

Pharma & Healthcare Update

February 01, 2024

YEAR END REGULATORY UPDATE 2023: HEALTHCARE INDUSTRY IN INDIA

The most significant developments in the healthcare industry in the last quarter of 2023 are:

- New criminal law prescribes lesser punishment for doctors causing death by negligence.
- Import of human gametes prohibited in addition to human embryos.
- State allied and healthcare councils to be constituted within three years of commencement of the National Commission for Allied and Healthcare Professions Act.
- Numerous other regulations proposing to regulate the healthcare industry remain at different stages of operationalisation.

INTRODUCTION

The last quarter of 2023 has brought about steady developments for the Indian healthcare industry. The legal frameworks regulating different categories of healthcare professionals are in the process of being overhauled, and remain at different stages of implementation. A further extension has been granted to state governments to constitute the state-level Allied and Healthcare Councils envisaged under the National Commission for Allied and Healthcare Professions Act, 2021 ("**NCAHP Act**"), the National Nursing and Midwifery Commission Act, 2023, the National Dental Commission Act, 2023 are still in the process of being operationalised, while the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 remain in abeyance

Some of the key developments that have taken place in the second half of 2023 in the healthcare industry in India have been captured below.

NEW CRIMINAL LAW PRESCRIBES LESSER PUNISMENT FOR DOCTORS FOR CAUSING DEATH BY NEGLIGENCE VIS-À-VIS OTHER OFFENDERS

The Bharatiya Nyaya Sanhita, 2023 ("**BNS**") received the assent of the President on December 25, 2023 and replaced the Indian Penal Code, 1100 ("**IPC**"). The BNS covers all aspects of criminal law including offences, punishments, procedures and defenses and enhances punishment for various offences previously prescribed under the IPC.

A notable development in the BNS relevant to the healthcare sector in India is the change brought about in section 106 (previously section 304 A under the IPC) relating to the offence of causing death by negligence. The new law differentiates between ordinary negligence, and negligence by a registered medical practitioner ("**RMP**")¹ in the course of performing a medical procedure, and prescribes a lesser punishment for RMPs, where the act causing the death of any person by negligence is done by him while performing medical procedure. The punishment prescribed for such acts done by RMPs is imprisonment for a term which may extend to two years as compared to five years for other offenders and fine.

GOVERNMENT PROHIBITS IMPORT OF HUMAN GAMETES INTO INDIA

The Directorate General of Foreign Trade ("**DGFT**") – central body responsible for formulating and implementing the Foreign Trade Policy in India – regulates the import and export of goods through the country. The import of goods is regulated under the Indian Trade Classification (Harmonised System of Nomenclature) (ITC (HS)) based Import Policy under Schedule I updated by the DGFT from time to time under various chapters categorised on the basis of the nature of the product.

The policy conditions for the import of human embryo and human gametes are stipulated under chapter 5 of the ITC (HS) Schedule I (Import Policy).² Under the Import Policy, import of Human Embryo has been prohibited since 2015. The DGFT has issued a notification dated October 23, 2023³ to amend the policy condition to include the prohibition of import of human gametes into India in accordance with the Assisted Reproductive Technology (Regulation) Act, 2021 ("**ART Act**") and the Surrogacy (Regulation) Act, 2021

The ART Act prohibits the commercialisation and import of human gametes and embryos, and prescribes a fine of between five and ten lakhs for the first contravention, and imprisonment for a term ranging between three and eight years along with a fine.⁴

EXTENSION GRANTED TO STATE GOVERNMENTS TO CONSTITUTE STATE ALLIED AND HEALTHCARE COUNCILS

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The NCAHP Act came into force in May 2021 and intends to provide standards for the education and services provided by allied healthcare professionals which include behavioural health professionals (mental health counsellors excluding clinical psychologists). To practise their profession, allied healthcare professionals are required to be registered under the state and national registers. The NCAHP Act provides for the setting up of a National Commission for Allied and Healthcare Professions at central level.

At the state level, the NCAHP Act requires every state government to constitute a State Allied and Healthcare Council ("**State Council**") for exercising the powers and discharging the duties laid down under the NCAHP Act, within six months from the date of commencement of the NCAHP Act. However, owing to administrative difficulties and legislative/statutory formalities/procedures such State Councils could not be constituted by the State governments within the stipulated timeline. The stipulated period was extended by the government to two years and six months from the date of commencement of the NCAHP Act through the National Commission for Allied and Healthcare Professions 5th (Removal of Difficulties) Order, 2023.⁵ In the latest order, i.e. National Commission for Allied and Healthcare Professions 6th (Removal of Difficulties) Order, 2023,⁶ the government has further extended the timeline to constitute the State Councils until May 2024 (three years from the date of commencement of the NCAHP Act).

CONCLUSION

As indicated by the developments from the second half of 2023, the focus remains on ensuring consumer welfare and safety from deceptive practices on online marketplaces. The new criminal laws also seek to ensure protection of the interests of healthcare professionals in the country. The implementation of the new laws and guidelines remains to be seen in the new year.

– Varsha Rajesh, Tanya Kukade, Eshika Phadke and Dr. Milind Antani

You can direct your queries or comments to the authors.

¹An RMP for the purposes of the said provision means a medical practitioner who possesses any medical qualification recognised under the National Medical Commission Act, 2019 and whose name has been entered in the National Medical Register or a State Medical Register under that Act.

²Accessible at: <https://www.dgft.gov.in/a2f1c046-c008-4d01-95ac-0751b9663e90>

³Accessible at: <https://content.dgft.gov.in/Website/dgftprod/c4c2a975-a8d3-4272-a094-f177c5c3d1f6/Notification%2039%20dt%2023-10-23%20Eng-.pdf>

⁴Section 33(2) of the ART Act

⁵Accessible at: [https://egazette.gov.in/\(S\(hg0mex02wjekew41jt0ljhdn\)\)/SearchMinistry.aspx?id=206117](https://egazette.gov.in/(S(hg0mex02wjekew41jt0ljhdn))/SearchMinistry.aspx?id=206117)

⁶Accessible at: [https://egazette.gov.in/\(S\(m3vfqrwb2yhrwhrf0gpw0yuu\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(m3vfqrwb2yhrwhrf0gpw0yuu))/ViewPDF.aspx)

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