

Pharma & Healthcare Update

December 30, 2020

REGULATORY YEARLY WRAP 2020: HEALTHCARE IN INDIA

INTRODUCTION

This year has seen two significant legislations having an impact on the healthcare space. The passage of a new consumer protection framework brings much needed clarity on product liability regulation in India while the enactment of the National Medical Commission Act, 2019 overhauls the regulation applicable to healthcare practitioners themselves.

In this wrap, we have provided a brief overview of the developments in the healthcare sector. For the developments in the digital health sector, please refer to our digital health wrap.

INDIA 'S NEW CONSUMER PROTECTION LAW COMES INTO FORCE.

The Ministry of Consumer Affairs, Food and Public Distribution ("**Consumer Affairs Ministry**") by way of notification dated July 15, 2020¹ and July 23, 2020² has notified the Consumer Protection Act, 2019 ("**CPA 2019**") – India's new consumer protection regulatory framework – with effect from July 20, 2020 (with some provisions coming into effect belatedly on July 24, 2020). The CPA 2019 repeals the Consumer Protection Act, 1986 ("**CPA 1986**") which had earlier governed this space. The CPA 2019 will apply to the pharmaceutical, medical device and healthcare sector as well.

Alongside the notification of the CPA 2019, the Consumer Affairs Ministry has also notified various rules under the CPA 2019 including rules for (i) establishing the Central Consumer Protection Authority as the regulator responsible for the enforcement of the CPA 2019, (ii) the Consumer Protection Commissions at the central, state and district levels to adjudicate disputes arising under the CPA 2019, and (iii) rules specifically governing e-commerce platforms (both inventory and marketplace platforms).

The CPA 2019 is a considerably more comprehensive consumer protection legislation than its predecessor. The CPA 2019 has specific provisions for product liability and outlines when the liability would be imposed on the product manufacturer, product seller or the product service provider.

HEALTH MINISTRY NOTIFIES NEW REGULATION TO GOVERN MEDICAL PROFESSIONALS

The Ministry of Health and Family Welfare ("**Health Ministry**") by way of notifications dated September 24, 2020 repealed the Indian Medical Council Act, 1956³ ("**IMC Act**") (the law governing medical education and practice in India) and enacted the National Medical Commission Act, 2019 ("**NMC Act**") in its stead.⁴

The NMC Act is administered and enforced by the National Medical Commission ("**NMC**") the members of which are appointed by the Central Government. This is a sharp departure from the constitution of the Medical Council of India ("**MCI**") – the governing body under the IMC Act – which primarily comprised members elected from and by the medical fraternity. Like its predecessor, the NMC Act regulates the qualifications required to become a medical practitioner in India, the setting up of medical colleges and the general regulation of the medical profession in India.

The passage of the NMC Act was fraught with protests from the medical fraternity who object to the overreaching powers of the Central Government both in the appointment of the members of the NMC and in superseding the NMC altogether.

The NMC is also empowered to grant a limited license to practice medicine at a mid-level as community health providers to persons connected with the modern scientific medical profession ("**CHP Provision**"). The license may be granted to persons who are eligible to be community healthcare providers as per the criteria specified by the Government (no criteria has been specified thus far). The stated aim of the Central Government in enacting this provision is to provide healthcare to rural populations where medical practitioners are not available. Nonetheless, the CHP Provision remains controversial as many doctors believe that the provision lowers the threshold for entry into the medical profession and encourages quackery.

As the NMC Act has been recently brought into force, we are yet to see the impact of the law at the ground level. For now, the rules and regulations made under the IMC Act continue to remain in force as if they were made under the NMC Act until the NMC issues fresh guidance on the subject.

AYUSH PRACTITIONERS TO BE FORMALLY TRAINED IN SURGICAL PROCEDURES

The Central Council of Indian Medicine ("**CCIM**") has issued a notification dated November 19, 2020 amending the Indian Medical Central Council (Post Graduate Ayurveda Education) Regulations, 2016 to include formal training in various types of surgery for post-graduate Ayurveda students ("**Notification**").⁵ The Notification permits post-graduate Ayurveda student to be trained in over 50 different types of surgery ranging from general surgery to eye and ear procedures.

The Notification has been highly controversial with the Indian Medical Association (India's largest voluntary association of allopathic doctors) ("**IMA**") protesting the Notification by organizing demonstrations. The IMA believes that the performing surgery amounts to practicing modern, allopathic medicine which is outside the domain of Ayurveda practitioners. On the other hand, the CCIM's position is that procedures listed in the Notification are considered to be procedures that are a part of the Ayurvedic system of medicine. As a result, practicing these procedures should not be considered as the practice of modern medicine.

CONCLUSION

While the number of developments in the healthcare space have been sparse, the impact of each of them is significant. Both the CPA 2019 and the NMC Act are long-awaited legal reforms that have been in the wings since 2019. In 2021, we are excited to see the impact of these laws at the ground level.

– Shreya Shenolikar, Darren Punnen & Dr.Milind Antani
You can direct your queries or comments to the authors

¹ <https://consumeraffairs.nic.in/sites/default/files/Act%20into%20force.pdf>
² <https://consumeraffairs.nic.in/sites/default/files/Provisions%20of%20Act%20comes%20into%20force.pdf>
³ <http://egazette.nic.in/WriteReadData/2020/221940.pdf>
⁴ <http://egazette.nic.in/WriteReadData/2020/221939.pdf>
⁵ Notification, available at: <http://egazette.nic.in/WriteReadData/2020/223208.pdf>

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