Pharma & Healthcare Update

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DOCTORS UNDER WATCH FOR PROFESSIONAL MISCONDUCT - NATIONAL MEDICAL COMMISSION IN ACTION

INTRODUCTION

On 23rd May 2022, the Ethics and Medical Registration Board ("**EMRB**") under the National Medical Commission ("**NMC**") released a draft of the Registered Medical Practitioner (Professional Conduct) Regulations, 2022 ("**Draft Regulations**").[1] NMC was constituted by the National Medical Commission Act, 2019 which seeks to regulate the medical education and medical professionals. NMC invited comments from the public until June 22, 2022. The Draft Regulations aim at circumscribing the contours of professional conduct of Registered Medical Practitioners ("**RMPs**") through specified norms and guidelines. The NMC replaced the Medical Council of India ("**MCI**") in 2020. The Draft Regulations upon notification will supersede the erstwhile Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 ("**MCI Code**").[2]

The Draft Regulations are required to be adopted by every practitioner of modern medicine registered under the National Medical Commission Act ("**NMC Act**") to practise his profession in India.[3] A Registered Medical Practitioner ("**RMP**") is defined to include any person whose name is either in the State or Medical Register, Indian Medical Register or the National Medical Register.[4] The RMP has to supply his assent of agreement and abide by the Draft Regulations to acquire registration under the NMC Act.

The Draft Regulations primarily intend to govern:

- *Professional conduct of RMPs*
- *Duties of RMPs towards patients*
- *Responsibilities of RMPs to each other*
- *Duties of RMPs towards the public and allied healthcare profession*
- *Professional misconduct of RMPs*

ANALYSIS OF THE DRAFT REGULATIONS

Some of the key provisions of the Draft Regulations are analysed below:

Accepted system of medicine

RMPs can only practice the system of medicine in which he/she are trained and certified i.e. modern medicine or allopathy and are barred from association with any other system of medicine simultaneously.[5] The Draft Guidelines have defined the modern medicine or allopathy to indicate a healthcare discipline that involves a scientific understanding of disease processes and uses rational and evidence-based treatment methods.[6]

Nomenclature used by RMPs[7]

The Draft Regulations restrict the use of prefix Medical Doctor (Med. Dr.) before their names only for RMPs registered under the NMC Act. RMPs can display as suffix only NMC recognized and accredited medical degrees / diplomas. RMPs cannot claim to be clinical specialists unless the NMC has certified their specialization. The requirements placed on the RMPs under the MCI Code to display the relevant information including prescription, certificate, unique registration ID assigned to him/her by the EMRB on the prescription or the money receipt issued by the RMP to the patient, continue to exist. The self-employed RMPs are also required to display a unique registration ID assigned to them by the EMRB in their prescription or certificate.

RMPs qualified abroad and seeking registration to practice after clearing the Foreign Medical Graduate Examination/ National Exit Test ("**FMGE/NEXT**") must use NMC-approved equivalent Medical prefixes and suffixes to provide clarity to patients and the public at large.

Prescription of Drugs by RMPs[8]

The Draft Guidelines require every RMP to prescribe drugs using the generic names written legibly and rationally to avoid prescription of unnecessary medication and irrational fixed dose combinations. Whereas, the MCI Code only provides a general guideline for the RMPs to prescribe drugs with generic names, 'as far as possible'. The prescription has to be in line with the Generic Medicine and Prescription Guidelines delineated under the Draft

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Regulations ("**Prescription Guidelines**").

Prescription Guidelines define a generic name as a "non-proprietary or approved name of a drug" and provide guidance to RMPs towards inter alia rational and optimal prescription of drugs. The Prescription Guideline is issued keeping in view the high spending on health care and it is expected that the prescription of generic drugs may bring down the spending on healthcare in India and is likely to improve access to health care for the masses.

The Prescription Guidelines provide a relaxation for prescription of drugs with a narrow therapeutic index, biosimilars and in similar exceptional cases. Although, the Draft Regulations fail to provide the exceptional cases under which the relaxation of prescription of proprietary medicines applies. It must be understood that the Prescription Guidelines do not prohibit the prescription of fixed dose combinations entirely but seek to encourage their use and prescription judiciously. Further, it requires RMPs to avoid prescribing branded generic drugs. Such restrictions placed on the RMP in prescription of medicines may impact the manufacturers of proprietary or branded generic medicines and may bring in a shift in the pharmaceutical market in India.

Thus, implementation of the Prescription Guidelines must be undertaken in a rational manner to ensure diluting the impact that the guidelines may have on the manufacturers as well as the pharmaceutical market in India.

*Continuing Professional Development Programme ("**CPD**")*[9]

CPD has replaced the Continued Medical Education Programme ("**CME**") under the MCI Code aiming for holistic development of the RMPs by introducing learner centred lifelong programmes as compared to the episodic events undertaken for RMP education presently. The MCI Code encouraged RMPs to participate in professional meetings as part of CPD, for at least 30 hours every five years, organized by reputed professional academic bodies or any other authorized organisations. The compliance of was required to be informed regularly to MCI or the State Medical Councils as the case may be.

While the Draft Regulations have retained this requirement to ensure continued education of the RMPs, it has introduced certain additional compliances. The training and 30 credit hours for the CPD can only be organized by recognized medical colleges and health institutions or medical societies accredited by EMRB or the State Medical Councils. The credit hours awarded to the RMP should be updated online against the Unique Registration Number of RMP on the EMRB-NMC website. The renewal of license of the RMP is required to be done every five years upon submission of the documentation of CPD credit hours.

The Draft Regulations contain Continuous Professional Development Guidelines ("**CPD Guidelines**") which lay down the purpose of CPD, list of organisations who can deliver CPD, procedure for delivery and review of CPDs, regulatory bodies whose permission is required to conduct a CPD, requisite application process, guidance for RMPs, credit requirement and hours, and prescribes the forms for seeking approvals. While the preamble also makes reference to the assignment of CPD points, the CPD Guidelines fail to prescribe the procedure to undertake such assignment.

The CPD Guidelines provides the breakup of the programmes that RMPs are required to participate in based on the nature of activity and mode of the programme. It also places certain responsibilities on the organisation conducting the CPD which includes the requirement to submit a report to the State Medical Council/EMRB at the NMC regarding the CPD conducted.

Categories of CPDs under the CPD Guideline:

- **Category 1 CPD**: 70% programmes devoted to knowledge updates and skill developmentwithin a specified subject area essential for patient care. These are based on contemporary issues.
- **Category 2 CPD:** 30% programmes devoted to cross-disciplinary areas for improving quality of care.
- **Category 3 CPD:** Self-directed online CPD/ scholarly work. Scholarly activities/CPD carried out by RMP internationally through conferences/research work will also be included within this category.

The CPD Guideline proposes the creation of a CPD Committee under the EMRB for assessment of eligibility and promotion of CPDs. The Draft Regulations impose penalties on the RMPs for non-compliance with the mandatory requirement of obtaining CPD points and may reject the renewal of the license of the RMP at the end of five years upon failure to comply.

Endorsements and Advertisements[10]

The Draft Guidelines extend the restriction on undertaking endorsements by RMPs in their individual capacity or as part of an organization/association/society to not give to any person or to any companies or to any products or to software/platforms, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report, etc. as provided under the MCI Code.

The Draft Regulations permit the RMPs to make formal announcements in any media (print, electronic or social media) within 3 months regarding the following:

- On starting practice
- On change of type of practice
- On changing address
- On temporary absence from duty
- On resumption of practice
- On succeeding to another practice
- Public declaration of charges

The Draft Regulations widen the ambit of medium through which announcements may be made by the RMPs thus recognizing the growing role of social media and other media. Although, the Draft Regulations restrict the

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announcements to be made within 3 months of undertaking the listed activities. But fails to prescribe penalties or course of action upon failure of RMP to comply with the said guideline.

The Draft Guidelines enable a RMP or any other person including corporate hospitals, running a maternity home, nursing home, private hospital, rehabilitation center, or any type of medical training institution, etc. to place announcements in the lay press. The guideline enables announcements to be made regarding the name of the institution, type of patients admitted, kind of training and other facilities offered and the fees.

Use of Social Media by RMPs[11]

RMPs are permitted to engage in public education without solicitation of patients through social media. The conduct of RMPs on social media is regulated through *Guidelines on Social Media* issued under the Draft Regulations. Social media is recognized as separate from telemedicine consultation and the conduct of RMPs on social media is governed by norms of truth, respect and professionalism.

The guidelines prescribed under the Guidelines on Social Media are in consonance with the general requirements under the Advertisement Standards Council of India Code ("**ASCI Code**") which is a voluntary code for self-regulation in advertising in India. The Guidelines on Social Media require RMPs to provide only verifiable and factual information through social media and such information should not be misleading or deceptive and should not exploit the patient's vulnerability or lack of knowledge. While the ASCI Code is a voluntary code, the MCI Code cements the compliances in undertaking advertisements on the RMPs given the nature of trust placed in the profession by the society.

The Guidelines on Social Media restrict RMPs from discussing the treatment of patients on public social media or prescribing medicine to patients on the public social media platform. Where a patient approaches the RMP through public social media, the RMP is required to guide the patient towards a telemedicine consultation or in-person consultation as the situation warrants.

RMPs are restricted from posting patients' photographs or scan images (CT/PET scans) on social media. Once an image is posted in social media, it becomes data that is owned by the social media company or the general public. RMPs are restricted from requesting or sharing patient testimonials/recommendations/endorsements/reviews on social media or displaying images of cured patients or surgery/procedure videos displaying impressive results on social media under any circumstances.

Informed Consent[12]

The Draft Regulations have retained the informed consent requirements in consonance with the MCI Code. The Draft Regulations require that the name of the operating surgeon must be mentioned in the medical records. RMPs can dilute the requirement of consent in case of emergency and act in the best interest of the patient. The medical records should describe the basis of the decision taken in the emergency.

RMPs are required to abide by the informed consent requirements in the Guidelines on Informed Consent in Clinical Practice ("**Informed Consent Guidelines**") attached to the Draft Regulations. The Informed Consent Guidelines do not apply to medical research which is governed under the ICMR Guidelines, 2017. The Informed Consent Guidelines delineate the types of consent, emergencies, special situations, use of clinical data, etc. It allows consent to be taken impliedly for certain clinical examinations while necessitating the requirement of obtaining explicit consent for all procedures, treatments, surgery and interventions that have commonly known risks to the patients. Consent for surgery – major or minor – can in no circumstances be treated as a blanket consent when the patient is admitted. The consent requirement for surgery as provided under the Informed Consent Guidelines is procedure-specific.

Although, the Draft Regulations require the consent of both – the patient and the spouse – while undertaking operative procedures which may result in permanent sterilization. The inclusion of a husband's consent over the reproductive health decisions of the woman may raise concerns.

The Informed Consent Guidelines also enable medical students to examine patients by taking verbal consent and provide the patient with the right to refuse examination by a medical student.

Consultation through telemedicine[13]

The Draft Regulations enable consultation through Telemedicine subject to the revised Guidelines for Practice of Telemedicine in India ("**Revised Telemedicine Guidelines**") under the Draft Regulations. The Revised Telemedicine Guidelines enable health workers (including nurse, allied health professional, mid-level health provider, etc.) to facilitate a consultation for a patient with an RMP and in doing so the health worker can assist in taking the history, examining the patient and conveying the findings to the RMP.

The Revised Telemedicine Guidelines prescribe additional guidelines for RMPs and Technology Platforms enabling Telemedicine. RMPs are prohibited from participating in telemedicine through platforms which provide ratings by patient or others including reviews, advertisements, and promotions of RMPs in any means. Additional obligations placed on telemedicine platforms to ensure that RMPs have completed CPD for onboarding on the platform.

While the name, qualifications, registration number, contact details of every RMP is required to be listed on the platform, the Revised Telemedicine Guidelines provide that the contacts details of the RMPs should only be shared with the patient being consulted. The onus of ensuring the credibility of the RMPs and the information of the RMP as mentioned on the portal, registration with the State or National Medical Register must eb verified by the owners/administrators of the Technology Platform.

Public Education and Awareness[14]

The Draft regulations have recognized the responsibility of the RMPs to disseminate scientific advice on public health issues in the public interest without self- promotion or advertisements. In light of the pandemic that took over the world, the Draft Guidelines encourage RMPs to educate the public on quarantine regulations and the measures for prevention of epidemics and communicable diseases. The Draft Regulations place an additional responsibility on the RMPs to notify the public health authorities of all cases of notifiable disease during an epidemic or any other

communicable disease under their care subject to the laws and regulation of the authorities.

Engagement with Industry

The Draft Regulations prohibit RMPs or their families from receiving any gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums or access to entertainment or recreation from pharmaceutical companies, commercial healthcare establishments or medical device companies or corporate hospitals. It provides no avenue for providing even low-value brand reminders to RMPs, Hospitals or clinics. This could lead to the disallowance of a wide variety of expenses borne by companies in engaging RMPs given the wide terminology used for imposing the prohibitions. However, the prohibition does not apply to RMPs receiving salaries and benefits as employees of these organisations. The absence of allowance for professional engagements of RMPs while only permitting employment is impractical.

Further, the Draft Regulations prohibit RMPs from being involved in any third-party educational activity like CPD, seminar, workshop, symposia, conference, etc., which involves direct or indirect sponsorships from pharmaceutical companies or the allied health sector. The Draft Regulations restrict the scope of the RMPs in being involved in any company sponsored events or associating in such events even as a speaker which is currently permitted under the MCI Code. Participation of RMPs in international conferences and congress has also not been addressed by the Draft Regulations. Providing clarity on who is included within the ambit of allied health sector is much needed for the industry to prepare for the compliances and relooking their business activities.

The Draft Regulations fail to provide exemptions for involvement of RMPs in educational or medical research and may act as an impediment in the dissemination of information pertaining to new and innovative products or patented drugs.

An RMP himself or as part of any society, organization, association, trust, etc. should be transparent regarding the relationship with the pharmaceutical and allied health sector industry. The monetary thresholds provided under the MCI Code for undertaking action against the RMP by the MCI has been done away with, implying a blanket prohibition on undertaking certain activities by RMPs entirely.

Further, the Draft Regulations also do not address the activity of accepting samples by RMPs and the activity of providing such samples to RMPs by the pharmaceutical or medical device companies or the participation of the RMP in clinical trials. Any remuneration provided to the RMP for such participation may be considered as a violation of the Draft Regulations.

An additional obligation placed on the RMPs requires them to provide an affidavit regarding their financial earnings or benefits received in the past five years from any pharmaceutical company or allied health sector to monitor the association of the RMP with the allied health sector.

Complaint procedure[15]

- Any violation of the Draft Regulations is construed as professional misconduct. Such violations can be tried by the EMRB or the National or State Medical Councils all of whom have the powers of a civil court under the Draft Regulations. The procedure to register a complaint for professional misconducted is laid down in the Draft Regulations as follows:
- The aggrieved person can file a complaint with the State Medical Council in whose jurisdiction the RMP is located, at the time of cause of action arising, through the website or offline within 2 years. The jurisdiction provisions are made applicable to cause of action arising in both instances i.e. through teleconsultation or in-person consultations.
- Alternatively, the EMRB or the State Medical Council can initiate suo-moto action against RMPs while taking cognizance of gross misconduct, if majority of the EMRB or the State Medical Council members agree to proceed against the RMP.
- RMPs shall have the right to file a reply to the complaint within 15 working days from the date of receipt of the complaint.
- EMRB/State or National Medical Council will conduct an inquiry into the complaint following the principles of natural justice.
- Upon receipt of the complaint, the State Medical Council will refer the case to a designated committee formed to dispose the complaint.
- In case of multiple hearings, the RMP's absence in two consecutive hearings or three hearings in total without sufficient cause shall constrict his right to hearing. In such instances the EMRB/ State or National Medical Council can issue an ex-parte decision on the complaint without giving a notice to the party.
- EMRB/ State or National Medical Council can make the following recommendations after the hearing is completed:

a. dismiss the complaint;

b. reprimand or warn the RMP;

c. recommend counselling or sensitization to the RMP;

d. an alternative penalty can be considered in line with the *Guidelines on Penalties*;

e. suspend the RMP pending the full decision;

f. remove the RMP from the National Medical Register;

g. impose financial penalty on the RMP;

The EMRB/State or National Medical Council cannot review their orders and the order will be executed only after the expiry of the period of appeal.[16]

Appeal mechanism[17]

RMPs aggrieved by the decision of the State Medical Council shall have the right to appeal to the EMRB within sixty days from the date when the order was passed by the State Medical Council. The latter may extend the period for filing the appeal by further sixty days if it is satisfied that the appellant was prevented by sufficient cause from presenting an appeal.

Further, RMPs aggrieved by the decision of EMRB can appeal to the National Medical Council within sixty days from the date when the order was passed by the EMRB.

IMPLICATIONS ON COMPANIES

The Draft Regulations propose a blanket prohibition on RMPs from accepting gifts, brand reminders, honorariums, etc. thereby restricting the ability of companies in providing or offering the same to the RMPs.

Additionally, the Supreme Court in the *Apex Laboratories Pvt. Ltd. v. Deputy Commissioner of Income Tax*,[18] ("***Apex Laboratories***") case deliberated the legal position on business income deductions for expenditure on provision of freebies to HCPs, resurfacing the debate on promotion of drugs in India. The Supreme Court examined whether expenses incurred by the company for providing medical practitioners with expensive gifts such as hospitality, conference fees, gold coins, LCD TVs, fridges, laptops, etc. to promote its health supplement 'Zincovit' is eligible for tax deductions. The Supreme Court held that the activities undertaken by the assessee are against public policy and fall within the purview of being 'prohibited by law' and would not be allowable expenses under Section 37(1) of the IT Act. The Court interpreted the MCI Code to not only prohibit the receipt of freebies by doctors, but also their distribution by pharmaceutical companies to doctors.

Another major development impacting the pharmaceutical companies is the amendment to Section 37(1) of the IT Act under the Finance Act, 2022. This amendment brings within its ambit any person, whether a doctor or not, and makes compliance with any law, rule, regulation or guideline mandatory for claiming tax deductions under the IT Act. Due weightage may be given by tax authorities for compliance by pharmaceutical companies of all laws, rules, regulations or guidelines including the UCPMP, despite its voluntary nature. Hence, companies would be required to be in compliance with the MCI Code and the UCPMP in undertaking promotional activities in order to claim deduction of expenses under Section 37(1) of the IT Act.

Further, expenses incurred for activities not included within the factual matrix of the *Apex Laboratories* may be permitted if the company is able to satisfy the assessing officer as to the nature of expenses being permitted under the MCI Code and the UCPMP. Upon the notification of the Draft Regulations, compliance with the MCI Code will be replaced with compliance with the Draft Regulations which prescribe further restrictions in dealings of pharmaceutical companies with RMPs. **Conclusion**

The Draft Regulations may bring about a sweeping change in the practice of medicine in India since the NMC proposes to regulate every aspect of the profession and places numerous checks on the RMPs. Notable additions to the erstwhile MCI Code regulating the professional conduct of the RMPs include the addition of prefix Med. Dr. for qualified medical professionals under the NMC Act, RMP to practise one system of medicine, undertaking 30 credit hours of CPD, prohibition on self-promotion and advertisement, regulation of use of social media by RMPs, procedure for handling complaints of professional misconduct of RMPs, appeal mechanism, etc.

The Draft Regulations have recognized the growing role of social media in the consultation, prevention and treatment of diseases in the past two years which brough the world to a standstill. The need for the healthcare industry to adapt to technology was felt strongly and the regulation of conduct of RMPs in this new arena required revamp. The Draft Regulations have also recognized the growing importance of teleconsultation while drawing a line between the use of social media and recognized platforms for undertaking such consultations.

Although, the Draft Regulations have certain aspects that need to be relooked at from a practical implementation perspective in order to prevent unreasonable restrictions on the RMPs in practising their profession such as consent requirements from spouse in sterilization procedures, prescription of generic medicines, credit hours in CPD for renewal of license to practise medicine, acceptance and provision of samples to RMPs, applicability of the MCI Code on pharmaceutical and medical device companies, before adoption of the Draft Guidelines as a mandatory code. Stricter enforcement is also likely to disincentivize RMPs from engaging with companies in any way.

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You can direct your queries or comments to the authors

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[1] See National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022, available at https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/NMC%20RMP%20REGULATIONS%202022%20Draft%20Final%20YM.pdf (Last visited on June 2, 2022)

[2] Accessible at: https://wbconsumers.gov.in/writereaddata/ACT%20&%20RULES/Relevant%20Act%20&%20Rules/Code%20of%20Medical%20Ethics%20Regulations.pdf

[3] Regulation 3, Draft Regulations.

[4] Regulation 2(i), Draft Regulations.

[5] Regulation 3(d) and 3(f) of the Draft Regulations.

[6] Regulation 2(e) of the Draft Regulations.

[7] Regulation 4 and 8 of the Draft Regulations.

[8] Regulation 8 of the Draft Regulations.

[9] Regulation 5, Draft Regulations

[10] Regulation 10 and 11 of the Draft Regulations.

[11] Regulation 11 B of the Draft Regulations

[12] Regulation 19, Draft Regulations.

[13] Regulation 29 of the Draft Regulations

[14] Regulation 33, 34, 35 and 36 of the Draft Regulations.

[15] Regulation 38, 39, 40, 42 and 43 of the Draft Regulations.

[16] Regulation 42 of the Draft Regulations

[17] Regulation 45, Draft Regulations.

[18] Apex Laboratories Pvt. Ltd. v. Deputy Commissioner of Income Tax, Large Tax Payer Unit II, Civil Appeal No. 1554/2022 (Arising out of Special Leave Petition (Civil) No. 23207 of 2019).