Commission (NMC) Act to replace the Indian Medical Council Act, 1956, very few shed tears. The government moved fast to notify the new law in the gazette on August 8, 2019. Without delay, five sets of rules were notified on September 13 and 16, 2019, for the operationalisation of the National Medical Commission, for the appointment of its members, and for its internal governance. Within a month after that (on October 14), as required under the rules, the then health minister drew lots from among the nominations for the selection of part-time members of the NMC [4]. Indeed, the health minister claimed that "members from diverse background" were included in the NMC, that it was "a huge and visionary reform", and its functioning was fully committed to "transparency" [4].

The selection of full-time members, however, including presidents of four boards — namely, Boards for Under Graduate Education, Post Graduate Education, Medical Assessment and Rating, and Ethics and Medical Registration — took the government a year; the full NMC was constituted as a regulatory body and notified to actually replace the MCI only on September 24, 2020.

Although the MCI's actions in the name of enforcement of ethics in the profession were scandalous, what led to its downfall was its mismanagement and corruption in the regulation of medical education, which is a highly commercialised field. All official reports on the MCI deal extensively with medical education and devote little space to its failures in the enforcement of medical ethics and professional integrity among healthcare providers. With the passing of the NMC Act 2019, the media's focus on the NMC's handling of medical education has only increased. There is comparatively little discussion on ethical issues in the NMC Act and Rules, on whether they protect patients, improve their access to remedies against ethics violations, and whether and how the NMC Ethics Board will follow procedures to uphold the rule of law and principles of natural justice in medicine.

In this editorial, therefore, I intend to focus on the responsibility of the NMC to uphold ethics and improve the ethical standards of the profession and medical establishments.

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Self-regulation and role of non-doctors

According to Sir Donald Irvine [5], professional regulation has two strands — "One is the self-discipline required of individual doctors to conduct themselves as doctors should. … The other strand is the collective self-discipline that obligates the profession to make sure that current practice is broadly in line with public expectations, and that each doctor does indeed practise in accordance with the standards of the day" [5: p 203]. Historically, a massive movement for the recognition of basic uniform qualifications for doctors in England led to the establishment of the self-regulatory General Medical Council (GMC) in 1858. Professional self-regulation was understood as ***a regulatory arrangement*** between society and the medical profession, whereby the latter ***are allowed to manage their own affairs*** with minimum interference provided they ensure that their members are competent, have a high level of integrity, and provide protection to patients. In India, the colonial government established the national and state medical councils as largely self-regulatory bodies. After independence, the MCI Act, 1956, continued the same policy.

Meg Stacey [6], a then "lay" member of the GMC in the UK, called this arrangement a "regulatory bargain" which was given legitimacy till the evidence showed that the profession had not kept its part of the bargain. This started a move from self-regulation towards a regulatory model, with proportionately more selected, as opposed to elected, members and non-doctors [7] making up half or more of the members in regulatory bodies. The focus shifted from the etiquette and moral conduct of doctors to the safety of patients in medical practice with the enactment, in 2004, of the Fitness to Practice (FTP) Rules. In 2012, the Medical Practitioners Tribunal Service (MPTS) was established, providing a separate forum from the GMC for doctors' trials [8].

In this context, it is essential to do a preliminary assessment of the NMC Act and Rules, and of the composition of the NMC, to gauge whether they do away effectively with the control of the medical regulator by doctors, and provide an important, if not dominant, role to non-doctor members.

Who are the NMC members?

Almost two years after their appointment, the NMC website does not have even a brief profile of its members. Despite this, in the first week of April 2022, I attempted to carry out a background check on them and was very disappointed. The government has selected and appointed 31 members — 20 of them part-time and 11 full-time [9]. In practice, *the full-time members* will control the Commission's affairs as administrative powers are concentrated in their hands. A look at their backgrounds reveals that:

- All full-time members are doctors, except the NMC secretary, who is an Additional Secretary in the Ministry of Health and Family Welfare deputed to the NMC as a full-time administrator. Both in the MCI and in the present state medical councils (SMCs), governments have always appointed a bureaucrat as a full-time administrator.
- Of the 20 part-time members, nine are ex-officio Vice Chancellors (VCs) of universities, nine are ex-officio members from SMCs and only two are non-ex-officio members.
- Of the nine VCs, six are VCs of the health science universities and thus, doctors. Two are VCs of non-health universities — one is a doctor and the other a dentist. The last member is a Director of the Medical Education department in a Union Territory.
- All nine ex-officio members from the SMCs are doctors, perhaps elected members (although no clear information is available).
- Of the two non-ex-officio persons appointed at the discretion of government, one is definitely a doctor, but I could not ascertain the background of the other. So, even among the part-time members, there is insignificant representation of "lay" people. Effectively the government has replaced a doctor-dominated Council with a doctor-dominated Commission.

In the Ethics and Medical Registration Board (EMRB), all three full-time members are doctors. The fourth is a part-time member and a non-medical Indian Administrative Service officer, while the second part-time post lies vacant. Ethics is meant to protect patients who are vulnerable in relation to doctors, so one would have expected at least one full-timer to be a non-doctor, if not two. Interestingly, although we have a critical mass of well-trained bioethicists in India, the government has appointed none on this board. Besides, there is no evidence to show that the members appointed on the EMRB have any significant training in professional and normative ethics, let alone recognised qualifications in ethics.

Thus, the claim that the Commission has diverse representation [4] is not borne out by the facts. By keeping non-medical individuals out of the regulatory body, the government has chosen to have doctors to regulate doctors. It is not possible to analyse the social diversity of the members as we do not have information on their caste, tribe, religious and other ethnic backgrounds, but there is no indication that attention has been paid to ensuring such diverse representation. So, the only new feature is that these doctors are nominated by the government and not elected. The assumption is a paternalistic one, that patients, and the people in general, need no representation because the government appoints good doctors who will protect them from the bad doctors and from any other transgression by the profession.

Transparency

Transparency is generally considered crucial for the success of regulation and regulatory bodies. Transparency creates a space for people to demand action, and make the regulator accountable, and thus reduces corruption. Self-regulation by doctors gives them a monopoly, makes such a regulatory body a semi-secret society, and results in a serious lack of transparency, precluding public accountability of the profession. This was a criticism advanced against the MCI, and all reports demanding its replacement also demanded a new transparent regulator. The term "transparent" appears prominently in the introduction to the NMC Act [10]. However, what has been put in place over the last two years under the Act is anything but transparent.

The search committee that selected ten full-time members of the NMC (including its Chair, four Presidents of Boards), full-time members of the Boards and two non-ex-officio part-time members, has provided no information on how many persons were considered initially, and the reasoning based on which specific individuals were selected. As mentioned earlier, the information on members and their social background is not available in the public domain.

Two good provisions in the NMC Act, 2019, are on conflicts of interest (CoI) and on members' declaration of their assets. Under Section 5(4) the search committee, before recommending an individual for a post, is supposed to *satisfy itself that such person does not have any financial or other interest* which is likely to affect prejudicially his (sic) functions as such Chairperson or Member". Further, Section 6(6) requires every member of the Commission to make a *"declaration of his assets and his liabilities at the time of entering upon his office and at the time of demitting his office"*; and to declare "his professional and commercial engagement or involvement in such form and manner as may be prescribed", which *"shall be published on the website of the Commission"* (emphasis added) [10]. Rule 12 of the Act stipulates that: "The Chairperson and every other Member of the Commission *shall file return of assets and liabilities* in Form A ..." [11].

Some good intentions are clear here, but so are major flaws. First, in the NMC Act, the requirement for declaration of assets at the time of assuming office and when demitting office is obviously to assess whether members have amassed wealth, and thus to monitor corruption. But, in the Rules the requirement to declare assets at the time of demitting office has been removed and with it, any possibility of monitoring any disproportionate increase in wealth. Second, while the Act stipulates that the search committee should select only those not having CoI and provides that members declare CoI at the time of assuming office, the Rules omit the point about members not having CoI and, for unexplained reasons, want members to declare their CoI at the time of assuming as well as demitting office. Third, while the law says that the declaration of assets must be made available on the NMC website, the Rules are silent on this. Hence, neither the declaration of assets nor the declaration of CoI is in the public domain, on the website.

In formulating the Rules, precise details of meetings, sitting fees, TA/DA, quorum and so on, have been meticulously provided. However, the vital information — that detailed minutes of the meetings will be made public on the website — has been conveniently forgotten.

Ironically, its lack of transparency was one of the chief grounds for dismantling the MCI, but the same policy has been dusted off and brought back into the NMC.

Rule of law and natural justice

An important question one must ask about the EMRB is whether it will provide easy access to aggrieved patients for getting their complaints resolved. While it is still too early to pass a final judgment — since the revised code of ethics and procedure for grievance redressal are still awaited — there are a few indications that make us pessimistic.

First, unlike medical education where regulatory power is centralised in the hands of the NMC, the state medical councils are still the likely sites from which most complaints will be received and decided. None of these councils has been overhauled, and it is not clear whether the NMC has the powers to reform them. If they remain beyond the bounds of reforms, patients can hope for little relief from the newly formed NMC.

Second, while the state councils remain unchanged, Sections 30(3) and (4) of the NMC Act [10] make it very clear that only a medical practitioner aggrieved by a decision of the state council in favour of a patient, or any other individual will be allowed to appeal to the EMRB and, if still aggrieved, to the NMC. No such right of appeal is available to a patient [12]. Clearly, regulations meant to enforce ethical conduct are, in fact, robbing patients of access to justice.

Third, it is well established in law that a body that receives complaints and investigates them cannot also pronounce judgment on them; that needs to be done by a court. There was an inherent CoI in the old MCI, which, as the medical regulator, was both the investigator of misconduct as well as the judge. In 2012, the UK separated these functions with the enactment of the Medical Practitioners Tribunal Service (MPTS) [8]. Unfortunately, there is no evidence that these two functions will be separated in the NMC and the state medical councils. If the regulator, controlled by doctors, continues to be the investigator, the prosecutor and

the judge of the misconduct by other doctors, then it is unlikely that patients will receive justice from the regulator.

Fourth, and last, does the new law in any way make it easier for aggrieved patients to seek justice from the Commission and the state councils? Here, too, there is no change. The minimum requirement for such ease is geographical access. The state councils are located in the state capitals, and the NMC in Delhi. No arrangement has been made at district and sub-district levels to facilitate access for complainants.

Conclusion

The government's overriding concern in enacting the NMC Act was medical education and not the ethics of the profession. The neglect of ethics is visible both in the drafting of various provisions in the Act and Rules, as well as in the absence of provisions to facilitate justice for patients and aggrieved people, and failure to preserve natural justice by separating investigation and prosecution from adjudicatory functions in complaints of misconduct. The most significant failure is that while a shift is made from self-regulation of the profession to a state-controlled regulatory regime, the control by doctors over the regulatory mechanism is kept intact. And most importantly, the provisions of transparency regarding CoI and assets of members are half-hearted, with no provision made to break open the secrecy of functioning of the medical regulator. Overall, citizens of the country will need to continue their struggle to make the medical regulator accountable.

Declaration of competing interests

In March 2022, the author participated in online meetings organised by the Ethics and Medical Registration Board of the NMC to solicit views from experts on three topics: (1) Code of Ethics, (2) Generic Drug Prescription, and (3) Doctors' relation with pharma companies. Although the quantum is not known, the author may be paid a "sitting fee" as determined by the NMC for meetings on each issue. The author declined to participate in the second round of meetings on these issues.

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